

**A COMPARATIVE STUDY ON THE
PATENTABILITY OF NANOTECHNOLOGY
RELATED INVENTIONS:
LESSONS RELEVANT TO SOUTH AFRICA**

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TABLE OF ABBREVIATIONS:

AFM	Atomic Force Microscope
AIA	America Invents Act (2011)
ASTM	American Society for Testing and Materials
BRICS	Brazil-Russia-India-China-South Africa
CAFC	Court of Appeals for the Federal Circuit
CIPC	Companies and Intellectual Property Commission
CNT	Carbon Nanotube
CPC	Cooperation Patent Classification
DST	Department of Science and Technology
EPC	European Patent Convention (1973)
EPO	European Patent Office
ESTASAP	European South African Science and Technology Advancement Programme
IBSA	India-Brazil-South Africa
ISA	International Search Authorities
IP	Intellectual Property
IPC	International Patent Classification
IPR	Intellectual Property Rights
IPR-PFRD Act	The Intellectual Property Rights from Publicly Financed Research and Development Act (2008)
MEMS	Micro-electromechanical System
MPEP	Manual of Patent Examining Procedure
Mpf	Means Plus Function
MWNT	Multi-walled Carbon Nanotube
NAS	National Academy of Sciences
NIC	Nanotechnology Innovation Centres
NIOH	National Institute for Occupational Health
NIPMO	The National Intellectual Property Management Office
NM	Nanometre
NNI	National Nanotechnology Initiative
NNS	National Nanotechnology Strategy
NNT	Nanoscience and Nanotechnology
OECD	Organization for Economic Co-operation and Development
PCT	Patents Co operation Treaty (1970)
PO	Patent Office
POC	Point of Care Diagnostic Prototypes
R&D	Research and Development
SANi	South African Nanotechnology Initiative
SEM	Scanning Electron Microscope
STM	Scanning Tunnelling Microscope
SWNT	Single-walled Carbon Nanotube
TB	Tuberculosis
TBA	Technical Board of Appeal
TEM	Transmission Electron Microscope

TRIPS	Agreement on Trade- Related aspects of Intellectual Property Rights (1994)
UCT	University of Cape Town
USPTO	United States Patent and Trademark Office
U.S.C	United States Code
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WITS	University of the Witwatersrand
WTO	World Trade Organisation

INTRODUCTION

The field of Intellectual Property is an important and very necessary area of law that provides protection to those responsible for creating property that will ultimately benefit society. Patent law protects property within the field of science and technology. Research and development have substantial economic value, therefore it is essential that their growth be promoted. It is crucial that patent law is frequently reviewed as new technologies are constantly emerging and existing patent frameworks may not sufficiently accommodate these new and overly complex technologies. Additional guidelines may be required so as to fill in these “blanks” and avoid problems ensuing between existing patents and new patent applications. Additional guidelines may be required as to the relevant prior art, which has to be taken into account when examining inventions in the area of nanotechnology, bearing in mind the multi-disciplinary character of this new technology.

Patent systems are the necessary framework in which the protection of inventions is regulated and innovation is encouraged to stimulate technological development by offering financial incentives in return for public disclosure of the invention. This in turn promotes competition ultimately resulting in economic growth, as local and foreign investors may be interested in investing in the R&D of an invention. Although by the adoption of the International Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) in 1994, minimum standards binding all Members of the World Trade Organization (WTO) as regards the availability of patents 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,¹ have been introduced, governments continue to have the freedom to formulate and implement measures to effectively manage and develop intellectual property in their national intellectual property policies and strategies, provided that they are in compliance with the TRIPS Agreement standards.² As a result national patent laws still differ from one country to another and it is

¹ TRIPS Article 27: Patentable subject matter.

² Other important TRIPS patent provisions relate to the rights a patent confers on its owner (Article 28), disclosure requirements (Art. 29), exceptions to rights conferred by a patent (Art. 30), conditions under which compulsory licenses can be granted (Art. 31), the term of patent protection (Art. 33), and, e.g., the

decisive for inventors that they are familiar with those existing, often very important differences. Thus, comparing the patent systems of developed countries, such as Europe and the U.S., to those of a developing country such as South Africa, could provide potential applicants with valuable guidance.

Patents are valuable not only to the inventor, as the exclusive holder of the rights but also serve as a comprehensive source, providing vital commercial, legal and technical information pertaining to the invention. This enables improvements and advancements of technologies already described in published patent applications and patents. Such improvements may qualify as a new invention provided that certain requirements are met. The most significant being novelty and non-obviousness.

Patent law and nanotechnology, when separately considered, are interesting subjects but when nanotechnology is viewed in light of patent law, certain characteristics of this technology challenge traditional IP practices, making for stimulating inquiry. Understandably this is not the first time a new technology has emerged and faced challenges relating to its patentability, however, different technologies may present different challenges. On the surface, nanotechnology may display a palpable deficiency, due to its newness the term “nano” is used generically to describe anything of a diminutive nature. A tremendous amount of confusion has ensued. For this reason it is essential that a comprehensive understanding is had of nanotechnology.

South Africa has made large financial contributions to further research in the field of nanotechnology, making this a locally relevant topic. This study hopes to uncover the fascinating science that is nanotechnology and determine the scope of its subject matter. Essential elements necessary for drafting a comprehensive patent application for a nano-related invention will be examined in detail. The substantive requirements will be addressed individually, clarifying the challenges that nanotechnology presents and achievable solutions to overcome these challenges will be proposed. The application process South Africa employs for patents differs to that of Europe and the USA. These differences will be

enforcement of intellectual property rights in general (Art. 41 *et seq.*).

discussed in greater detail and possible improvements to existing patent practices will be presented. Furthermore current nanotechnology projects in respect of which South Africa is involved will be revealed as well as any international contributions to the field of nanoscience and nanotechnology. Ultimately inferring whether South Africa is internationally competitive within this field.

CHAPTER 1

THE SCIENCE OF NANOTECHNOLOGY

1. NEW ADVANCEMENTS IN TECHNOLOGY: THE DEFINITION AND SCOPE OF NANOTECHNOLOGY

Globally nanotechnology has become a buzzword. It has a multidisciplinary application and as such this fascinating new technology is expected to facilitate great advances in many different fields of science and technology, including that of medicine, electronics, biomaterials, energy production, generation and storage. Herein also lies the potential for all of the abovementioned fields to converge, creating infinitely varied applications of previously separate disciplines.³ Due to its uniquely vast application many questions pertaining to its patentability are raised.

Despite all this attention, the exact definition still remains perplexing and a challenge for legal practitioners and inventors alike.⁴ The reason for this partly pertains to its newness and rapid development. Another reason may be attributed to its vast application, different fields of science and technology may refer to one term as describing a particular structure and this same description could denote a completely different structure in a different field. Furthermore multiple terms can be used to describe the same structure.⁵

Attempts have been made to try and standardise the definitions and terms used for nanotechnology. For example the EPO developed classification Y01N⁶ and the USPTO,

³ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012)[At 6-7]

⁴ Berger "Legal Implications of the Nanotechnology Patent Land Rush" <http://www.nanowerk.com/spotlight/spotid=1919.php> (accessed 02/05/2012) [Hereinafter "Berger Nano Patent Land Rush"]

⁵ Mills, Fitzsimmons and Rodkey 2010 *Nanotech. L. & Bus.* 223-235

⁶ The EPO's definition: "The term nanotechnology covers entities with a controlled geometrical size of at least one functional component below 100 nanometres (nm) in one or more dimensions susceptible of making physical, chemical or biological effects available which are intrinsic to that size." See: [http://documents.epo.org/projects/babylon/eponet.nsf/0/623ECBB1A0FC13E1C12575AD0035EFE6/\\$File/nanotech_accebrochure_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/623ECBB1A0FC13E1C12575AD0035EFE6/$File/nanotech_accebrochure_en.pdf) (accessed 08/08/2013)

introduced Classification 977 to classify nanotechnology patents.⁷ In addition, various international organisations such as ASTM International,⁸ British Standards Institute, The International Organisation for Standardisation,⁹ The Institute of Nanotechnology and NNI¹⁰ have attempted to define structures in nanotechnology by using similar language. Unfortunately despite these efforts the parameters for the definitions given are not always the same.¹¹ Therefore it becomes vitally important to understand the scope of what is in fact covered by the claims of a specific patent.

After comparing several definitions, the general, category definition given to identify this technology is the following: Nanotechnology refers broadly to the field of applied science and technology with the unifying theme being the manipulation of matter on an atomic and molecular scale.¹² Scale is therefore the dominant feature. The term “nano” derives from the Greek word for dwarf and refers to a measurement and not to an object. This subject matter has the scale of approximately 1-100 nanometres (nm) in at least one dimension, a

⁷ Class 977 defines nanotechnology narrowly: “This Nanotechnology art collection provides for disclosures related to:

1. Nanostructure and chemical compositions of nanostructure;
2. Device that include at least one nanostructure;
3. Mathematical algorithms e.g. computer software, etc., specifically adapted for modelling configurations or properties of nanostructure;
4. Methods of apparatus for making, detecting, analysing or treating nanostructure; and
5. Specified particular uses of nanostructure.

As used above, the term “nanostructure” is defined to mean an atomic, molecular or macromolecular structure that:

1. Has at least one physical dimension of approximately **1-100 nanometres**; and
2. Possesses a special property, provides a special function or produces a special effect that is uniquely attributable to the structure’s nanoscale physical size.” See:

<http://www.uspto.gov/web/patents/classification/uspc977/def977.htm> (accessed 21/07/2013)

⁸ Berger Nano Patent Land Rush <http://www.nanowerk.com/spotlight/spotid=1919.php> (accessed 02/05/2012)

⁹ Mills, Fitzsimmons and Rodkey 2010 *Nanotech. L. & Bus.* 232

¹⁰ NNI’s definition: “Nanotechnology is the understanding and control of matter at dimensions between approximately **1 and 100 nanometers** (nm), where unique phenomena enable novel applications... Encompassing nanoscale science, engineering and technology, nanotechnology involves imaging, measuring, modelling and manipulating matter at this length scale.” See: <http://www.nano.gov/nanotech-101/nanotechnology-facts> (accessed 08/08/2013)

¹¹ Mills, Fitzsimmons and Rodkey 2010 *Nanotech. L. & Bus.* 233

¹² Nanodeltech <http://nanodeltech.com/nanotechnology/nanotechnology-and-energy.html> (accessed 07/05/2012)

billionth of a meter.¹³ Therefore it deals with developing materials, systems, devices and other structures that possess novel properties and functions as a result of their nanoscale size. To give a physical indication of the size of matter dealt with on nanoscale; individual atoms are 1 nm wide, a sheet of paper is 100,000 nm thick;¹⁴ a single human hair is about 10,000 nm wide;¹⁵ a red blood cell is about 7,500 nm wide and a DNA molecule 2-2,5 nm wide (falling within the nanoscale measurement).¹⁶

With this in mind, one would assume that this technology refers to the mere reduction in size of matter or a device and therefore one would pose the question, is the invention “new” and therefore eligible for a patent?

This manipulation of atoms and molecules can render a very different physical, chemical or biological result on nanoscale than that same material as bulk matter. The change in physical properties due to their small size is referred to as the “quantum effect”¹⁷ or “scale effect.”¹⁸ Reasons for this difference can be attributed to the following; due to the relatively larger surface area to volume ratio, nanoscale material can become more chemically reactive thereby changing their strength and other properties.¹⁹ Also, below 50 nm the traditional laws of physics give way to quantum effects inciting different optical, electrical and magnetic behaviours than from those of the same material but produced on a larger

¹³ Almeling 2004 *STLR* ¶1. Also see: Hicks, Grissett and Brown <http://www.wcsr.com/resources/pdfs/nano030310.pdf> (accessed 04/05/2012) [At 1] and Watal and Faunce http://wipo.int/wipo_magazine/en/2011/02/article_0009.html (accessed 02/05/2012)

¹⁴ Watal and Faunce http://wipo.int/wipo_magazine/en/2011/02/article_0009.html (accessed 02/05/2012)

¹⁵ Gardner 2008 *PCOST* 3

¹⁶ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012)[At 15]

¹⁷ Wetter http://www.fpif.org/articles/big_continent_and_tiny_technology_nanotechnology_and_africa (accessed 17/03/2013)

¹⁸ Zech 2009 *SCRIPTed* 149

¹⁹ Valverde and Linkov 2011-2012 *Nanotech. L. & Bus.* 30

scale.²⁰ These new physical properties that emerge enable exciting new applications. Some examples are increased strength, lighter weight, flexibility, conductivity, durability and resistance.²¹ These new properties are very important when determining the patentability of a nanotechnology invention. This aspect will be examined more thoroughly in Chapter 2 when determining novelty and non-obviousness.

2. NANOSCIENCE VERSUS NANOTECHNOLOGY

A distinction should also be drawn between the following two concepts, “nanoscience” and “nanotechnology.” Nanoscience refers to the science and research of nano-related subject matter. Once these findings have been developed and tested they are then reformed to create nanotechnology. Nanotechnology therefore refers to the applied science and the products containing nanoparticles.

3. ORIGINS

The origins of nanotechnology date back to 1959 when physicist Richard Feynman presented his well-known talk “There’s Plenty of Room at the Bottom.”²² He proposed a process whereby one could manipulate individual atoms and molecules by using a set of precise tools to build and operate another proportionally smaller set.²³ This process would be repeated until the desired scale was achieved. Due to the direct manipulation of single atoms, this was considered a more powerful form of synthetic chemistry.²⁴ He also noted that there would be scaling issues due to changing the magnitude of various physical

²⁰ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 3]

²¹ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 8-10]

²² Hicks, Grissett and Brown <http://www.wcsr.com/resources/pdfs/nano030310.pdf> (accessed 04/05/2012) [At 1]

²³ Suprotec http://www.suprotec.ie/estore/index.php?dispatch=pages.view&page_id=9 (accessed 09/12/2012)

²⁴ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 6-7]

phenomena: “gravity would become less important, surface tension and Van der Waals attraction²⁵ would become more important, etc.”²⁶

The term "nanotechnology" was defined in 1974 by Professor Norio Taniguchi from the Tokyo Science University in his paper: “*Nano-technology' mainly consists of the processing of, separation, consolidation, and deformation of materials by one atom or by one molecule.*”²⁷ In the 1980's, Dr. Eric Drexler explored the definition given by Taniguchi and popularized this technological marvel of nanoscale by writing books and giving speeches on the topic. His book entitled “*Engines of Creation: The Coming Era of Nanotechnology*” is considered the first book on the topic of nanotechnology.²⁸

It can be said that nanoscience and nanotechnology came into being in the early 1980's as several major developments occurred: the beginning of cluster science and the invention of the scanning tunneling microscope (STM) and Atomic Force Microscope (AFM).²⁹ These developments set in motion the possibility for further nanotechnology related discoveries to be made.

4. TYPES/ “MAKES” OF NANOTECHNOLOGY

Some of the most prominent nanotechnologies, also referred to as the “building blocks” are: nanoparticles, carbon nanotubes and quantum dots. Other “makes” of nanomaterials are developing rapidly.

²⁵ According to the Encyclopaedia Britannica: Van der Waals Attraction or Force is the sum of the attraction and repulsion forces between atoms, molecules and surfaces and other intermolecular forces. See: <http://www.britannica.com/EBchecked/topic/622645/van-der-Waals-forces> (accessed 24/08/2013)

²⁶ Nano Research Foundation <http://www.nanotechnologyresearchfoundation.org/nanohistory.html> (accessed 09/12/2012). Also see: Suprotec http://www.suprotec.ie/estore/index.php?dispatch=pages.view&page_id=9 (accessed 09/12/2012)

²⁷ Suprotec http://www.suprotec.ie/estore/index.php?dispatch=pages.view&page_id=9 (accessed 09/12/2012)

²⁸ Nano Research Foundation <http://www.nanotechnologyresearchfoundation.org/nanohistory.html> (accessed 09/12/2012)

²⁹ Pouris 2010 *University of Pretoria* 21

4.1. Nanoparticles

These are particles that behave as a whole unit in terms of transport and properties. They are classified according to size, between 1-100 nm. But there is an important distinction that must be taken into account, nanoparticles that have existed for decades, in the form of antique ceramics and carbon black (the most abundant of these). However, these do not fulfill definition given for nanoparticles namely the “planned” manipulation of atoms and molecules as they occur naturally.³⁰

The large surface area is responsible for the improved performance of catalysis and electrodes that are used in batteries and fuel cells. Due to the dimensions of nanoparticles being below critical wavelengths of light they are transparent and therefore appealing for packaging, cosmetics, sunscreens and coatings.

Examples of nanoparticles are metal oxide ceramic, zinc oxide, silicate and chitosan, which is used in hair conditioners and skin products for better absorption.³¹

4.2. Fullerenes

Fullerenes are made entirely from carbon and there are two types; buckyballs and carbon nanotubes. **Carbon Nanotubes** (CNT) are the most significant new nanomaterials. They are long thin cylinders of atomic layers of graphite that come in a variety of structures, possessing a wide variety of properties. Single walled carbon nanotubes (SWNT) consist of a single cylindrical wall. And the multi-walled carbon nanotubes (MWNT), have cylinders within cylinders.³² MWNT have the same properties and morphology, however their resistance to chemicals is far superior. When a general reference is made to nanotubes, it is usually the SWNT that are being referred to. Nanotubes are advantageous due to the

³⁰ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 6]

³¹ Nanotechnology Now <http://www.nanotech-now.com/current-uses.htm> (accessed 09/12/2012)

³² OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 8-10]

following qualities they possess; high electrical conductivity, tensile strength, highly ductile, high heat conductivity, mobility and they are relatively inactive chemically.³³

A drawback to using nanotubes is the difficulty with which they interact with other materials. To fully exploit its strength in composite materials it needs to be attached to a polymer. This unfortunately reduces the very properties they are used for.³⁴ Low yield is another drawback, only once a system is devised to scale up production will this nanomaterial be invaluable to any industry where strength and weight are factors in their products.³⁵ Examples of ideal applications for carbon nanotubes include nanoelectrical and nanomechanical devices.³⁶

4.3. Quantum dots

Quantum dots are nanoparticles made from a semi conductor material, traditionally chalcogenides of metals like zinc or cadmium.³⁷ They range from 2-10 nm and display optical and electrical properties that are different than those in bulk.³⁸ These structures are capable of confining a single electron or a few thousand. The energy states of these electrons can be controlled by applying a specific voltage.³⁹ When excited, photons are emitted and this reaction is visible to us as light. This light can be controlled during production to emit any colour of light. The ability to “tune” or control this emission from the

³³ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 8-10]

³⁴ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 8-10]

³⁵ Nanotechnology Now <http://www.nanotech-now.com/current-uses.htm> (accessed 09/12/2012)

³⁶ IBM Research <http://www.research.ibm.com/nanoscience/nanotubes.html> (accessed 12/12/2012)

³⁷ Nanoco Group PLC <http://www.nanocotechnologies.com/content/AboutUs/AboutQuantumDots.aspx> (accessed 12/12/2012)

³⁸ Nanoco Group PLC <http://www.nanocotechnologies.com/content/AboutUs/AboutQuantumDots.aspx> (accessed 12/12/2012)

³⁹ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012)[At 10-11]

quantum dot is attained by changing its core size. This is called the “size quantisation effect.”⁴⁰ The smaller the dot, the higher the energy and the closer it is to the blue end of the spectrum. The bigger the dot, the lower the energy and the closer it is to the red end of the spectrum.⁴¹ Here the energy levels are more closely spaced. Quantum dots can also be tuned beyond visible light and into infra-red or ultra-violet light.

Full colour imaging is possible for biological samples and a large number of different sized dots can be excited by a light source with a single wavelength. This is immensely advantageous as current imaging is done using naturally florescent molecules, e.g. organic dyes, each dye is attached to each kind of molecule in a sample. However, only about three of these dyes emit light over a broad range of wavelengths resulting in their spectra overlapping. In addition only about three different dyes can be used at the same time.⁴²

At the end of the production process quantum dots physically appear as powder or in a solution. A small quantity of quantum dots, for example, 1 kg will produce enough actual quantum dots for industrial scale production. A company by the name of Nanoco Technologies has patented this molecular seeding process thereby consistently producing quantum dots for this large scale production.⁴³

Other possible applications include drug delivery, qubits in quantum computing and photovoltaic cells.⁴⁴

⁴⁰ Nanoco Group PLC <http://www.nanocotechnologies.com/content/AboutUs/AboutQuantumDots.aspx> (accessed 12/12/2012)

⁴¹ Nanotechnology Now <http://www.nanotech-now.com/current-uses.htm> (accessed 9/12/2012)

⁴² OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 10-11]

⁴³ Nanoco Group PLC <http://www.nanocotechnologies.com/content/AboutUs/AboutQuantumDots.aspx> (accessed 12/12/2012)

⁴⁴ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 10-11]

5. ACTIVE AND PASSIVE NANOTECHNOLOGY

James Tour made an important distinction between two areas in nanotechnology, namely active and passive nanotechnology. A good example of passive nanotechnology would be nanoparticles incorporated into sunscreen. The presence of the nanoparticles significantly improves the performance of the product in which it is incorporated. Active nanotechnology on the other hand, carry out complex functions. Here structures are able to perform movements or dispense treatments, for example nanomachines or nanorobots.⁴⁵

6. TOOLS USED FOR NANOTECHNOLOGY

There are two main types of microscopes used in nanotechnology that apply different techniques, without which nanoparticles would remain invisible. The scanning electron microscope (SEM) and transmission electron microscope (TEM), both apply the same technique whereby the sample is stationary and in line with a high speed electron gun. The other type or class of microscopes, where the microscope is stationary and the sample moves, is the atomic force microscope (AFM) and the scanning tunnelling microscope (STM).⁴⁶ This equipment is essential in understanding and developing nanomaterials and building nanostructures. When using the SEM, TEM and STM microscopes, nanoscale samples must be meticulously prepared, they must be electrically conductive and carefully handled as they can easily be damaged by the high energy electrons that are fired at them.

7. BUILDING NANOSTRUCTURES

The diversity of nanotechnology ranges from extending and improving conventional device physics to completely new revolutionary approaches based on molecular self-assembly. With this in mind there are two processes when building nanostructures, the “top-down” and the “bottom-up” approach. When applying the top-down approach bulk matter is

⁴⁵ Zech 2009 *SCRIPTed* 150

⁴⁶ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 11]

processed by removing matter until only nanoscale features remain (namely, the process described by Richard Feynman).⁴⁷ This is referred to as the traditional approach. Nanopatterning is a generic term used to describe this process and nanolithography refers to the fabrication of nanostructures, such as nanowires and quantum dots. A larger amount of material is required which is then reduced in size. Unfortunately cast-off material can result in unnecessary waste.⁴⁸ The main problem with this approach is the imperfect surface structures. These imperfections can cause further challenges in device design and fabrication.⁴⁹ However, the top-down approach is responsible for the bulk of production of nanomaterials.

The bottom-up approach is more time consuming, nanostructures are built atom by atom, molecule by molecule. This approach begins with constituent materials such as gases or liquids and uses electrical, chemical or physical forces to “build up” the nanomaterial. This method is used for creating nanowires, carbon nanotubes and quantum dots. The next revolutionary step whereby materials will be created using this approach is by molecular self-assembly.⁵⁰ This is achieved by using attractive forces like static electricity, Van der Waals forces and a variety of short range forces to position these constituent molecules in a specific arrangement.⁵¹ In other words by placing certain molecular scale components together they will spontaneously self-assemble from the bottom up into a specific ordered structure without outside assistance.⁵² This process promises a greater possibility of producing nanostructures with an impressive level of customisability, having less defects

⁴⁷ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 11-12]

⁴⁸ Nano.gov <http://www.nano.gov/nanotech-101/what/manufacturing> (accessed 13/12/2012)

⁴⁹ Gitam.edu http://www.gitam.edu/eresource/nano/nanotechnology/role_of_bottomup_and_topdown_a.htm (accessed 13/12/2012)

⁵⁰ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 11-12]

⁵¹ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 11-12]

⁵² Nano.gov <http://www.nano.gov/nanotech-101/what/manufacturing> (accessed 13/12/2012)

and more consistent chemical compositions.⁵³ However, this process is difficult to control, time consuming and capable of only producing simple structures and yielding very little.⁵⁴ This concept is mostly at a theoretical stage.⁵⁵

8. APPLICATIONS AND OPPORTUNITIES FOR NANOTECHNOLOGY

Existing industries will over the next few decades, if economically viable, dramatically improve their existing products. The clothing, electronics, communications, pharmaceuticals, healthcare and manufacturing industries will be strongly affected by the advancements of nanotechnology. Energy technologies, chemical materials, national security, and even space exploration will benefit from this technology. Mass-produced consumer products incorporating nanoparticles that are currently available to the public include; applications in the car industry, glass for windows, lenses for sunglasses, sunscreens and cosmetics, textiles, sports equipment and televisions.

The short to long-term opportunities within the field of nanotechnology are extensive. For the purposes of this study I will focus on the fields of science South Africa considers relevant. South Africa's active projects and future goals will be discussed in chapter 3.

8.1. Application: Medicine

Nanotechnology offers extraordinary opportunities in the field of medicine. New and improved methods and approaches for the detection and treatment of diseases, viruses and surgical procedures will be further explored in this section.

⁵³ Gitam.edu

http://www.gitam.edu/eresource/nano/nanotechnology/role_of_bottomup_and_topdown_a.htm (accessed 13/12/2012)

⁵⁴ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 12]

⁵⁵ Boysen and Muir <http://www.dummies.com/how-to/content/nanotechnology-top-down-or-bottom-up.html> (accessed 13/12/2012)

a) Drug Delivery

This is considered to be one of the most profitable applications of nanotechnology in medicine. Nanoparticles have the ability to act as carriers for targeted drug delivery. Due to their small size, nanoparticles can interact at the same molecular and cellular level as the cells in the body thereby gaining access to areas in the body that were otherwise inaccessible. These particles are engineered so that they are attracted to diseased cells, allowing for the direct treatment of only those cells. This technique reduces damage to healthy cells in the body and allows for earlier detection of disease. Due to their size they are able to penetrate certain protective membranes, this opens the possibility to treat diseases precisely thereby hopefully reducing the side effects of traditional treatments and minimizing damage to healthy cells.

Nanoparticle encapsulation allows for the drug to be protected while it travels through the body on route to the area targeted for treatment. The drug is contained in a capsule in order to avoid damaging parts of the body it must travel through that are not affected by the disease and for the purpose of maintaining its biological and chemical properties.⁵⁶ Once the drug reaches its target, it is released at a rate that is appropriate for the effective treatment of the disease. Nanotechnology can improve both the release of the medication and degradation of the material of the capsule in the body thereby optimizing treatment. This process is currently focused on treatment for diseases such as cancer but other possible applications are being investigated such as the treatment for neurological disorders such as Parkinson's, Huntington's, Alzheimer's, ALS and diseases of the eye.

⁵⁶ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 15-17]

Other applications of nanocapsules include:

- The treatment of viruses, the nanocapsule will contain an enzyme that will prevent the reproduction of virus molecules in the bloodstream, killing the virus before it can multiply.⁵⁷
- Severe burns can be treated with dressings coated with nanocapsules containing antibiotics that will be released at the onset of an infection the bacteria will cause the nanocapsules to open, releasing the medication.⁵⁸

b) Nanosensors and Lab-on-a-chip Technologies

Researchers are developing sensors that can be used to monitor the body in a variety of ways thereby assisting in the early detection and identification of diseases.⁵⁹ For example, subcutaneous chips are already being developed to continuously monitor key body parameters including pulse, temperature and blood glucose. Optical micro-sensors implanted into the deep tissue can monitor tissue circulation after surgery. A micro-electromechanical system (MEMS) device and accelerometers can be used to measure strain, acceleration, angular rate and related parameters for monitoring and treating paralyzed limbs and for the improvement of artificial limbs. Implantable sensors can also work with devices, like fluid injection systems that can administer treatment automatically if required. Initial applications could include chemotherapy, directly targeting tumors and dispensing precise amounts of medication at specific intervals that may be convenient for the patient, for instance while they are asleep.⁶⁰ Sensors to monitor the hearts activity level

⁵⁷ Understandingnano “Nanotechnology in Medicine- Nanomedicine” <http://www.understandingnano.com/medicine.html> (accessed 15/12/2012) [Hereinafter “Understandingnano Medicine”]

⁵⁸ Understandingnano Medicine <http://www.understandingnano.com/medicine.html> (accessed 15/12/2012)

⁵⁹ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 16]

⁶⁰ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 15-17]

can be achieved by implanting a defibrillator to regulate heartbeats.⁶¹

c) Nano Devices

Nanotechnology hopes to develop a new generation of smaller and more powerful devices that will restore lost sight and hearing. Some of the approaches being investigated for sight and hearing are:⁶²

➤ Sight

A miniature video camera attached to a blind person's glasses will capture visual signals that are then processed by a microcomputer worn on a belt. This microcomputer will then transmit these signals to an array of electrodes that are placed in the eye. Another approach is with a sub-retinal implant that is designed to replace the photoreceptors in the retina. This implant will use a microelectrode array that is that powered up to 3,500 microscopic solar cells.

➤ Hearing

A transducer is implanted onto a bone in the inner ear, causing the bones to vibrate and move the fluid in the ear stimulating the auditory nerve. An array at the tip of the device uses up to 128 electrodes, five times higher than current devices and capable of stimulating a fuller range of sounds. This implant is connected to a small microprocessor and microphone in a device that can clip behind the ear. It will capture and translate sounds into electric pulses transmitted by wire through a tiny hole made in the middle ear, enabling hearing.

⁶¹ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 16]

⁶² OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 16-17]

d) Repair and Replacement of Damaged Tissue and Organs

Currently damaged tissue and organs are replaced with artificial substitutes. Examples of these conventional methods include pacemakers implanted in heart surgeries and prosthetic limbs that replace natural limbs. Nanotechnology could offer a new range of biocompatible coatings for implants, improving adhesion, durability and lifespan. Nanopolymers could be used to coat devices such as artificial hearts or catheters that are in contact with blood to disperse clots or even prevent them from forming. Research has also been conducted in the following areas: tissue regeneration scaffolds with the ultimate goal being to grow large complex organs. Other examples include nanoscale polymers that can be moulded onto heart valves and polymer nanocomposites for bone scaffolds. These, researchers hope, will be available within the next five to ten years. Bones can be regrown using carbon nanotube scaffolds. Nanostructures are also promising for temporary implants, whereby the implant will biodegrade avoiding the eventual removal in a subsequent surgery. Flexible nanofiber membrane mesh can be applied to heart tissue in open-heart surgery.⁶³ This mesh can be infused with antibiotics, painkillers and other medications that can be dispersed periodically in small quantities and directly applied to the internal tissue. These nanofibers can also stimulate the production of cartilage in damaged joints.⁶⁴

e) New Therapeutic Methods

Other possible applications of nanotechnology include:

- Nanoparticles could aid in the ultrasensitive detection of substances and potentially deadly infections would be avoided. Recent findings revealed that with specially treated nanoparticles, bacterial pathogens may be detected in very low concentrations. This will

⁶³ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 16]

⁶⁴ Understandingnano Medicine <http://www.understandingnano.com/medicine.html> (accessed 15/12/2012)

have massive implications for safety in medicine and food.⁶⁵

- Imaging agents used to analyze biological samples can be used to detect tumors or cancer in its earliest stages.⁶⁶
- Nanobubbles are another new approach for the treatment of diseases; these are formed around gold nanoparticles. There are two types that facilitate different functions. If the nanobubble forms around a hollow gold nanoparticle and is heated with a laser, it can destroy cancer cells. Applying the same process but forming the nanobubble around a solid gold nanoparticle will cause a temporary opening in the cell wall thereby allowing drugs to be injected into the cell. This technique could be used to destroy or modify certain types of cells.⁶⁷
- Eventually it is hoped to create nanostructures, nanorobots that can be programmed to repair damaged cells in the body, mimicking the human bodies natural antibodies.⁶⁸

These new methods for the treatment of diseases can dramatically affect a patient's quality of life. It is hoped that these miracle drugs reach those who are adversely affected by some of the above-mentioned diseases.

8.2. Application: Energy

Globally, attention has been directed to the pending crisis the world is facing when it comes to energy supply. Natural resources are quickly being depleted to the detriment of the environment. This could have a serious ripple effect, affecting not only manufacturing industries but also the availability of food and clean water.

The burning of fossil fuels used to produce our energy supply continues to exacerbate

⁶⁵ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 28]

⁶⁶ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 15]

⁶⁷ Understandingnano Medicine <http://www.understandingnano.com/medicine.html> (accessed 15/12/2012)

⁶⁸ Understandingnano Medicine <http://www.understandingnano.com/medicine.html> (accessed 15/12/2012)

another global problem, namely global warming. The challenge to discover alternative renewable energy sources has become a worldwide priority. Ideally the objective is to increase sustainable energy supply and decrease pollution by ensuring these new technologies are for clean energy. Nanotechnology could be the answer to solving this pending crisis with more efficient, less expensive and environmentally sound alternatives that will optimize production, generation, distribution and storage methods from existing energy sources. By applying nanotechnology, conventional energy sources: fossil, nuclear fuels and renewable energy sources: geothermal energy, wind and hydro energy and biomass can be greatly improved upon.

Nanotechnology applications in the field of energy are discussed in further detail below:

a) Fossil Fuels

Nano coatings for the wear and protection of oil and gas drilling equipment will ensure a longer lifespan and nanoparticles can be used to improve oil production. A gel-based nanocatalyst can liquefy coal and turn it into gas; this method can improve efficiency and reduce cost.⁶⁹

b) Solar Energy

Solar energy is an extraordinary method used to harness energy and is currently the most important source of alternative energy. Due to the increased surface area to volume ratio, nanoparticles can enhance the absorption of sunlight and increase conductivity, resulting in a more efficient photovoltaic effect.⁷⁰ Materials traditionally used are expensive consequently using nanostructured alternatives will greatly reduce these costs.⁷¹

⁶⁹ Nanotechnology Now <http://www.nanotech-now.com/current-uses.htm> (accessed 09/12/2012)

⁷⁰ Soutter <http://www.azonano.com/article.aspx?ArticleID=3068> (accessed 18/12/2012)

⁷¹ Malsch <http://nanotech-now.com/Ineke-Malsch/IMalsch-energy-paper.htm> (accessed 07/05/2012)

To maximize light yield, anti reflection coatings can be applied to solar panels.⁷² This can be achieved by scattering silver nanocubes over a thin gold layer.⁷³

Currently carbon nanotubes, quantum dots and fullerenes are being used to manufacture solar cells, making these more efficient and less expensive.⁷⁴ Researchers are developing dynamic solar cells whereby quantum dots are used for their ability to absorb different wavelengths of light.⁷⁵ Current applications of nanotechnology to solar panels include, self-cleaning solar panels and dye enhanced solar cells. These dye-enhanced solar cells chemically mimic the biological process of photosynthesis; an organic dye monolayer is used to help absorb sunlight, as a plant would.⁷⁶

By treating the glass in buildings with organic solar cells, energy consumption in buildings will be greatly reduced. This new technology was announced by New Energy Technologies and allows for glass to be coated with organic semiconductors that dissolve to create thin photovoltaic cells.⁷⁷ This is achieved by combining silver nanowires, titanium dioxide nanoparticles and polymer that absorbs infra red light.⁷⁸ This can then be spray painted onto surfaces, including cars and buildings.

