MIPLC Studies 5

Mario Cisneros

Patentability Requirements for Nanotechnological Inventions

An Approach from the European Patent Convention Perspective

Nomos

MIPLC Munich Intellectual Property Law Center Augsburg München Washington DC

MIPLC Studies

Edited by

Prof. Dr. Christoph Ann, LL.M. (Duke Univ.)
Technische Universität München

Prof. Robert Brauneis
The George Washington University Law School

Prof. Dr. Josef Drexl, LL.M. (Berkeley)
Max Planck Institute for Intellectual Property, Competition and Tax Law

Prof. Dr. Thoas M.J. Möllers
University of Augsburg

Prof. Dr. Dres. h.c. Joseph Straus,
Max Planck Institute for Intellectual Property, Competition and Tax Law

Volume 5

Mario Cisneros

Patentability Requirements for Nanotechnological Inventions

An Approach from the European Patent Convention Perspective

Nomos

MIPLC Munich Intellectual Property Law Center

Augsburg München Washington DC

Die Deutsche Nationalbibliothek verzeichnet diese Publikation
in der Deutschen Nationalbibliografie; detaillierte bibliografische Daten
sind im Internet über http://www.d-nb.de abrufbar.

Die Deutsche Nationalbibliothek lists this publication in the Deutsche
Nationalbibliografie; detailed bibliographic data are available in the
Internet at http://www.d-nb.de.

ISBN 978-3-8329-4588-6

1. Auflage 2009

To Victoria

Acknowledgments

I would like to thank to everyone who contributed in one or another way to my dissertation. First, I would like to show my gratitude to the members of the Managing Board of the Munich Intellectual Property Law Center, especially Prof. Joseph Straus. Next, I thank my supervisor Prof. Scott Kieff for his patience, support and guidance. I acknowledge the directors of the Program, especially Seth Ericsson. I wish to thanks to my classmates at the MIPLC LLM Program, for inspiring me with their ideas, discussions and debates. I would also like to thank my parents and two sisters. Most importantly, this dissertation would not have been possible unless the support and love of my wife, Victoria.

Table of Contents

I. Introduction

Nanotechnology is the term used to categorize technologies related to structures and devices that are most conveniently measured for size at the nanometer scale – a nanometer is one billionth of a meter.[1] Given this broad definition, many fields of science can be covered by the term and in theory any process able to take full control or to manipulate matter atom by atom or in clusters up to 100 nanometers is understood as part of nanotechnology. This classification represents the multi-disciplinary nature of the field, which is also confirmed by the broad use of these new structures in dissimilar areas such as material science, electronics, biology, chemistry, biomedicine, mechanics, and any combination of them.[2]

The field has experienced an accelerated development during the last 20 years. The newness of the topic, combined with the high potential of the technology in terms of capacity to impact people's lives and the business universe expected to be generated, has produced extensive discussions and controversy, inviting debate on the social, economic, ethical and legal aspects of nanotechnology, its development, implementation and use.[3]

The economic benefit that is promised to the owners, or those controlling the knowledge and inventions around nanotechnology, has encouraged them to follow aggressive strategies with the intention of obtaining exclusive benefits by the legal appropriation of those developments. This legal appropriation is partially pursued by the filing of patent applications.

One of the objectives of this Thesis is to analyze such strategies, particularly the way in which applicants are trying to get broad protection of their inventions and the impact this may generate in the possibility to promote further development of the technology by universities and other companies. The analysis will focus on how the patent system allows protection of basic and broad aspects of nanotechnology and

1 Jeremy J. Ramsden, *What is nanotechnology?* Nanotechnology Perceptions 1, 2005, p3–17.

2 A further definition of nanotechnology is provided by the European Patent Office (EPO): "The term nanotechnology covers entities with a controlled geometrical size of at least one functional component below 100 nanometers in one or more dimensions susceptible of making physical, chemical or biological effects available which are intrinsic to that size. It covers equipment and methods for controlled analysis, manipulation, processing, fabrication or measurement with a precision below 100 nanometres." The definition is available at http://www.epo.org/topics/issues/nanotechnology.html, (last visited September, 2009).