⁷² Dr. Luther http://www.hessen-nanotech.de/mm/NanoEnergy_web.pdf (accessed 14/12/2012) [At 11 and 21]

⁷³ Understandingnano "Nanotechnology in Solar Cells" <http://www.understandingnano.com/solarcells.html> (accessed 18/12/2012) [Hereinafter "Understandingnano Solar Cells"]

⁷⁴ Gardner 2008 *PCOST* 6

⁷⁵ Gardner 2008 *PCOST* 6

⁷⁶ Soutter <http://www.azonano.com/article.aspx?ArticleID=3068> (accessed 18/12/2012)

⁷⁷ Soutter <http://www.azonano.com/article.aspx?ArticleID=3068> (accessed 18/12/2012)

⁷⁸ Understandingnano Solar Cells <http://www.understandingnano.com/solarcells.html> (accessed 18/12/2012)

c) Biomass

Glucose is the most abundant form of energy available in bio-systems. Glycolysis is based on a form of cell respiration seen in animals.⁷⁹ Researchers have developed a nanowire biofuel cell that will convert chemical energy from biofluids into electricity using glucose oxidase and laccase as a catalyst.⁸⁰ This is a new approach for self-powered nanotechnology; generating electricity from the environment. This method can be applied to wireless sensors, electronics and implantable biomedical devices.⁸¹

d) Geothermal Energy

Geothermal energy is a sustainable and a cost efficient source of energy. Nanotechnology could increase the opportunities to develop geothermal resources by enhancing thermal conductivity or facilitating in the development of non-corrosive materials that could be used for geothermal energy production.⁸² For example nano-coated wear resistant drill probes could extend the lifespan and efficiency of systems for the cultivation of oil and natural gas deposits, thereby being more cost effective.⁸³

Another possible application for nanotechnology is for the recovery of unconventional sources of natural gas. Nano applications can aid in accessing and exploiting this energy source. Nanocatalysts and nanoscale membranes could aid in gas to liquid production and

⁷⁹ Gardner 2008 *PCOST* 7

⁸⁰ Berger "A Nanoscale Biofuel Cell for Self-Powered Nanotechnology Devices"
<http://www.nanowerk.com/spotlight/spotid=19573.php> (accessed 21/12/2012) [Hereinafter "Berger Nanoscale Biofuel Cell"]

⁸¹ Berger Nanoscale Biofuel Cell <http://www.nanowerk.com/spotlight/spotid=19573.php> (accessed 21/12/2012)

⁸² Nanodeltech <http://nanodeltech.com/nanotechnology/nanotechnology-and-energy.html> (accessed 07/05/2012)

⁸³ Berger "Nanotechnology Applications Could Provide the Required Energy Breakthroughs"
<http://nanowerk.com/spotlight/spotid=7424.php> (accessed 07/05/2012) [Hereinafter "Berger Breakthroughs"]

separating different types of gases.⁸⁴

e) Heat Energy

Energy that can otherwise be considered “wasted” could be harnessed and reused as fuel. Most appliances and electronics radiate heat when used for a long period, e.g. a computer: this simple observation has led researchers to develop electrical converters that convert heat into electricity by using biological molecules. These molecules are abundant and biodegradable.⁸⁵ Using carbon nanotube sheets would be very effective in harnessing this energy; these sheets could be wrapped around the exhaust of a car or cover a geyser.⁸⁶

f) Wind and Hydro Energy

Nanomaterials can be used for lighter, stronger and more resistant rotor blades for wind and tide power plants.⁸⁷ For example nanotube filled epoxy rotor blades.⁸⁸ Providing better wear and corrosive protection. Nanocoatings could be applied to the bearings and gearboxes, enhancing their wear ability thereby lasting longer and reducing future costs.⁸⁹

g) Hydrogen

More efficient hydrogen energy generation could be achieved with new processes and nanocatalysts. Hydrogen could be used in nanoporous materials for the application in micro

⁸⁴ Malsch <http://nanotech-now.com/Ineke-Malsch/IMalsch-energy-paper.htm> (accessed 07/05/2012)

⁸⁵ Gardner 2008 *PCOST* 4

⁸⁶ Understandingnano “Nanotechnology and Energy” <http://www.understandingnano.com/nanotechnology-energy.html> (accessed 07/05/2012) [Hereinafter “Understandingnano Energy”]

⁸⁷ Berger Breakthroughs <http://nanowerk.com/spotlight/spotid=7424.php> (accessed 07/05/2012)

⁸⁸ Understandingnano Energy <http://www.understandingnano.com/nanotechnology-energy.html> (accessed 07/05/2012)

⁸⁹ Dr. Luther http://www.hessen-nanotech.de/mm/NanoEnergy_web.pdf (accessed 14/12/2012) [At 4]

fuel cells used in mobile electronics and automobiles.⁹⁰

In terms of distribution, nanotube wiring will improve this as it provides increased strength, conductivity and stability at very high temperatures reducing energy losses in current transmission.⁹¹ Ideally electric cables and pipelines should be replaced with carbon nanotubes.⁹²

Hydrogen is an atomic energy carrier; it is primarily a storage medium for energy.⁹³ This energy can be converted into electrical and other sources of energy. It is advantageous in that it can be transported over extended distances without losing much of its efficiency.⁹⁴ Fullerenes are ideal to store large volumes of hydrogen as it can be condensed in high densities in SWNT. A further development for storage is “nanoblades,” which are exceptionally thin, uniform, with high surface areas.⁹⁵

Nanotechnology could enable cost effective generation, storage and transport for geothermal energy production.

h) Nuclear Energy

Nuclear energy production leaves behind dangerous waste products that need to be safely contained. Nanocomposites can be used in the form of radiation resistant containers that will safely confine nuclear waste.⁹⁶ Nano engineered barriers can assist in preventing the

⁹⁰ Dr. Luther http://www.hessen-nanotech.de/mm/NanoEnergy_web.pdf (accessed 14/12/2012) [At 4]

⁹¹ Gardner 2008 *PCOST* 11

⁹² Understandingnano Energy <http://www.understandingnano.com/nanotechnology-energy.html> (accessed 07/05/2012)

⁹³ Nanodeltech <http://nanodeltech.com/nanotechnology/nanotechnology-and-energy.html> (accessed 07/05/2012)

⁹⁴ Gardner 2008 *PCOST* 10

⁹⁵ Gardner 2008 *PCOST* 11

⁹⁶ Dr. Luther http://www.hessen-nanotech.de/mm/NanoEnergy_web.pdf (accessed 14/12/2012) [At 4]

migration of hazardous waste, i.e. in the case of an accidental leak.⁹⁷ Due to the dangerously high levels of radiation, nanorobotics could also be useful in decontaminating a nuclear accident site.

i) Fuel Cells

Properties of nanoparticles will improve energy and storage capacity and product service life.⁹⁸ Nano optimized membranes and electrodes can enhance the efficiency of membranes used in fuel cells to separate hydrogen ions from other gases (like oxygen) and reduce costs.⁹⁹ This can be applied in mobile electronics and automobiles.¹⁰⁰

j) Batteries

Nanotechnology could be applied to create new types of batteries that will last far longer than conventional batteries. The increased surface area of the nanoparticle results in increased power density to battery size.¹⁰¹ Further applications could include smaller containers that are environmentally friendly, safe for humans and have the ability to recharge batteries much faster.¹⁰²

Carbon nanotubes can be applied in supercapacitors as they yield higher energy densities.¹⁰³ Possible applications of these batteries include mobile electronics and automobiles.

⁹⁷ Nanodeltech <http://nanodeltech.com/nanotechnology/nanotechnology-and-energy.html> (accessed 07/05/2012)

⁹⁸ Gardner 2008 *PCOST* 9-10

⁹⁹ Understandingnano Energy <http://www.understandingnano.com/nanotechnology-energy.html> (accessed 07/05/2012)

¹⁰⁰ Dr. Luther http://www.hessen-nanotech.de/mm/NanoEnergy_web.pdf (accessed 14/12/2012) [At 4]

¹⁰¹ Gardner 2008 *PCOST* 8

¹⁰² Understandingnano Energy <http://www.understandingnano.com/nanotechnology-energy.html> (accessed 07/05/2012)

¹⁰³ Dr. Luther http://www.hessen-nanotech.de/mm/NanoEnergy_web.pdf (accessed 14/12/2012) [At 30]

k) Other Nano Applications

- Nanoparticle monitors could be used to detect any impurities in hydrogen and ensure clean energy.¹⁰⁴
- Lasers, microwaves or electromagnetic resonance based on nano-optimized components could be used for wireless power transmission.¹⁰⁵
- Nanosensors could be used to manage highly decentralized power feeds.¹⁰⁶
- Nanoporous foams and aerogels could be used for thermal insulation for buildings or industrial processes.¹⁰⁷
- Nanosensors that can control the release of pesticides and nutrients and specific intervals for precision farming will optimize biomass energy production.¹⁰⁸
- Inorganic buckyballs used in lubricants can reduce friction thereby reducing energy consumption.¹⁰⁹

These applications, as discussed, illustrate the potential benefits that range from reducing waste and pollution to creating more efficient resource technologies at a lower cost.

8.3. Application: Water Sanitation

The issue of clean water is of particular importance in developing countries.

Nanotechnology could contribute in providing less expensive, more durable and more efficient water desalination methods. Some of these nanotechnology methods are already available, while others are still being developed.

¹⁰⁴ Gardner 2008 *PCOST* 11

¹⁰⁵ Dr. Luther http://www.hessen-nanotech.de/mm/NanoEnergy_web.pdf (accessed 14/12/2012) [At 6 and 32]

¹⁰⁶ Dr. Luther http://www.hessen-nanotech.de/mm/NanoEnergy_web.pdf (accessed 14/12/2012) [At 4]

¹⁰⁷ Malsch <http://nanotech-now.com/Ineke-Malsch/IMalsch-energy-paper.htm> (accessed 07/05/2012)

¹⁰⁸ Dr. Luther http://www.hessen-nanotech.de/mm/NanoEnergy_web.pdf (accessed 14/12/2012) [At 4]

¹⁰⁹ Understandingnano Energy <http://www.understandingnano.com/nanotechnology-energy.html> (accessed 07/05/2012)

Inexpensive methods of water filtration include the use of nanomembranes and nanoclays, these systems are easy to clean and portable.¹¹⁰ With these applications, water is purified and depolluted more efficiently than with conventional filters. These nanomembranes have tiny pores (>10 nm); liquid is pressed through this membrane separating it from the contaminants.¹¹¹ Nanotubes can be used for these nanoporous membranes on large-scale production of water desalination. Nanomesh is another filter option, made from carbon nanotubes; it is flexible and can be placed on a flat substrate or wrapped around traditional cylindrical filters or any other support.¹¹² This mesh allows the water to flow through, thereby separating clean water from any parasites, microorganisms, fungi, viruses and toxins that the water contained.

Other methods include magnetic nanoparticles that remove heavy metal contaminants and salts from liquids, and decompose organic pollutants.¹¹³ Some of these contaminating substances can then be collected and recycled.

9. RISKS

With all new technologies, the potential for new risks should also be taken into account. When considering health and environmental risks, data collected in respect of the same material on bulk scale seems inadequate to rely on as the same material at nanoscale can have a very different effect.¹¹⁴ With further research a greater understanding of nanomaterials will be had resulting in the safe management of this material.

¹¹⁰ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 23]

¹¹¹ Hill <http://www.nanotech-now.com/columns/?article=220> (accessed 24/12/2012)

¹¹² Hill <http://www.nanotech-now.com/columns/?article=220> (accessed 24/12/2012)

¹¹³ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 23]

¹¹⁴ Maynard http://tinhoahoc.com/Nanotechnology/RiskRelatedResearch_Maynard_7-06-Final.pdf (accessed 12/12/2012) [At 10]

9.1. Free and Fixed Nanoparticles

Two types of nanostructures should be distinguished when addressing risks to health and the environment. “Free nanoparticles” and “fixed manufactured nanoparticles.”¹¹⁵ In the latter instance, nanoscale particles are incorporated into a substance, material or device. Therefore, no direct contact will be had by workers, consumers or the environment.¹¹⁶ These nanoparticles are immobilised and therefore pose no risk unless an accident were to occur resulting in discarded or destroyed nanoparticles. Consequently concerns mainly relate to free nanoparticles.

Present nanotechnology focuses on the “planned” manipulation of materials and particles on nanoscale. These can be produced from almost any chemical; those currently in use have been made from transition metals, silicon, carbon (i.e. carbon black, carbon nanotubes, quantum dots) and metal oxides.¹¹⁷ Although several of these have been produced on an industrial scale for decades (i.e. carbon black), quantum dots and carbon nanotubes have only been around for the last two decades. The two distinguishing features of these engineered nanoparticles are their specific physical size of less than 100 nm and the fact that they are deliberately produced. Free nanoparticles on the other hand occur as a by-product at some stage of production or use, such as in the case of welding, sandblasting or even diesel fuel.¹¹⁸

¹¹⁵ Berger “Nanotechnology Risks – The Real Issues”
<http://www.nanowerk.com/spotlight/spotid=1781.php> (accessed 13/09/2012) [Hereinafter “Berger The Real Issues”]

¹¹⁶ Berger The Real Issues
<http://www.nanowerk.com/spotlight/spotid=1781.php> (accessed 13/09/2012)

¹¹⁷ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 28]

¹¹⁸ Gulumian “Nanoparticles, Nanoscience and Nanotechnologies in South Africa”
http://www2.unitar.org/cwm/publications/event/Nano/Abidjan_25-26_Jan_10/22_South_Africa.pdf (accessed 07/09/2012) [At 2] [Hereinafter “Gulumian Nano in SA”]

9.2. Nanoparticles and the Human Body

Thus far it has been established that nanoparticles can be toxic. As explained earlier the larger surface area of the nanoparticle makes it more reactive, this characteristic could make them more toxic than the same material on a larger scale.¹¹⁹ However, it is also argued that the specific nanostructure will have to be investigated, as the mere presence of nanomaterial is not a threat in itself. To properly assess the health hazards of manufactured nanoparticles the whole life cycle of these particles should be evaluated, including their fabrication, storage and distribution, application and potential abuse, and their disposal. Their impact on humans or the environment may vary at different stages of their life cycle.¹²⁰

Due to their size, free nanoparticles can enter the body in various ways reaching and compromising organs and tissue in the body. They can be inhaled, ingested and absorbed via the skin.¹²¹ If inhaled this could cause inflammation in the respiratory tract possibly resulting in tissue damage and subsequent systemic effects. Also if inhaled it is possible for the nanoparticle to be carried throughout the body via the bloodstream whereby other vital organs and tissues can be compromised.¹²²

The effect of these nanoparticles being distributed in the body is highly dependant on the specific nanoparticle. The shape, composition, size and surface characteristics (surface coatings, surface chemistry) all have an influence on the behaviour of the nanoparticle and

¹¹⁹ Maynard http://tinhoahoc.com/Nanotechnology/RiskRelatedResearch_Maynard_7-06-Final.pdf (accessed 12/12/2012) [At 10-12]

¹²⁰ Gulumian 2012 *S Afr Sci* 4-6

¹²¹ Berger The Real Issues <http://www.nanowerk.com/spotlight/spotid=1781.php> (accessed 13/09/2012) Also see: Maynard http://tinhoahoc.com/Nanotechnology/RiskRelatedResearch_Maynard_7-06-Final.pdf (accessed 12/12/2012) [At 10-12]

¹²² OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 30]

its mobility.¹²³ It is important to note that each nanostructure is engineered to perform a specific function and therefore should be studied in light of its own unique biological or ecological responses.¹²⁴ Therefore each specific class or group of nanoparticle will have to be assessed.¹²⁵ A further investigation would need to be conducted into the life cycle of the specific nanoparticle. By dissecting the different stages any changes that occur in the nanomaterial will be revealed. This could assist in detecting and treating the indications of the effects more efficiently, preventing permanent damage.

9.3. Nanoparticles and the Environment

Even if nanoparticles are not harmful to humans they could be to other species thereby disrupting ecological balance.¹²⁶ This disruption could then in turn affect the food chain. Nanoparticles can be released into the environment accidentally or gradually. Some of the ways can include, leakage or emission during production, transportation or storage of the raw, intermediate or finished products, the use of the product and finally when the product is discarded as waste. Distribution and transformation in the air, soil and water are other possibilities.¹²⁷ Products containing nanoparticles can be highly durable and could therefore remain in the environment long after disposal; this can result in an accumulation of waste that can harm the environment especially if they cannot be recycled. Therefore the importance of considering the whole life cycle of the nanoparticle in the product or application in which they are incorporated is emphasised when evaluating risk.

¹²³ Maynard http://tinhoahoc.com/Nanotechnology/RiskRelatedResearch_Maynard_7-06-Final.pdf (accessed 12/12/2012) [At 10-12]. Also see: Berger The Real Issues <http://www.nanowerk.com/spotlight/spotid=1781.php> (accessed 13/09/2012)

¹²⁴ Valverde and Linkov 2011-2012 *Nanotech. L. & Bus.* 31

¹²⁵ Gulumian "Proposals on the Implications of Nanotechnology Risks to South Africa. What are the urgent research needs?" http://www.csir.co.za/nre/pollution_and_waste/pdfs/Gulumian_Proposals%20on%20the%20implications.PDF (accessed 12/12/2012) [At 16] [Hereinafter "Gulumian Nano Risks"]

¹²⁶ Maynard http://tinhoahoc.com/Nanotechnology/RiskRelatedResearch_Maynard_7-06-Final.pdf (accessed 12/12/2012) [At 10-12]

¹²⁷ Berger The Real Issues <http://www.nanowerk.com/spotlight/spotid=1781.php> (accessed 13/09/2012)

9.4. Risk Assessment

Very little has been done in researching the potential hazard of nanomaterials and there is a great deal of uncertainty surrounding their fate. It will take several years before reliable and comprehensive risk assessment standards are established for this technology.¹²⁸ Efforts have been made in this regard; the NNI has established a long-term risk assessment strategy.¹²⁹ However, an interim risk assessment strategy to manage the potential health and environmental risks is very necessary.¹³⁰ Both the private and public sectors should work together in researching and sharing their findings.

Currently the traditional method of assessing risk is applied. These risk assessments, set for the same matter in bulk should only apply as guidelines. It is imperative for regulators to consider the implications of the unusual properties of these nanoparticles. To rely on existing knowledge will create false assumptions of safety.¹³¹ A new research approach may be advantageous when determining the risks of this new technology as the current testing methods to determine toxicity might not prove useful or sufficient. For example, the manner in which nanoparticles can be absorbed by the body do not fall within the norms of what toxicologists usually consider when evaluating exposure.¹³²

Billions are being invested to capitalise on this rapidly developing technology and with this, research to explore the potential risks is sorely lagging behind. These risks need to be assessed as soon as possible, before preventable and predictable problems result in

¹²⁸ Valverde and Linkov 2011-2012 *Nanotech. L. & Bus.* 30

¹²⁹ Gulumian Nano Risks http://www.csir.co.za/nre/pollution_and_waste/pdfs/Gulumian_Proposals%20on%20the%20implications.PDF (accessed 12/12/2012) [At 2]

¹³⁰ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 5]

¹³¹ Maynard http://tinhoahoc.com/Nanotechnology/RiskRelatedResearch_Maynard_7-06-Final.pdf (accessed 12/12/2012) [At 13]

¹³² Valverde and Linkov 2011-2012 *Nanotech. L. & Bus.* 26

setbacks that could otherwise be avoided. The goal should be to narrow the already wide and growing gap between the lack of research and products already available commercially.

In summary, findings based on bulk matter cannot be relied on entirely, not only due to their size but also due to different interactions had with the body. Each nanoparticle should be evaluated separately and at different stages of its lifecycle as changes in the nanomaterial might affect exposure and risk.¹³³ The level of risk management also depends on the relevant branch of industry in question.¹³⁴

9.5. Risk and Investment

Another inherent risk of a new technology is that of investment. Due to the inherent element of unpredictability associated with this technology it is imperative that reference is made to the importance of drafting a high quality patent application (this aspect will be discussed in detail in chapter 2). Investment prospects are encouraged if a company can show that the entire “value-chain” of an invention has been protected.¹³⁵ Economic gain is a primary incentive for innovation and as such this aspect should be mentioned.

10. THE FUTURE OF NANOTECHNOLOGY

Mihail Roco at the NNI, identifies the Four Generations of Nanotechnology as:¹³⁶

¹³³ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 35]

¹³⁴ OECD <http://www.oecd.org/science/safetyofmanufacturednanomaterials/44108334.pdf> (accessed 08/09/2012) [At 32]

¹³⁵ Wild <http://www.iam-magazine.com/issues/article.ashx?g=29c766f2-a9b8-4b94-89d5-d35b9ec8e614> (accessed 31/07/2012) [At 31]

¹³⁶ Boysen and Muir <http://www.dummies.com/how-to/content/nanotechnology-top-down-or-bottom-up.html> (accessed 13/12/2012). Also see: Maynard http://tinhoahoc.com/Nanotechnology/RiskRelatedResearch_Maynard_7-06-Final.pdf (accessed 12/12/2012) [At 12]

1. Passive Nanostructures: **2000 - 2010**

Here materials are designed to perform a specific task. Examples are: nanoparticles, nanotubes, nanocomposites, nanocoatings and nanostructured materials.

2. Active Nanostructures: **2010 - 2020**

We find ourselves in this generation of nanotechnology. Here nanomaterials are used for multitasking. Examples include: electronics, sensors, targeted drugs and adaptive structures.

3. Systems of Nanosystems: **2020 - 2030**

Thousands of components interact with each other in the form of guided molecular assembly, 3D networking, robotics and supra molecules.

4. Molecular Nanosystems: **2030 - 2040**

Here integrated molecular systems, including systems within systems that are capable of accomplishing far more than we are currently able to. Examples are: molecules “by design”, hierarchical functions and evolutionary systems. Examples are: sophisticated molecules for manufacturing of genes inside the DNA of targeted cells and nanosurgery for healing wounds on a cellular level.

CHAPTER 2

IP & NANOTECHNOLOGY

Nanotechnology is a unique and rapidly developing field; it is unlike any technology before it: it's unpredictable nature, complex characteristics, and cross-industry application have created a great deal of uncertainty amongst researchers, inventors and investors seeking to develop, protect or invest in nanotechnology related products. The regulations and procedures of patent law are not technology specific and apply to all technologies in the same manner; however a new generation of technology will bring with it a new generation of IP challenges. In order for a nanotechnology patent to be valid and adequately protected, it is imperative that the technology is understood not only by the patent practitioner who is responsible for ensuring that the inventor gains from the full use of his invention but also the patent examiner who has the cumbersome duty of evaluating the validity of a nanotechnology invention in light of the state of art and other substantive requirements set by patent law.

This chapter will explore the challenges facing new nanotechnology patent applications, some of which originate from past nanotechnology patents, i.e. patented "building blocks" and the use of overly broad claims. Others relate to the technology itself, i.e. the inherent characteristics of nanotechnology, lack of standardised definitions and cross-industry application. Objections and criticism received by earlier patents serve as excellent insight to drafting better patent specifications that are likely to succeed if submitted for re-examination or litigation. It is arguable that retrospectively many patents that were granted for nanotechnology inventions in the past would have been rejected based on the knowledge that has since been acquired.

In light of this study, it is important to explore the differences and similarities in the processes and requirements set for patents by different patent systems. The U.S. and Europe have well-developed IP systems and their patent systems are often used as models for other countries to base their patent systems on. The requirements for a valid patent will be addressed individually and important factors to consider when drafting the patent application will be discussed throughout this chapter. This investigation will be conducted

within the context of the USPTO and EPO's approach when examining the validity of nanotechnology patents. In chapter 3, these approaches will be compared to the South African patent system and the present position South Africa finds itself in regarding nanotechnology patent applications.

1. SOME OF THE CHALLENGES OF NANOTECHNOLOGY IN PATENT LAW

The primary objective of patent law is to encourage innovation for economic gain. Patent systems are in place to give inventors the financial incentive to create products and negotiate access to their technology by marketing their invention thereby contributing to the economic development of the country. Nanotechnology has the potential to significantly improve known technologies and create new technologies in varied fields, ultimately having an immense impact on not only the economy but also on society's quality of life. With the promise of a better future an influx of nanotechnology patents was experienced worldwide, resulting in some of the challenges currently facing new nanotechnology patent applications.

1.1. Patented "Building Blocks"

Often referred to as the patent "land grab," one of the main challenges facing present nanotechnology patent applications is that many of the fundamental "building blocks" of this science have already been patented forming part of prior art and preventing other applications from ever becoming patents.¹³⁷ These patents comprise the fundamental concepts upon which later developments are based and could cover a wide range of basic nanotechnology inventions that could be applied to a broad spectrum of fields.¹³⁸ Furthermore these early nanotechnology patents have very broad claims and are expected

¹³⁷ Hicks, Grissett and Brown <http://www.wcsr.com/resources/pdfs/nano030310.pdf> (accessed 04/05/2012) [At 11]

¹³⁸ Nanowerk News "Nanotechnology and Intellectual Property Issues" <http://nanowerk.com/news/newsid=1187.php> (accessed 02/05/2012) [Hereinafter "Nanowerk News IP Issues"]

to overlap in scope with patents in other fields.¹³⁹ This after-effect can be attributed to nanotechnology's vast cross-industry application and that these patents were not examined in light of different art units that may have been applicable to the particular invention.

This issue is best illustrated with an example of how these patented nanotechnology building blocks can result in infringements and impede further innovation.¹⁴⁰ Carbon nanotubes (CNTs) are considered to be one of the most significant of the nanomaterials discovered thus far, due to their incredible properties and vast commercial application. They can, for example, be applied in materials and compounds for reinforcement used in construction, the field of medicine and pharmaceuticals, nanoelectronics and nanomechanical devices, biotechnology, agriculture, energy production, storage and distribution and telecommunications. As a result of their enormous commercial appeal and potential application, an enormous number of patents were sought for CNT based products. These patents claimed nanotubes in compositions of matter, methods of production and products containing or incorporating nanotubes thereby creating a dense patent thicket whereby an inventor would have to reach licencing agreements for multiple patents from multiple fields so as to avoid possible infringements from occurring.¹⁴¹

These patents could claim CNT related inventions in a variety of ways. Drew Harris, a lawyer and Managing Editor of Nanotechnology Law and Business explains that there are three primary types of claims:¹⁴²

1. Composition of matter claims
2. Product, device, apparatus or systems claims
3. Method claims

¹³⁹ O'Neil *et al* 2007 *Nanotech. L. & Bus.* 595

¹⁴⁰ Nanowerk News IP Issues <http://nanowerk.com/news/newsid=1187.php> (accessed 02/05/2012)

¹⁴¹ Berger "Growing Nanotechnology Problems: Navigating the Patent Labyrinth" <http://nanowerk.com/spotlight/spotid=1367.php> (accessed 02/05/2012) [Hereinafter "Berger Growing Nano Problems"]

¹⁴² Berger Growing Nano Problems <http://nanowerk.com/spotlight/spotid=1367.php> (accessed 02/05/2012)

The term “building block” patent therefore refers to the above-mentioned claims claiming CNTs as the subject matter of the invention. In other words the application claims nanotubes or nanotube based products or methods for making nanotubes or products incorporating nanotubes as the invention. An infringement occurs when every element of the claim or equivalent of the claim is found in the later claimed process or product of the patent.¹⁴³ The claimed elements determine the scope of a patent.

Harris further explains that CNT patents are divided into two categories, “basic building block” patents and “applied building block” patents. The term “basic building block” patent is used to describe patents claiming fundamental properties of CNTs such as nanotube compositions of matter, general techniques applied in producing nanotubes and the tools commonly used to change and manipulate nanotubes. This description would lead one to assume that this general category of patents is likely to be infringed across a broad spectrum of industries. On the other hand, the term “applied building block” patent refers to patents claiming specific products incorporating CNTs and specific methods for manufacturing those products. Examples include, apparatus and method claims directed to nanotube transistors, nanotube based sensors and nanotube embedded in polymer resins. In summary it can be said that due to the specificity of this category only a select number of companies in specific industries would be affected by potential infringements.¹⁴⁴

Companies that have invested in conducting research of CNT based products are likely to infringe these categories of CNT patents. The novelty of the invention and scope of the claims will be argued thereby challenging the validity of the patent. Negative repercussions of these thickets include legal uncertainty, significant legal costs and licencing costs for companies seeking to manufacture and develop such products. Investment prospects and mass production will also be adversely affected.¹⁴⁵

¹⁴³ Manual of Patent Examining Procedure § 2131 [Hereinafter MPEP]

¹⁴⁴ Berger Growing Nano Problems <http://nanowerk.com/spotlight/spotid=1367.php> (accessed 02/05/2012)

¹⁴⁵ Berger Growing Nano Problems <http://nanowerk.com/spotlight/spotid=1367.php> (accessed 02/05/2012)

In the light of the example of CNTs, patent thickets could severely undermine the primary incentive of patents viz. to provide the inventor with the exclusive monopoly to use and commercialise the product or process in return for the public's use thereof and could serve as a deterrent to innovate. Furthermore innovation is limited rather than encouraged, as inventors will attempt to create their inventions around existing patents.¹⁴⁶ It is necessary to confront this complex nanotechnology patent landscape with meticulous review in order to safeguard against new nanotechnology patents from infringing upon earlier patents. By circumnavigating this labyrinth, uncertainty amongst researchers, developers, policy makers and investors as to who owns which part of nanotechnology IP will be reduced.

1.2. Broad Claiming

As discussed, early nanotechnology patents not only claim fundamental concepts necessary for further advances in the field but also tend to claim these concepts in an overly broad manner thereby encompassing far more than the actual invention is capable of accomplishing. The use of unduly broad claims in patent applications leads to uncertainty regarding scope of coverage of the patent.¹⁴⁷ Inevitably these patents will overlap and infringe upon earlier patents in other fields, eventually resulting in invalidation. Arguably some of these early nanotechnology patents were unintentionally drafted with the use of general and broad claims in the specification due to the newness of the technology, i.e. the lack of standardised definitions and not fully comprehending the adaptability of this discipline in multiple fields. These patents were consequently granted due to the lack of prior art and knowledge necessary for the examiners to thoroughly and accurately determine novelty and non-obviousness.

The issue of broad claiming can be described by referring back to the discussion on building block patents, i.e. when nanotubes are claimed as the subject matter of the invention, the claim is broad because it is claiming protection for all nanotubes or nanotube based products and/or the methods for making nanotubes and/or products incorporating

¹⁴⁶ Watal and Faunce http://wipo.int/wipo_magazine/en/2011/02/article_0009.html (accessed 02/05/2012)

¹⁴⁷ O'Neil *et al* 2007 *Nanotech. L. & Bus.* 604

nanotubes as the invention. These patents receive protection for basic concepts that have general application thereby hindering newer patent applications and creating an “overlapping patent landscape”¹⁴⁸ for patents containing nanotubes as part of the invention. Although desirable to the patent holder who stands to profit from his exclusive IP rights, as he owns the monopoly to determine whom, when and how the technology can be used irrespective of the field in which it is applied. He will also expose himself to a wider range of potential infringers.

Broad claims increase the risk of negative claim interpretation and there is also a greater probability that the specification will not cover the entire width of the claimed invention thereby putting into question the fulfillment of the enablement requirement. As seen in earlier patents the use of overly broad claims will encourage litigation as broad claims are often more easily challenged and investors will be hesitant to invest in a product with broad claims even if that product will be profitable.¹⁴⁹ The patent practitioner can avoid these costly and time consuming downstream problems, i.e. litigation and re-examination, by ensuring the claims are not broader than the description of the invention contained in the specification, when drafting the patent application. Claims are only enforceable if they are valid and they will only be valid if the breadth and scope of the claim is “enablingly” disclosed, i.e. the invention can be worked across the entire width of the claims. Investors will ultimately be assured of the defensibility and validity of a patent if care was taken to submit an application with a focused claim.

1.3. Problems with a Standardised Definition

Another major challenge is the absence of a standardised definition for nanotechnology and nanotech concepts.¹⁵⁰ There has been a great deal of criticism surrounding the lack of

¹⁴⁸ The term “overlapping patent landscape” refers to a patent thicket, i.e. a dense maze of overlapping IP rights.

¹⁴⁹ Wild <http://www.iam-magazine.com/issues/article.ashx?g=29c766f2-a9b8-4b94-89d5-d35b9ec8e614> (accessed 31/07/2012) [At 30-31]

¹⁵⁰ Berger Nano Patent Land Rush <http://www.nanowerk.com/spotlight/spotid=1919.php> (accessed 02/05/2012). Also see: Chapter 1, section entitled “1. NEW ADVANCEMENTS IN TECHNOLOGY: THE

proficiency of patent examiners in the field of nanotechnology and for the absence of a standardised definition reference.¹⁵¹ As discussed briefly in the previous chapter, initiatives by various organisations are in place to create a uniform definition for nanotechnology terms. The EPO introduced the Y01N tagging system to classify nano-related documents¹⁵² and in the US, experts in both the public sector, for example USPTO and private sector, The Institute of Nanotechnology are collaborating to devise a first standard of nanotechnology nomenclature.¹⁵³

In 2004, the USPTO's introduced Classification 977 as a cross-referencing system that was designed to aid in searching prior art related to nanotechnology and organise nanotechnology related subject matter in a logical manner. This class contains 263 subclasses and allows for patents to be referenced in two ways, firstly in an area related to specific technology and then a supplemental search resource is provided for nanotech classifications.¹⁵⁴ Class 977 has assisted in more efficient searches and reduced a great deal of ambiguity relating to nanotechnology terms. Furthermore it has aided in eliminating some of the uncertainty relating to the ownership rights of nanotechnology IP.¹⁵⁵

However despite the USPTO's efforts there are still some problems with Class 977, in particular, inconsistencies regarding the definition and scope of the current definition given to nanotechnology. This classification merely groups relevant patents together for prior art searches. It fails to assess or communicate a relationship between these patents or identify overlapping or infringing claims. As a result all pre-2004 patents were assessed at the

DEFINITION AND SCOPE OF NANOTECHNOLOGY" and the USPTO, EPO and NNI nanotechnology definitions provided in footnotes 4,5 and 8.