3 Allhoff Fritz, *Nanotechnology & Society: Current and Emerging Ethical Issues*, Lin, Patrick, 2008.

whether these patents may in the future be declared invalid, when important patents will start being used to litigate among competitors.[4]

A further aspect of the Thesis will concentrate on how patentability requirements may be applied to the particularities and complexity of nanotechnological inventions and essentially on the considerations that patent applicants should take into account while prosecuting these patent applications at the patent office. Considerations on patentable subject matter, novelty and inventive step requirements will be covered.

Lastly, the Thesis is to elaborates on the general nature of patent law and its applicability to specific technology fields.[5] In this regard, it will be shown how patent law has been applied in the past to solve problems generated by new and complex technologies, which have generated the same or similar concerns; how law will be applied to this new field in a way to keep the patent system useful for the objectives it pursues, and how these developments can help to answer the uncertainties that the patenting of nanotechnological inventions is generating. Also, an attempt to answer the question of how the current patent system can be used to protect both the generator's commercial interest and the consumer's right of accessibility to the progress of science will be made, focusing on the question whether the requirements of patentability need to be reinterpreted in view of the particularities of nanotechnology.

The assessment on patentability requirements will concentrate on nanotechnological inventions developed in the field of materials and surface science, as described by class Y01N in the International Classification System administered by the World Intellectual Property Organization (WIPO), an area which represents a substantial portion of the recently filed patent applications worldwide.[6] This area includes important developments such as nanocomposite materials, carbon nanotubes, fullerenes, nanostructured materials and dendrimers.

4 *Principles for Nanotech Oversight*, ICTA, AFL-CIO, FoE, IUF, ETC Group, Third World Network, Loka Institute, July 2007, available at http://www.icta.org/pubs/index.cfm (last visited September, 2009).

5 For a general discussion on the theory that patent law is general in nature but specific when applied on particular technical fields *see* Dan L. Burk and Mark A. Lemley*, Is Patent Law Technology-Specific?,* UC Berkeley Public Law Research Paper No. 106; and Minnesota Public Law Research Paper No. 02-14, 2002.

6 The EPO has also developed a class under the European Classification System (ECLA) for nanotechnological inventions. This class is labeled as Y01N "Nanotechnology", with a subclass Y01N6/00: Nanotechnlogy for materials and surface science. A description is available at http://v3.espacenet.com/eclasrch?ECLA=/espacenet/ecla/y01n/y01n.htm (last visited September, 2009).

II. Patentable Subject Matter

The European Patent Convention[7] (EPC) defines four main requisites to grant a patent for an invention. These basic requisites establish that the invention (i) is not explicitly excluded from patentability, (ii) is new, (iii) involves an inventive step and (iv) is susceptible of industrial application.[8]

Before analyzing the application of patentability requirements to nanomaterials, we will make some clarifications on the distinctiveness of nanotechnology and its development originated from scientific discoveries or nanoscience. This differentiation will serve as introduction to the discussion on patentable subject matter, specifically on the patentability of discoveries and basic laws of science, which are much related to the advance of nanotechnology.

1. Nanoscience v. nanotechnology

Basic research and science has been historically related to the discovery of natural phenomenon and the analysis of how matter, organisms or laws of science work and interact among them. The understanding of these basic principles and the analysis of natural elements have then inspired researchers to build upon new developments by the application of that knowledge. While the activities related to the understanding of the rules and laws governing materials and processes are in general considered as basic research activities, the application of that knowledge into tangible and usable results and the generation of technology is typically identified as applied science or technology development[9]. In this way, applied science involves the intention to solve a real problem, many times by using the knowledge generated by the basic research.[10]

7 Convention on the Grant of European Patents (European Patent Convention), 13th Edition, entered into force in December 2007, available at http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/contents.html (last visited September, 2009).

8 EPC, Chapter I, Patentability, Articles 52, 53, 54, 56 and 57.

9 For a discussion of this and other definitions of basic research, *see* Jane Calvert and Ben R. Martin, *Changing Conceptions of Basic Research?*, Science and Technology Policy Research, University of Sussex, 2001. Available at http://www.oecd.org/dataoecd/39/0/2674369.pdf (last visited August, 2009)

10 *See*, Hans Poser, *On Structural Differences Between Science and Engineering*, PHIL & TECH 4:2, 1998.

Nanotechnology has an intimate relationship with basic science.[11] Many inventions available today would not be possible without the pioneers that understood and explained the basic laws of physic and chemistry that after some time were applied to develop inventions.[12] In this way, much of the knowledge coming from these areas is responsible for the later development of nanotechnology and the generation of patentable inventions.[13] The concept can be illustrated with an example, the case of Albert Fert from the Université Paris-Sud, France and Peter Grünberg, from the Institut für Festkörperforschung, Germany, two researchers who won the Nobel Prize in physics in 2007 for their discovery of giant magnetoresistance during the 90's.[14] Giant magnetoresistance is the occurrence of a high change in electrical resistance of a material when immersed in a weak magnetic field.[15] This completely new phenomenon discovered by the two scientists generated a world of inventions in the field of electronics, particularly in the design of nanostructures to be used, for example, in the improvement of hard drive reader heads.[16] It was a few years after the discovery of the phenomenon that IBM started to use and patent the application of this new principle of physics in useful inventions.[17]

Given that nanotechnology and nanoscience are so closely related and that basic research is so important — more so than for other fields — to allow further development in the field, we would expect to find provisions in the patent system oriented to allow the generators of this knowledge to enjoy exclusivity with regard to their developments. If this were the case, inventors involved in basic research would be allowed to get exclusivity on the results generated by their work. Nevertheless, some of these creations are explicitly, or in other ways, excluded from patentability.

11 D. R. Basset, *Nanoscience and nanotechnology: an overview*, Center for Workforce Development, University of Washington, 2006.

12 *Id.*

13 *Id.*

14 Press release, The Royal Swedish Academy of Sciences, December 2007. Available at http://nobelprize.org/nobel_prizes/physics/laureates/2007/press.html (last visited May, 2009).

15 G. Binasch, P. Grünberg, F. Saurenbach, and W. Zinn, *Enhanced magnetoresistance in layered magnetic structures with antiferromagnetic interlayer exchange*, Phys. Rev. B 39, 4828, 1989.

16 *See*, T. Yoshida et al., Magnetoresistance effect of InAs deep quantum well structures grown on GaAs substrates by molecular beam epitaxy, 1997 International Conference on Solid-state Sensors and Actuators, Chicago, June 16-79, 1997.

17 *See,* for example, Dill, Frederick Hayes et al., US Patent 5,898,548, *Shielded magnetic tunnel junction magnetoresistive read head*, issued on 1997.

In the next section these provisions will be evaluated to show how they may impact on the protection of nanotechnology and if the patent system, as it is defined today, promotes researchers and institutions entering into challenging projects related to basic science in the field of nanotechnology. These questions will be approached by analyzing the rules of the current system for examples of instances where basic research is essential to develop uses and applied solutions from nanotechnology.

2. Inventions and discoveries

Basic research is defined as the investigation conducted with the main purpose of discovering new issues or to develop theories about natural phenomenon.[18] The knowledge generated by this activity is in many cases non-patentable, either because it is simply excluded as patentable subject matter or because it fails to fulfill the other basic patentability requirements.

Article 52 of the EPC states that a patentable invention includes "[…] any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application."[19] The Convention doesn't define what an invention is, nevertheless it provides a non-exhaustive list with examples of what doesn't constitute an invention.[20] According to this provision, discoveries and scientific theories are not considered inventions and therefore excluded from patentability.[21] While EPC is clear on the point that a discovery is not patentable, it is silent on the definition of discovery. In this regard, the European Patent Office (EPO) has provided some clarification on what constitutes an invention under Article 52(2), but it has not provided any formal definition for the word *discovery*, obliging a case by case analysis in order to asses the requirement with regard to each particular technology.[22]

It appears that EPO has not dealt in depth with the clarification of a general definition seems to be because patentability concerns in connection with discoveries were approached from different perspectives. This may be due to the difficulty associated with providing a general rule on the understanding of the meaning of *discovery*. These alternative approaches have centered on the development of the

18 Merriam-Webster Online Dictionary. http://www.merriam-webster.com/dictionary/research (last visited May, 2009)

19 EPC, Article 52, Patentable Inventions.

20 *Id.* at (2).

21 *Id.* at (2)(a).