¹⁵¹ Berger Nano Patent Land Rush <http://www.nanowerk.com/spotlight/spotid=1919.php> (accessed 02/05/2012)

¹⁵² Gosain http://www.daniel.adv.br/eng/articlesPublications/ranaGosain/NANOTECHNOLOGY_PATENT_PROTECTION_BRAZIL_AND_THE_WORLD_MARKET.pdf (accessed 22/05/2012) [At 3]

¹⁵³ O'Neil *et al* 2007 *Nanotech. L. & Bus.* 597

¹⁵⁴ Paradise 2012 *NJTIP* 170

¹⁵⁵ O'Neil *et al* 2007 *Nanotech. L. & Bus.* 595 and 597

examiner's discretion.¹⁵⁶ In 2005 USPTO enforced a stricter definition of nanotechnology resulting in a decline of nano-related patents received by the office.¹⁵⁷

A standardised reference of definitions and terminology is needed, especially due to the multidisciplinary nature of nanotechnology. The same term can refer to significantly different structures depending on the field it is applied to. The NNI and USPTO use similar definitions but not all definitions have the same parameters. The same structure can be described in various ways resulting in difficulty determining what is included and excluded from a term used in a claim.¹⁵⁸ For example, silicon nanocrystals with the average diameter of 1-30 nm, as opposed to, nanocrystals light emitting a spectral range no greater than 60 nm. The patent examiner must determine the scope of the claim therefore it is recommended and in the best interest of the applicant to define the terms he uses to describe the properties in his invention. If the applicant fails to do so the broadest, most reasonable interpretation consistent with the specification will be given.¹⁵⁹ In other words the terms used in the claim are interpreted within the context of any definition given in the specification and if no definition is given, the "plain meaning" will be given, i.e. the meaning a person skilled in the art of the relevant field would give the term when reading the specification.¹⁶⁰

The field of nanotechnology poses a particular challenge when interpreting the terms of a nanotechnology invention due to the many meanings that are available; the same structure can have multiple terms describing it or the same term can have different meanings.¹⁶¹ Furthermore, cases where the applicant acts as his own lexicographer and defined unknown terms could also make it difficult for the examiner to determine novelty. By creating a

¹⁵⁶ Paradise 2012 *NJTIP* 170 and 184-186

¹⁵⁷ Pouris 2010 *University of Pretoria* 108-109

¹⁵⁸ Mills, Fitzsimmons and Rodkey 2010 *Nanotech. L. & Bus.* 223-235

¹⁵⁹ *In re Hyatt* 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000)

¹⁶⁰ MPEP § 2111

¹⁶¹ Mills, Fitzsimmons and Rodkey 2010 *Nanotech. L. & Bus.* 233

uniform definition reference for nanotechnology terms, confusion relating to similar terms used in different fields will be reduced.

It is maintained that many of the issues relating to nanotechnology patents stem from the lack of a standardised definition therefore a uniform, standard reference would: limit broad claims, simplify the task of the examiners when interpreting undefined terms and unify concepts used in different fields thereby eliminating doubt and ultimately avoiding the invalidation of patents at a later stage.

1.4. The Multidisciplinary Application of Nanotechnology

Nanotechnologies have a vast application enabling processes and products in multiple fields. This was illustrated by the examples given regarding the many applications of carbon nanotubes.¹⁶² It is therefore imperative to have a comprehensive view of the nanotechnology patent landscape when evaluating the validity of nanotechnology patent applications.¹⁶³

Patent examiners are technically trained in a particular field and are tasked with evaluating the validity of the invention claimed in the patent application. In the past inventions were examined under a single classification or related classes of technology¹⁶⁴ whereas nanotechnology inventions can combine different fields of science and technology and the examiners are not necessarily equipped with the varied expertise required to examine such an invention, as a result the risk of overlooking prior art in other relevant sectors is increased and the granted patents, will in all probability be invalidated in court at a later stage due to overlapping claims.¹⁶⁵

¹⁶² See: Chapter 2, section entitled, "1. SOME OF THE CHALLENGES OF NANOTECHNOLOGY IN PATENT LAW: 1.1. Patented 'Building Blocks'"

¹⁶³ Watal and Faunce http://wipo.int/wipo_magazine/en/2011/02/article_0009.html (accessed 02/05/2012)

¹⁶⁴ Gosain

http://www.daniel.adv.br/eng/articlesPublications/ranaGosain/NANOTECHNOLOGY_PATENT_PROTECTION_BRAZIL_AND_THE_WORLD_MARKET.pdf (accessed 22/05/2012) [At 3]

¹⁶⁵ Watal and Faunce http://wipo.int/wipo_magazine/en/2011/02/article_0009.html (accessed 02/05/2012)

The multidisciplinary application of this technology is of particular importance when determining whether the requirements of novelty and non-obviousness have been met. It is problematic for the examiner to search for all of the relevant prior art due to the fact that they may be located in various areas or fields of technology.¹⁶⁶ In an attempt to resolve this issue the USPTO's responded by appointing examiners from the various relevant fields thereby creating a team to examine patents that incorporated more than one discipline,¹⁶⁷ thus ensuring all of the potentially relevant prior art sectors be consulted.

It is fair to conclude from the above that although the field of nanotechnology is new and continues to be a challenge for examiners, who still have limited expertise and have to cope with deficiencies of definitions, etc., the Patent Offices have undertaken all the measures necessary to minimize inadequate results of searches and examination. As in case of all new technologies, it will probably still take some time to deal with nanotechnology the same way as with other more traditional technologies.

2. THE PATENT APPLICATION PROCESS

The application process is the most important step in protecting an invention. In order to maximise the inventions potential benefit, it is essential to ensure this step be dealt with the greatest care and foresight so as to guarantee a strong and valid patent.

2.1. The Claim/s

The claim is the most valuable part of the patent application as it determines the scope of the invention.¹⁶⁸ Two requirements must be met when drafting the claim, the subject matter the inventor considers his invention to comprise of and the scope of what the inventor includes as part of his invention must be described exactly as the inventor will only

¹⁶⁶ Wild <http://www.iam-magazine.com/issues/article.ashx?g=29c766f2-a9b8-4b94-89d5-d35b9ec8e614> (accessed 31/07/2012) [At 30]

¹⁶⁷ Watal and Faunce http://wipo.int/wipo_magazine/en/2011/02/article_0009.html (accessed 02/05/2012)

¹⁶⁸ Carvalho <http://www.nanotech-now.com/columns/?article=229> (accessed 31/07/2012)

be protected in respect of the content of this disclosure. The protection he receives will then prevent third parties from producing the same process or product the inventor has claimed as his invention. Furthermore he should define the type of claim; by doing so the extent of protection sought for his invention will be refined and this distinction can be important when determining whether the invention was anticipated by prior art. By disclosing all the elements of the invention claimed in each claim of the patent application, the inventor will be able to rebut any objections of obviousness raised by providing the limitations of his invention as evidence.

a) Types of Claims

➤ Species and Genus Claims

A species claim defines one element at a time (it is specific) as opposed to a generic claim where the element claimed is defined widely enough to include all of the species of that genus (a general claim).¹⁶⁹ The inventor should claim as many species as possible of the genus that is sought by the invention, including a description of the different types of nanoscale structures the components can take: for example he should describe these structures as nanoparticles, nanotubes or nanocrystals.¹⁷⁰ Furthermore, in order to avoid including an infringing claim the applicant should also differentiate between the classes of materials and give clear characteristics of the structure: for example a nanoparticle that is 60 nm in all dimensions.¹⁷¹ The inventor should also discuss how he measured and characterized the subject matter by including the instruments he used. It is important to describe the types of materials used to prepare the structure, for instance semiconductors or metals. By giving more detailed information the applicant reduces his risk of the examiner concluding the invention forms part of prior art.

¹⁶⁹ Alstadt <http://faculty.law.pitt.edu/alstadt/> (accessed 04/04/2013) [*Select “claim drafting” to open this document] [At 28 section 26]

¹⁷⁰ Mills, Fitzsimmons and Rodkey 2010 *Nanotech. L. & Bus.* 234

¹⁷¹ Mills, Fitzsimmons and Rodkey 2010 *Nanotech. L. & Bus.* 234

For example, a generic claim would be broad: “A composite material, comprising one or more nanostructures, wherein one or more nanostructures comprise one or more: nanocrystals or nanowires.” Whereas a species claim will include further limitations on the above by adding: “A ‘nanostructure’ is a structure having at least one characteristic dimension of less than about 100 nm.”

A further example is U.S. Patent 7,101,761: “*Method of fabricating semiconductor devices with replacement, coaxial gate structure.*”¹⁷² Claim 1 reads:

“The invention claimed is:

- 1. A method comprising: providing a nanostructure covered on a substrate; oxidizing a first portion of the nanostructure to define a sacrificial layer between the substrate and a second portion of the nanostructure; forming a first support structure over the nanostructure; forming a second support structure over the nanostructure; and removing the sacrificial layer from the nanostructure such that second portion of the nanostructure is suspended a distance from a surface of the substrate between the first and second support structure.”*

From this excerpt the term “*nanostructure*” seems broad enough to cover various types of nanostructures. However dependent Claims 5 and 7 confine the term nanostructure to include “*nanowire structures*” and “*nanotube structures:*”

“5. The method of claim 1, wherein the nanostructure comprises a nanowire structure.

7. The method of claim 1, wherein the nanostructure comprises a nanotube structure.”

Despite these limitations, Claims 5 and 7 cannot be read into Claim 1 due to the doctrine of claim differentiation, in terms of which Claims 5 and 7 cannot be used to narrow the scope of the Claim 1.¹⁷³

¹⁷² Issued on September 5, 2006 to Intel Corporation

¹⁷³ See: Section entitled “2.2. Interpretation of the Claim” for further explanation (below)

By referring to the specification, a more detailed description is given of the types of nanostructures referred to in this patent and limits these nanostructures further by referring to their size:

“As used herein, the term nanostructure refers to any structure having a diameter less than about 50 nm, such as a nanowire or a nanotube. The term nanowire is used herein to describe any nanowires, including silicon nanowires. The term nanotube is used herein to describe any nanotubes, including single-walled or multiple-walled carbon nanotubes.”

Consequently the specification has narrowed and clarified the otherwise broad, generic claim as described in Claim 1 by providing specific characteristics of the nanostructures.

There are instances where the state of art disclosing a genus class will anticipate the species claimed within that genus. Assessing whether the species was anticipated by prior art is evaluated on a case-by-case basis by applying the doctrine of anticipation.¹⁷⁴ The courts approach in assessing anticipation will be discussed in further detail under the section regarding non-obviousness.

➤ Method versus Apparatus Claims

Patent law distinguishes between two statutory classes, method claims and apparatus claims. A product or apparatus claim refers to the device itself, for example a nanomachine. Therefore an infringement will occur where third parties use all the elements of claimed invention. A method or process claim comprises the various steps required to make or use the invention. An infringement will occur where third parties perform each of the steps claimed as the invention.¹⁷⁵

¹⁷⁴ AIPPI <http://www.aippi-us.org/images/GR209usa.pdf> (accessed 02/04/2013) [At 4-6]

¹⁷⁵ Strand <http://www.lexology.com/library/detail.aspx?g=df5ab67a-9322-44bd-bf2a-db71cbb77169> (accessed 08/04/2013)

This distinction is important as these claims can sometimes be treated differently when applying for a patent. A machine can be described as complex molecular structure, resulting in uncertainty as to whether the invention should be treated as a compound or an apparatus. The determining factor for interpreting the invention claimed will depend on the manner in which the applicant describes the invention.¹⁷⁶ If the patent applicant describes the invention as a nanomachine, i.e. an apparatus, it will be treated as such and vice versa for compound claims.

Furthermore the distinction can be relevant in determining whether the invention is anticipated, for instance a prior art device can anticipate the claimed process.¹⁷⁷ This will happen when a prior art device, in its normal and usual operation would perform the method claimed. In other words where the prior art device and the device described in the patent application responsible for effecting the process claimed are the same; it will be assumed the prior art device will inherently perform the claimed process. Where applicable, the applicant can claim both the use and the method of the invention, as this will ensure the inventor receives the full benefit from his invention. However this will only be possible if both the method and apparatus claimed are inventive.¹⁷⁸

2.2. Interpretation and Scope of the Claims

I. USA

The required contents for the specification are set out in § 112 Patent Act,¹⁷⁹ namely a full written description of the subject matter that the inventor claims as his invention and these claims must be expressed in “*full, clear, concise, and exact terms.*” Furthermore the description must include the manner and process for making and using the invention so as

¹⁷⁶ Zech 2009 *SCRIPTed* 152-153

¹⁷⁷ MPEP § 2112.02

¹⁷⁸ Alstadt <http://faculty.law.pitt.edu/alstadt/> (accessed 04/04/2013) [*Select “claim drafting” to open this document] [At 19 section 18]

¹⁷⁹ Title 35 of the U.S.C

to enable a person skilled in the pertinent art to make and use the same. Additionally the best mode for doing so must be provided.

Often patents believed to have complied with this section will be subjected to claim interpretation by a court in order to determine their true scope.¹⁸⁰ A claim interpretation hearing otherwise referred to as a “Markman” hearing, will outline the meaning of the claim language, i.e. the claims in respect of which the inventor has described the subject matter that comprises his invention. The judge, typically a lay-person, with regards to the claimed technology will review the claim terms for their intended meaning in order to determine the scope of the claim.¹⁸¹ The purpose of this procedure is to determine whether the inventor has a valid claim and if valid, whether it has been infringed. The court therefore focuses on the scope of the patent to determine infringement and if the scope is unclear, the patent will have to be reviewed in order to determine the inventor’s intended meaning of the terms used to claim his invention.

The *DuPont* case is arguably one of the first nanotechnology cases and may be particularly relevant to future nanotechnology related patent applications as it touches on the following important issues: broad claims, non-obviousness and the unpredictability of claim construction. In this case, Cabot, the largest supplier of CMP slurries, sued DuPont in a five patent suit for infringement relating to the ingredients and methods used in the chemical mechanical polishing technique known as CMP.¹⁸² This technique is used for planarization or polishing the surface of a substrate, for example a semiconductor wafer, by way of combining chemical and mechanical forces. The “slurry” comprises abrasive (nanoscale) particles and a chemically reactive solvent that is deposited onto a rotating polishing pad, which is then placed over a substrate. The chemical ingredient weakens the surface thereby

¹⁸⁰ O’Neil *et al* 2007 *Nanotech. L. & Bus.* 598

¹⁸¹ O’Neil *et al* 2007 *Nanotech. L. & Bus.* 598-599

¹⁸² *DuPont Air Products Nanomaterials L.L.C v. Cabot Microelectronics Corporation*, Civil Action no. CV06-2952-PHX-ROS (D. Ariz. 2006), Markman_Order_072508 [At 2-3] [Hereinafter the *DuPont* case]

creating a thin layer of crust, which is then removed by the mechanical ingredient, i.e. the rotating pad thereby flattening and polishing the surface of the wafer.¹⁸³

The Federal Circuit stated that claim construction is a question of law and referred to the *Markman* case, in respect of which the term “Markman Hearing” was coined to describe a pre-trial phase to the hearing whereby the parties are given the opportunity to contest the meaning of key terms and phrases in their patent applications. This case is particularly significant because the court held that the language of a patent is a matter of law for a judge to resolve (and not a matter of fact for a jury to decide on). Furthermore the court recognized two categories of evidentiary roles, namely intrinsic evidence and extrinsic evidence.¹⁸⁴ Intrinsic evidence refers to the specification, claims and the prosecution history (viz. the negotiations between the USPTO and the inventor) of a specific patent. Extrinsic evidence includes all other sources, for example expert testimony, dictionaries, treatises and technical drawings.¹⁸⁵

Phillips v. AWH Corp. was also referred to, in terms of which the court revisited the rules on claim construction and established an evidentiary priority method for interpreting claims.¹⁸⁶ The court stated the importance of giving claim terms their ordinary meaning, if the ordinary meaning is not clear to a lay judge the meaning should be understood in light of a person skilled in the pertinent art.¹⁸⁷ In other words, the broadest, most reasonable meaning understood by such a skilled person, that is consistent with the specification, should be given. The court recognised that the applicant can act as his own lexicographer, specifically defining the terms used to describe his invention. Should intrinsic sources of evidence determine the “*special meaning*” of the claim terms, the inventor’s definitions will

¹⁸³ *DuPont* case [I. Technical Background at 2-3]

¹⁸⁴ *Markman v. Westview Instruments Inc* 116 S.Ct 1384 (1996)

¹⁸⁵ O’Neil *et al* 2007 *Nanotech. L. & Bus.* 599

¹⁸⁶ *Phillips v. AWH Corp.* 415 F. 3d.1303 (Fed. Cir. 2005) (en banc) [Hereinafter the Phillips case]

¹⁸⁷ *Phillips* case [At 1314]

govern the interpretation.¹⁸⁸ The court stated that the prosecution history is not as useful as other intrinsic evidence as it only represents the negotiations between the USPTO and the inventor and can therefore lack clarity of the final claim language. However it can show how the examiner understood the invention, which is helpful in determining the scope of the invention.¹⁸⁹ If the terms are still unclear after this step, extrinsic evidence should be consulted. The court emphasised that intrinsic evidence should be given greater weight than extrinsic evidence as it is unlikely to be a reliable interpretation for the following reason: extrinsic evidence is not part of the patent. Such an interpretation may be driven by litigation, it might not reflect the understanding of the skilled artisans and it may change the meaning that was otherwise indicated by intrinsic evidence.¹⁹⁰ The judge stated that claim construction is similar to the determination of obviousness: it too is considered a factual finding. Cabot acted as their own lexicographer and used terms that were within the meaning of technical dictionaries in order to avoid uncertainties relating to the terms used in their claim. At the Markman hearing the court favoured Cabot, accepting their definitions given for specific terms.

The *Phillips* case emphasises the relevance of the specification to the claim construction examination and the court stated that it is the “single best guide to claim meaning”¹⁹¹ due to the fact that it describes the invention in full, clear, concise and exact terms. Furthermore it may reveal specific definitions given by the inventor, especially where he acted as his own lexicographer or reveal subject matter that he specifically wanted to exclude or include in his claim. The court also noted that the specification must be interpreted within the context of when the application was filed.

Occasionally courts will apply the doctrine of claim differentiation to clarify the scope of the coverage provided for by a patent claim.¹⁹² It is assumed that two claims in the same patent

¹⁸⁸ *Phillips* case [At 1316]

¹⁸⁹ *Phillips* case [At 1303]

¹⁹⁰ *Phillips* case [At 1303]

¹⁹¹ *Phillips* case [At 1315]

¹⁹² O’Neil *et al* 2007 *Nanotech. L. & Bus.* 599

are not intended to have the same scope. Therefore this doctrine disallows the broadening of a claim beyond that which is disclosed in the specification and prohibits the narrowing of broad claims by incorporating limitations of narrower claims. For example when a patent describes a “table with plurality of legs” as the independent claim and the dependant claim recites “legs.” The independent claim is not recited in the dependant claim and the dependant claim will protect tables with four legs whereas the independent claim will protect tables with four or more or less legs. Thereby ensuring the broad claim scope is relied upon when a claim on its own may be understood as having either a broad or narrow interpretation.

II. EUROPE

According to Article 69 of the European Patent Convention of 1973, *“The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.”* In addition, *“For or the period up to grant of the European patent, the extent of the protection conferred by the European patent application shall be determined by the claims contained in the application as published. However, the European patent as granted or as amended in opposition, limitation or revocation proceedings shall determine retroactively the protection conferred by the application, in so far as such protection is not thereby extended.”*

The European Patent Convention of 1973 adopts a balanced approach when interpreting the claims of the patent. The intention is to find balance between a strict, literal meaning and using the claims as guidelines. According to the EPC’s Protocol on the Interpretation of Article 69, *“it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.”*

This approach is appropriate when interpreting the claims of nanotechnology patents in that the technology is new and adequate definitions have not yet been formulated. The description and drawings included in the patent will be referred to clarify instances of ambiguity regarding the claims.

2.3. Drafting the Claim

A claim cannot comprise entirely of “means plus function” (mpf) elements, these are well known elements that form part of prior art. Examples are screws, nuts and bolts, glue or Velcro. An invention will not be eligible for a patent if the application claims these elements as the invention without describing a corresponding structure associated with the mpf term.¹⁹³

I. USA

In light of the interpretation process adopted by the courts it is evident that claim construction is extremely important when drafting a patent application as definitions of technical terms, grammatical and semantic interpretation can all lead to uncertainty regarding the scope of the invention.¹⁹⁴ A better understanding of the courts approach in analysing and deciding the claim construction will allow for improved patent applications.

As indicated by cases the claims and specification can provide important signs as to what the intended meaning of the claim language may be. The patent practitioner should meticulously check for “minor” differences in claim terms from one claim to another in order to assure they accurately reflect the breadth and scope of the invention.¹⁹⁵ The claim should be written with the broadest possible meaning supported by specification,¹⁹⁶

¹⁹³ Crouch <http://www.patentlyo.com/patent/2013/01/means-plus-function-claiming.html> (accessed 02/04/2013)

¹⁹⁴ Carvalho <http://www.nanotech-now.com/columns/?article=229> (accessed 31/07/2012)

¹⁹⁵ Carvalho <http://www.nanotech-now.com/columns/?article=229> (accessed 31/07/2012)

¹⁹⁶ MPEP § 2131

balance should be the objective: it should be written broadly enough to adequately protect the invention but also narrow enough to avoid including potential prior art, thereby risking invalidity.¹⁹⁷ The claim should not be limited by specific uses and methods of processing, as this will prevent the inventor from gaining from the full monopoly of his invention.¹⁹⁸ For example where a patent for nanocomposite material used in coating applications is sought, the patent attorney will not only claim the use of the material but also extend the scope of the claim to include the material itself. Thereby extending the protection to all possible fields that could use the invention, including those he did not consider.

The inventor should define key terms used to describe the invention. By not defining unknown terms, he runs the risk of a broad interpretation, which can result in structures in the art being included that he would otherwise specifically exclude. Furthermore the court could apply the plain meaning, i.e. the dictionary definition of the term and this could harm the applicant's application. The patent practitioner has the autonomy to define and use claim terms in any way he chooses, therefore it is in the best interest of the applicant that the terms are clearly defined. When defining terms conflict between dictionary meaning and meaning from context of specification should be avoided (as done by Cabot in the *DuPont* case). Using very broad claim language, such as "nanostructures" or "nanoparticles", increases the risk of terms being construed incorrectly, interpreting a meaning not intended by the applicant.¹⁹⁹

Claim construction will determine the value, breadth, strength, validity and ultimately the enforceability of the patent. By taking into account the above-mentioned factors, a carefully and well-constructed high quality patent will be drafted. A strong patent will be easier to enforce and more likely to receive protection for a variety of possible modifications, improvements and other infringing products or methods using the basic knowledge applied in the patented invention.

¹⁹⁷ Alstadt <http://faculty.law.pitt.edu/alstadt/> (accessed 04/04/2013) [*Select "claim drafting" to open this document] [At 30]

¹⁹⁸ Cisneros 2009 *Nomos* 27-28

¹⁹⁹ O'Neil *et al* 2007 *Nanotech. L. & Bus.* 597

II. EUROPE

The same principles regarding drafting the claims, apply to European patents. Short of repeating the above discussion, the claim must clearly and concisely define the subject matter in respect of which protection is sought.²⁰⁰ The claims must be supported by the description, including a description of technical features of the claimed invention. These technical features can be structural or functional.²⁰¹

The only contrasting feature is the form of a U.S. patent (i.e. the one-part claim). European applications normally contain the so-called two-part claim.²⁰² This means the claim is interpreted by the examiner in two-parts, initially the claim lists some features then contains the phrase “*characterised in that*” or “*with an improvement comprising,*” after which it lists one or more further features (the second part). The latter features are referred to as characterising features and these features constitute the invention. This section of the claim is referred to as the characterising portion. The former or pre-characterising features are found in the prior art and the examiner will firstly find the closest prior art, that is the document that shares the most features with the invention and then request that the claim be delimited therefrom. Should the applicant include a novel feature in the pre-characterising portion, he or she will be asked to remove it and this will not affect the patentability of the invention. If a pre-characterising feature was included in a U.S. patent application, it may invalidate the application.

3. REQUIREMENTS FOR A VALID PATENT

The basic requirements for a valid nanotechnology patent will be addressed individually and within the context of the USPTO and EPO respectively.

²⁰⁰ EPC Art 84

²⁰¹ EPC Rule 43(1)

²⁰² Ius Mentis <http://www.iusmentis.com/patents/uspto-epodiff/> (accessed 07/12/2012)

I. TITLE 35 U.S.C. §101 PATENTABILITY REQUIREMENTS

In the USA, the requirements for a valid patent are: 1) Novelty, 2) Non Obviousness, 3) Utility, and 4) Enablement.²⁰³

The predictability of the field of technology influences the abovementioned requirements therefore it is necessary to have a good understanding of this technology in order to adequately protect nano-related inventions.²⁰⁴ The inherent nature of nanotechnology presents a particular challenge when determining the predictability of an invention; it is unpredictable in terms of its properties and relationships with other materials making it difficult to protect. The predictability of an invention will influence the validity of the patent; it is therefore a significant factor to consider when drafting the patent application. This aspect will be discussed further under the requirement of non-obviousness, utility and enablement respectively.

1) Excluded Subject Matter

MPEP clearly sets out the guidelines regarding the eligibility of patentable subject matter. Accordingly a patent cannot be obtained for an idea or suggestion, abstract ideas, physical phenomena and laws of nature.²⁰⁵ However there can be exceptions to these exclusions, for example a novel quantum circuit can be patented but the quantum mechanic process underlying the circuit is not patentable i.e. the theory motivating the end result. Several of these ineligible topics will be discussed for the purposes of directly comparing the different approaches adopted by the USPTO and EPO regarding the same subject matter.

²⁰³ Almeling 2004 *STLR* ¶3. Also see: Hicks, Grissett and Brown <http://www.wcsr.com/resources/pdfs/nano030310.pdf> (accessed 04/05/2012) [At 4] and Mills, Fitzsimmons and Rodkey 2010 *Nanotech. L. & Bus.* 225

²⁰⁴ Mills, Fitzsimmons and Rodkey 2010 *Nanotech. L. & Bus.* 225

²⁰⁵ MPEP § 2106

a) Scientific Theories

The National Academy of Science (NAS) defines a scientific theory, “*as a well-substantiated explanation of some aspect of the natural world, that can incorporate facts, laws inferences and tested hypotheses.*”²⁰⁶ Scientific theories are based on a large body of knowledge that has been repeatedly confirmed through observation and experimentation.

From this definition it can be assumed that scientific theories are examples of law of nature or natural phenomena and consequently excluded as patentable subject matter.²⁰⁷

Although not specifically excluded, some of the reasons relating to their ineligibility include:

1. The U.S. Supreme Court describes four categories of invention types for utility patents in terms of Title 35 U.S.C. § 101; “*any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof*” can be patented. Scientific theories do not fall within any of these categories and occur “*without the hand of man.*”²⁰⁸
2. Scientific theories lack novelty; a law of nature is assumed to have existed irrespective when a person discovers it.²⁰⁹ An invention must be new and not merely unknown. (The principles relating to discoveries, discussed in the section that follows, also apply to scientific theories).
3. Patent law is usually interested in the end result, the product or use of the invention and not the theory or research leading to that end result. Scientific theories are useful in that they are the foundations on which advancements in the field of science and technology are made. However they lack a specific use, in other words

²⁰⁶ National Academy of Sciences http://www.nap.edu/openbook.php?record_id6024&page=2 (accessed 24/04/2013) [Page 13 at 2]

²⁰⁷ Gupta http://works.bepress.com/cgi/viewcontent.cgi?article=1000&context=deepak_gupta (accessed 24/04/2013) [At 4-5]

²⁰⁸ *Association for Molecular Pathology et al. v. Myriad Genetics Inc. et al* 569 US _ (2011) [Hereinafter the *Myriad* case]

²⁰⁹ *Mayo Collaborative Services v. Prometheus Laboratories Inc.* 566 U.S. ___, 132 S.Ct. 1289 (2012) [At 1, (3)] [Hereinafter the *Mayo* case]

they have generic utility,²¹⁰ which arguably could stifle future developments in the field of science and technology by creating a monopoly. Consequently they do not fulfil the utility requirement.

Here follows a hypothetical example illustrating this rationale; humans have been lighting fires for centuries and this was done without realising oxygen fuels combustion. The first person to discover the necessity of oxygen to create and maintain a flame would not have been able to patent the method for making a fire because this occurrence is a law of nature. It is fair to say that his observations resulted in understanding the importance of one element, oxygen, to create the other, fire. However even if prior art did not disclose the importance of oxygen to create a fire and a person skilled in the art was not aware of this principle, the discoverer would still not have the right to preclude others from making fires.

In the *Mayo* case, the patent at issue claims a diagnostic method that relies exclusively on a law of nature, Claim 1 of the '623 patent reads as:

“A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointesti-nal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointesti-nal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per 8x10⁸ red blood cells indicates a need to increase the amount of said drug subsequently admin-istered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per 8x10⁸ red blood cells indicates a need to decrease the amount of said drug subsequently ad-ministered to said subject.”²¹¹

²¹⁰ Gupta http://works.bepress.com/cgi/viewcontent.cgi?article=1000&context=deepak_gupta (accessed 24/04/2013) [At 10]

²¹¹ *Mayo* case [At 5-6, IA]

The Supreme Court found this claim to be ineligible and stated, *“if a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself. A patent, for example, could not simply recite a law of nature and then add the instruction “apply the law.”*²¹² The claims in this patent do not alter or transform the natural law that is applied, it simply describes the relationships between the concentrations of certain metabolites in the blood and the probability that a dosage of a thiopurine drug would either be ineffective or cause harm. The three-steps described in Claim 1 read as instructions for dosage. The way in which the drug will be metabolized by the body depends on the individual and the method for determining metabolite levels are considered well known by those in the relevant field of art.²¹³ Consequently the diagnostic method claimed as the invention cannot be patented. The Supreme Court also repeatedly emphasized that it would be incorrect to grant patents for natural laws, referring to them as *“the basic tools of scientific and technological work,”* as this would inhibit future discoveries from being made.²¹⁴

b) Discovery versus Invention

U.S. patent law refers to an invention as an invention or discovery. In terms of § 101, *“whoever invents or discovers a new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent for it subject to the conditions and requirements of this title.”* Therefore a discovery can be patented if the invention claimed fulfills the requirements set for any invention, i.e. novelty, utility, non-obviousness and enablement.

Despite U.S. patent law stating, *“invents or discovers”* case law reveals that the courts have differentiated between these two concepts. In *Morton v. New York Eye Infirmary*, the

²¹² *Mayo* case [At 8-9, IIA]

²¹³ *Mayo* case [At 10, IIA]

²¹⁴ *Mayo* case [At 3, (3)]

invention claimed was the use of ether to anesthetize patients during surgical procedures. The court held that the use of this substance claimed was a discovery and not an invention by explaining, “*the discovery of a new principle, force, or law operating did not entitle the discoverer to a patent unless he went beyond the mere domain of discovery and connected the new principle, force, or law operating with some particular device which allowed him exclusive control under patent law.*”²¹⁵ The court concluded that the invention simply claimed the use of the ether (a known substance) by a well-known means to a new use.²¹⁶ Therefore the invention lacked novelty; finding a new use for a known substance does not within itself deserve the protection of a patent. If the inventor applies a principle to an object, thereby going beyond the mere discovery of the substance, such an object may be eligible for a patent. In relation to this case, the fact that ether can be applied during surgical procedures does not make it more than a discovery.

The *Myriad* case is a very recent case dealing with the patentability of naturally occurring products or natural phenomena, which are considered to be discoveries. At issue, whether human genes are patentable. Myriad was responsible for identifying two genes that influence the possibility of developing breast or ovarian cancer, namely BRCA1 and BRCA2. Up until this time it was known that these types of cancer are hereditary but Myriad established their precise location. Myriad held several patents relating to this discovery, namely, methods for using the sequence of these mutations to test for breast cancer, a kit to perform the test and the “genes” themselves. The latter was at issue. The Supreme Court held that Myriad simply separated the gene from the surrounding genetic material and this act did not amount to an invention. They did not create or alter the genetic information encoded in BRCA1 and BRCA2, nor the genetic structure of DNA. Therefore the genes were not patentable as DNA fragments occur in nature.²¹⁷ The court concluded that a fragment of a human genome is a product of nature. Furthermore they distinguished and discussed cDNA (complementary DNA), which is derived from DNA however it does not occur

²¹⁵ *Morton v. New York Eye Infirmary* 17 F. Cas. 879, 844 (S.D.N.Y. 1862) U.S. (No 9,8650) [Hereinafter the *Morton* case]

²¹⁶ *Morton* case [At 810 and 813]

²¹⁷ *Myriad* case [At II B]

naturally, it is synthetic and is therefore patentable.²¹⁸

On 13 June 2013, the Supreme Court ruled against this patent. If it had been found valid, it would have meant Myriad would have had the exclusive rights to isolate an individual's BRCA1 and BRCA2 genes thereby being the only institution to test patients and preventing further research on these genes by others. Furthermore they would have been able to exclusively synthetically create BRCA cDNA. The Supreme Court held that the genes and the information they hold is not patentable simply because it is isolated from surrounding genetic material.²¹⁹

Therefore in both cases, the respective inventions claimed were simply discoveries, neither had created or altered their discovery and although both were useful discoveries, their actions did not amount to an act of an invention in light of the provisions of the U.S.C.

➤ Naturally Occurring Products

Nanotechnology often draws from "inventions" already existent in nature therefore it is important to discuss the topic of naturally occurring products and their patentability. Laws of nature, natural phenomena, and naturally occurring products are not patentable, however there are exceptions. For example:

1. If the inventor is able to isolate the substance and it is unknown to the public at this date, it can be patented;
2. A variation of the substance that displays a substantial advantage over the naturally occurring substance can be patented;²²⁰
3. Finding a new use for an old naturally occurring structure based on unknown properties. However in this instance the patent will only protect the use and not the

²¹⁸ *Myriad* case [At II C]

²¹⁹ *Myriad* case [At III]

²²⁰ Tech Transfer <http://www.techtransfer.umich.edu/resources/inventors/patents.php> (accessed 07/04/2013)

product itself.²²¹ This will be considered anticipated and not patentable if the use claimed is aimed at a result or property of that composition or structure.

Diamond v. Chakrabarty, was an influential case on the topic of modified naturally occurring substances.²²² The subject of the patent was a bacterium developed, *pseudomonas putida*, which was capable of breaking down crude oil. At issue was whether genetically modified organisms could be patented in terms of Title 35 U.S.C. § 101. Chakrabarty's patent comprised three types of claims: first, process claims for the method of producing the bacteria; second, claims for an inoculum comprised of a carrier material floating on water, such as straw and the new bacteria; and lastly, claims to the bacteria themselves. The patent examiner allowed the first two claims, but rejected the third claim for the bacteria. He reasoned: that microorganisms are "*products of nature*", and as living things they are not patentable subject matter under § 101.

The court not only discussed the provisions of § 101 in that bacteria (as a living organism) is specifically excluded as patentable subject matter but also whether allowing the patent for the bacteria itself would result in a monopoly thereby impeding further progress in the field of scientific research.²²³ The applicant argued that he produced the new bacterium with distinctly different characteristics from any microorganism found in nature and this developed bacteria had the potential for significant utility thereby fulfilling the provisions of § 101 (as a non-naturally occurring manufacture or composition of matter). Therefore this was a product of human handiwork and not that of nature.²²⁴ The court was satisfied with Chakrabarty's arguments.