22 *See*, for example, V 0008/94.

novelty requirement and on the nature of the technical character contained in the invention. This last indirect requirement, the technical character of the invention — discussed at length in cases related to biotechnological inventions and other fields— has been developed as a test to define what constitutes an invention.[23] Nevertheless, while the restriction on patentability of discoveries is designed to avoid patenting of laws of nature and basic concepts of science, considered to be in the public domain to allow a general and unrestricted use of them,[24] not all inventions based on a discovery are excluded from patentability.[25]

It is clear that the basic laws of nature governing the functioning of nano-technological inventions are not subject matter eligible to be patented as they are considered scientific theories, explicitly excluded as such by the EPC and lacking of technical character.[26] Most of the time, this restriction is not a problem for inventors, given that what is discovered or invented is not the law of nature allowing, for example, nanotubes to perform in a way completely different to the way a normal sized hollow fiber would perform, but it is the structure of the nanotube itself which makes the invention patentable. In many cases, the inventor is not aware of what makes the invention to perform in a particular way nor able to explain the scientific principle behind the behavior of the invention; nevertheless in the case of nanotechnology, researchers are working close to an undistinguishable line between discovering new properties of matter and developing new materials or devices. In any case, given the complexity of nanotechnology in terms of the knowledge needed to manipulate it, inventors are often very knowledgeable about scientific concepts that allow them to find applications and develop patentable inventions. The process of research and development may flow in two directions: from the development of the invention to the research and modeling of the properties presented by the invention or, in the opposite directions, from the discovery of the scientific principle to the development of the use of such knowledge in an invention. In some environments the latter may be favored and promoted, leading to the generation of discoveries and scientific knowledge that may be difficult to patent. This is mostly true for researchers working with nanotechnology at universities, where the generation of knowledge is one of the primary objectives of the institutions. This is in stark contrast to the research carried out by companies where the main objective is usually to develop a product to obtain a financial or economic return on such

23 *See*, for example, T 0619/02 for a discussion on the technical character of an invention related to an "Odour evaluation method".

24 As indicated by the EPO in case T 0870/04, "The purpose of granting a patent was not to reserve an unexplored field of research for an applicant."

25 *See*, G 0002/88. In this case, the TBA affirmed this point by clarifying "[...] the fact that the idea or concept underlying the claimed subject-matter resides in a discovery does not necessarily mean that the claimed subject-matter is a discovery "as such".

26 *Id. supra* note 19.

investment. In this way, researchers at the universities may be creating non-patentable knowledge that is then used by others to create inventions subject of patents. the issue of how knowledge developed by basic research may be subject of patents will be discussed further in the Thesis.

Recently, universities and pubic research institutions have started to play a significant role as holders of important patents. For example, the Max Planck Society, a non-profit organization, has its own office in charge of patenting and commercializing inventions generated by its institutes, which in year 2004 accounted 115 running licenses, most of them based on patents.[27] A similar situation can be found in the US. After the enactment of the Bayh-Dole Act, the number of patents granted to Universities has increased considerably.[28] The ten universities receiving the most patents for inventions in 2005 amounted 1,294 grants, many of them with equivalents in European countries, which is a clear example of the certainty that universities are now commercializing, or willing to commercialize, the technology that they produce.[29] The relatively recent tendency of universities in filing more patents may be influenced by several factors. One of them is the need for external financing. Another is the need to retain researchers by allowing them to generate further income apart from what they earn as a salary. Some universities share the financial benefit generated by the exploitation of a patent in thirds among the university, the researcher and the Technology Transfer Office. Yet another reason relates more to the pressure that society places on the academy to show the manner in which the taxes they pay are used to generate useful knowledge that then is given back to the society in the form of technology to solve real problems. It is probable that society in general supports the idea of universities filing patent applications more because patenting is perceived as proof that researchers are working on solutions to real problems and not on basic research, popularly considered as less useful, rather than because patenting is going to increase availability of the technology. Some arguments could be made in favor of the idea that by patenting new technologies, universities are favoring to put those inventions to use in a way beneficial for the society; however, Technology Licensing Offices

27 Hertel Bernhard, Class lecture, Science, IP & Start Ups, Munich Intellectual Property Law Center, Munich, Germany, , April, 2008.

28 Bayh-Dole Act is codified in 35 U.S.C. § 200-212. The statute allows US Universities to take control of the inventions generated from research founded by the Government. For a general discussion on the implicances of the enactment of the Bayh-Dole Act, *see* Mowery, David C., Nelson, Richard R., Sampat, Bhaven N. and Ziedonis, Arvids A., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, Research Policy, Vol. 30, pp. 99-119, 2001.

29 USPTO, Press Release #06-24, April 2006. Available at http://www.uspto.gov/web/offices/com/speeches/06-24.htm (last visited September, 2009).

usually use managing indicators such as number of patents filed, number of licenses granted and earnings from royalties. This shows that the financial benefit is the main objective of the enterprise. If making the technology available to society in general were the objective of universities, they would put any generated knowledge in the public domain and allow others to use and improve upon that technology. Even if high investment is needed to put the invention in the market and we assume that patents facilitate putting inventions to use, third parties may still have the possibility to patent manufacturing process or specific uses of such technology in a way that investing in commercialization is also promoted.

However, much of the knowledge generated by universities is widely disclosed and placed in the public domain, as they are able to appropriate the benefits of research only to a limited degree, and only a limited portion of such knowledge in the field of nanotechnology can be patented. That knowledge, considered as valuable by the market, may include basic laws of physics or chemistry but also, and most importantly, the description of mechanisms and theoretical foundations on why nanostructures enjoy different properties compared to equivalent normal sized structures and the models and methodologies to predict such behavior.

It is strange that open patent licenses, similar to those now popular for software, are not widely used by more universities and publicly founded research projects teams. In any case, it is clear that people and organizations working in basic research have less control on how that information is later exploited, whether to impede its use or to oblige developers of new technology incorporating that knowledge to allow its use under an open license.

3. Non patentable knowledge

According to the EPC, there is no requirement for the applicant to explain why the invention works or to provide a theoretical model to allow the public to understand the functioning of the invention. The only requirement regarding disclosure is to include in the patent description the information needed to allow a person skilled in the art to put the invention at use.[30] In this way, much information related to the invention stays out of the patent document. However, in some cases the applicant may be forced to disclose the theory behind the invention to fulfill the disclosure requirement. EPO's case law indicates that "if the invention seemed, at least at first, to offend against the generally accepted laws of physics and established theories, the

30 EPC, Article 83, Disclosure of the Invention, requires that "the European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art".

disclosure should be detailed enough to prove to a skilled person conversant with mainstream science and technology that the invention was indeed feasible (i.e. susceptible of industrial application)."[31] This decision may demand a stricter requirement of disclosure from the applicant in cases where theories and scientific laws are not yet well established, as may be the case of nanotechnology, requiring the applicant to disclose more information in order to allow others to reproduce the invention. It should be noted however, that the mentioned requirement may be closely related to the disclosure and the industrial applicability requirement and the applicant may need to include the information on the functioning of the invention to prove the industrial applicability of it, in addition to the requirement of Article 83. In line with this idea, and also on the point of industrial applicability of scientific knowledge to be considered a patentable invention, the Technical Board of Appeal at the EPO (TBA) ruled that "In cases where a substance […] was identified, and possibly also structurally characterized and made available through some method, but either its function was not known or it was complex and incompletely understood, and no disease or condition had yet been identified as being attributable to an excess or deficiency of the substance, and no other practical use was suggested for the substance, then industrial applicability could not be acknowledged. […] Even though research results might be a scientific achievement of considerable merit, they were not necessarily an invention which could be applied industrially."[32] This case shows that the EPO may oblige the applicant to disclose the information needed to understand the functioning of complex invention to consider them patentable, a requirement that is not essential in some other fields of technology.[33] What impact do these criteria have on patentability of nanotechnology?