The *Diamond* case demonstrates how the inventor, by modifying the naturally occurring substance, was able to make an otherwise un-patentable object patentable. In contrast, the

²²¹ *Funk Brothers Seed Co. v. Kalo Inoculant Co.* 333 U.S. 127, 135 (1948) [Hereinafter the *Funk Bros.* case]

²²² *Diamond v. Chakrabarty* 447 U.S. 303, 206 USPQ 193 (1980) [Hereinafter the *Diamond* case]

²²³ *Diamond* case [At 319]

²²⁴ *Diamond* case [At 310]

Myriad case (where identifying the exact location and isolating the BRCA1 and BRCA2 genes did not qualify as an invention in light of § 101)²²⁵ and the *Funk Brothers* case (below) can be referred to wherein neither of the patentees, in the respective cases could show that they had done the same.

In *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, the invention claimed a method of producing a multi-purpose inoculant: a root-nodule bacteria that was used and packaged for sale to inoculate the seeds of leguminous plants. The use of the bacteria described, Rhizobia, was well known and so was the method for selecting the strong strains and producing the bacterial culture from them. Furthermore it was known that no single species of this bacterium worked with all species of leguminous plants. The patentee however discovered strains of each species of root-nodule bacteria that could inoculate plants belonging to different groups of plants.²²⁶ He created and sold packages containing the claimed invention: a mixture of different species of Rhizobia, suitable for a variety of plants. Funk Brothers Seeds sold similar multi-purpose inoculant packages thereby infringing the patent held by Kalo (the patentee). The Supreme Court held that the properties in the bacteria were a “*work of nature*”²²⁷ and therefore not patentable, thereby reversing the Court of Appeals opinion that the packaging of these strains together went beyond the laws of nature and discovery.²²⁸ Kalo did not alter the bacteria in any way (as opposed to Chakrabarty) he merely discovered that certain strains of each species of these bacteria could be mixed. The bacteria performed in its natural way independently from the patentee’s actions. Therefore these packages could not be described as an invention within the meaning given by patent law. The court stated, “*if there is to be invention from [a discovery of a law of nature], it must come from the application of the law of nature to a new and useful end.*”²²⁹

²²⁵ See: Section entitled “I. USPTO REQUIREMENTS: 1) Excluded Subject matter: b) Discovery versus Invention” (above)

²²⁶ *Funk Bros.* case [At 132]

²²⁷ *Funk Bros.* case [At 135]

²²⁸ *Funk Bros.* case [At 133]

²²⁹ *Funk Bros.* case [At 136]

These cases clearly illustrate the Supreme Court's interpretation and application of U.S. patent laws provisions regarding naturally occurring products, i.e. that the manner of implementing a natural principle must itself be patentable. Consequently a patent on a machine, manufacture, or composition of matter that is based on a law of nature will be possible since machines follow the laws of physics in their operation and chemical compositions of matter follow the laws of chemistry. Where the underlying principles of science are combined with human intervention, i.e. the processing of naturally occurring materials, transforms these substances into an object for manufacture or composition of matter or an improvement thereof, the result can be patented.²³⁰ However the requirements for novelty and non-obviousness must also be met for a valid patent.²³¹

c) Selection Inventions

It is highly probable for the subject matter of a nanotechnology patent to coincide with the subject matter disclosed in prior art, for instance where an invention claims to use varying sizes of nanoparticles thereby infringing upon those disclosed in the prior art while simultaneously introducing new sizes that were not disclosed. In other words this patent will, in a sense, "overlap" with the prior art. The question then arises whether such an invention will still be patented.

The EPO refers to these patents as "selection inventions," U.S. statutory law on the other hand, does not make this distinction consequently the USPTO examines all patents in the same manner when determining their validity. Therefore the same principles discussed in the above sections regarding patentable inventions will apply here (§ 101).

²³⁰ Hicks, Grissett and Brown <http://www.wcsr.com/resources/pdfs/nano030310.pdf> (accessed 04/05/2012) [At 11]

²³¹ Hollaar <http://digital-law-online.info/lpdi1.0/treatise54.html> (accessed 07/04/2013)

In terms of the provisions of patent law, there are no laws that prohibit new and non-obvious claims from overlapping with prior art.²³² The validity of overlapping patents will be assessed within the scope of the patent and are decided on a case-by-case basis.

Anticipation plays a significant role in assessing whether the overlap is sufficiently specified in the claims. The term “anticipation” refers to a situation where each and every element of the prior art is disclosed exactly in the claimed invention.²³³ The content of the term “sufficient specificity” is dependant on the facts of the case; if the claims are directed to a narrow range and the reference teaches a broad range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with “sufficient specificity” to constitute an anticipation of the claims.²³⁴ In other words if the prior art discloses a range which overlaps with the claimed range and no specific examples are given, for instance where the temperature range of 100-500 °C does not describe a claimed range of 330-450°C with sufficient specificity to conclude the claimed range was anticipated by the prior art. Consequently despite the slight overlap, between the reference’s preferred range (150-350°C) and the claimed range, it is not sufficient for anticipation.²³⁵

Therefore overlapping patents may be valid when “*prior art which teaches a value or range that is very close to, but does not overlap or touch, the claimed range does not anticipate the claimed range.*”²³⁶ Furthermore all inventions must fulfil all of the substantive requirements of a valid patent. Novelty and non-obviousness will be determined by assessing the predictability of the invention claimed. Arguably it should be easier to obtain a patent for a selection invention in an unpredictable field of art, such as nanotechnology

²³² Baluch 2005 *Nanotech.L. & Bus.* 345

²³³ MPEP § 2131

²³⁴ MPEP § 2131.03 II

²³⁵ *Atofina v. Great Lakes Chem. Corp* 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006)

²³⁶ MPEP § 2131.03 III

than in any other field of technology.²³⁷

2) **Novelty**

Novelty is the primary obstacle for the patentability of a nanotechnology invention. Nanomaterials can be objects of manufacture or compositions of matter and many nanotechnology methods are associated with a machine or transform materials from one form to another.²³⁸ Nanotechnology is often referred to as a “refining” or “enabling” technology as it improves existing technologies,²³⁹ making it particularly difficult to determine novelty. An invention will be considered novel if certain conditions are met, namely, at the time the invention was made, it was not disclosed to the public thereby not forming part of the state of art and was not anticipated by prior art.²⁴⁰ Relevant prior art is established by locating art that most closely resembles the invention and this will be used as a comparison to determine novelty. In order for an invention to be anticipated, the anticipation must be inherent, in other words the invention is an obvious progression from prior art.

Title 35 U.S.C. § 102 lists the conditions for novelty:

“A person shall be entitled to a patent unless-

- a. The invention was known or used others in this country, or patented or described in a printed publication in this or foreign country, before the invention thereof by the applicant for patent, or*

²³⁷ AIPPI <http://www.aippi-us.org/images/GR209usa.pdf> (accessed 02/04/2013) [At 1 and 6]

²³⁸ Title 35 U.S.C § 101

²³⁹ Nanotechnology Public Engagement
https://docs.google.com/viewer?a=v&q=cache:7euScJRhaFQJ:www.npep.co.za/pdfs/articles-and-factsheets/Health/fact%2520sheet.pdf+Nanotechnology+Public+Engagement+“Nanotechnology+and+Health”&hl=en&gl=za&pid=bl&srcid=ADGEEESi3nE6055JHZOMuQSoEZcxLS-nLMhNvpVYd489PylCc7M6wkYFJpOowa240LFnC8mS0hs0kJEgMXTwIkJhu1_JKjE75IW-i5kf1ciCj6xxxSyZdFb32aJ1FamKVsZfkCHx4AY-8&sig=AHIEtbSWJgdsIQSC1bRoV7u2ZrvH77eLhQ (accessed 07/11/2012) [At 1]

²⁴⁰ MPEP § 2112

- b. *The invention was patented or described in a printed publication in this or foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or*
- c. *He has abandoned the invention*
- d. *The invention was first patented... or was the subject of an inventor's certificate... in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or*
- e. *He did not himself invent the subject matter sought to be patented."*

The above excerpt sets out five situations where an invention will not be considered novel. Firstly, any printed publications are referred to as prior art references. This includes any published written material, in any language, anywhere in the world. For example journals, white papers, graduate theses, patents, published patent applications, web pages and poster presentations given at meetings. Prior art references must disclose every element of a claimed invention in order to anticipate it.²⁴¹ The doctrine of "*inherent anticipation*" may apply where all the elements are not disclosed expressly, for instance the elements of the claim may be inherent in a disclosed composition or process.²⁴² Hence this doctrine will apply when an inherent prior art feature, process or product established to form part of the state of art and neither the applicant nor the public were aware of this; the claimed invention comprising of the inherent prior art features, process or product will not necessarily be new and patentable based on this discovery. Therefore the patent can still be anticipated irrespective of whether the inherent feature was known at the time of the patent. This doctrine will not apply if prior art disclosing the claimed subject matter does so accidentally or unwittingly.²⁴³ Furthermore the anticipatory inherent feature, process or

²⁴¹ MPEP § 2131

²⁴² MPEP § 2112

²⁴³ Hicks, Grissett and Brown <http://www.wcsr.com/resources/pdfs/nano030310.pdf> (accessed 04/05/2012) [At 6-7]

product must be foreseeable in the prior art, “probability” and “possibility” will not suffice.²⁴⁴

Additionally the inventor will lose his right to patent his invention if he delays filing his application within the twelve-month period granted. This consequence serves as encouragement for an inventor to file within this grace period. He cannot abandon his invention, this can happen for example when the inventor criticises his own work in a peer reviewed journal or white paper. Furthermore, an invention will not be novel if the inventor is prevented from filing a patent application in a foreign country more than one year prior to filing a U.S. application. Finally, the inventor must invent the invention in respect of which he seeks a patent; it cannot be copied from someone else.

Recently significant changes were made to the provisions pertaining to the definition of “prior art” in terms of § 102. These changes were implemented by the America Invents Act (AIA), which took effect on March 16, 2013. In terms § 3 of the AIA, the U.S. will adopt the first-to-file system and the scope of prior art available whereby patent applications can be rejected and patents invalidated is expanded.

The new § 102(a) states that a person shall be entitled to a patent unless:

“(1) The claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective date of the claimed invention; or

(2) The claimed invention was described in [an issued U.S. patent], or in [a published U.S. patent application or a published PCT application designating the U.S.], in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.”²⁴⁵

²⁴⁴ MPEP § 2112 IV

²⁴⁵ Leahy-Smith America Invents Act of 2011

Differences between pre-AIA provisions and the AIA provisions include: the former definition distinguishes between prior art relating to the application filing date and other prior art relating to the date of the invention. The new § 102 discards this distinction and prior art is exclusively defined in terms of the effective filing date. The “*effective filing date*” is the priority date of the application, such as the filing date of a parent patent application,²⁴⁶ a PCT application or a foreign patent application.²⁴⁷ Furthermore it adds, “*or otherwise available to the public*” thereby removing geographic limitations from what constitutes prior art.

Furthermore § 102 (b) describes certain exceptions for disclosures that are made within one year of the effective filing date by the inventor or person who has derived his invention from the inventor’s disclosure.²⁴⁸ This grace period does not apply for sales or offers for sale or public use and these limitations are extended worldwide.

These changes could affect the difficulty with which an applicant will be able to obtain a patent. By expanding the available prior art to include prior art patents and published applications (including published PCT applications, only where the U.S. has been designated) it may be more difficult to meet the requirements of novelty and non-obviousness. At present the AIA is not yet in force.

A common misconception relating to nanotechnology inventions is that they are merely miniaturized versions of prior art, i.e. they are smaller versions consisting of the same subject matter as their larger scale versions. This reduction in size will only be novel if the elements and features of the invention produce new, non-obvious and unexpected results.²⁴⁹ Therefore size in itself does not necessarily establish novelty; the properties and

²⁴⁶ A “parent patent application” is a divisional patent application that contains matter from a previously filed application.

²⁴⁷ USPTO.gov http://www.uspto.gov/aia_implementation/faqs_first_inventor.jsp (accessed 13/06/2013)

²⁴⁸ IPO http://www.ipo.org/wp-content/uploads/2013/03/Patent_Reform_Chart_Comparison_of_AIA_and_Pre-AIA_Laws_FINAL.pdf (accessed 13/06/2013) [At 2]

²⁴⁹ *Graham v. John Deere Co. of Kansas City* 383 U.S. 17-18 USPQ 459 (1966) [Hereinafter the *John Deere* case]

characteristics of nanomaterials that are often different to those of the same material in bulk will determine novelty. For example electronic properties of nanoscale materials can in bulk conduct electricity and be an insulator at nanoscale. The mechanical properties of material are highly dependant on atomic scale effects, as the strength increases the material generally becomes less ductile, for example graphite is usually soft and brittle but carbon nanotubes are extremely strong. Chemical properties change as the size of the material is reduced the ratio of the surface area to volume increases dramatically. Therefore the reduction in size can change a material's chemical structure and increase its chemical reactivity. These examples illustrate how properties and materials at nanoscale can have very unpredictable effects.

3) Non-obviousness

The requirement of non-obviousness extends the inquiry of novelty by determining whether the invention is adequately new. There must be a clear difference between the properties of the claimed invention and those in relevant prior art in order for the invention to be considered novel and non-obvious. Once novelty is established it must then be determined whether the invention is obvious to a person skilled in the pertinent art. If such a person considers it to be obvious, the invention will not warrant a patent. A patent cannot be obtained if the differences between the subject matter sought to be patented 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.²⁵⁰ The phrase "*subject matter as a whole*" is of particular importance, the scope and content of prior art and differences between prior art and claimed invention and the level of ordinary skill in the pertinent art must be compared.²⁵¹

Every element of the claim must have been publically known in the prior art at the time of the patent application for the invention to be un-patentably obvious.²⁵² "*Ordinary skill*"

²⁵⁰ Title 35 U.S.C § 103

²⁵¹ MPEP § 2131B

²⁵² MPEP § 2131

refers to a person who has ordinary skill in the field or area of the relevant invention.²⁵³ The area of the art will usually dictate the level of skill required for a person to be considered skilled in that art. Some areas of art require a general knowledge and others require industry specific experience or a certain qualification.²⁵⁴ According to MPEP § 2131, several factors are considered to determine level of skill in the art:

1. The type of problems encountered in the art;
2. Prior art solutions to those problems;
3. Rapidity with which innovations are made;
4. Sophistication of the technology;
5. Educational level of active workers in the field.

This hypothetical person should have a special knowledge of all the prior art in the specific field relevant to the invention, at the time of the patent application. Therefore if a person skilled in the art who is working in the field of art at the time of the invention is able to combine these known prior art elements using a known method and with no change to their respective functions and this combination yields a predictable result, the invention will be obvious.

Examiners must consider the broad application of nanotechnology inventions when considering relevant prior art. The examiner should have knowledge of all prior art pertaining to the invention, however, with the possible convergence of various fields in one invention the examiner may not have the necessary skill required to examine other relevant art units or may overlook some of these. This will increase the risk of the invention overlapping with patents in these overlooked fields. It is essential that examiners are able to distinguish between inventions that are new and relevant prior art for a valid patent.

²⁵³ MPEP § 2131 C

²⁵⁴ Hicks, Grissett and Brown <http://www.wcsr.com/resources/pdfs/nano030310.pdf> (accessed 04/05/2012) [At 7]

Obviousness is a question of law based on underlying factual questions. In *Graham v. John Deere Co. of Kansas City*, the Supreme Court coined this factual inquiry, the “Graham factors.” These factors are intended to assist the examiner in determining obviousness by:²⁵⁵

1. Determining the scope and content of the prior art;
2. Ascertaining the differences between the claimed invention and the prior art;
3. The level of ordinary skill in the pertinent art.

Furthermore secondary considerations, such as objective evidence, will be very persuasive and must be included in the enquiry of obviousness. This includes commercial success, a long-felt but unsolved need, failure of others, evidence that the claimed invention was copied by others and unexpected results or properties not in prior art.²⁵⁶ This information will “give light to the circumstances surrounding the origin of the subject matter sought to be patented.”²⁵⁷ This evidence can form part of the specification (as the declaration).

In terms of commercial success, the success of the product must be as a result of the invention claimed in the patent. It is necessary to determine reasonable expectation of success in combination with prior art references in a manner suggested by the theory of obviousness. Some degree of predictability is required, any evidence that shows that those in the field would not consider reasonable expectation of success in that combination or modification is important. There must be a link between this success and the invention claimed.

²⁵⁵ *John Deere* case [At 1 and 148]

²⁵⁶ *John Deere* case [At 17-18]

²⁵⁷ *KSR International Co. v. Teleflex Inc.* 550 U.S. 398, 82 USPQ2d (2007) [At 1727, 1734] [Hereinafter the *KSR* case]

These factors were reaffirmed in the *KSR* case, whereby the following guidelines to establish a prima facie case of obviousness were added. Obviousness will be established if the patent application claims a combination of prior art elements whereby:²⁵⁸

1. Combining prior art elements according to known methods to yield predictable results;
2. Simple substitution of one known element for another to obtain predictable results;
3. Use of known technique to improve similar devices (methods, or products) in the same way;
4. Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
5. It would be “obvious to try.” Choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
6. Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
7. Some teaching, suggestion or motivation in prior art that would have led a person of ordinary skill to modify the prior art reference or combine the prior art references to arrive at the claimed invention.

Non-obviousness is possibly the most difficult barrier in determining the patentability of a nanotechnology invention. As established from these guidelines, the element of predictability plays a substantial role in determining non-obviousness, usually if a person skilled in the art can anticipate the effect of the change within the subject matter to which the claimed invention pertains, the art is predictable. Within the context of nanotechnology, nanoscale materials generally display different characteristics due to their increased surface area to volume ratio than the same material in bulk. Nanomaterials are considered to be inherently unpredictable, making it more difficult to determine the obviousness of a nanotechnology invention. Therefore it should be relatively simple to corroborate non-

²⁵⁸ *KSR* case [At 1395-1397]

obviousness by showing a person skilled in the field would not combine the known elements to yield the improvement due to the unpredictability of the field.

Generally an invention will be considered obvious if it is purely a smaller version of the prior art, whereby it performs the same function and produces the same result. However, if prior art does not enable a person skilled in the art to produce a version of the known device on nanoscale, the nanoscale device will be non-obvious even if the size is the only difference.²⁵⁹ A product is not obvious as a matter of law unless the process for making that product is also obvious.²⁶⁰ Furthermore an invention at nanoscale will not be obvious if it produces new, improved properties or facilitates new uses for known compositions. The patent can be obtained for the use of that known property in a particular environment.²⁶¹ Another instance is if the invention claims to overcome a technical problem pertaining to the prior art thereby affording a significant technological advantage over prior art,²⁶² the solution can be claimed as the invention.

The inventor is not obliged to submit data or other evidence showing these improved results when he files his application, however by including this information he may avoid the examiner assuming the invention is obvious.²⁶³ This information is likely to be available, especially if the inventor requested all the experimental data be kept and catalogued properly. It serves as the best form of evidence to rebut a prima facie case of obviousness especially if the patent practitioner anticipates this argument. He will also save an enormous amount of time. Such evidence is of particular importance when applying for a nanotechnology patent due to the unpredictable nature of this field. By anticipating arguments for obviousness, the application can be drafted in such a way that the challenges

²⁵⁹ Abe <http://www.fasken.com/files/Publication/1db6f3c3-a757-4067-af7c-901a5498ecd8/Presentation/PublicationAttachment/da755b60-42ff-44e8-9e57-582e2a83b8f7/NANOTECHNOLOGY.PDF> (accessed 02/05/2012) [At 10]

²⁶⁰ Dr. Stipkala <http://ipfrontline.com/depts/article.aspx?id=4755&deptid=3> (accessed 02/05/2012)

²⁶¹ Abe <http://www.fasken.com/files/Publication/1db6f3c3-a757-4067-af7c-901a5498ecd8/Presentation/PublicationAttachment/da755b60-42ff-44e8-9e57-582e2a83b8f7/NANOTECHNOLOGY.PDF> (accessed 02/05/2012) [At 10]

²⁶² Watal and Faunce http://wipo.int/wipo_magazine/en/2011/02/article_0009.html (accessed 02/05/2012)

²⁶³ Dr. Stipkala <http://ipfrontline.com/depts/article.aspx?id=4755&deptid=3> (accessed 02/05/2012)

faced by the inventor can be described and shown how they were overcome, thereby reducing the need to argue unpredictability of art and lack reasonable expectation of success. Therefore by considering the predictability of the invention, potential inquiries that will be costly and delay the process can be circumvented and a clear, concise application will be submitted.

MPEP states that each case must be decided on its own facts and the Graham factors as well as secondary considerations are part of the obvious analysis. *In re Dillon*, Dillon's invention claimed hydrocarbon fuel compositions containing these tetra-orthoesters and the method of reducing soot emissions during combustion by combining these esters with the fuel before combustion.²⁶⁴ The examiner rejected the application as obvious due to similar prior art compositions and similar uses. The court stated "*a prima facie case of obviousness is not made unless both (1) the new compound or composition is structurally similar to the reference compound or composition and (2) there is some suggestion or expectation in the prior art that the new compound or composition will have the same or a similar utility as that discovered by the applicant.*"²⁶⁵ The court concluded there was no suggestion in the prior art references, alone or in combination of the particulate-reducing property and use discovered by Dillon for her new compositions. Therefore a prima facie case of obviousness was not made.²⁶⁶ Dillon's invention was not obvious, it claimed a new method of reducing particulate emissions that was neither taught nor suggested by prior art.

It is important to mention the AIA has also altered § 103, by changing the date on which to assess the obviousness of an invention from the pre-AIA criterion: "*the time the invention was made*" to "*before the effective filing date of the claimed invention.*"²⁶⁷ Therefore the

²⁶⁴ *In re Dillon* 919 F.2d 688, 16 U.S.P.Q.2d (BNA) 1897 (Fed. Cir. 1990) (en banc) [At 2 and 3] [Hereinafter *Dillon case*]

²⁶⁵ *Dillon case* [At 51]

²⁶⁶ *Dillon case* [At 256 and 270]

²⁶⁷ IPO http://www.ipo.org/wp-content/uploads/2013/03/Patent_Reform_Chart_Comparison_of_AIA_and_Pre-AIA_Laws_FINAL.pdf (accessed 13/06/2013). [At 1]

EPO's approach (first-to-file) will be followed and the filing date of the patent application will be the deciding factor in determining the priority date of a claimed invention.

4) Utility

An invention must be useful; it must perform some function or fulfil a specific need. The term "useful" refers to the subject matter of the invention, it must have a useful purpose including operativeness; i.e. the machine must perform its intended operation.²⁶⁸

There are several challenges regarding nanotechnology and the requirement of utility. These will be outlined in separate sections.²⁶⁹

a) Nanotechnology's Multidisciplinary Application

When it comes to nanotechnology's multidisciplinary application there is a divide between theory and practice. Theoretically the utility requirement should be applied uniformly to all technologies, however in practice, courts apply a more stringent standard in determining the patentability of chemical inventions than that applied for mechanical inventions. As new technologies emerge, they are placed in existing contexts by the courts rather than being dealt with in their own right. An example of this "categorising" was seen with biotechnology: it was compared to previous technologies and found to best suit the context of chemical inventions by the Federal Circuit. Therefore it can be said that patent law can be industry and technology specific.

This treatment of new technologies can be problematic due to the unique challenges each new technology brings with it. Nanotechnology obviously challenges this traditional practice due to its multidisciplinary application; it can involve chemistry, biology, physics, computer-science, pharmaceutical drugs, varying fields of engineering and other disciplines. An example of how all these fields can converge is best illustrated in medical treatment and

²⁶⁸ Title 35 U.S.C § 101

²⁶⁹ Almeling 2004 *STLR* ¶6 -¶ 40

diagnostics. Here nanotechnology can be applied to both scientific and industrial fields thereby extending its breadth of application. The vast application of quantum dots further illustrates this point as quantum dots can be applied within the pharmaceutical arts and in several other arts making it difficult to place them in any single category.

It is crucial that when nanotechnology inventions are examined, Patent Offices and courts determine which context is appropriate by considering all disciplines and industries and the scope of a new converging industry. In *Fujikawa v. Wattanasin*, the role of the utility requirement was discussed in the context of “*pharmaceutical arts*.” Traditionally an invention must show substantial or practical utility before the patent will be granted. The court stated that practical utility is determined on a case-by-case basis.²⁷⁰ Furthermore the court confirmed the measure applied in the area of pharmaceutical arts, namely that the applicant must provide sufficient evidence of pharmaceutical activity in order to constitute adequate proof of practical utility of a compound and stated this evidence should eliminate any doubt those skilled in the relevant art would have regarding the success of the invention.²⁷¹

It is likely that the chemistry based utility context will be applied to nanotechnology inventions. The reason being that despite its multidisciplinary application nanotechnology is essentially the manipulation of molecules and atoms and chemistry is the area of science that deals with the composition and change of matter from one form to another. Another reason to apply this more demanding standard is the unpredictability factor of nanotechnology. The mechanical based utility standard will probably be applied to nanotechnology inventions that also involve mechanics and electronics. This would be advantageous to the applicant as it is less demanding. It is also possible that the courts may rely on both the chemistry-based precedent and the mechanical-based standard where both would be applicable.²⁷²

²⁷⁰ *Fujikawa v. Wattanasin* 93 F.3d 1559 (Fed. Cir. 1996) [At 15 and 19] [Hereinafter the *Fujikawa* case]

²⁷¹ *Fujikawa* case [At 16 and 17]

²⁷² Almeling 2004 *STLR* ¶16- ¶19 and ¶24- ¶28

In summary nanotechnology's interdisciplinary nature extends its technological and industrial context making it difficult to determine which context best applies to an invention.²⁷³ A patent practitioner should contemplate the diverse fields in relation to which the invention could be applied when drafting the patent application in order to ensure the claim does not infringe upon prior art in a different field to that in which the inventor has considered his invention to apply.

b) The Invention must be Operable

Inventions must work as the inventor has claimed it to work before the invention can be patented. Should a person skilled in the art reasonably doubt the claimed utility of an invention, the burden to provide evidence to sufficiently rebut this lies with the applicant. Inoperability must be due to the impossible or inoperable nature of the inventions. An impossible invention cannot be patented; in *EMI Group North America, Inc. v. Cypress Semiconductor Corp.*, the invention claimed relied on a theoretical "vapour induced explosion mechanism" which was found to lack utility because it relied on an impossible mechanism.²⁷⁴ This case features metallic fuses for semiconductor chips, these chips typically have redundant circuitry due to the way they are manufactured. Each chip is tested and the dysfunctional portions of the chip are disconnected whereby the redundant circuitry takes over the function. The specification described this theoretical mechanism for blowing the disclosed metallic fuse. An expert testified that this fuse simply could not explode due to vapour pressure; the court accepted this testimony. Moreover Cypress' fuses and processes could not infringe EMI's patents because they did not explode according to the claimed mechanism. The court stated; "when a claim itself recites incorrect science in one limitation, the entire claim is invalid, regardless of the combinations of the other limitations recited in the claim."²⁷⁵

²⁷³ Almeling 2004 *STLR* ¶9

²⁷⁴ *EMI Group North America, Inc. v. Cypress Semiconductor Corp.* 268 F.3d 1342 (Fed. Circ.2001) [At I.] [Hereinafter the *EMI* case]

²⁷⁵ *EMI* case [At B.]

Nanotechnology inventions are likely to confront similar objections as examiners who are not experienced in this field may presume some inventions are unrealistic in their claims resulting in improper evaluations. The operability of an invention must be evaluated objectively. The standard is low therefore it is not an insurmountable issue.²⁷⁶ Should the examiner doubt the operability of the invention the inventor can simply supply additional evidence (i.e. showing that the invention has a use) to refute this supposition.

c) The Invention must be Practical

The requirement of utility can be challenged if the practical use of the invention is uncertain. Included in the utility requirement is the requirement of substantial utility or practical utility. Practical utility denotes the public's need to use the invention or benefit from the invention in some practical way, i.e. a "real world use."²⁷⁷ Currently the understanding of this standard comes from the PTO's 2001 Utility Examination Guidelines requiring all inventions to have a "well-established utility."²⁷⁸ The asserted utility must be specific and substantial. This occurs if a person of ordinary skill in the art would immediately appreciate why the invention is useful and the utility is specific, substantial and credible. Practical utility is easily shown in mechanical or electrical inventions. However it is not always possible to show for in chemical inventions, as many of their uses are uncertain. *In re Ziegler*, the practical use of the invention was not asserted, resulting in uncertainty as to its usefulness and ultimately resulting in its rejection.²⁷⁹ This case concerned polypropylene, a polymer of propylene molecules wherein the applicant disclosed that solid granules of polypropylene could be pressed into a flexible film that was "plastic-like" without disclosing the practical use for the polypropylene or its film. The court felt this disclosure was insufficient to assert utility.

²⁷⁶ *Almeling* 2004 *STLR* ¶10- ¶14 and ¶29- ¶31

²⁷⁷ MPEP § 2107 I B

²⁷⁸ MPEP § 2107.02 II

²⁷⁹ *In re Ziegler* 8992 F.2d 1197 (Fed Cir. 1993)

An example illustrating uncertain uses for some nanotechnology inventions would be an assembler. This nanomachine is capable of building other nanomachines and reproducing itself in the same process. The fact that this nanorobot is far from existing makes its potential use uncertain, as it is still unknown if and how it will work and what it will be used for. This uncertainty makes it easy for examiners to assert lack of utility. The unpredictable nature of nanotechnology leads to uncertainty regarding the actual use of nanotechnology inventions. It is therefore important for the applicant to clearly show in their patent application, specific real-world use for their invention and show that the unique properties of their nanotechnology invention are not too uncertain. Most nanotechnology inventions have practical utility, however with overly broad claims, examiners may misunderstand the invention in one of two ways: they could adopt a simplistic view in that nanotechnology is merely a smaller version of pre-existing technology or take the stance that as a result of nanotechnology's tendency to be unpredictable, it has no real world use. By clearly describing the function or purpose of the nanotechnology invention, this requirement will be met.

d) Upstream-research Problems Created by Patents at the Research Phase

Traditional patent law focuses on the end result and not the research leading to that result. An important consideration is that nanotechnology patent applications for upstream research are likely to be basic because they are not fully developed final products. This allows for overly broad claims to be made encompassing far more than what the final product will actually offer. Although it is argued that the utility requirement limits patents on research, this argument is unlikely to succeed in the case of nanotechnology inventions as most of this technology is in a research phase.²⁸⁰

An example of nanotechnology at an upstream research phase is that of dendrimers. They are three-dimensional molecules that have a hollow core capable of carrying other molecules. It is a very versatile tool making it difficult to tell how potentially vast its application will be. Possible applications include: drug delivery and sensor technologies,

²⁸⁰ Almeling 2004 *STLR* ¶19- ¶23 and ¶36- ¶40

thereby spanning the medical, electronic and chemical industries.²⁸¹ It is difficult to determine the scope of the patent when an invention can be applied to several different fields of science and technology. As a result of nanotechnology being a relatively new field without much prior art, researchers will not know how far the patent extends or whether their actions are likely to infringe other patents.

The patent entitled “*Angiogenic Inhibitory Compounds*”, illustrates this argument. The first claim reads:

1. *“A method of prophylactic or therapeutic inhibition of angiogenesis in a patient, which comprises administering to the patient of an effective amount of at least one compound sufficient to inhibit or prevent angiogenesis, wherein said compound is a dendrimer having a plurality of terminal groups and wherein at least one of said terminal groups has an anionic- or cationic-containing moiety bonded or linked thereto.”*²⁸²

Therefore the term “dendrimer” is understood in its broadest sense to include within its scope all forms and compositions of these dendrimers. Thereby granting the holder of the patent very broad rights over basic processes using dendrimers. This could consequently have an adverse affect on further advancements from being patented.

5) Enablement and Written Description (Specification)

The bulk of patent applications comprises drawings and the specification that describes and illustrates the invention, explaining how it works and how others can make use of it.

In terms of Title 35 U.S.C. § 112(a) the requirements for the specification are as follows:

²⁸¹ Almeling 2004 *STLR* ¶19- ¶23 and ¶36- ¶40

²⁸² U.S. Patent No. 6,426,067 (issued July 30,2002) <http://www.patentbuddy.com/Patent/6426067> (accessed 07/04/2013)

- a) A complete written description
- b) Enablement
- c) Best mode

These will be discussed separately:

a) Written Description

A comprehensive written description of the invention must be included in the specification, this includes complete details of how to make and use the invention. The purpose of this is to ensure sufficient disclosure (is provided) to enable a person having ordinary skill in the art to make and use the full scope of the claimed invention without undue experimentation.²⁸³ Particularly with a nanotechnology inventions, the inventor must provide as much guidance as possible and demonstration in the specification, indicating clearly and adequately how to make and use all the embodiments of the invention and how all these embodiments may differ from each other and how the various embodiments solve particular problems.²⁸⁴

Not every description of the invention requires the same amount of detail. The standard for written description is highly dependant on the complexity and the predictability or unpredictability of the invention and the relevant field in which it is based. In other words the level of complexity and predictability of the art will dictate if more teaching in the specification is required.²⁸⁵ Predictable fields such as traditional mechanical or industrial applications will require a lower level of written description as more knowledge is available in these fields. The field of nanotechnology on the other hand is a new, rapidly developing field considered to be unpredictable, therefore more detail will be required in the written

²⁸³ Abe <http://www.fasken.com/files/Publication/1db6f3c3-a757-4067-af7c-901a5498ecd8/Presentation/PublicationAttachment/da755b60-42ff-44e8-9e57-582e2a83b8f7/NANOTECHNOLOGY.PDF> (accessed 02/05/2012) [At 10]

²⁸⁴ Hicks, Grissett and Brown <http://www.wcsr.com/resources/pdfs/nano030310.pdf> (accessed 04/05/2012) [At 10]

²⁸⁵ MPEP § 2164.03

description of the invention as additional guidance or direction may be needed to enable this more complex invention. By providing as much information as possible at this stage, there will be less of a need to argue the knowledge of the person skilled in the art and state of prior art should the inventor find himself defending his invention in court.²⁸⁶

In brief the level of detail required varies depending on the scope of the claim and the complexity and predictability of the relevant technology. The more that is known about the field and nature of the invention, the less information that needs to be provided regarding the manner in which to use and make the invention. The bar is set high when dealing with nanotechnology inventions in meeting this requirement: it is therefore essential to describe in detail nano-related subject matter due to the inherent nature of nanotechnology which makes for difficult predictions of properties and performance of nanoscale structures. A nanotechnology invention can comprise more than one area of art accordingly the invention must be disclosed adequately to allow for enablement in the various distinct areas of art.²⁸⁷ In other words a person skilled in each of the relevant technologies must be able to make or use the invention for this requirement to be met.

Moreover it is difficult to determine what constitutes a nanoscale structure due to the lack of standardised definitions. Researchers, policy makers and institutions all struggle to determine the scope of “nanotechnology” and it can be argued that as a result of this, it requires the most description out of any technical field. Consequently it is important to use general, well-known terms of the art to describe the invention. Any unclear terms should be defined; concise statements and the intended scope of these terms should be provided. Due to the possibility of a nanotechnology invention having more than one application or use, a well-drafted specification supporting an interdisciplinary approach is essential to ensure a variety of patentable claims will be supported and protected.²⁸⁸ However, this

²⁸⁶ Mills, Fitzsimmons and Rodkey 2010 *Nanotech. L. & Bus.* 237

²⁸⁷ MPEP § 2164.05(b)

²⁸⁸ Hicks, Grissett and Brown <http://www.wcsr.com/resources/pdfs/nano030310.pdf> (accessed 04/05/2012) [At 10]

disclosure should be limited to providing only enough information so as to enable the invention claimed.

b) Enablement

Enablement is closely tied to utility. By providing working examples of the invention, the applicant offers evidence that enablement is possible.²⁸⁹ Occasionally it is difficult to provide working examples of nanotechnology inventions, reasons for this include; the instruments necessary to carry out the invention are still being developed or the invention exists theoretically and not physically in a lab. Consequently this requirement is sometimes not met, especially when dealing with unpredictable arts. Despite this situation it is possible to enable with a prophetic example.²⁹⁰ However, working examples will always provide stronger evidence in overcoming the lack of enablement brought up by the examiner. The applicant should provide as many working examples as possible especially when the claim is broad.

A person of ordinary skill must be able to make or use the invention without undue experimentation, this means the skilled person should be able to make or use the invention by way of the disclosures made by the inventor in the specification.²⁹¹ There are three tests that are applied to determine undue experimentation:²⁹²

1. Wands Test
2. Scripps Test
3. Subset Test

²⁸⁹ MPEP § 2164.05

²⁹⁰ MPEP § 2164.02

²⁹¹ MPEP § 2164.01

²⁹² Mills, Fitzsimmons and Rodkey 2010 *Nanotech. L. & Bus.* 235

The Wands Test has the widest application and is usually applied by the Federal Circuit in cases involving new technologies, it comprises the following factors:²⁹³

1. Quantity of experimentation required based on the content of disclosure provided
2. Amount of direction or guidance provided by the inventor
3. Presence or absence of working example
4. Nature of the invention
5. State of prior art
6. Relative skill of those in the art
7. Level of predictability or unpredictability of the art
8. Breadth of the claim

The examiner cannot base his conclusion on only one of the above factors; he must consider the evidence relating to each of these factors as a whole to determine whether the invention is enabled.²⁹⁴

In *In re Kumar*, the Kumar invention claimed aluminum oxide particles that were nano-sized, ideal for chemical mechanical polishing of ultra smooth surfaces.²⁹⁵ The examiner allowed the process to make the nanoparticles but rejected the product claimed as obvious in terms of § 103(a). Claim 1 and 19 of the Kumar patent reflected the overlap at issue:

“1. A collection of particles comprising aluminum oxide, the collection of particles having an average diameter of primary particles from about 5 nm to about 500 nm and less than about one in 10⁶ particles have a diameter greater than about three times the average diameter of the collection of particles.

19. A collection of particles comprising aluminum oxide, the collection of particles having an average diameter from about 5 nm to about 500 nm and a distribution of particle sizes such

²⁹³ MPEP § 2164.01(a)

²⁹⁴ *In re Wands* 858 F. 2d 731, 737, 8 U.S.P.Q.2d (BNA) 1404, 1407 (Fed. Cir. 1988)

²⁹⁵ *In re Kumar* 418 F.3d 1363 (Fed. Cir. 2005) [Hereinafter the *Kumar* case]

that at least about 95 percent of the particles have a diameter greater than about 40 percent of the average diameter and less than about 160 percent of the average diameter.”²⁹⁶

The claims at issue were directed at the particles themselves and not the method of producing these particles. The Board of Appeals rejected Kumar’s claims on grounds of obviousness and whether cited prior art was enabled. The prior art patent the courts referred to in their assessment of the later patent (the “Kumar Patent”) was the “Rostoker Patent.” The court based its decision on mathematical calculations, thereby comparing Kumar’s product claims with the particles described in the Rostoker Patent in order to determine the values between the nanoparticles size claimed and the prior art.²⁹⁷ The particles Kumar claimed overlapped in both particle size and size distribution with the Rostoker particles, resulting the court’s decision of obviousness. Kumar argued the Rostoker Patent did not disclose the method the Kumar patent applied to create the submicron sized particles claimed in the Kumar invention. Therefore despite the Rostoker Patent disclosing a method for making these particles, it was not the same method adopted by Kumar (i.e. laser pyrolysis)²⁹⁸

The Board of Appeals confirmed the examiners rejection however indicated that the USPTO erred in their argument in respect of which they rejected the Kumar patent based on obviousness. The USPTO had based their argument on the Rostoker Patent enabling the Rostoker invention irrespective of whether the Rostoker Patent enabled the invention claimed by the Kumar Patent. The court stated that in terms of obviousness, the enquiry is based on whether the prior art enables a person skilled in the art to make or use the later claimed invention.²⁹⁹ In other words the pertinent question should be whether the Rostoker Patent enabled a person of ordinary skill in the art to produce nanoparticles with the same size and distribution as those claimed by Kumar. The Board of Appeals referenced the *John*

²⁹⁶ *Kumar case* [At 1363-1364]

²⁹⁷ *Kumar case* [At 1364-1365]

²⁹⁸ *Kumar case* [At 1363-1364]

²⁹⁹ *Kumar case* [At 1368]

Deere case in that obviousness is a legal conclusion based on underlying facts and stated that a prima facie case of obviousness could be made when the only difference between the invention claimed and the prior art is the range or value of a particular variable i.e. the overlap. The court thereby concluded that the nanoparticles claimed by Kumar overlapped in size and diameter with those claimed in Rostoker Patent.

This case will be relevant to an applicant that may need to prove his nanotechnology invention is not obvious. The applicant could argue that the examiner cannot render the invention obvious if the prior art process applied is different from that applied in the later claimed invention. Furthermore if the prior art process does not enable a person skilled in the art to make the product claimed, the invention will not be obvious.³⁰⁰ Consequently, the difference in process applied to produce the invention can be used to argue the claim of obviousness. A claim will not be obvious if prior art fails to show how to make and use an invention at nanoscale.³⁰¹

c) Best Mode

The inventor must also include a description of the best mode of the invention that he knows at the time of filing for a patent, i.e. a description of what the inventor believes is the best mode of his invention. This serves as a safeguard for full disclosure, thereby preventing the inventor from keeping the best mode for himself and disclosing the second-best mode.³⁰² Examples and representative data such as diagrams, figures, formulas should be provided to support the best mode of the invention.

By disclosing the technological knowledge upon which the invention is based, the public is placed in “possession” of what the inventor claims as his invention. A person having ordinary skill in the art should reasonably conclude from this disclosure that the inventor

³⁰⁰ Baluch 2005 *Nanotech.L. & Bus.* 346

³⁰¹ Schwaller and Goel 2006 *Nanotech. L. & Bus.* 156

³⁰² Hicks, Grissett and Brown <http://www.wcsr.com/resources/pdfs/nano030310.pdf> (accessed 04/05/2012) [At 8]

had possession of claimed invention at the date the patent application was filed. The patent application must be drafted so as to ensure the written description and enablement match the breadth of the claims, i.e. the claim must be supported by the specification.³⁰³

The patent practitioner responsible for drafting the patent application should be aware of the challenges and common causes for rejection relating to nanotechnology inventions. Broad claims, difficulty to prove the invention and insufficient details to enable the reproduction of the invention claimed are some of the grounds in respect of which the application can be rejected. The patent practitioner should apply his knowledge of the examination process, common objections and understanding of the invention in relation to which the application pertains in order to ensure the full scope of coverage of the invention claimed is protected. He should advise and guide the inventor on any issues or shortfalls that may need to be addressed and overcome these in the application. Furthermore the patent practitioner together with the inventor should define the terms used, include all of the limitations of the invention, ensure the level of detail required is met and guarantee the specification supports the claim. Full disclosure should ensure the inventor does not claim more than what he has actually invented and should leave the examiner trusting the validity of the application. In instances where enablement is not satisfied but utility is established, the patent will still be granted. For example where a person skilled in the art does not know how to effect use of the invention.³⁰⁴

The AIA has also impacted the provisions pertaining to “best mode” by relaxing this requirement. A patent can no longer be invalidated or cancelled if the applicant fails to disclose the best mode.³⁰⁵ Consequently the applicant must still include this aspect of his invention but the consequences for not disclosing the best mode will not invalidate his application.

³⁰³ MPEP § 2164.08

³⁰⁴ MPEP § 2164.07 II

³⁰⁵ AIPLA <http://www.aipla.org/advocacy/congress/aia/Pages/summary.aspx> (accessed 13/06/2013)

II. EPC REQUIREMENTS FOR A PATENT

In terms of the EPC, the requirements for a patent include; 1) novelty, 2) an inventive step, and 3) industrial application (i.e. the invention must relate to technically demonstrable functioning products or production process in any field of technology).³⁰⁶

1) Excluded Subject Matter

The EPC excludes the following from being patentable: discoveries, scientific theories, mathematical methods, aesthetic creations, presentations of information, schemes, rules and methods for performing mental acts, playing games or doing business and programs for computers.³⁰⁷

The EPO's treatment of natural scientific theories and discoveries will be discussed.

a) Scientific Theories

Referring back to the previous chapter and the distinction made between nanoscience and nanotechnology; nanotechnology is based on the development of scientific research therefore without further developments in the field of science many of the results, i.e. the inventions, would not have been possible. Consequently devices and processes for manufacturing that are based on scientific theories can be patented.

The purpose of this exclusion is to avoid basic concepts of science and laws of nature from being patented as these are considered to be part of the public domain. According to the Manual for Examiners for the EPO, scientific theories are considered to be a more

³⁰⁶ EPC Art 52(1). *Also see:* Guidelines for Examination in the European Patent Office, Part G "Patentability" [http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/\\$FILE/guidelines_for_examination_2013_part_g_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/$FILE/guidelines_for_examination_2013_part_g_en.pdf) (accessed 20/04/2013) [Chapter I at 1] [Hereinafter "EPO Guidelines Part G"]

³⁰⁷ EPC Art 52(2)(a)-(d)

generalised form of discoveries.³⁰⁸ The EPO has not defined the parameters of what either comprise. Short of a formal definition, the eligibility of such research should be decided by the TBA on a case-by-case basis and the same principles should apply to both. In certain cases exceptions should be made and the research that is indispensable to the development of nanotechnology products or uses should receive protection from patent law.

b) Discovery versus Invention

In contrast to U.S. patent law, the EPC expressly distinguishes between these two concepts. The difference between a discovery and an invention will be discussed within the context of naturally occurring products.

➤ Naturally Occurring Products

The principal inquiry, in terms of the EPC when dealing with a patent application that claims a naturally occurring product as the invention relates to whether the invention claimed is merely a discovery or whether the requirements of a valid patent have been met in terms of Article 52(1). An interesting example of a patentable nanotechnology invention that imitates naturally occurring structures is that of CNTs. Some researchers believe these low energy structures are present in nature as self-generating structures however, it is argued that other conditions are necessary for these phenomena to occur. Consequently it can be said that CNTs are present in nature but no factual evidence exists to base the idea that there are naturally generated CNTs.³⁰⁹ With this example in mind, a discussion relating to when a naturally occurring substance will be eligible for a patent, will follow.

As established discoveries are specifically excluded from the EPC,³¹⁰ however nanotechnology often blurs the line between what a discovery and invention comprise, as

³⁰⁸ EPO Guidelines Part G

[http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/\\$FILE/guidelines_for_examination_2013_part_g_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/$FILE/guidelines_for_examination_2013_part_g_en.pdf) (accessed 20/04/2013) [Chapter II at 3.2]

³⁰⁹ Cisneros 2009 *Nomos* 32

³¹⁰ EPC Art 52(2)(a)

naturally occurring substances can concurrently be very complex nanomachines.³¹¹ Part G, Chapter II of The Manual for Examiners for the EPO provides; if a new property of a known material or article is found, it is considered to be a discovery because it has no technical effect thereby disqualifying it as an invention within the meaning of Article 52(1). However, it will still be possible to patent the invention if it has a practical use and all the requirements for a valid patent are met (i.e. novelty, inventive step and industrial application). Furthermore, finding a previously unrecognised substance occurring in nature will also be considered a discovery unless it can be shown to produce a technical effect: this effect may be patentable. For example, a substance occurring in nature is found to have an antibiotic effect. Therefore the mere description of a naturally occurring substance denotes a discovery and not an invention.³¹² Discoveries are pure knowledge therefore only when the inventor applies this knowledge, for example where he shows a way of providing the substance and not merely describing it, can this applied knowledge be considered an invention and subsequently its patentability determined, for instance where the inventor discovers a means to synthesise or isolate such a substance by means of a technical process.³¹³ Once the inventor is capable of showing that he has devised a means to reproduce the substance, i.e. the invention, the novelty and inventiveness of the substance claimed as the invention can be determined. The inventor must sufficiently describe the method for reproducing the invention, particularly within the field of chemistry, so as to meet the requirement of enablement, i.e. a skilled person in the pertinent art must be able to prepare the compound according to the specification of the claimed invention. In other words a simple disclosure of only the chemical formula would not suffice and the patent may be invalidated.³¹⁴ Despite no existing separate provisions, in practice, chemical patents

³¹¹ Zech 2009 *SCRIPTed* 151-152

³¹² Zech 2009 *SCRIPTed* 151-152

³¹³ EPO Guidelines Part G
[http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/\\$FILE/guidelines_for_examination_2013_part_g_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/$FILE/guidelines_for_examination_2013_part_g_en.pdf) (accessed 20/04/2013) [Chapter II at 5.2(i) Rule 27(a)]

³¹⁴ *Asahi Kasei Kogyo KK's Application* [1991] R.P.C. 485 [Page 494 at 10] [Hereinafter *Asahi Application*]

will contain examples describing the manner in which the compound claimed can be made.³¹⁵

For the requirement of novelty to be met, neither a newly synthesised nor naturally occurring substance can be part of the state of art at the time the invention is claimed. In other words neither could previously have been made available to the public. The public's lack of knowledge of the existence of such substances does not negate its existence in nature prior to its first discovery. It may be possible that the necessary instruments or techniques were not available to enable an earlier discovery of such a substance from being made. Once novelty is established the next part of the examination is to determine whether the process to reproduce the substance involves an inventive step. This requirement is met when the substance is artificially modified and this modification is inventive or the isolation and synthesis of the newly discovered natural substance is inventive.³¹⁶ The standard principles relating to all inventions when determining whether this requirement is met, will apply here.

The EPO allows for the substance itself and the new property to be patented. In other words the use of the property and the subject matter that contains such property can be patented. For example, if a microorganism is discovered to exist in nature and to produce an antibiotic, the microorganism itself may also be patentable as one aspect of the invention. The applicant should disclose the technical effect and claim every aspect of the material including the material itself, supported by the use and the use of such matter in a particular function.³¹⁷ By providing a description of the technical effect the inventor will rebut any assumptions that the nanotechnology invention lacks an inventive step. In practice, the TBA seems to set a further requirement to be met for this type of substance to be patented, namely that the substance must be characterised by structure, generation process or any other parameter. Additionally the substance must be new,³¹⁸ therefore a

³¹⁵ *Asahi Application* [Page 517 at 50]

³¹⁶ *Zech 2009 SCRIPTed* 151-152

³¹⁷ *Cisneros 2009 Nomos* 31-35

³¹⁸ *Cisneros 2009 Nomos* 34-35

naturally occurring nanomaterial can be patented if the description contains a characterisation unknown and not previously available to the public.

Lastly the isolated substance or substance that is produced by means of a technical process must be susceptible of industrial application in order to be patentable.³¹⁹ This too must be disclosed in the application.

Two possible situations seem to emerge, namely where the researcher discovers a structure originating in nature and patents it and secondly, where an invention is generated independently, patented and the patent later declared invalid due to the discovery of the same structure in nature.³²⁰ In terms of European patent law, the inventor is not obliged to disclose the motivation, origin or creative process that led to the conception of the invention and the courts therefore do not distinguish between these two situations. However, in many other jurisdictions, such as the U.S., the inventor may be required to disclose all relevant prior art known by him at the time the invention was made. Failure to comply with this request could result in an invalid patent. It is therefore in the best interest of the applicant to refer to natural substances when describing the state of art in such a way that the examiner can thoroughly determine the novelty of the invention.

In conclusion, an invention claiming naturally occurring substances as its subject matter should display unexpected and or new technical effects. The patentability of such an invention should be examined in the same manner and meet the same criteria as any other area of technology.³²¹

³¹⁹ EPO Guidelines Part G

[http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/\\$FILE/guidelines_for_examination_2013_part_g_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/$FILE/guidelines_for_examination_2013_part_g_en.pdf) (accessed 20/04/2013) [Chapter II at 5.2(i) Rule 29(1) and (2)]

³²⁰ Cisneros 2009 *Nomos* 33

³²¹ EPO Guidelines Part G

[http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/\\$FILE/guidelines_for_examination_2013_part_g_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/$FILE/guidelines_for_examination_2013_part_g_en.pdf) (accessed 20/04/2013) [Chapter II at 5.2]

c) Selection Inventions

The EPC will treat patents that have subject matter overlapping with prior art as a separate category of inventions; they are referred to as selection inventions.³²² This overlap constitutes a selection of the prior art and if certain other conditions are met, the patent will be granted.³²³ When determining whether an invention overlaps with prior art, European patent law focuses on the question of novelty and inventive step and not the scope of the patent (as in U.S. patent law). When dealing with selection inventions, a three-part enquiry is applied:

1. Determine whether the invention claimed is a discovery or an invention;
2. Assess the novelty of the invention claimed; and
3. Determine whether the invention has an inventive step.

These applications are decided on a case-by-case basis. The same principles in determining novelty and inventive step are applied in the case of overlapping ranges; the whole content of the prior art document is taken into account. These overlapping ranges include numerical ranges and chemical formulae.

The EPO's approach in assessing novelty in such applications involves determining whether the selected elements are disclosed in an individualized form in the prior art.³²⁴ A selection from a single list of specifically disclosed elements does not confer novelty. When a selection from two or more lists of a certain length is made in order to arrive at a specific combination of features then the resulting combination of features, not specifically

³²² Zech 2009 *SCRIPTed* 153-154

³²³ Henriksson <http://www.awapatent.com/?id=19350> (accessed 16/01/2013)

³²⁴ EPO Guidelines Part G
[http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/\\$FILE/guidelines_for_examination_2013_part_g_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/$FILE/guidelines_for_examination_2013_part_g_en.pdf) (accessed 20/04/2013) [Chapter VI at 8 (i)]

disclosed in the prior art, will confer novelty.³²⁵ This is referred to as the "two-lists principle." In terms of the Manual for Examiners for the EPO, examples of selections from two or more lists include the selection of:

1. Individual chemical compounds from a known generic formula whereby the compound selected results from the selection of specific substituents from two or more "lists" of substituents given in the known generic formula. The same applies to specific mixtures resulting from the selection of individual components from lists of components making up the prior art mixture.
2. Starting materials for the manufacture of a final product.
3. Sub-ranges of several parameters from corresponding known ranges.³²⁶

The basis for this possibility is the practice that a prior art disclosure of a broad range does not necessarily represent a disclosure of a sub-range within that range. Novelty must be determined by satisfying the following criteria:

1. The overlap or selected sub-range must be narrow when compared to the larger known prior art range.
2. The selected sub-range must be sufficiently far removed from any specific examples disclosed in the larger known range and from the end points of the known range.
3. The selected range must result from a purposive selection; it must provide a new technical teaching. The overlapping invention must be another invention; it cannot merely embody the prior art description. It must not be an arbitrary specimen from the prior art.³²⁷

³²⁵ EPO Guidelines Part G

[http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/\\$FILE/guidelines_for_examination_2013_part_g_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/$FILE/guidelines_for_examination_2013_part_g_en.pdf) (accessed 20/04/2013) [Chapter VI at 8 (i)]

³²⁶ EPO Guidelines Part G

[http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/\\$FILE/guidelines_for_examination_2013_part_g_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/$FILE/guidelines_for_examination_2013_part_g_en.pdf) (accessed 20/04/2013) [Chapter VI at 8 (i)(a), (b) and (c)]

³²⁷ Henriksson <http://www.awapatent.com/?id=19350> (accessed 16/01/2013)

In terms of the first and second criteria, subjective reasoning can be applied to determine whether an invention involving a sub-range is distinguishable from the prior art disclosure.³²⁸ The meaning of "narrow" and "sufficiently far removed" has to be decided on a case-by-case basis.³²⁹ The new technical effect occurring within the selected range may also be the same effect as that attained with the broader known range, but to a greater extent. The third criterion is more difficult to determine due to ambiguity and uncertainty of whether the technical effect occurred within the claimed sub-range or the entire known range. If a technical effect occurs only in the claimed sub-range, this effect in itself does not confer novelty on that sub-range. However if a technical effect occurs in the selected sub-range and not in the whole of the known range, the third criterion is met and it can be concluded that the invention is novel and not merely a specimen of the prior art.³³⁰ The state of the art must reveal the invention to the skilled person in a technical teaching and must display new, unexpected or significantly improved effects within the selected sub-range.³³¹ In other words this sub-range has been selected specifically to provide a technical advantage or resolve a technical issue in prior art, making it novel.

In addition to the above it must be determined whether a person expected to have the necessary skill and knowledge in the applicable field of art would consider applying technical teachings of prior art in the range of overlap.³³² If it can be fairly assumed he would, the invention will lack novelty. Where prior art discloses sufficient information enabling a person skilled in the art to replicate the invention, for example by defining the particle size ranges, a patent claim within that range will be considered anticipated and the patent will be invalid. Overlapping patents create a great deal of uncertainty regarding IP rights and constrain the inventor to design around existing patents.

³²⁸ Henriksson <http://www.awapatent.com/?id=19350> (accessed 16/01/2013)

³²⁹ Henriksson <http://www.awapatent.com/?id=19350> (accessed 16/01/2013)

³³⁰ EPO Guidelines Part G [http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/\\$FILE/guidelines_for_examination_2013_part_g_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/$FILE/guidelines_for_examination_2013_part_g_en.pdf) (accessed 20/04/2013) [Chapter VI at 8 (ii)(c)]

³³¹ Zech 2009 *SCRIPTed* 153-154

³³² Watal and Faunce http://wipo.int/wipo_magazine/en/2011/02/article_0009.html (accessed 02/05/2012)

In *Smithkline Beecham Biologicals*, the TBA applied the above criteria to the Smithkline patent application on Hepatitis B vaccine adjuvant lipid measuring 60-120 nm to determine novelty.³³³ An earlier patent had a similar adjuvant with particles measuring 80-500 nm. The TBA found the Smithkline patent to be novel because the overlap was:

1. Narrow- only 10% of the larger range in the earlier patent
2. At the extreme lower end of the prior art range
3. Exhibited significantly improved adjuvancy; the smaller particles resulted in an unexpected and favourable shift in immune response.

In addition the prior art gave little guidance on how to prepare the smaller particles. A skilled person who followed the vaccine supplier's protocol would have produced particles of between 115-952 nm. The technical teachings in the prior art were therefore not considered relevant to Smithkline patent application.

In *BASF v. Orica Australia*, it was held that a prior patent held by BASF, disclosed polymer nanoparticles larger than 111 nm did not destroy the novelty of a later application by Orica that disclosed nanoparticles that were smaller than 100 nm. The claims of the case in dispute were as follows:

"1. Very small water-insoluble polymer particles capable of forming a stable aqueous dispersion wherein the particles have a maximum average diameter of 100 nm and a core-sheath structure in which the core contains addition polymer and the sheath contains hydrophilic polyoxyalkylene chains containing an average of 6 to 40 oxyalkylene units per chain characterized in that

(a) at least 20 wt% of the polyoxyalkylene chains are attached to the addition polymer of the core via covalent bonds and

(b) the sheaths contain sufficient of the polyoxyalkylene chains for the mass ratio of the core to sheath to be from 98:2 to 60:40.

³³³ *Smithkline Beecham Biologicals v. Wyeth Holdings Corporation* Boards of Appeal of the EPO, T-0552/00 (30 October 2003) (3D-MPL/SMITHKLINE) [At 25]

10. A process for the preparation of a stable aqueous dispersion of water-insoluble polymer particles wherein the particles have a core-sheath structure in which the core contains addition polymer and the hydrophobic moiety of an amphiphile and the sheath contains solvated hydrophilic polyoxyalkylene chains of the amphiphile and the polyoxyalkylene chains have an average of 6 to 40 oxyalkylene units per chain characterised in that

- (a) ethylenically unsaturated monomer is polymerised in an aqueous medium in the presence of the amphiphile,
- (b) the hydrophobic moiety of the amphiphile contains at least one ethylenic double bond
- (c) sufficient polyalkylene chains are present in the aqueous medium to ensure that the mass ratio of the cores to sheaths is from 98:2 to 60:40 and
- (d) the polymerisation is initiated at under 40°C.

14. A stable aqueous dispersion of water-insoluble polymer particles characterized in that the dispersion contains particles as claimed in any one of Claims 1 to 9 or as made by a process according to any one of Claims 10 to 13.

15. A coating composition containing film-forming material characterized in that the film-forming material includes an aqueous dispersion as claimed in Claim 14.

Claims 2 to 9 are dependent on Claim 1, Claims 11 to 14 are dependent on Claim 10.”³³⁴

BASF argued Orica’s patent disclosed all of the elements claimed by their patent thereby destroying novelty. This disclosure included the description of aqueous dispersions having all the features of the claimed polymer particles, their maximum diameter and the number of oxyalkylene units comprised the sheath portion of the particles. Additionally, all the features of the claimed method of preparation, including polymerization initiation temperatures of below 40 °C of the respective dispersions were deemed identical and for that reason, BASF argued the particle sizes of up to 100 nm, although not explicitly mentioned in BASF’s patent, were implicitly disclosed in their patent.

³³⁴ BASF v. Orica Australia Boards of Appeal of the EPO, T-0547/99 (8 January 2002) [At I.]

BASF also contended that Orica's patent was obvious to a person skilled in the art and therefore lacked an inventive step. According to BASF, such a skilled person could achieve the same beneficial properties from the sterically stabilized polymer dispersion by selecting from the set of reaction conditions disclosed, which would result in the formation of particles in the claimed size range up to 100 nm. In other words there was no inventive step in achieving these improved smaller particles, "routine operations" would enable the same outcome. Furthermore BASF concluded the results from Orica's patent, i.e. improved gloss was an obvious and immediate consequence of using dispersions with smaller particles, which resulted in better penetration of such dispersion into a porous substrate. Therefore Orica's patent lacked an improvement of the rheological properties of the claimed dispersions and the glossy coatings derived therefrom.

Orica argued Claim 1 was novel as BASF's patent did not disclose aqueous dispersions comprising polymer particles having a maximum diameter of 100 nm, nor did it disclose that the sheath portion of the particles comprised polyoxyalkylene chains containing an average of 6 to 40 oxyalkylene units per chain. The lowest particle size disclosed was 111 nm and the polymerisation initiation temperature used was higher than the maximum of 40 °C permitted by Claim 10 of Orica's patent. Furthermore they argued the claimed subject matter was inventive over the closest prior art because BASF's patent did not disclose the solution of the existing technical problem, i.e. the provision of sterically stabilized dispersions having an improved rheological properties at high solids content suitable for the preparation of high gloss coatings.

The appeal was dismissed, BASF failed to show their patent disclosed particles having a maximum average diameter of 100 nm and a method for preparing these particles. The court concluded the smaller nanoparticles claimed by Orica's patent displayed greatly improved technical properties, providing a significant technical advantage over the prior art and this difference was held sufficient to satisfy the inventive step requirement. The Board agreed with Orica in that the subject matter claimed was not obvious, the state of the art did not suggest or specify the claimed solution to the technical problem existing with respect to the closest prior art and a skilled person would not have expected the results rendered by the claimed solution.

It is therefore possible in certain instances for an invention to be deemed valid despite the invention claimed containing small, unplanned or accidental amounts of a material or substance that are part of the prior art. Interestingly, selection patents are usually rejected by the German Federal Court of Justice due to the lack of novelty of the invention. The EPO's approach is preferred in the treatment of selection inventions.³³⁵

2) Novelty

The EPC states that a patent will be granted for any invention that is new; newness is dependant on the invention not forming part of the state of art.³³⁶ The invention must possess an essential technical feature that differs from the technical features in the state of art; that is *"everything made available to the public by any means of written or oral description, by use or in any other way, before the date of filing of the European patent application."*³³⁷ Consequently any product, substance or material containing the invention, anywhere in the world and disclosed in any form will be included in the state of art.³³⁸ However an oral disclosure made to a non-expert who is not able to communicate this disclosure to experts or exploit it himself, will not destroy the novelty.³³⁹

The availability of this information to the public should be interpreted as a hypothetical possibility.³⁴⁰ In other words irrespective of the public's knowledge, interest or motive to access such information, if it was available to the public at the time the patent application was filed, the invention that incorporates the relevant prior art will also be part of the state of art and the invention will lack novelty.

³³⁵ Zech 2009 *SCRIPTed* 154

³³⁶ EPC Art 54 (1)

³³⁷ EPC Art 54 (2)

³³⁸ Otherwise referred to as absolute novelty. (Art 52(5))

³³⁹ Singer and Stauder *European Patent Convention* 107

³⁴⁰ Cisneros 2009 *Nomos* 33

Assessing novelty not only comprises determining the facts available to the public before the relevant date (i.e. the date the prior to which the application was filed) but also assessing the information revealed by the technical teaching to a person skilled in the pertinent art. Novelty will be determined by comparing each citation or known technical teaching, individually and separately to the invention claimed (as opposed to determining the inventive step where the mosaic approach can be applied). A citation will only be considered part of the state of art if it is “reproducible” i.e. a person skilled in the art can reproduce the invention.³⁴¹

3) Inventive Step

The EPO uses the “problem-and-solution” approach to determine whether an invention involves an inventive step. In terms of this approach, once novelty is established, the invention must provide a solution to a technical problem in a non-obvious way.³⁴² In other words the invention must provide an advance over the state of art.³⁴³ Assessing whether a technical problem exists comprises the following structured objective enquiry:

1. Firstly identify the prior art that most closely resembles the invention;
2. Determine the technical results achieved by the claimed invention when compared to the closest prior art, i.e. define the technical problem;
3. Determine whether the invention claimed objectively overcomes this technical problem (thereby ascertaining whether an inventive step exists);
4. Lastly, it must be determined in light of the prior art and the technical problem, whether a person skilled in the pertinent art, “*would have suggested the claimed technical features for obtaining the results achieved by the claimed invention.*”³⁴⁴

³⁴¹ Singer and Stauder *European Patent Convention* 106

³⁴² Singer and Stauder *European Patent Convention* 150

³⁴³ Singer and Stauder *European Patent Convention* 142

³⁴⁴ *The Proctor & Gamble Company v. Unilever PLC / Unilever N.V.* Boards of Appeal of the EPO, T-0167/93 (3 May 1996) (Bleaching agents) [At 4.3.1]

The closest prior art is determined by comparing the invention claimed with each item of prior art, the prior art document that discloses the most technical features in common with the claimed invention will be used. There must be distinguishing technical features in order for the invention claimed to be novel and the effects achieved by these features must be compared and evaluated against the relevant prior art document. The differences will be compared in order to determine whether a technical problem exists and whether the claimed invention will provide a solution to this problem. This solution must significantly improve the relevant prior art; a mere observation, for example will not sufficiently justify the improvement as an invention. Furthermore this improvement cannot have been anticipated by prior art.

The “could-would” test is applied once the technical problem to be solved has been identified. The question is whether any teaching in the prior art as a whole, “would” (not simply could, but **would**) have prompted the skilled person, faced with the objective technical problem, to modify or adapt the closest prior art while taking that teaching into consideration and thereby arriving at something falling within the terms of the claims and achieving that which the invention achieves. In other words the prior art must have prompted the skilled person to solve the technical problem. It is not simply whether the skilled person would have arrived at the same result, i.e. the invention that solves or improves the problem revealed by closest prior art but rather whether he was induced towards the invention. This incitement could be implicit. Furthermore the skilled person must have addressed this specific problem, arriving at the same solution as that claimed before the filing or priority date of the claim under examination.³⁴⁵

A “skilled person” for these purposes, is a person having a comprehensive general and technical level of knowledge in the relevant field of art. He has no inventive capability and is only expected to refer to close or neighbouring technical fields in order to determine relevant prior art.³⁴⁶ This comparison is different to that of novelty in that the novelty is

³⁴⁵ EPO Guidelines Part G

[http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/\\$FILE/guidelines_for_examination_2013_part_g_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/$FILE/guidelines_for_examination_2013_part_g_en.pdf) (accessed 20/04/2013) [Chapter VII at 5.3]

³⁴⁶ Singer and Stauder *European Patent Convention* 144 and 170

determined by comparing the prior art document as a whole with that of the invention. Inventiveness is determined by comparing each of the elements of the prior art with the invention, elements from various documents can be combined (mosaic approach). The most important consideration is whether the teaching acquired from the combination of features in these documents or parts thereof is obvious to a person skilled in the art.³⁴⁷

In the *Blaschim* case, the patent in suit related to a process of preparing 2-(6'-methoxy-2'-naphthyl) propionic acid and esters thereof via rearrangement of a ketal of 2-halo-1-(6'methoxy-2'-naphthyl)-propan-1-one.³⁴⁸

Claim 1 reads:

"1. A process for preparing products having general formula:

FORMULA

wherein

R is selected from the group comprising an hydrogen and a bromine atom; and

Y is selected from the group comprising an alkyl radical having from 1 to 6 carbon atoms, a haloalkyl radical having from 2 to 6 carbon atoms and a benzyl radical; which comprises the rearrangement of products having general formula

FORMULA

wherein

R has the above-mentioned meaning;

R' is selected from the group comprising an alkyl radical having from 1 to 6 carbon atoms and a benzyl radical;

R" is selected from the group comprising an alkyl radical having from 1 to 6 carbon atoms and a benzyl radical;

R' and R", together, are an alkylene radical having 2-6 carbon atoms which, together with the

³⁴⁷ Singer and Stauder *European Patent Convention* 145-146

³⁴⁸ *BLASCHIM S.p.A v. Syntex Pharmaceuticals International Limited* Boards of Appeal of the EPO, T-0597/92 (1 March 1995) (Rearrangement reaction) [At 4.4.] [Hereinafter the *BLASCHIM* case]

FORMULA

group, forms a heterocyclic ring;

*X is a halogen atom in the presence of a Lewis acid, excluding Ag+.*³⁴⁹

The closest prior art, agreed to by the parties, was the rearrangement reaction in the Ag⁺ ions described in document (1). This document relates to reactions for preparing 2-(6'-methoxy-2'-naphthyl) propionic acid or esters thereof by rearrangement reaction of a 1-(6'-methoxy-2'-naphthyl)-2-halo-propanone in the presence of a silver ion. Providing an alternate process for preparing 2-(6'-methoxy-2'-naphthyl) propionic acid or esters thereof was considered to be the problem that needed to be solved. The solution was to convert the ketone into a ketal, *"which rearrangement reaction is conducted in the presence of a metal salt in accordance with Claim 1."*³⁵⁰

The Board agreed in light of the examples provided in the patent in suit, the problem was convincingly solved by their claimed solution. Subsequently the Board had to determine whether or not it would have been obvious for a skilled person to substitute the silver (I) salt by any of the metal salts mentioned in Claim 1 as a rearranging agent.