One of the reasons nanotechnological inventions are so revolutionary is because they open a new world of properties not available under the law of physics recognized for normal scale matter. In some cases these properties seem to be against the generally accepted laws of physics and established theories, meaning that if it is necessary for the public to reproduce the invention, the results of the basic research would be necessary to be disclosed. In this way, in order to fulfill the disclosure requirement, a nanotechnological invention needs to be described in a detailed way, including an explanation on the basic functioning of the invention, explanation that may involve the disclosure of basic non-patentable knowledge. This means that even when disclosed, the basic general scientific knowledge that made the invention possible to work would not be allowed to be protected or included in claims of the patent but requested to be disclosed to allow others to reproduce the invention. These facts may cause the applicant to choose different protection

31 T 870/04.

32 *Id.*

33 This issue is further discussed in Chapter V "Industrial Applicability" of this Thesis.

methods, for example trade secrets in combination with patents, to cover the different aspects of the invention.

It is interesting to note the position of the US Patent & Trademark Office (USPTO) in this respect. The USPTO does not require the applicant to explain why the invention works but only to disclose the invention in a complete way, including the best mode known by the inventor at the moment of filing, to allow others to reproduce the invention.[34] While both approaches, USPTO and EPO, may appear similar in theory, perception on the completeness of disclosure to allow the person skilled in the art to reproduce the invention may vary. This variance may be present among different technology fields related to nanotechnological inventions.[35] Consequently, depending on the jurisdiction, applicants may be allowed to avoid disclosing important knowledge about the theory behind the invention or in other cases applicants may be forced to disclose more than that which is standard in other technology fields.

In cases where disclosure of basic knowledge is not necessary to comply with the disclosure requirement, researchers may decide not to disclose this new and inventive but non-patentable knowledge until they develop a range of useful applications to have the possibility to get patents and assure more control over a technology of general applicability. In this way, the researchers may decide to keep the knowledge secret until the most promising patentable applications have been patented. Even after that, if the knowledge is valuable enough and the disclosure requirement is low, they may decide to delay the disclosure of the information. The appropriate strategy to follow will depend not only on the researcher and the institution (not all researchers are interested only in the inmediate economical benefit of their research, many others base their reputation and carrier on scientific publications) but also on the future development by the EPO of the disclosure requirement threshold in the nanotechnological field.

To summarize, the system appears designed to reach a balance between excluding from patentability the basic and general information that is susceptible to use as fundamental general knowledge, for example scientific theories, and at the same time to allow patents on the application of those concepts provided that they are useful and have a technical character, even if they can be applied in general and various fields. It is of value to draft legislation that can be flexible enough to

34 *See*, In re Cortright, 165 F.3d 1353 (Fed. Cir. 1999). Nevertheless, note that the disclosure requirement, as defined in 35 U.S.C. §112, requires the applicant to provide a written description supporting the claims of the patent, the disclosure of the invention in a complete form to enable a third party to reproduce the invention and the disclosure of the best mode known by the inventor at the moment of filing the patent application. Also in the US, these requisites may be more difficult to fulfill in the case of nanotechnological inventions.

35 Wagner, R. Polk, *Of Patents and Path Dependency: A Comment on Burk and Lemley*. Berkeley Technology Law Journal, Vol. 18, p. 1341, 2004.

consider particularities and complexities of each field of technology, but when this flexibility is created by the unclear definition of terms like the distinction between *invention* and *discovery*, the interpretation of the patenting rules, in hands of the administrative authorities, may be based on arguments out of policy considerations and in this way, the system may be jeopardized in a way contrary to the objectives that it pursues.

4. Ethical concerns on nanotechnology and the impact on patentability issues

Discoveries are not the only subject matter excluded from patentability. According to EPC "[…] patents shall not be granted in respect of inventions the commercial exploitation of which would be contrary to *ordre public* or morality […]".[36]

Some products incorporating nanotechnological inventions have started to raise concerns on risks for the health of the people exposed to those materials. Nanoparticles is an area of main concern, for the reason that they can penetrate into the gas exchange region of the lungs, impeding in some cases the organism to defend against the presence of the strange substance.[37] Self-duplicating nanorobots, are also mentioned as a future concern from an environmental perspective, even when these devices are far from reality today.[38]

Environmental and public health concerns that may appear in connection with nanotechnology resemble the European experience with asbestos.[39] Learning from the experience of this case, some commentators believe that "consumers are involuntarily exposed to unlabeled nanomaterial ingredients in products, without being informed of potential risks [whereas] nanomaterials are disposed of and released into the environment despite unknown impacts and inadequate means to

36 EPC, Article 53(a), Exceptions to patentability. This provision is in line with TRIPS Agreement, Section 5, Article 27, Paragraph 2. TRIPS Agreement allows members to exclude from patentability inventions in order to protect " […] *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment […]".