The Appellant argued a skilled person would have recognized the particular metal salt used in the claimed process as suitable for promoting the rearrangement. The Board disagreed, referring to the cited documents and asserting no such suggestion or description had been made. The Board went on to say, *"in order to demonstrate obviousness it is not sufficient that a skilled person could have interpreted document (1) in such a way that the silver (I) salt was a Lewis acid, but it must be made credible that the skilled person would have interpreted that document accordingly. Because, in the present case, there is not the slightest hint in the prior art that a rearrangement reaction of alpha- haloalkylarylketones or ketals thereof could be assisted by any rearranging agent other than a silver salt, the skilled man could deduce from this document only that silver ions were necessary to conduct the*

³⁴⁹ BLASCHIM case [At II.]

³⁵⁰ BLASCHIM case [At 4.]

*rearrangement reaction and no reason can be seen why a skilled person would have interpreted the reaction in such a way that the silver (I) ion is acting as a Lewis acid.*³⁵¹

The Board concluded that it would not have been obvious to a skilled person to replace the silver (I) salt in the reaction described in document (1) by any Lewis acid, let alone, by a salt of one of the specific metals mentioned in Claim 1 of the patent at issue.

The EPC also provides for instances when a previously unrecognised problem is discovered and solved by the claimed invention despite appearing to be trivial and obvious in retrospect.³⁵² The term used to describe this type of solution is a “problem invention” which may be patentable under certain circumstances. The accepted understanding is that the duty lies with a skilled person to improve and solve problems in the state of art therefore if a solution follows in the course of routine work, this solution will generally not be considered inventive. However, in such cases the question becomes whether the side effect or “bonus” effect was expected by the skilled person. For instance in chemistry, *“analogy processes are only claimable as long as the problem, i.e. the need to provide certain patentable products as their effect, is not yet within the state of the art.”*³⁵³

In the *Rider* case, the applicant altered a known layered tablet, containing simethicone and antacids by providing a barrier between the layers of these two incompatible medicaments. The problem in the state of art was the migration of silicone materials. The use of barriers had been available and well known in the art to prevent interaction between two incompatible ingredients.³⁵⁴ However the trend in the art was to avoid barriers, consequently other methods in the state of the art had been successfully used to keep these ingredients separate. The effect of using a barrier to solve the well-known problem was known.³⁵⁵ The Board held that the correct enquiry would not be whether a person

³⁵¹ *BLASCHIM* case [At 4.4.6.]

³⁵² *Rider v. -* Boards of Appeals of the EPO, T-0002/83 (15 March 1984) (Simethicone Tablet) [At I.] [Hereinafter the *Rider* case]

³⁵³ *Rider* case [At 6.]

³⁵⁴ *Rider* case [At I. and II(c)]

³⁵⁵ *Rider* case [At 4.]

skilled in the art would have provided the barrier between the layers but rather whether he would have done so with the expectation of an improved or advantageous effect.

The Board discussed that on the surface, the solution offered by inserting this barrier to avoid the migration of the simethicone as “*satisfactory*” but “*devoid of any technical effect*” and therefore obvious.³⁵⁶ However, the applicants had discovered that the multilayered tablet (the Yen tablet) lead to unexpected and substantial reduction of simethicone activity. The applicant could not have expected, in light of the teaching of the prior art, the effects of inserting a barrier in the multilayered tablet. On this basis and the fact that the Yen tablet had not been part of the state of art at the priority date of the application, the Board concluded this modification involved an inventive step.³⁵⁷

This case illustrates the situation where the inventor had no choice in the way of improving the known problem (the Board referred to this situation as a “one-way street”), i.e. by using a barrier, which was a known alternative, but also thereby solving an unknown problem, namely the reduction of simethicone activity.³⁵⁸

Other indicators that have been developed by the EPO to assist in determining whether an inventive step exists, these include:³⁵⁹

1. A long felt need
2. Commercial success
3. A surprising effect or unexpected result
4. Prejudices in the art

³⁵⁶ *Rider* case [At II. and 7.]

³⁵⁷ *Rider* case [At V(c), 7. and 8.]

³⁵⁸ *Rider* case [At 6.]

³⁵⁹ Singer and Stauder *European Patent Convention* 161

Evidence of a long-felt need is often provided when no developments have been made regarding the state of art or where repeated unsuccessful attempts to solve the technical problem have been made over a long period of time. However the need must be general and not a need had only by an individual.³⁶⁰

The commercial success of the invention claimed is an additional consideration to corroborate the existence of an inventive step. The commercial success of the invention must originate from the technical features of the invention and not from other sources such as marketing and advertising the invention.³⁶¹ However according to the jurisprudence of the TBA, even if the commercial success is directly attributable to the claimed invention, this will not, in itself, signify the presence of an inventive step. Commercial success is secondary indicia and will not replace the objective conclusion of obviousness that was arrived at by applying the problem-solution approach.³⁶²

Unexpected additional effects can be indicative of an inventive step.³⁶³ The “effect” must originate from the subject matter claimed and should not be treated as a side effect simply because it is not expressly stated in the application.³⁶⁴ However, in light of the state of art, if this effect would have been obvious to a person skilled in the art, for instance due to a lack of alternatives, i.e. the “one way street” situation, the unexpected effect that occurs together with the expected effect (that which is expected to occur within the terms of the claim), will be considered a bonus effect and will not confer inventiveness on the claimed subject matter.³⁶⁵

³⁶⁰ Singer and Stauder *European Patent Convention* 165

³⁶¹ EPO Guidelines Part G

[http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/\\$FILE/guidelines_for_examination_2013_part_g_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/$FILE/guidelines_for_examination_2013_part_g_en.pdf) (accessed 20/04/2013) [Chapter VII at 10]

³⁶² *ILPEA S.p.A v. REHAU AG & Co.* Boards of Appeal of the EPO, T-0005/91 (24 June 1993) (Sealing gasket/ILPEA) [At 4.5]

³⁶³ *Biogen v. Boehringer Ingelheim Pharma AG* Boards of Appeal of the EPO, T-0301/87 (16 February 1989) (Alpha-interferons) [At III (iv), V (d) and 7.12-7.14]

³⁶⁴ Singer and Stauder *European Patent Convention* 164

³⁶⁵ *Rider* case [At 6.]

Prejudices in the art is an indicator similar to that of “long-felt need.” References will be made to a stagnating state of art or the age of the relevant citation. Only a generally accepted technical prejudice or an obstacle substantiated by facts will be considered. For instance, skilled people within a particular field will be able to assess whether the prejudice exists. Evidence of prejudices can be found by referring to statements in standard works for the field or textbooks that state the solution of the invention is impossible or overcome with disadvantages. Relying on a single reference in another patent document that the solution invention could not be achieved will not suffice.³⁶⁶

Indicative evidence has a secondary function, i.e. an applicant will only need to rely on indicative evidence to prove an inventive step if it has not been established in terms of the problem-solution approach.³⁶⁷

Inventive step is based on a qualitative assessment and may be the most difficult requirement to satisfy. It is highly probable that issues regarding nanotechnology inventions failing to meet this requirement will be raised, an examiner could easily assume the invention is simply the miniaturisation of a known structure i.e. where the size of a known device, machine, material or physical structure is reduced in size. The mere reduction in size of a known structure would render the invention obvious and therefore un-patentable. However it is possible to patent the miniaturised structure if the process in respect of which this is achieved is novel or if the miniaturised material complies with the following factors:

1. The material that was miniaturised displays new, improved or unexpected properties that were not present in prior art.
2. These new properties solve an unknown or known technical problem
3. These new properties were not suggested by prior art, and
4. A person skilled in the art would not extrapolate teachings provided by prior art to achieve this invention.

³⁶⁶ Singer and Stauder *European Patent Convention* 168- 170

³⁶⁷ Singer and Stauder *European Patent Convention* 162

This discussion is illustrated well in *Trustees of the University of Pennsylvania v. Affymetrix Inc.*, where the TBA recognized the general interest of downsizing and miniaturizing in the field of biological analytical devices. The Board stated that the requirement of an inventive step would only be met if an unexpected advantage or technical effect due to the reduced dimensions of the material were to occur. In this case an analytical method differed from the closest prior art in size of the flow channels for a specific analytical fluid. By reducing the size of these flow systems, including flow-inducing means allowed for the use of these devices in diverse applications. The Board concluded this miniaturization solved the technical problem existing in prior art and this improvement was not obvious in light of the disclosures made in the relevant prior art to a person skilled in the pertinent art nor would such a person anticipate this invention.³⁶⁸ Therefore if the inventor is able to show that the new material generates distinct properties that were not anticipated by prior art the invention will not be considered obvious. The applicant should specify the advantageous effects of the invention in the patent application, providing evidence of the closest prior art. If the claim relates to a chemical invention, reports on comparative trials should be provided during the examination proceedings (and opposition proceedings).³⁶⁹

3) Industrial Application

In terms of Article 57 of the EPC, “*an invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.*” This requirement may be particularly difficult for the inventor to show in the case of nanotechnology inventions as the invention may have multiple applications in various fields of technology. With most of nanotechnology still at the early development stages objections regarding whether the invention is merely a discovery may be raised.

Thus, the inventor is simply required to disclose in the specification at least one practical application of his invention in any industrial field that will enable a skilled person of the

³⁶⁸ *Trustees of the University of Pennsylvania v. Affymetrix Inc.* T 0070/99 (23 January 2003) (Analytical devices/UNIVERSITY OF PENNSYLVANIA) [At I. and 1.3.]

³⁶⁹ *BLASCHIM S.p.A v. Syntex Pharmaceuticals International Limited* Boards of Appeal of the EPO, T-0597/92 (1 March 1995) [At 4.4.7]

relevant art to use or make the invention.³⁷⁰ There can be more than one known use by the inventor. However, he is merely required to disclose one of these and it need not be the best one.³⁷¹ The inventor will receive protection for the infringement of his IP rights in the event of third parties trying to use or make the same invention for any purpose, irrespective of whether or not it was specifically disclosed by the inventor.³⁷²

As indicated above, the standard to meet the requirement of industrial application could possibly be applied more rigidly with nanotechnology inventions, especially when patent applications relate to inventions to be applied for nanotechnology research. The applicant may need to provide a more detailed disclosure with an extensive description and evidence of the use of his invention in such cases. Recent case law has revealed the interpretation of Article 57, as adopted by the TBA in cases where it is difficult to determine the “industrial applicability” of the invention claimed.

In the *Zymogenetics* case, the application claimed a Zcytor1 receptor as the invention, which could be used in different screening methods and more specifically to “*screen for ligands for the receptor, including the natural ligand, as well as agonists and antagonists of the natural ligand.*”³⁷³ Unfortunately details relating to the biochemical activity and cellular function of the Zcytor1 receptor had not been clarified in the application resulting in the need for the Board to examine the application further. The Board considered the treatments referred to in the application and as a result of these applications (in the areas of rheumatoid arthritis, multiple sclerosis, diabetes mellitus, etc.) being plausibly in relation to the function of the molecule, the Board was able to clearly identify a therapeutic or diagnostic use for the invention. Consequently the Zcytor1 receptor and moreover the products related thereto, i.e. the extracellular Zcytor1 fragment were decided by the Board to have “*a plausible*

³⁷⁰ EPC Art 83

³⁷¹ Ius Mentis <http://www.iusmentis.com/patents/uspto-epodiff/> (accessed 07/12/2012)

³⁷² Cisneros 2009 *Nomos* 50

³⁷³ *Zymogenetics Inc. v. -* . Boards of Appeal of the EPO, T0898/05 (3 March 2008) [At 15] [Hereinafter *Zymogenetics* case]

*application in an industrial (medico-pharmaceutical) activity” thereby meeting the necessary requirements.*³⁷⁴

The Board discussed other cases such as the *Max-Planck-Gesellschaft* case to arrive at their decision. In respect of which it was held that *“the mere fact that a substance (e.g. a polypeptide) can be made in some way does not necessarily mean that the requirements of Article 57 have been fulfilled, unless there is also some profitable use for which the substance can be employed.”*³⁷⁵ In contrast to the previous case, no clear role was identified for the claimed substance and the Board stated that *“there must be a borderline between what can be accepted, and what can only be categorized as an interesting research result which per se does not yet allow a practical industrial application to be identified”* and that *“even though research results may be a scientific achievement of considerable merit, they are not necessarily an invention which can be applied industrially.”*³⁷⁶

Therefore a patent will not be granted for an invention that is purely speculative or theoretical; it *“ must have such a sound and concrete technical basis that the skilled person can recognise that its contribution to the art could lead to practical exploitation in industry, i.e. to a concrete benefit, which is immediately derivable directly from the description, if it is not already obvious from the nature of the invention or from the background art. It is necessary to disclose in definite technical terms the purpose of the invention and how it can be used in industrial practice to solve a given technical problem, this being the actual concrete benefit or advantage of exploiting the invention.”*³⁷⁷

³⁷⁴ *Zymogenetics* case [At 31]

³⁷⁵ *Zymogenetics* case [At 2]; Also see: *Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V. v. - Boards of Appeal of the EPO, T870/04 (11 May 2005) (BDP1 Phosphatase/MAX-PLANCK)* [At Headnote]

³⁷⁶ *Zymogenetics* case [At 3]

³⁷⁷ *Zymogenetics* case [At Headnote: 1 and 5]

Accordingly the issue as to whether the requirement of Article 57 is met, can only be decided on a case-by-case basis and in relation to specific technical circumstances such as background art, the extent of the disclosure and post-published evidence.³⁷⁸

4. PROPOSED SOLUTIONS TO OVERCOME SOME OF THESE CHALLENGES

4.1. Specific Legislation

Due to the complexities of nanotechnology, there has been doubt by experts regarding the adequacy of current patent law provisions. This uncertainty extends to the manner in which courts will deal with nanotechnology cases that appear before them. Critics have proposed technology specific legislation as a solution for all things nano-related. Specific legislation would regulate the idiosyncrasies of this new technology with regard to IP law and risk management. It is argued that many of the issues this technology raise are not adequately dealt with within the scope of existing rules and regulations thereby demanding the need for extra guidelines to be implemented.

I. USA

Although limited, case law relating to nanotechnology has indicated that the CAFC will continue to consistently apply the same standards they have in the past when confronted with “new” technologies (for instance biotechnology in the past), that is to use the high standard of enablement which is determined by applying the Wands Test.³⁷⁹ Arguably one of the most relevant nanotech cases the Federal Circuit adjudicated was *In re Kumar*, in respect of which the court demonstrated its treatment of a nanotechnology patent. Here the case was decided on procedural grounds: no special or additional rules were applied. It was treated as any other case based on any other technology.³⁸⁰ Therefore one can conclude, based on the case law discussed throughout this chapter, that there is no real

³⁷⁸ *Zymogenetics* case [At 20]

³⁷⁹ Schwaller and Goel 2006 *Nanotech. L. & Bus.* 147-148

³⁸⁰ *In re Kumar* 418 F.3d 1368 (Fed. Cir. 2005). Also see: Baluch 2005 *Nanotech.L. & Bus.* 346

need for additional rules or legislation when nanotechnology related cases are the subject of litigation. It appears the rules and regulations of patent law sufficiently protect nanotechnology inventions.

II. EUROPE

A study was conducted within the context of Germany and Europe as to whether a need for nanotechnology legislation exists.³⁸¹ The findings based on this study revealed that existing patent laws would sufficiently address any of the issues nanotechnology may present.³⁸² It also commented; that despite patent law provisions having been developed to deal with comparatively simple inventions these provisions still prove adequate when dealing with new complex technologies. Almost all the challenges faced by nanotechnology patent applications can be resolved within the parameters of existing laws and by carefully and precisely drafting the claims of the patent application. The legal provisions pertaining to IP law currently being applied to this new technology adequately cover the issues raised. Therefore one can reasonably conclude that there is no need for extra technology specific legislation.

It is therefore unlikely that in the foreseeable future such legislation will be implemented.³⁸³ It is however possible that relevant individual legislative provisions may be “updated” to provide for nano-related subject matter.³⁸⁴

4.2. Standard Definitions

The USPTO, realising the need to improve on universally standardising nanotechnology terms entered into trilateral discussions with the EPO and Japanese Patent Office with the purpose of developing an effective and consistent international review of nanotechnology

³⁸¹ Beyerlein 2006 *Nanotech. L. & Bus* 540

³⁸² Beyerlein 2006 *Nanotech. L. & Bus* 547- 549

³⁸³ Beyerlein 2006 *Nanotech. L. & Bus* 548-549

³⁸⁴ Beyerlein 2006 *Nanotech. L. & Bus* 545

patent applications and the development of classes and subclasses.³⁸⁵ In 2011, the International Patent Classification (IPC) system introduced a new classification system to be used by all patent offices worldwide for the uniform classification of nanotechnology.³⁸⁶ The EPO's Y01N tagging system was replaced with the new symbol, B82B and B82Y. This new symbol should make it easier to identify and retrieve relevant patent documents in this field of technology.

In addition to these large-scale efforts the USPTO could improve on Class 977 by re-assessing the definitions and parameters of nanotechnology terms for the purpose of clarity and certainty regarding eligible subject matter. The retrospective classification of all pre-2004 nanotechnology patents could be another initiative whereby areas of science and technology with the most active patent litigation would be given priority.³⁸⁷ Reviewing the patent landscape will remove any uncertainty regarding valid IP rights.

In 2013, the EPO and USPTO launched a global classification system for patent documents; namely the Cooperation Patent Classification (CPC). The objective of the CPC is to combine the best practices of both offices and create a common and internationally compatible classification system. Worldwide patent examiners and patent users will be able to conduct patent searches by accessing the same classified patent document collections which will enhance the efficiency of prior art searches by eliminating unnecessary duplication of work.³⁸⁸

A uniform, consolidated database, comprising all the relevant prior art that is otherwise dispersed across various fields would significantly optimize the examination process. By having all nano-related patent documents in one place, examiners are less likely to overlook

³⁸⁵ Paradise 2012 *NJTIP* 185

³⁸⁶ EPO "Nanotechnology: A Special Tagging System" <http://www.epo.org/news-issues/issues/classification/nanotechnology.html> (accessed 31/07/2012)

³⁸⁷ Paradise 2012 *NJTIP* 197-198

³⁸⁸ European Patents Office "EPO and USPTO Launch Cooperation Patent Classification" <http://www.epo.org/news-issues/news/2013/20130102.html> (accessed 22/05/2013)

any relevant prior art, which in turn will ensure the validity of future nanotechnology patents.

4.3. Training the Examiners

It is fair to say that examiners have been at a disadvantage when examining the substantive requirements of a nanotechnology patent application. The need for proficient examiners is crucial in ensuring the quality and validity of granted nanotechnology patents. After having received criticism for their examiners not being proficient in the field of nanotechnology, the USPTO joined outside professionals and experts to aid in training and educating the examiners on nanotechnology concepts and terms. Having a better understanding of this science will assist them in carrying out more specialised prior art searches.³⁸⁹

By appointing a team of scientists representing different scientific disciplines, a patent application comprising more than one disciplinary component will be examined more efficiently.³⁹⁰ This will reduce the likelihood of relevant prior art in various fields applicable to the invention from being overlooked.

The USPTO activated a pilot programme whereby information on peer-reviewed publications and research in the public domain was collected.³⁹¹ In this way an “additional source” is made available to examiners allowing them to locate prior art that might otherwise not have been located during a typical patent examination process. This programme was effective until about 2011. A similar initiative should be activated for the purpose of gathering information from outside sources, including agencies, companies, researchers and investors.

³⁸⁹ Paradise 2012 *NJTIP* 186

³⁹⁰ Nanowerk News IP Issues <http://nanowerk.com/news/newsid=1187.php> (accessed 02/05/2012)

³⁹¹ Paradise 2012 *NJTIP* 200-201

4.4. Drafting

a) Information Disclosure Statement.

It is at the discretion of the applicant to submit an information disclosure statement, however it is highly recommended when dealing with nanotechnology inventions. This disclosure is considered a gesture of good faith and will demonstrate full disclosure of all information known by the inventor or patent practitioner at the time of the patent application.³⁹² This will give the examiner a better understanding of the technology and the field it applies to thereby reducing the risk of rejection based on an otherwise superficial search.

Most patent applicants will cite other patents as prior art but with limited prior art, it is suggested to extend the search to include scientific research papers and other published articles.³⁹³ The wider the prior art search, the stronger the patent and the greater the probability the patent will overcome any opposition.³⁹⁴

b) A Manual for Nanotechnology Patent Applications

Patent Offices could develop and publish a manual for prospective patent applicants, outlining guidelines as to the standard expected from a nanotechnology patent application. This manual could advise the applicant on ways to circumvent some of the issues commonly raised with nanotechnology patents. For instance, when drafting the application how the invention should be described within the nanoscale range, thereby creating uniformity regarding claim construction.

³⁹² Hicks, Grissett and Brown <http://www.wcsr.com/resources/pdfs/nano030310.pdf> (accessed 04/05/2012) [At 3]

³⁹³ Almeling 2004 *STLR* ¶12- ¶13

³⁹⁴ Wild <http://www.iam-magazine.com/issues/article.ashx?g=29c766f2-a9b8-4b94-89d5-d35b9ec8e614> (accessed 31/07/2012) [At 32]

A universal reference will ensure nanotechnology patent applications will be consistently drafted according to these high standards.

c) Limiting the Scope of the Patent

As discussed, nanotechnology is a relatively new, rapidly developing and a multidisciplinary technology, where patents with overly broad product claims could easily cause serious obstacles for innovative developments in a number of technological fields. It is therefore essential that the scope of the allowed patent claims is strictly commensurate to the new teaching of the patent, as enablingly disclosed in the patent specification. If this rule is strictly applied and followed, the original patent holder will only be in position to control improvements, which clearly use that teaching. In many cases further developments will "escape" the claims and such inventions, if patented, will be treated as independent. Particular attention has to be paid and restrictive practice followed, whenever the so-called "functional claims" are at stake.

Because a holder of a product patent owns the right to the technology claimed in all the industries in respect of which the invention can be applied and is in the position to grant licenses for the production or use of his patent in any of these various fields, arguably the claims could be limited to the uses he discloses and would not cover the general use of the product. Consequently by limiting the protection, others are given the opportunity to develop such improvements and further innovation within this field of technology. Furthermore, as an interdisciplinary technology it seems increasingly appropriate to apply this concept of limiting the scope of the patent thereby reducing the potentially negative impact of broad product claims on R&D and competition.

This can be achieved in cases where an invention can be used in several fields. The patent holder owns the right to the technology claimed in all the industries in respect of which the invention can be applied and is in the position to grant licences for the production or use of his patent in any of these various fields. Arguably this power should be limited and the patent holder should only be protected in relation to the uses he discloses and not the general use of the product. By limiting the scope of the patent to only protect the specific

use or uses described by the applicant, the relationship between the scope of the invention and the rights granted by the patent will be improved. This will curb overly broad claims from being included in patent applications, thereby achieving a better balance. The inventor will no longer be able to own the rights to general concepts thereby encouraging innovation. The appropriate scope for a nanotechnology patent is likely to be established as this technology matures.

This notion is further supported by the fact that companies will only invest in the R&D of products that are commercially and economically valuable therefore they should be limited by the uses they disclose.³⁹⁵ Perhaps these limitations should only apply to specific nanotechnology related cases, i.e. only those containing broad product claims, which would have a negative impact on innovation.

4.5. Patent Pools

The so-called Patent Pools could also provide some improvements. In reference to the CNT building block patent example,³⁹⁶ the establishment of a “Nanotube Patent Forum” was proposed with the intention to simplify some of the complicated and unfamiliar future patent issues that would have to be dealt with as more CNT based products are produced.

The common incentive in creating a patent pool is to share technology. Due to the cross-industry application of nanotechnology a forum could bring together different patent holders with companies developing and manufacturing similar nano-based products, thereby regulating cost-effective licencing agreements that could be reached between manufacturers and patent holders.³⁹⁷ Participating patent holders could agree to license

³⁹⁵ Cisneros 2009 *Nomos* 53

³⁹⁶ See: Chapter 1, section entitled “1. SOME OF THE CHALLENGES OF NANOTECHNOLOGY IN PATENT LAW: 1.1. Patented ‘Building Blocks’”

³⁹⁷ Berger Growing Nano Problems <http://nanowerk.com/spotlight/spotid=1367.php> (accessed 02/05/2012)

their technologies to one another in terms of a “joint licensing scheme” for example.³⁹⁸ This would benefit companies and patent seekers considering investment, by giving them insight as to the costs involved in obtaining licences and making it easier for them to navigate the complex patent landscape.³⁹⁹

International collaborations seem to be a new trend and are established on a voluntary basis whereby information and technologies can be shared by various technology holders who appreciate the benefit of pooling technologies instead of the immediate advantage of restricting access to their own technology.⁴⁰⁰ Such collaborations will allow for separate patented components held by separate entities to be joined. There are closed patent pools whereby access will be limited to the technology and open patent pools where the converse will apply.⁴⁰¹ This aspect will be discussed further regarding South Africa’s participation in international collaborations, such as BRICS and IBSA, in chapter 3.

³⁹⁸ Wipo Magazine “Special Edition World Intellectual Property Day 2009” http://wipo.int/wipo_magazine/en/pdf/2009/wipo_pub_121_2009_02.pdf (accessed 19/04/2012) [At 6] [Hereinafter “WIPO Intellectual Property Day”]

³⁹⁹ WIPO Intellectual Property Day http://wipo.int/wipo_magazine/en/pdf/2009/wipo_pub_121_2009_02.pdf (accessed 19/04/2012) [At 6]

⁴⁰⁰ WIPO Intellectual Property Day http://wipo.int/wipo_magazine/en/pdf/2009/wipo_pub_121_2009_02.pdf (accessed 19/04/2012) [At 4]

⁴⁰¹ WIPO Intellectual Property Day http://wipo.int/wipo_magazine/en/pdf/2009/wipo_pub_121_2009_02.pdf (accessed 19/04/2012) [At 6]

CHAPTER 3

SOUTH AFRICAN IP AND NANOTECHNOLOGY

I. SOUTH AFRICAN PATENT LAW

This chapter serves to uncover and discuss some of the differences and similarities between the South African patent system and those of more developed jurisdictions, such as those discussed in the previous chapter. South Africa is a developing country and the intention of this comparison is to determine whether adopting international patent practices would benefit the quality of the patents granted in South Africa or whether the current patent practices suffice, especially when dealing with more complicated technologies such as nanotechnology.

1. THE PATENT APPLICATION PROCESS: Claim/s

1.1. Interpretation of the Claims

South Africa is a non-examining country, meaning the merits of the invention claimed in a patent application are not investigated when the patent application is filed. Consequently there is no need to interpret and determine the scope of the claims at this stage. However once granted, proceedings may arise challenging the validity of the patent and the scope of the claims will then need to be determined (i.e. in post-grant proceedings).

This differs greatly from the U.S. and Europe,⁴⁰² both adopting an examining system whereby the scope of the claims will be interpreted during the application process by the examiners. Consequently aspects discussed in the previous chapter that would otherwise be

⁴⁰² However it should be noted that South Africa is not unique in this regard. Developed European countries such as, Belgium, Italy and France also do not have an examining system. Consequently the national patents for these European countries are not examined. The difference with South Africa exists in the extent that most patents granted for those countries are granted by the EPO and therefore the substantive patentability requirements are examined.

considered when interpreting the claims of a patent, for instance the prosecution history, will not be considered in post-grant proceedings.⁴⁰³

Case law is relied upon to determine the manner in which the scope of the claims will be interpreted. The current approach adopted by the courts involves a more contextual or purposive interpretation. The effect of this shift brings the former British textual interpretation approach, referred to as the “*pith and marrow*” approach,⁴⁰⁴ closer to the former (i.e. before the harmonization with European patent law) and much more liberal German approach. In respect of the latter approach, the courts applied so-called “*general inventive idea*” to determine the scope of the claims. The claims would be broadened to include the general inventive idea in cases where the description and the claims of the invention contained a “*sufficient disclosure*” to allow for a broader inventive idea to be protected.⁴⁰⁵

A relatively recent judgment reflecting this shift can be found in the *Triomed* case. At issue was the infringement of a pharmaceutical product⁴⁰⁶ containing omeprazole for inhibiting gastric secretion. The oral dose of the drug is intended to pass through the stomach and be delivered intact to the proximal part of the intestine, where it is rapidly dispersed so that it can be absorbed through the wall of the intestine into the blood stream. The active ingredient, omeprazole, is acid sensitive and therefore encapsulated in an enteric coating that is resistant to dissolution in the stomach (by the stomach acids) but will dissolve in the proximal part of the intestine. This coating is commonly used, however it is also acidic, therefore to ensure it does not deteriorate, it is mixed with an alkaline compound. A sub-

⁴⁰³ Brunetti and Coertzen https://www.aippi.org/download/committees/229/GR229south_africa.pdf (accessed 13/07/2013) [At 2 and 5]

⁴⁰⁴ Brunetti and Coertzen https://www.aippi.org/download/committees/229/GR229south_africa.pdf (accessed 13/07/2013) [At 3]

⁴⁰⁵ Dr. Pagenberg <http://www.law.washington.edu/casrip/symposium/number8/CM%20-%20Pagenberg%20CASRIP%20Interpretation%20of%20Patent%20Claims.pdf> (accessed 07/10/2013) [At 1]

⁴⁰⁶ South African Patent No. 87/2378

coating layer of film forming alkaline compounds forms a barrier between the core of omeprazole and the enteric coating thereby overcoming this problem.⁴⁰⁷

At issue was the composition of this sub-coating layer film. The respondent imported and distributed a pharmaceutical preparation known as Ulzec, in 10g and 20g doses, which allegedly infringed this patent. Claim 1 reads:

"1. An oral, pharmaceutical preparation in the form of enteric coated tablets or pellets, containing omeprazole as the active ingredient characterized in that it is composed of:

(a) alkaline core material containing omeprazole together with an alkaline reacting compound, or an alkaline salt of omeprazole optionally together with an alkaline reacting compound, and

(b) on said alkaline core material one or more inert reacting sub-coating layers comprising tablet excipients which are soluble or rapidly disintegrating in water, or polymeric, water soluble, film-forming compounds, optionally containing pH-buffering, alkaline compounds between the alkaline core material and

*(c) an outer layer, which is an enteric coating."*⁴⁰⁸

The active alkaline core of the respondent's product, Ulzec, is sub-coated with a single compound (polyvinyl pyrrolidone, which is a water soluble, film-forming polymer).

Therefore the allegedly infringing preparation differed from the claimed preparation only in that the sub-coating layer contained a single film-forming compound. The question then arose whether the applicant intended to exclude a sub-coating consisting of only one compound.

In the court a quo, the Commissioner of Patents applied a purely textual interpretation of the claim and held that the function of the claim is to describe the scope of the invention claimed which will convey the limitations of the invention to others thereby ensuring

⁴⁰⁷ *Aktiebolaget Hässle and Another v. Triomed (Pty) Ltd* 2003 (1) SA 155 (SCA) [At 2 and 4] [Hereinafter the *Triomed* case]

⁴⁰⁸ *Triomed* case [At 5]

infringements are avoided. He concluded that the patent had not been infringed because if read grammatically and in the ordinary sense, the words, as quoted, meant that there must be a plurality of film-forming compounds of the type described.

On appeal the judge disagreed with this literal interpretation of the claim and emphasized the importance of the context, saying that “*context is everything*,”⁴⁰⁹ when interpreting the claim. The judge referred to the *Catnic* case,⁴¹⁰ in which Lord Diplock applied the purposive approach:

*“... a patent specification is a unilateral statement by the patentee, in words of his own choosing, addressed to those likely to have a practical interest in the subject matter of his invention (i.e. “skilled in the art”), by which he informs them what he claims to be the essential features of the new product or process for which the letters patent grant him a monopoly. It is those novel features only that he claims to be essential that constitute the so-called “pith and marrow” of the claim. A patent specification should be given a purposive construction rather than a purely literal one derived from applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge. The question in each case is: whether persons with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that any variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked.”*⁴¹¹

In cases of infringement, the infringing article or process must be compared to the language of the claim; “*the language of the claim should be construed purposively, so as to extract from it the essence or the essential elements of the invention.*”⁴¹² The judge emphasized the

⁴⁰⁹ *Triomed* case [At 1]

⁴¹⁰ *Catnic Components Ltd & Another v. Hill & Smith Ltd* (1982) RPC 183 (HL) [Hereinafter the *Catnic* case]

⁴¹¹ *Triomed* case [At 8]

⁴¹² *Triomed* case [At 8]

importance of the context when interpreting the language used in any document, whether it is “a statute, or a contract, or, as in this case, a patent specification.”⁴¹³ The words should not be read in isolation but viewed in the context of the invention as a whole. Claims 3 and 4 provide as follows:

“3. A preparation according to claim 1 wherein the sub-coating comprises two or more sub-layers.

4. A preparation according to claim 3 wherein the sub-coating comprises hydroxypropyl methylcellulose, hydroxypropyl cellulose or polyvinylpyrrolidone.”⁴¹⁴

In light of Claims 3 and 4 the judge commented that the inventor was indifferent to the composition of the sub-coating layer as he only provided that it must have the functional characteristics specified in the claim, thereby increasing doubt as to whether the inventor intended that two or more excipients or compounds were essential elements of the invention. The judge concluded there was no reason why it should not consist of any one of those compounds alone and for this reason the respondent’s product did infringe the patent.⁴¹⁵

1.2. Drafting the Claims

In terms of section 32(4) of the South African Patent Act,⁴¹⁶ the claims must be clear, relating to a single invention and must be fairly based on the matter disclosed in the specification. The Act however also states that a person will not be able to object to a patent that comprises more than one invention.⁴¹⁷ In addition to this, Regulation 30 in the Patent Regulations of 1978 can be referred to, stating, “each category of claims (product, process, apparatus, use and the like) shall, as far as practicable, be arranged in order of

⁴¹³ *Triomed* case [At 1]

⁴¹⁴ *Triomed* case [At 12]

⁴¹⁵ *Triomed* case [At 11 and 16]

⁴¹⁶ Patent Act 57 of 1978

⁴¹⁷ Patent Act 57 of 1978, section 62

decreasing scope.”

There are no standard guidelines in place and in practice South African patent attorneys may refer to European drafting guidelines when drafting a patent application, as South African patent law is closer to European patent law than, for example, U.S. patent law. However European drafting guidelines are not strictly adhered to. This approach is in stark contrast to our overseas counterparts who place great emphasis on claim construction so as to avoid any uncertainty relating to the scope of the patent and the consequences that accompany a poorly drafted patent application.

As discussed in the previous chapter, there is extensive literature relating to the importance of claim construction and guidelines for drafting patent applications so as to maintain a high standard. These guidelines serve to ensure that the patent application is drafted in accordance with the manner in which it will be examined and interpreted by the Patent Offices or courts respectively. The applicant must describe his invention in detail, supplying sufficient information relating to what he includes as his invention and making certain the scope of the claims match the specification. Claim construction directly affects the validity of the claims and the extent of the protection afforded to the patent holder. The patentee would not want to jeopardise his exclusive rights due to inadequately drafted claims (i.e. narrow claims) or by using overly broad claims, which could result in infringement, thus illustrating the need for a claim drafting policy in South Africa.

Without regulated guidelines the language used in drafting the patent application may encompass far more than the actual invention can enable thereby increasing the number of claims sought to be patented. Furthermore by granting a patent that has more claims than warranted by the claimed invention increases uncertainty relating to IP rights. The EPO limits the number of claims to one independent claim in the same category in the patent application. The USPTO sets different fees for the patents that have more than one independent claim in the same patent. Independent claims “stand on their own” and contain essential features relating to the invention. Independent claims must fulfil the substantive requirements set for a valid patent. Dependant claims reference former claims (i.e. it can refer to one or more independent claims; one or more dependant claims; or both

independent claims and dependent claims) in the patent and will be interpreted in light of the limitations included in the claim it refers to.⁴¹⁸ Either of these approaches could be adopted by South Africa, which would then allow for more control regarding the breadth and number of claims made in a patent application.⁴¹⁹

A patent application should be drafted according to the higher standard adopted by countries, such as those discussed and comply with international standards to ensure a higher quality of patents is achieved. This will also contribute to the priority of patent applications filed first in South Africa and subsequently abroad. By reason of, differences in priority applications often cannot be remedied later on. The applicant will benefit from a well-drafted application, as a poorly drafted one could result in the applicant not gaining from the full monopoly of his invention.

2. REQUIREMENTS FOR A VALID PATENT

In terms of South African patent law the requirements for a valid patent include: 1) novelty, 2) an inventive step and 3) the invention must be capable of use or application in trade, industry and agriculture.⁴²⁰ These requirements are not dissimilar to those described for the EPC as South African patent law is based on the EPC and relies on it to define the undefined.⁴²¹

2.1. Excluded Subject Matter

The Act specifically excludes: discoveries; scientific theories; mathematical methods; schemes, rules or methods for performing mental acts, playing games or doing business;

⁴¹⁸ Guidelines for Examination in the European Patent Office, Part F “Independent and Dependent Claims” http://www.epo.org/law-practice/legal-texts/html/guidelines/e/f_iv_3_4.htm (accessed 07/10/2013) [Chapter IV At 3.4.]

⁴¹⁹ Pouris 2011 *S Afr J Sci* 9

⁴²⁰ Patents Act 57 of 1978, section 25

⁴²¹ Bellman and Melendez-Ortiz (eds) *Trading in Knowledge* 265 and 267

computer programs; and presentation of information.⁴²² However section 25(3) creates an opportunity for otherwise excluded subject matter to be protected. It provides for any ineligible subject matter from being treated as an invention, “*only to the extent to which a patent or an application relates to the particular thing as such.*” Therefore it is possible for the attorney responsible for drafting the claim to draft the application in such a way that an otherwise ineligible invention may satisfy section 25(3). For example by describing the invention as a “method” or “process comprising of the following steps.”⁴²³ Similar provisions can be found in the EPC Article 52(2) and (3). However it is important to mention that claim drafting by itself cannot achieve this.

a) Scientific Theories

The EPO’s approach to scientific theories and the content therein can be referred to.⁴²⁴

In summary, scientific theories are theories based on discoveries and discoveries are based on nature’s creations. Only when a scientific theory is applied to create something, can that product or process be patented.⁴²⁵ This product or process must be novel, involve an inventive step and be capable of use or application in trade, industry and agriculture.⁴²⁶

In the *Microsoft Corporation* case, the invention was described as a rapid method for updating probability distributions representing players’ performance. This was achieved by creating a factor graph and message passing algorithms. The technical effect of this interaction between processor and players was that an accurate and timeously computation could be had, allowing the system to manage millions of players. Although EPC Article 52(2), excludes all mathematical methods as patentable subject matter, it was argued that the

⁴²² Patents Act 57 of 1978, section 25(2)

⁴²³ Burrell *Patent and Design Law* [At 1.26.1]

⁴²⁴ See: Chapter 2, section entitled “II. EPC REQUIREMENTS: 1) Excluded Subject matter: a) Scientific Theories”

⁴²⁵ Burrell *Patent and Design Law* [At 1.26.2]

⁴²⁶ *Microsoft Corporation v. – Boards of Appeals of the EPO, T-0042/10* (28 February 2013) (Determining relative skills/MICROSOFT) [At 2.13.2]. Also see: *Gale’s Application* [At 324]

mathematical method was applied to the measurement and use of a particular data structure (i.e. the players skill) hence the mathematics was not purely abstract, it was functional.⁴²⁷ Claim 1 reads:

“A computer-implemented method of determining an indication of the relative skill (205) of at least a first player and a second player of a game based on the outcome of one or more such games involving those players said method comprising the steps of:

- (i) arranging a processor (204) to, for each player, set statistics (200) describing a probability distribution associated with skill of that player to default values;*
- (ii) at the processor (204) receiving information about the outcome (201) of one of the games;*
- (iii) arranging the processor (204) to form and store a factor graph comprising variable nodes and factor nodes, the factor nodes having associated calculation rules, said graph being formed using the received information about the outcome, and arranging the processor (204) to instantiate at least some of the variable nodes with the statistics; and arranging the processor to form and store the factor graph such that it comprises a plurality of first groups of nodes, each first group being associated with a particular player and comprising nodes linked in series; and*
- (iv) arranging the processor (204) to update the statistics associated with each player by applying message passing to the factor graph using the calculation rules;*
- (v) arranging the processor to repeat the process of updating the statistics as further game outcomes are received.”⁴²⁸*

The Board referred to *Re Gale's Application*, although this case presented a slightly different situation; Gale had found an algorithm (or particular method) for calculating a square root, which he had implemented as a computer program.⁴²⁹ The judge stated that the program did not *“embody a technical process which [existed] outside the computer”* and that although the computer *“will be a better computer when programmed with Gale's*

⁴²⁷ *Microsoft Corporation case* [At VIII.]

⁴²⁸ *Microsoft Corporation case* [At V.]

⁴²⁹ *Gale's Application* 1991 RPC 305 (CA) [At 324-327] [Hereinafter *Gale's Application*]

*instructions," it did not "solve a 'technical' problem lying within the computer."*⁴³⁰ The relevance of the comparison between these two cases lies within the same line of questioning Lord Justice Nicholls applied in *Re Gale's Application*, i.e. what is and what is not technical about a computer-implemented method. Therefore the relevant enquiry is, firstly: *"what does the method as a whole do, and does it produce an overall technical result? The second is: if there is no overall technical result, does the method at least have a technical effect within the computer? If both questions are answered in the negative, no technical problem has been solved and there can be no inventive step."*⁴³¹ In line with this enquiry the Board concluded the method, as defined in Claim 1, did not involve an inventive step.⁴³² Reasons for this were attributed to the fact that the aim of keeping players interested in the game and assessing and/or comparing their performance did not solve a technical problem existing in the state of art. Moreover the representation of performance by probability distributions and the updating of them were mathematical methods (which are excluded in terms of EPC Article 52(2)).⁴³³ Finally, the "processor" was the only technical feature in the claim, which would have been obvious to a skilled person who had the task of implementing the method to use a computer processor.⁴³⁴ The method described involved the collection of large amounts of data and the carrying out calculations on it, however, computer processors were designed to achieve this hence it would have been obvious to use them for his purpose.⁴³⁵

b) Discovery versus Invention

South Africa adopts the EPO's approach regarding discoveries. That which exists in nature is pure knowledge; it exists irrespective of man's knowledge of it and cannot be invented only discovered. However this knowledge, if applied to create a product or process (i.e. if applied

⁴³⁰ *Gale's Application* 1991 RPC 305 (CA) [At 327] Also see: *Microsoft Corporation* case [At 2.13.1]

⁴³¹ *Microsoft Corporation* case [At 2.13.2]

⁴³² *Microsoft Corporation* case [At 2.19]

⁴³³ *Microsoft Corporation* case [At 2.14]

⁴³⁴ *Microsoft Corporation* case [At 2.15]

⁴³⁵ *Microsoft Corporation* case [At 2.16]

practically) the discovery could constitute an invention.⁴³⁶ In order for the discovery and method to be protected it must also fulfil the substantive requirements for a valid patent.⁴³⁷

c) Selection Inventions

In terms of South African patent law no express provisions or case law appears to exist relating to selection inventions. Selection inventions are not treated as a separate category of patents and therefore one can assume the standard patentability criteria to determine the validity of the patent will be applied equally in all cases.

If we refer back to the previous chapter, the USPTO does not recognise selection inventions as a separate category of inventions resulting in the same treatment of all inventions.⁴³⁸ In contrast, the EPO treats this as a separate category and adopts special rules in such applications.⁴³⁹ Consequently South African courts should adopt the same approach as that of the USPTO in determining the validity of any invention claimed in a patent application.

The advantages of addressing this issue on either a local or international level could provide greater certainty regarding the treatment of these types of inventions by referring to clear and consistent standards.⁴⁴⁰

⁴³⁶ Burrell *Patent and Design Law* [At 1.26.2]. *Also see: Microsoft Corporation v. – Boards of Appeals of the EPO, T-0042/10* (28 February 2013) (Determining relative skills/MICROSOFT) [At 2.13.2] and *Gale's Application* [At 324]

⁴³⁷ Burrell *Patent and Design Law* [At 1.26.2 and 1.25.12]

⁴³⁸ See: Chapter 2, section entitled: "I. USPTO REQUIREMENTS: 1) Excluded Subject matter: c) Selection inventions"

⁴³⁹ See: Chapter 2, section entitled: "II. EPC REQUIREMENTS: 1) Excluded Subject matter: c) Selection inventions"

⁴⁴⁰ It is therefore seemingly necessary to develop an international policy to deal with these types of inventions and harmonise existing practices. This could be achieved by:

- A. If recognised as a separate category of inventions:
 - 1) Provision of a definition of "selection inventions", including applicable fields of technology. In other words will selection inventions be limited to specific fields of technology, such as chemical and pharmaceutical fields or will all fields of technology be included.
 - 2) Implementation of special rules or guidelines, for example:
 - Standards to determine the novelty and inventiveness of a selection invention

2.2. Novelty

The product or process claimed as the invention must be new. "Newness" is established by determining whether the invention forms part of the state of art immediately before the priority date of that invention.⁴⁴¹ The "*state of art*" includes all matter that has been made available to the public before the priority date of the patent, whether in South Africa or elsewhere in the world, by written or oral description, by use or in any other way.⁴⁴²

Therefore South Africa follows the absolute novelty norm, i.e. "*public*" extends beyond South African borders.⁴⁴³ Furthermore it includes, matter contained in a patent application in South Africa, which is, or will become, open to public inspection and where such matter has an earlier priority date than that of the invention.⁴⁴⁴ Consequently in the case of two pending applications that relate to the same invention, the earlier application can be used to destroy the novelty of the later application. A granted patent may be revoked if the invention does not fulfil the patentability requirements in terms of section 25.⁴⁴⁵

The specific manner in which the disclosure occurs is irrelevant as the Act uses broad terms, i.e. by way of written or oral description (section 25(6)). The prior disclosure can take place in any way preceding the date of filing the patent application but must include all of the claimed novel features relating to the invention in order for this disclosure to destroy the novelty of the invention claimed.⁴⁴⁶ Furthermore no distinction is made regarding the

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- Additional disclosures regarding the advantageous features of a selection invention and instances where evidence to this effect must be produced.

B. If not recognised as a separate category of inventions: consensus regarding the equal treatment of all inventions in respect of patentability criteria.

⁴⁴¹ Patents Act 57 of 1978, section 25(5)

⁴⁴² Patents Act 57 of 1978, section 25(6)

⁴⁴³ Pechacek <http://web.wmitchell.edu/cybaris/wp-content/uploads/2012/09/Pechacek.pdf> (accessed 03/07/2013) [At 201]

⁴⁴⁴ Patents Act 57 of 1978, section 25(7)

⁴⁴⁵ Patents Act 57 of 1978, section 61(c)

⁴⁴⁶ WIPO "Study on Patents and the Public Domain"
http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_4/cdip_4_3_rev_study_inf_2.pdf (accessed 12/07/2013)
[At 59]

person responsible for making the disclosure: it can be the inventor, applicant or an outside person.⁴⁴⁷

Certain instances are provided for when a disclosure will not affect or destroy the novelty of the invention claimed; namely where knowledge was acquired or disclosure or use was made prior to the filing date without the knowledge or consent of the inventor prior to the priority date, provided the applicant files the application with reasonable diligence after learning of the disclosure and *“as a result of the invention being worked in the Republic by way of reasonable technical trial or experiment by the applicant or patentee or the predecessor in title of the applicant or patentee.”*⁴⁴⁸ The technical trial or experimentation must be “reasonable”, in other words excessive and open disclosures would destroy the novelty of the invention.

2.3. Inventive Step

An invention will have an inventive step if it *“is not obvious to a person skilled in the art, having regard to any matter which forms, immediately before the priority date of any claim to the invention, part of the state of the art...”*⁴⁴⁹ The state of art will include subject matter disclosed in a pending application within South Africa and an invention used secretly but on a commercial scale in South Africa.⁴⁵⁰ The criteria described in the context of the EPO’s approach will be applicable here.⁴⁵¹ An invention will only have an inventive step if it overcomes any technical problems facing the prior art.⁴⁵² If a patented invention is found to

⁴⁴⁷ Dr. Gerntholtz Inc. <http://www.gerntholtz.com/services/south-african-clients/patents#.UZy5SKX5ndk> (accessed 22/05/2013)

⁴⁴⁸ Patents Act 57 of 1978, section 26(a) and (b)

⁴⁴⁹ Patents Act 57 of 1978, section 25(10)

⁴⁵⁰ Patents Act 57 of 1978, section 25(10), section 25(7) and (8)

⁴⁵¹ See: Chapter 2, section entitled: “II. EPC REQUIREMENTS: 3) Inventive Step”

⁴⁵² See: *Microsoft Corporation v. – Boards of Appeals of the EPO, T-0042/10* (28 February 2013) (Determining relative skills/MICROSOFT) [At 2.13.2]. Also see: *Gale’s Application* [At 324]

be obvious, the patent will be revoked.⁴⁵³

In *Ensign-Bickford* case, the Court discussed the traditional three-step test applied to determine obviousness in relation to the South African patent no. 79/3210 entitled, "Low-energy fuse consisting of a plastic tube the inner surface of which is coated with explosive in powder form."⁴⁵⁴

Three-step test is to determine whether:

1. The invention claimed was part of the state of art in terms of section 25(5) and (6) on the effective date of the patent
2. The invention claimed is a step forward when compared to prior art, viz. does it overcome any difficulty presented by the relevant prior art?
3. This "step" is inventive, in other words in light of the state of art would a person skilled in pertinent art consider the invention obvious?

This test has been applied in many cases as a useful measure to compare the differences between prior art and the invention claimed. This enquiry is not limited to the claimed invention but includes all the developing stages leading to the end result, i.e. the invention.

The *Ensign-Bickford* case is of particular significance because the judge felt the standard three-step enquiry required a more structured approach and therefore extended the enquiry to include:

⁴⁵³ Patents Act 57 of 1978, section 61(1)(c)

⁴⁵⁴ *Ensign-Bickford (South Africa) (Proprietary) Limited & Others v. AECI Explosives & Chemicals Limited* (21 September 1998) [unreported judgement] [Hereinafter the *Ensign-Bickford* case]

1. What the inventive step is considered to be?
2. What was the state of the art relevant to that step, at the priority date?
3. In what respect does this “step” overcome the problem faced by relevant prior art.
In other words in what way does the claimed invention advance or differ from the relevant state of the art?
4. Would this “step” be obvious to a person skilled in the pertinent art?⁴⁵⁵

Although the content is similar, the effect of the change in the order of the steps of the enquiry places the onus on the applicant to produce evidence showing the invention is non-obvious and to identify the differences between his invention and prior art thereby proving it involves an inventive step rather than merely reviewing the prior art (as the first step of the previous enquiry does). Consequently the court will review the relevant prior art after the patentee has supplied the court with sufficient evidence showing the invention is inventive.

In terms of the “Three-step” enquiry, the onus of proof rests with the person alleging the invention to be obvious. This court referred to the *Firestone* case, illustrating the traditional approach adopted by the courts; “*the onus of proving that the patent in suit was invalid on any of the alleged grounds rested on Firestone (the defendant), and that that onus could be discharged on a balance of probabilities.*”⁴⁵⁶ This principle viz. that the defendant is responsible for proving the invention is invalid has been followed in many cases.⁴⁵⁷ However the *Ensign-Bickford* case, exchanged the burden and the patentee became the party responsible for producing evidence to support the inventiveness of the patent at issue.

In the past, evidence in the form of testimony from a witness regarding the validity of the

⁴⁵⁵ *Ensign-Bickford* case [At 23 of the unreported judgement]

⁴⁵⁶ *Gentiruco A.G. v. Firestone (South Africa) (Pty) Ltd* 1971 BP 58 [At 108B]

⁴⁵⁷ See: *Kimberly- Clark Corporation & Another v. Johnson & Johnson (Pty) Ltd* 1983 BP 160 [At 162A] “...the onus of proof that the plaintiff’s patent is described in the Buell patent (an alleged prior disclosure of the invention in issue) rests on the defendant...” and concluded that the defendant [emphasis added], by not leading an expert to address invalidating Buell disclosures, had “...set itself an onus which is difficult to discharge...” The validity of the patent was accordingly upheld.

patent was considered irrelevant when determining whether the invention was inventive. In this case however, the judge referred to the *Mölnlyck v. Procter & Gamble* case,⁴⁵⁸ stating that a court will almost invariably consult expert evidence. This primary evidence will be used to determine whether or not in the opinion of the expert witness, the invention (or relevant inventive step) would have been obvious to a person skilled in the pertinent art. Expert evidence will be considered to determine the meaning of technical terms and identify certain invalidating features disclosed in the prior art. All other evidence is secondary.⁴⁵⁹ Secondary evidence, including commercial success and “long felt want” will be considered to assist the court in assessing the primary evidence. The judge considered the “primary evidence” supplied by the patentee to be lacking.

The principle that the onus rests with the patentee to challenge the arguments of the party invoking the invalidity of the patent has been confirmed and followed in several other cases.⁴⁶⁰ This case also referred to the importance of the nature of the field in respect of rebutting a prima facie case of obviousness. The court concluded that the patentee failed to provide sufficient evidence thereby encouraging future patentees in similar circumstances not to make the same mistake. In particular by providing the court with expert evidence to support the inventive step claimed in the patent at issue.

2.4. Application or Use in Industry, Trade or Agriculture

The fact that South African patent law lists “trade, industry or agriculture” separately suggests a need to determine the meaning of these terms. The Act does not define these terms, however the source of this inclusion can be found in the Paris Convention.⁴⁶¹

⁴⁵⁸ *Mölnlycke AB and Another v. Procter & Gamble Limited and Others* (No.5) [1994] RPC 49 (CA)

⁴⁵⁹ *Ensign-Bickford* case [At 26 of the unreported judgement]

⁴⁶⁰ Also see: *SmithKline Beecham plc. and Another v. Sandoz AG and Another* (96/3472) [2010] ZACCP 3 (14 April 2010) [At page 22] and *Sunsmart Products (Pty) Ltd v. Flag and Flagpole Industries (Pty) Ltd t/a National Flag* (97/10535, 99/3281, 7385/2004) [2005] ZACCP 2 (7 November 2005) [At 9]

⁴⁶¹ Paris Convention for the Protection of Industrial Property (1883), Art 1(3): “Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive...”; also see: Bodenhausen 1967 *BIRPI* 1

An invention simply cannot be the subject of a patent unless it can be applied or used in trade, industry or agriculture.⁴⁶² This denotes that any invention not having a practical use or that is not “useful” cannot be patented. However South African patent law does not expressly include the same criteria as seen by the U.S. patent requirement of utility, namely that an invention should have substantial or practical utility. Furthermore the applicant is not obliged to disclose the best mode of the invention. The specification must fully describe the invention and the manner in which a person skilled in the pertinent art can use or make the invention. Failure to provide sufficient instruction to enable the invention in the specification can result in invalidity.⁴⁶³ A patent may be invalidated if the invention does not perform in the manner or fulfil that which it has been described to do in the specification.⁴⁶⁴ The onus will rest on the person alleging the invention has no practical use.

3. PROCEDURAL DIFFERENCES

Despite some similarities to European patent law there are some important differences to be noted with regard to the procedure followed by the South African patent system.

3.1. Non-examining System

A significant difference between the procedure followed by Europe and the USA to that of South Africa is the patent granting process. South Africa, as well as Belgium, France and Italy employ the “Registration System” whereby patents are granted if the financial and administrative/ formal requirements are met.⁴⁶⁵ In South Africa, the CIPC is responsible for granting patents.

⁴⁶² Patents Act 57 of 1978, section 25(1)

⁴⁶³ *Ensign-Bickford* case [At 36 of the unreported judgement]

⁴⁶⁴ Patents Act 57 of 1978, section 32(3)(b) and section 61(1)(d), (e)

⁴⁶⁵ Access Campaign <http://www.msf.org.za/publication/why-south-africa-should-examine-pharmaceutical-patents> (accessed 22/05/2013) [At 2]

In a non-examining patent system, the applicant is responsible for conducting the patent search. The CIPC will merely verify the documents or forms but not the substance of the product or process. Therefore it is assumed that the invention claimed is valid and deserving of a patent protection without examining the invention to ensure it satisfies the claim.

Patents are more easily attainable in South Africa: they are also less expensive and readily obtained in comparison to our overseas counterparts where the backlog and delay in examining patent applications has been emphasised in various reports.⁴⁶⁶

In summary: due to the fact that the invention's novelty, inventiveness or usefulness is not examined, the validity of the patent cannot be guaranteed unless the patent is later challenged in court (post-grant proceedings). An applicant will not invest in a frivolous invention, however it is possible that an applicant may be unjustly awarded with IP rights to the detriment of inventions potentially deserving patent protection. The breadth and scope of the invention may be extended resulting in overly broad claims thereby creating more uncertainty within the IP landscape and impeding further research or innovation in certain fields.

There should be checks and balances in place to assess the validity of a patent application before it is granted. Without filtering South African patents, an inaccurate patent status is depicted, as there may be many patents within those statistics that are not worthy of patent protection. A commendable alternative to an examining body would be that adopted by Turkey. Turkey does not have an examining body to investigate the substance of the inventions in respect of which patents are sought. However the Turkish Patent Office sends these applications to Russia, Sweden, EPO or Denmark for examination.⁴⁶⁷ Other non-examining countries that have similar agreements in place with the EPO include Belgium,

⁴⁶⁶ For instance in 2007, the total number of pending patents in the world was 4.2 million. The USPTO had the largest backlog, 28.4% of the total (1,178 090 pending patents) and the average pendency time was 32 months. The EPO had 550 079 pending patents with an average pendency time of 45 months. See: WIPO "Intellectual Property Indicators" http://www.wipo.int/export/sites/www/freepublications/en/intproperty/941/wipo_pub_941.pdf (accessed 12/10/2013) [At 44-45]; Also see: Straus 2008 *The Journal of World Intellectual Property* 60

⁴⁶⁷ Pouris 2011 *S Afr J Sci* 9

France and Italy. South Africa could establish similar agreements with the EPO or other Patent Offices that would be willing to examine South African patent applications, thereby improving the quality of the patents granted in South Africa and guaranteeing their validity.

This suggested approach is further inspired by the inaccurate local CIPC database, in respect of which, only the registration cover is provided and one would need to physically visit the Office to find the relevant patent in the archives, as electronic versions are not available. This makes it very difficult for interested stakeholders, abroad and locally, to check the novelty of their invention. It is therefore encouraged that all the information pertaining to South African patents be available online and updated regularly in the near future as the current search system does not conform to international best practice nor does it meet the requirements of public interest.⁴⁶⁸

4. FILING FOR A SOUTH AFRICAN PATENT APPLICATION

In practice the best approach to take when filing a national patent application would be to file a provisional patent application. Upon filing the complete patent application a PCT application should be filed simultaneously. The advantages of following this strategy allow for improvements or developments relating to the invention to be included in the complete specification and thereby also included in the PCT application. In other words by filing a PCT application first, the applicant will not be able to benefit from these improvements. This is an important consideration especially when dealing with nanotechnology related inventions as it is an area predominately at the research phase and developments are rapid therefore it is important to file a patent application as soon as possible to ensure protection with the advantage of having the time to improve upon the invention and realise the full potential of the invention claimed.

The obligatory novelty search performed by International Search authorities (ISAs) can take up to 30-31 months: After 30 months from the priority date, the applicant must decide in which PCT contracting states to further pursue the applications, i.e. pay the necessary fees,

⁴⁶⁸ Pouris 2011 *S Afr J Sci* 7

provide translations, etc. In those selected countries the national patent granting proceedings will follow and patents will be granted or applications rejected. Notwithstanding the intentions of the applicant to operate locally, it will be beneficial to have the PCT examination report.

II. SOUTH AFRICA'S EFFORTS IN THE FIELD OF NANOTECHNOLOGY

South Africa, like the U.S. and Europe, took notice of the interest surrounding the field of nanoscience and nanotechnology (NNT), appreciating the significant opportunities that accompany this technology. With this realisation SANi was established which was formed and commissioned in 2002 to set out the aims and objectives South Africa intends to achieve by 2014.⁴⁶⁹ Together with the active involvement of the Department of Science and Technology the National Nanotechnology Strategy⁴⁷⁰ (NNS) was adopted in 2005. This was followed by a 10 year Research Plan on NNT, published in 2010 to ensure the successful implementation of the NNS.⁴⁷¹ The government, namely the Department of Science and Technology (DST), has made large financial contributions to fund the research and development of nanotechnology. Furthermore universities, industrial companies and science councils are actively participating in this endeavour.⁴⁷² South Africa has made a long-term investment in developing NNT in South Africa.

⁴⁶⁹ Gulumian Nano in SA [At 4]

http://www2.unitar.org/cwm/publications/event/Nano/Abidjan_25-26_Jan_10/22_South_Africa.pdf (accessed 07/09/2012)

⁴⁷⁰ Claassens and Motuku 2006 *Nanotech. L. & Bus.* 220

⁴⁷¹ Nanotechnology Public Engagement

https://docs.google.com/viewer?a=v&q=cache:7euScJRhaFQJ:www.npep.co.za/pdfs/articles-and-factsheets/Health/fact%2520sheet.pdf+Nanotechnology+Public+Engagement+“Nanotechnology+and+Health”&hl=en&gl=za&pid=bl&srcid=ADGEESi3nE6055JHZOMuQSoEZcxLS-nLMhNvpVYd489PylCc7M6wkYFJpOowa240LfnC8mS0hs0kJEgMXTwIkJhu1_JKJE75IW-i5kf1ciCj6xxxSyZdFb32aJ1FamKVvsZfkCHx4AY-8&sig=AHIEtbSWJgdsIQSC1bRoV7u2ZrvH77eLhQ (accessed 07/11/2012) [At 3]

⁴⁷² Cele, Ray and Coville 2009 *S Afr J Sci* 242

1. SOUTH AFRICA'S NATIONAL NANOTECHNOLOGY STRATEGY

The NNS sets out three generations of progress that South Africa expects to achieve over the next decade or so:⁴⁷³

- First Generation: Projected impact: 1-3 years.

Nanotechnology is already in use in the form of improvements on current technologies or products that manipulate matter on nanoscale or use nanomaterials. Examples of these applications include nanoparticles that are used in coatings, paints, sunscreens and membranes for water purification.

- Second Generation: Projected impact: 3-10 years

This phase includes new ways of making products or enhancing existing processes.

Examples include:

- The development of water treatment systems and secondary use of effluents to make low cost nanoporous absorbents for brine stabilisation and water purification;
- Energy storage, conversion, distribution. Low cost solar and fuel cells, portable power, intelligent materials and thermal regulation;
- Aerospace;
- Medicine (drug delivery systems and bioanalysis followed by prosthetics; biopharmaceuticals, bio mimetic systems and cheaper, more portable nano-analysis tools and systems);
- Electronics (processor, memory and display technologies);
- ICT and associated technologies
- Cleaner process engineering will produce value added chemicals and speciality products including bio catalytic systems and novel heterogeneous catalysts;

⁴⁷³ The Department of Science and Technology of South Africa
<http://www.info.gov.za/view/DownloadFileAction?id=127107> (accessed 27/04/2012) [At 8]

- Value addition by beneficiation of gold, platinum group metals (PGM) and other mineral resources as high performance catalysts, absorbents in polymer nanocomposites and in energy saving materials;
 - Smart and functional materials including lubricants and barrier coatings, ultra hard and super strong materials, electro and photo-chromic materials with applications in all manufacturing sectors, industry, medical and domestic markets.
- Third Generation: Projected impact: 10 years +

This stage of development encompasses new ways of making entirely new products.

Examples include:

- Nanorobotics and self-assembly sensors;
- Devices capable of monitoring health, food and the environment thereby pre-empting potential dangers such as pathogens;
- Powerful and inexpensive electronic devices incorporated into various household appliances, for instance fridges with internet connectivity;
- Light and super strong materials for aircrafts and cars and many new applications;
- Intelligent medication for curing killer diseases, such as cancer etc.

In terms of the NNS there are six focus areas pertinent to South Africa namely, the lack of clean water, energy and health (in particular diseases such as TB). Therefore the field of medicine and improved drug delivery systems, water desalination and other sustainable energy sources are at the forefront of the research being conducted. In addition, the field of mining is of great economic importance to South Africa, therefore the chemical and bioprocessing, mining and minerals and advanced manufacturing are also being researched.⁴⁷⁴ These focus areas can be divided into two development clusters: social (the first three listed) and industrial (the last three).⁴⁷⁵ These areas were identified in NNS as

⁴⁷⁴ Cele, Ray and Coville 2009 *S Afr J Sci* 242. Also see: The Department of Science and Technology of South Africa <http://www.info.gov.za/view/DownloadFileAction?id=127107> (accessed 27/04/2012) [At 13]

⁴⁷⁵ Claassens and Motuku 2006 *Nanotech. L. & Bus.* 221 and 223

priorities in the development of nanoscience and nanotechnology in order to effect social development in South Africa.

1.1. Private and Public Sectors Contributing to R&D of Nanotechnology in South Africa

There is a flurry of activity in both the private and public sectors within South Africa.⁴⁷⁶ In 2007, the following Nanotechnology Innovation Centres (NIC) were established: iThemba Laboratories, and within well-known institutions such as Mintek and the CSIR.⁴⁷⁷ These centres are determined to train and develop young scientists in order to stimulate nanotechnology development in this country.⁴⁷⁸

a) The Public Sector

➤ The CSIR

The National Centre for Nano Structured Material (NCNSM), within the CSIR, focuses on the design and modelling of novel nanostructured materials and energy.⁴⁷⁹ The acquisition of modern facilities has improved the ability for the CSIR to fabricate a wide spectrum of nanomaterials for both research and industrial applications. These include carbon nanotubes, nanocomposites, polymers, quantum dots and metal nanoparticles such as silicon and titanium dioxide (TiO₂) and nano-biotech.⁴⁸⁰

⁴⁷⁶ Cele, Ray and Coville 2009 *S Afr J Sci* 242

⁴⁷⁷ Gulumian Nano in SA http://www2.unitar.org/cwm/publications/event/Nano/Abidjan_25-26_Jan_10/22_South_Africa.pdf (accessed 07/09/2012) [At 11]

⁴⁷⁸ Nanowerk News "South Africa Launches First Nanotechnology Innovation Centers" <http://www.nanowerk.com/news/newsid=3429.php> (accessed 07/11/2012) [Hereinafter "Nanowerk News Innovation Centres"]

⁴⁷⁹ Nanowerk News Innovation Centres <http://www.nanowerk.com/news/newsid=3429.php> (accessed 07/11/2012)

⁴⁸⁰ Gulumian 2012 *S Afr Sci* 6

Recent projects the CSIR focused on in its first three years include the following:

1. Fabrication of selected novel nanostructured material for application on solar cells, printed electronic devices, bio sensors and nanopolymers with the aim of developing better and cheaper solar cells;
2. The synthesis and characterisation of quantum dots with application in medical sensors, solid-state lighting and optical devices;
3. Development and synthesis of polymer nanocomposites for a variety of applications;
4. The synthesis of nanostructured material for specific energy related applications;
5. Material modelling and stimulation with the aim of understanding and predicting fundamental properties of nanomaterials.⁴⁸¹

An overview of the CSIR's objectives was summarised by Prof Ray in 2007, stating that within the following:

- 5 – 10 years: Sophisticated electronic devices that use nanoscale circuitry and memory;
- 10 – 15 years: An introduction of pharmaceutical products, drug delivery and health monitoring devices; and
- 30 – 40 years: Completely new forms of devices and processes to emerge.⁴⁸²

➤ Mintek

Mintek is responsible for focusing their research on the following areas: mining and minerals, health and water.⁴⁸³ South Africa has a great wealth of minerals such as gold, platinum, titanium, palladium; nanotechnology can add enormous value to these

⁴⁸¹ Nanowerk News Innovation Centres <http://www.nanowerk.com/news/newsid=3429.php> (accessed 07/11/2012)

⁴⁸² Nanowerk News Innovation Centres <http://www.nanowerk.com/news/newsid=3429.php> (accessed 07/11/2012)

⁴⁸³ Nanowerk News Innovation Centres <http://www.nanowerk.com/news/newsid=3429.php> (accessed 07/11/2012)

minerals.⁴⁸⁴ Mintek together with three gold mining houses have joined in researching the use of gold in catalysis for the oxidation of carbon monoxide to carbon dioxide, molecular diagnostics and metal–polymer composites.⁴⁸⁵ Mintek is also responsible for developing Point of Care Diagnostic Prototypes (POC). This project will be discussed in greater detail further on.

➤ Research Group iThemba LABS National Research Foundation

The laboratories research focuses on nanoclusters and nanocomposites (silver, palladium, copper) in terms of their mechanism of formation.⁴⁸⁶

➤ Institutions of Higher Education

Various South African Universities are cooperating with the NIC in conducting research in various areas of nanotechnology. Some of these projects will be discussed further on.

b) The Private Sector

The commercial benefits of applying novel nanomaterials in the fabrication of products or industrial processes has generated a tremendous amount of interest in various industrial sectors resulting in existing companies such as SASOL, SAPI and Gold mines, such as Anglo Gold, Harmony Gold, Goldfields, contributing to the advancements of research in the field of nanotechnology in South Africa.⁴⁸⁷

⁴⁸⁴ Science in Africa <http://www.sciencein africa.co.za/2003/november/nanotech.htm> (accessed 07/11/2012)

⁴⁸⁵ Gulumian 2012 *S Afr Sci* 6

⁴⁸⁶ Gulumian Nano in SA http://www2.unitar.org/cwm/publications/event/Nano/Abidjan_25-26_Jan_10/22_South_Africa.pdf (accessed 07/09/2012) [At 13]

⁴⁸⁷ Gulumian Nano in SA http://www2.unitar.org/cwm/publications/event/Nano/Abidjan_25-26_Jan_10/22_South_Africa.pdf (accessed 07/09/2012) [At 13]

2. SOUTH AFRICAN NANOTECHNOLOGY PATENTS

2.1. The Definition Applied to “Nanotechnology” in South Africa

According to the NNS, the term nanotechnology is defined in reference to scale only: “a billionth of a metre.”⁴⁸⁸ Therefore any object with this measurement will be classified as nanotechnology. However, this is a very limited definition, a more detailed definition is given by the IPC system in terms of class B82B and B82Y.⁴⁸⁹ When determining the appropriate class for nano-related inventions, South African patent attorneys will refer to this definition.