37 *See,* Commission de l'Ethique de la Science et de la Technologie, Ethic, Risk and Nanotechnology: Responsible Approaches to Dealing with Risk, 2008.

38 *Id.*

39 Asbestos is the name given to a group of naturally occurring minerals. This product was broadly used during decades as thermal insulator in buildings, to find later the high risk of disease the material causes for people exposed to it, obliging to invest millions in isolating or replacing the textile from all buildings. For example, the EPO headquarters, along the Isar river in Munich, Germany, was partially closed for the period 2008-2010 for asbestos removal.

detect, track or remove the new materials."[40] [41] While experts consider that there is still much to understand from the toxicity and other risky factors of nanoparticles, questions arise, e.g. how governments may decide to protect the population while a clear risk assessment is developed and to the extent nanotechnology is considered a real risk for pubic health, may this lead to declaring some nanotechnological inventions excluded from patentability.[42] Investigating how the convention was understood in other relevant cases may help to predict the spirit of this rather general provision.

The concept of *ordre public* and morality, as considered in Article 53 of EPC has been developed in case law by EPO. The TBA established that "Under Article 53(a) EPC, inventions the exploitation of which is likely to seriously prejudice the environment are to be excluded from patentability as being contrary to *ordre public*".[43] This is a clear indication that inventions capable of producing environmental damage are considered excluded from patentability. However, the exclusion from patentability would need to be justified on factual details at the moment of deciding the exclusion.[44] The EPO, in affirming that "a decision in this respect presupposes that the threat to the environment [needs to] be sufficiently substantiated at the time the decision is taken by the EPO" seems to limit the possibility to exclude from patentability substances which have not yet been proven as harmful for people or environment, but that may in the future be considered as such.[45]

In providing an example of inventions that are considered as contrary to *ordre public*, the EPO presents the case of anti-personnel mines, as an *obvious* example.[46] Apart from discussing the obviousness of the example, we can agree in the danger that these devices may represent for people in general, but it is at least arguable why, based on this same principle, EPO allows patentability of other weapons.

In trying to find a balance, the Boards of Appeal has constructed the meaning of morality and *ordre public* for the field of plant varieties, and clearly established that this concept should be defined narrowly under a case-by-case analysis.[47] While the

40 David M. Berube*, Intuitive Toxicology: The Public Perception of Nanoscience, Nanotechnology and Society: Current and Emerging Ethical Issues*, F. Alloff, P. Lin, 2008.

41 ETC, *Principles for the Oversight of Nanotechnologies and Nanomaterials*, 2008. Available at http://www.icta.org/pubs/index.cfm (last visited September, 2009)

42 *Id.*

43 T 0356/93.

44 *Id.*

45 *Id.*

46 *See*, Guidelines for Examination in the European Patent Office, European Patent Office, December 2007. Available at http://www.epo.org/patents/law/legal-texts/guidelines.html (last visited May, 2009).

47 *Id. supra* note 43.

mentioned Board affirmed that an invention cannot be considered patentable or non patentable merely because the product is subject to an authorization or a bar to be commercialized in the market of some member countries, it established that the risk of hazard to the environment may constitute an impediment for patentability.[48]

The patentability exclusions based on morality and *ordre public* have been criticized in the past under the argument that rights granted by patents are defined as negative rights, transferring to the patent owner the right to exclude others in using, manufacturing, etc. the invention, but not the right of exploiting the invention. This negative right can be understood also in terms of authorizations needed by the patent owner to manufacture and commercialize the technology, authorization that doesn't come from the grant of the patent but usually from other governmental procedures.[49] The most visible examples come from the pharmaceutical industry, where even after obtaining a patent for a new medicine the patent owner must receive authorization to put the pharmaceutical product into the market. Such further authorization is based partially on the requirement that the product does not pose a danger to public health.[50] In this way, the inventors are not excluded from the possibility of obtaining protection for valuable technology and at the same time public health is protected by controls and other mechanisms developed by governments. Other examples can be found in the chemical, automotive or electronic industry.