2.2. Applications of Nanotechnology in South Africa

South Africa actively began research in the field of nanotechnology in 2005. Therefore when examining South Africa’s position, we can refer back to the distinction made between, “nanoscience” and “nanotechnology.” Nanotechnology related activities are limited to research; they are not fully developed manufacturing technologies at this time. This can be seen from the academic institutes and research centres conducting this research.

It would be very difficult and unfair to compare South Africa’s level of competitiveness on an international scale especially with the leading countries having started their research in this field approximately six years earlier than South Africa.⁴⁹⁰ Therefore with regard to the commercialisation of such research, it is hoped that this is realised by 2015.⁴⁹¹ Some of the current projects include:

⁴⁸⁸ The Department of Science and Technology of South Africa “National Nanotechnology Strategy” <http://www.info.gov.za/view/DownloadFileAction?id=127107> (accessed 27/04/2012) [At 7]

⁴⁸⁹ Refer to the WIPO website for the comprehensive definition of B82B- B82Y: <http://web2.wipo.int/ipcpub/#refresh=page¬ion=scheme&version=20130101&symbol=B82> (accessed 04/07/2013)

⁴⁹⁰ Pouris 2010 *University of Pretoria* 139

⁴⁹¹ Pouris 2010 *University of Pretoria* 11

a) Gold-based Nanoparticles

Much of the work conducted at Mintek is focused around semi commercial products in the health sector. These products include the use of gold nanoparticles, relating to drug delivery system research and quick diagnostic tests. Researchers have uncovered the extraordinary optical, catalytic and magnetic properties of this precious metal, making them especially appropriate for healthcare applications,⁴⁹² thereby placing the study of gold nanoparticles at the forefront of nanotechnology research in both the industrial and academic sectors.

Mintek and three major gold mining houses, namely AngloGold Ashanti, Gold Fields and Harmony Gold have come together to establish the AuTEK Biomed consortium.⁴⁹³ Research projects include:

1. The use of gold in catalysis for the oxidation of carbon monoxide to carbon dioxide which can be applied to purify air at room temperature.⁴⁹⁴
2. The creation of gold-based nano-chemo-therapeutics for the treatment of cancer, malaria and Aids.⁴⁹⁵ Despite the extended history of the use of gold colloids in therapeutics, research has, in the past twenty years, focused on developing and optimising methods for the preparation of gold nanoparticles.⁴⁹⁶ Platinum based

⁴⁹² Nanotechnology Public Engagement

https://docs.google.com/viewer?a=v&q=cache:7euScJRhaFQJ:www.npep.co.za/pdfs/articles-and-factsheets/Health/fact%2520sheet.pdf+Nanotechnology+Public+Engagement+“Nanotechnology+and+Health”&hl=en&gl=za&pid=bl&srcid=ADGEESi3nE6055JHZOMuQSoEZcxLS-nLMhNvpVYd489PylCc7M6wkYFJpOowa240LFnC8mS0hs0kJEgMXTwIkJhu1_JKjE75IW-i5kf1ciCj6xxxSyZdFb32aJ1FamKVszfkCHx4AY-8&sig=AHIEtbSWJgdsIQSC1bRoV7u2ZrvH77eLhQ (accessed 07/11/2012) [At 3]

⁴⁹³ Gallagher <http://www.iol.co.za/news/south-africa/nanotechnology-to-target-major-diseases-1.276672#.UJp2wklyfQ> (accessed 07/11/2012)

⁴⁹⁴ Gulumian Nano in SA http://www2.unitar.org/cwm/publications/event/Nano/Abidjan_25-26_Jan_10/22_South_Africa.pdf (accessed 07/09/2012) [At 12]

⁴⁹⁵ Gallagher <http://www.iol.co.za/news/south-africa/nanotechnology-to-target-major-diseases-1.276672#.UJp2wklyfQ> (accessed 07/11/2012)

⁴⁹⁶ Nanotechnology Public Engagement

<https://docs.google.com/viewer?a=v&q=cache:7euScJRhaFQJ:www.npep.co.za/pdfs/articles-and-factsheets/Health/fact%2520sheet.pdf+Nanotechnology+Public+Engagement+“Nanotechnology+and+Health”&hl=en&gl=za&pid=bl&srcid=ADGEESi3nE6055JHZOMuQSoEZcxLS->

drugs are currently being used. The use of gold in place of platinum could be highly advantageous as gold drugs accumulate in the mitochondria. On accumulation, these drugs become toxic and kill the cells. It has however been specified by the head researcher, that these gold-based drugs need to be modified so as to target and destroy only the cancerous cells.⁴⁹⁷

3. In 2005, research was conducted to see if gold compounds can act as inhibitors to HIV.⁴⁹⁸
4. A remarkable development by Mintek is the portable test kits for advanced rapid diagnostic testing of various infectious diseases. Research on both chemical and electrochemical rapid diagnostic methods have been conducted for the testing of both human and animal health diseases. A great deal of the focus has been on developing low cost, stable and accurate point-of-care (POC) diagnostic tests kits for TB and malaria. These gold-based POC prototypes were tested using serum and blood samples. These devices are simple enough to be used by any individual in the comfort of their own home without the assistance of a trained professional to diagnose the disease of interest. After clinical evaluations, these devices should be available to the majority of the public thereby improving the quality of life by diagnosing any relevant disease a person may have.⁴⁹⁹

[nLMhNvpVYd489PyICc7M6wkYFJpOowa240LFnC8mS0hs0kJEgMXTwIkJhu1_JKjE75IW-i5kf1ciCj6xxxSyZdFb32aJ1FamKVzFkCHx4AY-8&sig=AHIEtbSWJgdsIQSC1bRoV7u2ZrvH77eLhQ](http://www.iol.co.za/news/south-africa/nanotechnology-to-target-major-diseases-1.276672#.UJp2wkItyfQ) (accessed 07/11/2012) [At 3]

⁴⁹⁷ Gallagher <http://www.iol.co.za/news/south-africa/nanotechnology-to-target-major-diseases-1.276672#.UJp2wkItyfQ> (accessed 07/11/2012)

⁴⁹⁸ Gallagher <http://www.iol.co.za/news/south-africa/nanotechnology-to-target-major-diseases-1.276672#.UJp2wkItyfQ> (accessed 07/11/2012)

⁴⁹⁹ Nanotechnology Public Engagement

https://docs.google.com/viewer?a=v&q=cache:7euScJRhaFQJ:www.npep.co.za/pdfs/articles-and-factsheets/Health/fact%2520sheet.pdf+Nanotechnology+Public+Engagement+“Nanotechnology+and+Health”&hl=en&gl=za&pid=bl&srcid=ADGEEsi3nE6055JHZOMuQSoEZcxLS-nLMhNvpVYd489PyICc7M6wkYFJpOowa240LFnC8mS0hs0kJEgMXTwIkJhu1_JKjE75IW-i5kf1ciCj6xxxSyZdFb32aJ1FamKVzFkCHx4AY-8&sig=AHIEtbSWJgdsIQSC1bRoV7u2ZrvH77eLhQ (accessed 07/11/2012) [At 3]

b) TB and Nanotechnology

In 2007, the WHO ranked South Africa fifth on the high burden TB countries in the world.⁵⁰⁰ The treatment for TB is the intake of four antibiotics: isoniazid, rifampicin, pyrazinamide and ethambutol that are to be taken daily. This daily routine of taking each of these four antibiotics for months can be grueling for many patients, who have to travel long distances for a nurse to ensure that they get this medication.⁵⁰¹ When combining this with the side effects of the medication, many patients despair before completing the course of treatment, which then causes multidrug-resistant strains to emerge, giving the disease ample opportunity to spread.⁵⁰² The lack of healthcare staff to help administer the drugs on a daily basis is yet another obstacle that arises with this treatment for TB.

Researchers at the CSIR have incorporated these four antibiotics into nanoparticles which are taken up by the white blood cells that effectively transport them throughout the body while slowly releasing the antibiotics. According to the leading researcher, *“these nanoparticles have superior properties for absorption in the small intestine to improve bio-availability and uptake into circulation.”*⁵⁰³ The required dosage is every 7-10 days, which would increase the likelihood of the patient completing his or her treatment to the point that the disease will be completely eliminated.⁵⁰⁴

⁵⁰⁰ Makoni M <http://www.scidev.net/en/features/case-study-south-africa-uses-nanotech-against-tb-1.html> (accessed 07/11/2012)

⁵⁰¹ Makoni M <http://www.scidev.net/en/features/case-study-south-africa-uses-nanotech-against-tb-1.html> (accessed 07/11/2012)

⁵⁰² Nanotechnology Public Engagement https://docs.google.com/viewer?a=v&q=cache:7euScJRhaFQJ:www.npep.co.za/pdfs/articles-and-factsheets/Health/fact%2520sheet.pdf+Nanotechnology+Public+Engagement+“Nanotechnology+and+Health”&hl=en&gl=za&pid=bl&srcid=ADGEESi3nE6055JHZOMuQSoEZcxLS-nLMhNvpVYd489PylCc7M6wkYFJpOowa240LFnC8mS0hs0kJEgMXTwIkJhu1_JKJE75IW-i5kf1ciCj6xxxSyZdFb32aJ1FamKVszfKChx4AY-8&sig=AHIEtbSWJgdsIQSC1bRoV7u2ZrvH77eLhQ (accessed 07/11/2012) [At 4]

⁵⁰³ Makoni <http://www.scidev.net/en/features/case-study-south-africa-uses-nanotech-against-tb-1.html> (accessed 07/11/2012)

⁵⁰⁴ Nanotechnology Public Engagement <https://docs.google.com/viewer?a=v&q=cache:7euScJRhaFQJ:www.npep.co.za/pdfs/articles-and-factsheets/Health/fact%2520sheet.pdf+Nanotechnology+Public+Engagement+“Nanotechnology+and+Health”&hl=en&gl=za&pid=bl&srcid=ADGEESi3nE6055JHZOMuQSoEZcxLS->

In 2010, it was reported by this team that these drugs had been tested on TB-infected mice to determine whether this weekly nano-dose was as effective as the conventional daily treatment regiment. The preclinical trial data was promising: it revealed the nanoparticles were absorbed by all the major tissues thereby matching the efficiency of the daily intake of the drugs.⁵⁰⁵ If successful, this new method for delivering TB drugs could overcome the issues mentioned above, patients will complete their treatment, the need for healthcare staff will only be required on a weekly basis as opposed to daily and all of this could be achieved cost effectively. It is estimated that this project will complete preclinical trials by 2016.⁵⁰⁶

c) Nanotechnology and Other Medical Treatment

Treatments using nanocapsulation, for example coating anti malaria drug chloroquine with nanomaterials including liposomes which can deliver the drug by penetrating the cell membrane thereby taking action on the diseased cells in a more targeted and efficient way.⁵⁰⁷

Examples of South African patent applications for targeted drug delivery include:

➤ ZA 2013/04573: "A drug delivery device"⁵⁰⁸

The invention described in this patent relates to a biodegradable drug delivery device, which is implanted in the cranium. Claim 1 reads:

[nLMhNvpVYd489PylCc7M6wkYFJpOowa240LFnC8mS0hs0kJEgMXTwIkJhu1_JKJE75IW-i5kf1ciCj6xxxSyZdFb32aJ1FamKVvsZfkCHx4AY-8&sig=AHIEtbSWJgdsIQSC1bRoV7u2ZrvH77eLhQ](http://www.scidev.net/en/features/case-study-south-africa-uses-nanotech-against-tb-1.html) (accessed 07/11/2012) [At 4]

⁵⁰⁵ Makoni <http://www.scidev.net/en/features/case-study-south-africa-uses-nanotech-against-tb-1.html> (accessed 07/11/2012)

⁵⁰⁶ Pouris 2010 *University of Pretoria* 81

⁵⁰⁷ Makoni <http://www.scidev.net/en/features/case-study-south-africa-uses-nanotech-against-tb-1.html> (accessed 07/11/2012)

⁵⁰⁸ Applicant: University of the Witwatersrand. PCT application nr: WO2012070034

“1. An implantable intracranial device for the delivery of a pharmaceutically active agent to a human or animal for treating a mental or neurological disorder, the device comprising: a pharmaceutically active agent for treating the disorder; polymeric nanoparticles into or onto which the pharmaceutically active agent is embedded; and a polymeric matrix incorporating the nanoparticles.”

This invention is suitable for the treatment of mental or neurological disorders, such as Alzheimer's disease, schizophrenia or other psychoses.

- ZA 2013/04634: “Polymeric matrix of polymer-lipid nanoparticles as a pharmaceutical dosage form”⁵⁰⁹

Claim 1 reads:

“1. A pharmaceutical dosage form for the release of at least one pharmaceutically active ingredient, the pharmaceutical dosage form comprising: a polymer matrix formed from at least two cross-linked polymers; polymer-lipid nanoparticles formed from at least one polymer and at least one phospholipid and which are incorporated within the polymer matrix; and at least one pharmaceutically active ingredient.”

This invention relates to a pharmaceutical dosage form for delivering a pharmaceutically active ingredient having poor absorption in the body. Levodopa is an example of a poorly absorbed pharmaceutical compound that is used in the treatment of Parkinson's disease.

⁵⁰⁹ Applicant: University of the Witwatersrand. PCT application nr: WO2012070031

- ZA 2013/04511: “An implant for the controlled release of pharmaceutically active agents”⁵¹⁰

“1. A pharmaceutical composition for the delivery of a pharmaceutically active agent, the composition comprising:

a thermoresponsive polymer composition which is in a liquid form at or about room temperature and in a solid or gelatinous form at or about body temperature, wherein the thermoresponsive polymer composition is formed from cross-linked poly(methyl vinyl ether) (PMVE) and an inorganic salt; and

a plurality of micro- or nano-particles which are pH responsive and which include at least one pharmaceutically active agent;

wherein the micro- or nano-particles are suspended in the thermoresponsive polymer composition.”

The above invention describes a pharmaceutical composition or dosage form for the constant and controlled delivery of at least one pharmaceutically active agent. The pharmaceutical composition is injectable. Once injected, it can form an implant due to its thermoresponsive nature (i.e. it contains pH responsive nanoparticles), which will respond to the site of injection to release entrapped drugs. The composition can be used to treat any disease or condition that results in a decrease in pH, for example the treatment of a solid tumor, gout, acidosis or ketosis.

- ZA 2010/06639: “Nanoparticle carriers for drug administration and process for producing same”⁵¹¹

“The invention claimed is:

1. A process for the production of nanoparticles for drug delivery, said nanoparticles being produced by:

preparing a double emulsion of water-oil-water including one or more polymers which form

⁵¹⁰ Applicant: University of the Witwatersrand. PCT application nr: WO2012070033

⁵¹¹ Applicant: CSIR. PCT application nr: WO2009105792. EP 2249817 A1. US 851 8450 B2.

the basis of the nanoparticles;
blending the drug to be delivered into one of the emulsion phases;
doping either the oil-phase or the outer water-phase with a carbohydrate;
doping the oil-phase, the outer water-phase, the internal water-phase, or both water phases with a surfactant; and
spray drying the drug-containing water-oil-water double emulsion having doped emulsion phases to remove both the oil-phase and the water-phases simultaneously, thereby forming nanoparticles having a particle size distribution of 100 nm to 1000 nm.”

This application is partly a continuation of the PCT Application: PCT/ZA2008/000012 and the content thereof has been referred to in this application. The present invention relates to a process for the production of nanoparticle carriers for oral administration. A spray drying technique is used to produce nanoscale solid particles and solid lipid nanoparticles that are laden with active agents that can be used as drug delivery systems for pulmonary airways.

d) Water Sanitation

South Africa has focused on water research for many years however with the addition of nanomaterials a cheaper, more durable and efficient treatment of water may be realised to reduce water-borne diseases such as cholera and typhoid. The University of Johannesburg is focused on developing novel solutions to treat water so as to meet drinking and environmental quality standards.⁵¹² Nanomaterials currently being used include, nanomembranes for filtration, magnetic nanoparticles and nanofiber devices for toxic elements and organic pollutant removal and nanostructured electro-catalytic membranes and zeolite absorbents for purification.⁵¹³

Prof Wei Hua Ho and Prof Vijaya Srinivasu Vallabhapurapu from UNISA and Prof Ivan William Hofsjager from Wits collaborated in the development of a water purification

⁵¹² Gulumian Nano in SA http://www2.unitar.org/cwm/publications/event/Nano/Abidjan_25-26_Jan_10/22_South_Africa.pdf (accessed 07/09/2012) [At 7]

⁵¹³ Claassens and Motuku 2006 *Nanotech. L. & Bus.* 222

invention that could be mass-produced. Consequently having great commercial value for nanoparticle-based water purification processes. This provisional patent application is entitled “*Method and Apparatus for Treating a Fluid*”⁵¹⁴ and was lodged on 14 November 2012.

This invention uses magnetic nanoparticles coated with a layer of material that removes certain contaminants from the water. The use of magnetic nanoparticles to purify the water is not novel, however the process in which they are applied is. Previously these magnetic particles would separate the impurities after the purification process was completed. The method used here incorporates the magnetic properties in the cleaning phase as well. A chemical reaction is required for physical excitation of the particles in the water. Previously this was done with a stirrer or similar device therefore the container and water would have to be agitated. This invention shows that the same effect can be achieved by having a moving magnetic field, as demonstrated by their small prototype. There are several advantages in using this process:

1. There are no moving parts, in contrast to the previous method (i.e. the stirrer) and therefore there is no wear and tear thereby greatly reducing maintenance costs.
2. Only the particles are being agitated and not the container or water. This process greatly reduces the energy required to achieve this agitation.
3. This electromagnetic technique moves the nanoparticles in the water, substituting the mechanical stirring of the particles. Therefore the whole process can be upgraded to an automated mass processing system.

e) Scale Up

The world is facing the same challenge when it comes to producing large quantities of nanomaterials that meet certain quality standards.⁵¹⁵ These reproduction methods need to be cost effective for commercial scale reproduction and environmentally friendly.

⁵¹⁴ Application nr: 2012/08567, Reference: PA 156 843/P

⁵¹⁵ See: Chapter 1, section entitled “4. TYPES/”MAKES” OF NANOTECHNOLOGY: 4.2 Fullerenes”

Mintek has made significant progress in ensuring that nanoparticle products they produce can be reproduced in large quantities. NIC are currently capable of producing 20 liters of nanoparticles per batch.⁵¹⁶ This volume can easily be increased to meet supply and demand.

➤ ZA 2008/01689: “A process for producing carbon nanotubes”⁵¹⁷

According to Claim 1, the invention is described as:

“1. A process for producing carbon nanotubes which includes supplying a continuous fluidized feed of a catalyst and at least one hydrocarbon to a reactor operating under conditions suitable to produce carbon nanotubes and characterised in that fluid flow is non-laminar within the reactor and in that the internal surfaces of the reactor are cleaned of deposits.”

As previously commented,⁵¹⁸ processes currently adopted for batch production of CNTs have their disadvantages, for example low yield and lack of industrial application or efficiency. This invention relates to a process whereby some of these drawbacks are reduced.

➤ ZA 2011/0535: “Method of producing nanoparticles”⁵¹⁹

Claim 1 reads:

“1. A method of producing nanoparticles in the size range 1 nm to 1000 nm through the synthesis of one or more precursor fluids, the method including providing a fluid medium comprising at least one precursor fluid and generating an electrical spark within said fluid

⁵¹⁶ Pouris 2010 *University of Pretoria* 174

⁵¹⁷ Applicant: University of the Witwatersrand. PCT application nr: WO2007026213. EP 1919826 A1 20080514. US 20080247939 A1.

⁵¹⁸ See: Chapter 1, section entitled “4. TYPES/“MAKES” OF NANOTECHNOLOGY: 4.2 Fullerenes“

⁵¹⁹ Applicant: University of Cape Town. PCT application nr: WO2013008112

medium to cause pyrolysis of said at least one precursor fluid in a relatively hot plasma zone to produce at least one radical species, and to form nanoparticles by nucleation in the fluid medium in a cooler reaction zone about the plasma zone, wherein said at least one radical species acts as a reactant or catalytic agent in the synthesis of material composing said nanoparticles.”

The process for the production of nanoparticles in relation to this invention involves chemical vapour synthesis (CVS). Definitions for pyrolysis and CVS are provided for in the application.

e) Up- and Down-Conversions

UNISA’s department of Physics is presently working on the synthesis of up-conversion and down-conversion nanophosphors. These can be applied in biological labelling, solar cells, solid-state lighting and display technologies. Energy transfer from metal nanoparticles attached to the surfaces of phosphor particles could enhance the intensity of the prepared phosphor. Metal nanoparticles can be applied in DNA tagging, diagnostics to specific cells, drug delivery (as discussed regarding gold-nanoparticles in the treatment of TB), cancer cell therapy, protein detection and tissue engineering. The optical properties of earth phosphors can be applied to solar cells, sensors (for example methane sensors in mines), memory chips and high-speed transistors.⁵²⁰

g) Fuel Cells and Nanotechnology

Owing to the international energy crisis, UNISA has increased research outputs and focus their research on the synthesis, characterisation and local production of membrane electrode assembly for fuel cells. The intention is to develop technologically sound,

⁵²⁰ According to the information circulated at UNISA’s BRICS International Symposium on Energy, Materials & Innovation, 2013.

environmentally friendly and commercially viable fuel cells for industrial and domestic use.⁵²¹

h) Quantum Dots

The University of Zululand has mainly focused on quantum dots and other forms of nanoparticles. This university is considered to be the leader in the research and fabrication of quantum dots as these materials find applications in diagnostics, security systems, biological probes, and optics. They are also responsible for the synthesis of nanoparticles for drug delivery.⁵²²

2.3. Patentability Issues Relating to South African Nanotechnology Patents

Herein reference is specifically made to the provisional patent application of the water desalination project and the six patent applications discussed.⁵²³ In respect of the provisional water desalination patent application, despite the invention not having been classed yet, it is in the view of the attorneys responsible for this patent application that it will probably be categorised in the “desalinisation” class (a general class) and only possibly in addition, it may be filed in the “nanotechnology” class. In relation to the PCT patent applications, only three of the six were classed in the B82Y class. Consequently if this is the practice adopted in South Africa, inventions that would qualify as “nanotechnology” inventions may not be filed as such, making it very difficult if not impossible to accurately determine relevant prior art and the true status of nanotechnology patents in South Africa.⁵²⁴

⁵²¹ According to the information circulated at UNISA’s BRICS International Symposium on Energy, Materials & Innovation, 2013.

⁵²² Gulumian Nano in SA http://www2.unitar.org/cwm/publications/event/Nano/Abidjan_25-26_Jan_10/22_South_Africa.pdf (accessed 07/09/2012) [At 10]

⁵²³ See: PA 156 843/P, ZA 2010/06639, ZA 2013/04573, ZA 2013/04634, ZA 2013/04511, ZA 2008/01689 and ZA 2011/0535.

⁵²⁴ This idea is further corroborated by: Claassens and Motuku 2006 *Nanotech. L. & Bus.* 226

The challenges presented by nanotechnology when determining the patentability of a nano-related invention, was discussed extensively in the previous chapter. In South Africa, all patent applications are treated equally, i.e. as long as the formal/ administrative formalities are complied with, the application will be granted. Consequently it is doubtful that nanotechnology patent applications will face similar problems during the patent granting phase but the validity may be challenged later on in court or if filed abroad in a country with an examining body.

Bearing in mind that in South Africa, at least at present and in foreseeable future, no examination of patent applications as to the substance is carried out, South African inventors/applicants in the area of nanotechnology should use the PCT System and select either the USPTO or the EPO as the search and examining authorities. Depending on the results of search reports and preliminary examination reports, then they can decide to pursue their applications in the countries of particular interest and, of course, also in South Africa. Needless to say that having a South African patent backed by either the USPTO or EPO preliminary examination or even better, a U.S. or an EPO patent, will strengthen their position in South Africa.

2.4. The Status of Nanotechnology Patents: South Africa and Abroad

WIPO's statistics for the period of 2009-2010 will be relied upon to give an overall indication of patent applications filed for the above period. In 2010, approximately 1.98 million patents were filed globally.⁵²⁵ This represents a 7.2% increase in patent applications filed worldwide from the previous year.⁵²⁶ The top five Patent Offices included:

⁵²⁵ WIPO Economics & Statistics Series 2012 "WIPO IP Facts and Figures"
http://www.wipo.int/export/sites/www/freepublications/en/statistics/943/wipo_pub_943_2012.pdf
(accessed 27/05/2013) [At 17] [Hereinafter "WIPO Statistics 2012"]

⁵²⁶ WIPO Statistics 2012
http://www.wipo.int/export/sites/www/freepublications/en/statistics/943/wipo_pub_943_2012.pdf
(accessed 27/05/2013) [At 12]

1. USA	490,226	(24.8% of the total patents filed for above period)
2. China	391,177	(19.8% of the total patents filed for above period)
3. Japan	344,598	(17.4% of the total patents filed for above period)
4. Republic of Korea	170,101	(8.6% of the total patents filed for above period)
5. EPO	150,961	(7.6% of the total patents filed for above period) ⁵²⁷

Therefore the USA, China and Japan were responsible for 62% of the total patents filed in 2010. In the field of Chemistry, specifically Micro structural technology and Nanotechnology, 2,466 patents were filed worldwide (0.2% share of the total patents filed in 2010).⁵²⁸

In 2010, 6,383 patent applications were filed in South Africa.⁵²⁹ This computes to less than 1% share of the total patent applications filed in this period. However it was recorded as the highest number of patent applications filed in relation to the 20 countries WIPO listed as “*Middle-and-Low income countries.*”⁵³⁰ Furthermore, 5 562 of these patent applications were filed by non-residents.⁵³¹ In 2011, WIPO statistics revealed 319 international applications were filed in South Africa via the PCT system. To put this in perspective out of the 1.98 million patent applications filed worldwide in 2010, a total of 182,112 were filed via the PCT system.⁵³² In relation to the South African patent applications filed by South African

⁵²⁷ WIPO Statistics 2012

http://www.wipo.int/export/sites/www/freepublications/en/statistics/943/wipo_pub_943_2012.pdf
(accessed 27/05/2013) [At 17 and 35- 38]

⁵²⁸ WIPO Statistics 2012

http://www.wipo.int/export/sites/www/freepublications/en/statistics/943/wipo_pub_943_2012.pdf
(accessed 27/05/2013) [At 21]

⁵²⁹ WIPO Statistics 2012

http://www.wipo.int/export/sites/www/freepublications/en/statistics/943/wipo_pub_943_2012.pdf
(accessed 27/05/2013) [At 38]

⁵³⁰ WIPO Statistics 2012

http://www.wipo.int/export/sites/www/freepublications/en/statistics/943/wipo_pub_943_2012.pdf
(accessed 27/05/2013) [At 18]

⁵³¹ Straus 2012 *AIPLA* 673

⁵³² WIPO Statistics 2012

http://www.wipo.int/export/sites/www/freepublications/en/statistics/943/wipo_pub_943_2012.pdf
(accessed 27/05/2013) [At 41]

applicants that were discussed:⁵³³ PCT applications were filed for all six⁵³⁴ and in two cases applications further prosecuted in the USPTO and the EPO, where the South African applicants were granted U.S. and EPO patents. CSIR was granted patents for “*Nanoparticle carriers for drug administration and process for producing same*” (US 851 8450 B2; EP 2249817 A1) and the University of the Witwatersrand for “*A process for producing carbon nanotubes*” (US 20080247939 A1; EP 1919826 A1 20080514). These U.S. and EPO patents of South African origin demonstrate that not only research currently being conducted in South Africa is producing patentable results and thereby contributing positively to the nanotechnology patent landscape, but could also contribute to international competitiveness of South Africa.

2.5. A Need for Nano legislation

As the South African courts come to deal with nanotechnology patent infringement cases, it will become obvious as to whether there will be a need for extra guidelines or legislation to regulate nano-related inventions. Presently no case law exists to base any projections on the future of how nanotechnology patents will be dealt with in years to come.

3. INTERNATIONAL COOPERATION

Due to the limited expertise and resources in the field of nanotechnology, there is a need for South Africa to collaborate with other countries already involved with this technology. This would not only benefit current local research but also accelerate the process to produce nano-related products on a commercial scale.

South Africa has collaborated internationally with other countries, such as ESTASAP (European South African Science and Technology Advancement Programme),⁵³⁵ BRICS

⁵³³ See: Chapter 2, section entitled: “2.2. Applications of Nanotechnology in South Africa”

⁵³⁴ See: ZA 2013/04573, ZA 2013/04634, ZA 2013/04511, ZA 2011/0535, ZA 2010/06639 and ZA 2008/01689 [the last two were filed with both the USPTO and EPO. See: Footnotes 511 and 517]

⁵³⁵ Wolbring <http://www.innovationwatch-archive.com/choiceisyours/choiceisyours-2008-02-15.htm> (accessed 21/05/2012)

(Brazil-Russia-India-China-South Africa) and IBSA (India-Brazil-South Africa). These bilateral and multilateral agreements ensure South Africa receives cooperation in the field of nanotechnology from countries that have better established centres.⁵³⁶

South Africa joined BRICS in 2010. Benefits of this cooperation in the field of nanotechnology include a partnership with China who is currently leading in the field of nanotechnology (in relation to the other BRICS countries). International cooperation is mutually beneficial to all the countries collaborating as the R&D pool for nanotechnology research becomes much larger and will allow scientists from various countries to come together and share not only their significant research but also other resources, such as scientific facilities, equipment and financial resources. Cooperating countries could assist one another in large-scale research projects that are far too large for one country alone. Furthermore due to the scope and complexity of nanotechnology South Africa could also benefit from the assistance of diversely skilled scientists from other countries.

All of the member countries of both IBSA and BRICS are also members of WTO and therefore reference TRIPS provisions in relation to all IP and trade related issues.⁵³⁷

⁵³⁶ Cele, Ray and Coville 2009 *S Afr J Sci* 242

⁵³⁷ This assumption is based on a publication on BRIC. See: Unilink http://www.ip-unilink.net/public_documents/Good_Practice_Guide_web.pdf (accessed 09/10/2013) [At 30-31]

CONCLUSIONS

Nanotechnology is reshaping technology, as we know it. The benefits, as discussed, are diverse and there are many opportunities that this research will afford South Africans and South Africa as a developing country. It is therefore important to promote education and create awareness so that a better understanding of NNT is had. Despite the fairly unknown long term effects of this new technology on health and the environment it can be said that the positive outcomes hoped to be achieved have the potential to not only solve urgent issues such as providing the world with clean drinking water or sustainable energy alternatives, but also treat diseases in a more effective and less invasive way.

Patenting nanotechnology inventions under the EPC and Title 35 of the U.S.C. may present some challenges. The unique and complex characteristics of this technology such as its multidisciplinary application, has made the examination process more difficult. Previously technologies were more conventional in that they could be placed in a single category and the examiner would be skilled in that specific field. Examiners are now confronted with inventions that have diverse applications resulting in the claims being applicable in multiple fields. Furthermore the examiner may not have specialised knowledge in all of these fields so as to fully understand the invention, resulting in some relevant areas of technology been overlooked. Moreover nanotechnology is at the early stages of development, i.e. mainly research phase and as such there is limited prior art and determining the utility of the claimed invention may be difficult. Furthermore the lack of a uniform nanotechnology definition, as given by various institutions complicates the matter in accurately examining a nano-related invention. However, despite these issues it was concluded from the research presented, that there is no need for additional, specific legislation or rules pertaining to nano-related patent applications. Many of these challenges can be overcome in terms of current patent law provisions as a well-drafted patent application can, for example, indicate whether a nano-related invention fulfils the prescribed requirements for a valid patent.

Although patents are deemed valid upon their issuance, their validity can be challenged on the grounds that the patentability requirements were not met, whether in a re-examination

or opposition proceeding before the USPTO or EPO, or in an infringement suit (post-grant proceedings, by the respective counterclaims). A strong, well-drafted patent application is imperative and can be realised by carefully considering common objections and criticisms made against nanotechnology patent applications in the past so as to avoid these same objections being repeated. Due to the lack of any examination in South Africa, the substance of the patent application is not assessed and many undeserving inventions may receive patent protection. This in turn creates an unclear patent landscape and uncertainty relating to IPR. By implementing drafting guidelines the quality of South African patent applications will vastly improve thereby reducing uncertainty regarding the validity of the patents produced by the country and clearly defining IPR. Furthermore the manner in which information relating to South African patents can be reviewed should be significantly improved, as it is a continuing struggle to access accurate and significant information relating to the content of the specification and status of a South African patent application. This can be achieved by implementing a stricter procedure whereupon the CIPC database could be updated regularly thereby reflecting the true status of patent applications filed in South Africa. In addition, providing an abstract of the invention would be invaluable to those seeking information on the state of art.

This study has compared the treatment of nanotechnology related inventions by the USPTO and EPO to that of South Africa. Due to the examination of U.S. and European patent applications, the validity of the invention claimed can be determined by addressing whether the requirements for a valid patent have been met. In contrast, South Africa does not share this examination approach and there are some foreseeable problems with this practice. For instance, basic formal requirements for a valid patent may be overlooked; “double” patents may be granted (double patents occur when a patent is granted for the same or a similar subject matter found in an earlier patent). It was suggested that South Africa establish agreements with the EPO or other Patent Offices that would be willing to examine South African patent applications.

However the South African government is in the process of reforming the current Patent Act 57 of 1978 in the form of the Draft National Policy on Intellectual Property of South Africa, which was published on 4 September 2013. This progress indicates a local consciousness

that current patent practices should be re-addressed and potentially improved upon. Some of the objectives of this policy include: strengthening the patentability criteria and implementing an examination process: however this will be limited to pharmaceutical products only. Despite the implementation of examination being limited to pharmaceutical products, this policy is a positive step towards elevating current patent law practices.

As nanotechnology is presently at its early stages of development, many of the unique challenges facing nanotechnology inventions, for example definitional and prior art issues, will be resolved as the courts face more infringement cases. This is likely to happen as more products come into the market. In relation to South Africa specifically, it is suggested that South African courts familiarize themselves with the case law of examining countries, such as Germany and the United Kingdom or USA. Although it is entirely at the discretion of the court to do so, this would provide valuable insight and guidance, as it is likely that foreign courts will experience these issues first.

Prospects for international harmonisation of practices amongst all Patent Offices around the world would aid in reducing uncertainties regarding the extent of IP rights conferred by nanotechnology patents, i.e. by adopting consistent and co-ordinated patent application practices, thereby simplifying the subsequent management of patents. Understandably this will be a long process involving many compromises in respect of the different approaches adopted by various countries, but would allow for new technologies, such as nanotechnology, to be dealt with in the same consistent manner within a reliable framework of standard practices.

In the context of local developments, collaborations of CIPC with foreign agencies could provide insight as to how some of the challenges presented by nanotechnology can be overcome thereby improving existing practices. Should the present thesis contribute to a better understanding of the problems addressed therein in South Africa and bring current practices in line with international practice, its actual purpose would be fulfilled.

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