A further critique levelled against *ordre public* and morality criteria on patentability requirements refers to the fact that these concepts are evolutionary and change throughout the years. Something that is against morality today may be accepted by society in the future and *vice versa*. Nanotechnological inventions which may not be allowed to be patented today may be accepted in the future, after technology evolves in a way that potential harm is controlled by technical measures. This would lead to an unfair situation in which a previous inventor, who could not receive patent rights based on this "out of date" moral criteria, is left out in the cold.

While there is contradiction in a patent system that functions to encourage the creation and disclosure of inventions that may be problematic for public health, the exclusion from patentability of nanotechnological products that are not yet proved to be dangerous may delay the development of technology that is later proved to be safe. At the same time, exclusion from patentability of nanomaterials that are considered risky may increase the investment and encourage parties to develop "risk-free" technologies.

48 *Id.*

49 Peter Drahos, *Biotechnology patents, markets and morality*, E.I.P.R. 21(9), 441-449, 1999.

50 *See*, for example, Regulation (EC) No 726/2004, for the authorization and supervision of medicinal products for human and veterinary use.

5. Concerns on the patent thicket

Other policy issues apart from *ordre public* and public health in connection with nanotechnological inventions are raising concerns. The early stage of development of nanotechnology and the rush of developers to file patent applications, a situation where the building blocks of nanotechnological inventions in areas such as biology or materials science may be patented, has been mentioned as an issue to consider. It has been remarked that these applicants following aggressive patenting strategies may take control over a wide range of basic inventions able to be applied in a broad spectrum of fields, with the ability to define whom, how, when and where the technology is going to be used.[51] The issue may have a big impact on nano-technology related businesses if the same patent owners, following a commercial strategy, decide to restrict access and not to allow potential users or improvers to have access to the technology. This may represent an issue for countries without research exceptions or with a narrow understanding of them.[52] The relevance of the subject is based on the perception that nanotechnology will generate such an immense impact on the future life of people, from a radical increase in the productivity of food generation techniques to the development of revolutionary methods to treat diseases, that governments should assure that private ownership will not generate an unbalanced situation concerning access to the advance and benefit of technology for the majority of the population.[53]

From a policy perspective, patent law is accepted to be a tool by which some economic objectives are meet. Accordingly, a substantial part of patent law was developed as an instrument to encourage generation and commercialization of technology, which produces economic development for the country.[54] By encouraging people to invent, to negotiate access to technology and to put in the market their inventions, the welfare of society is increased, among other reasons, by the improvement of life quality of people. Nevertheless, increasing welfare of society appears only as a secondary result of patent law, as there is no requirement in the statutes that an invention to be patentable needs to be beneficial for the society. In the same way, no distinction is made among patent rights granted to

51 Mark Lemley, *Patenting Nanotechnology*, Stanford Law School, John M. Olin Program in Law and Economics Working Paper No. 304, June 2005.

52 For a list with countries without research exception provisions *see* Carlos M. Correa, *The International Dimension of the Research Exception*, AAAS, 2005.

53 *Id. supra* note 51.

54 For a discussion on how patents can put inventions into use, see Kieff, F. Scott, *IP Transactions: On the Theory & Practice of Commercializing Innovation*, Stanford Law and Economics Olin Working Paper No. 311, October 2005 and Kieff, F. Scott and Troy, A. Paredes, *Engineering a Deal: Toward a Private Ordering Solution to the Anticommons Problem*, Stanford Law and Economics Olin Working Paper No. 330, November 2006.

inventions of different social benefit and the rights granted by a patent are equivalent for any invention in any field of technology.

Some critics assure that in certain cases patent law may deter innovation. The theory of the patent thickets has been identified as one of the ways patent law may discourage innovation. Bessen has summarized this theory.[55] “Heller and Eisenberg (1998) raise the concern that transaction costs may become prohibitive when firms must bargain with many different patent holders to obtain the rights needed to make a product”.[56] Besides, Bessen indicates “[…] that although cross-licensing and patent pools may resolve some problems of transaction cost and vertical monopoly, these institutions do not correct all problems associated with patent thickets.”[57] If this theory is applied to the future evolution of nanotechnology, taking into account the high volume of patents that will cover the area in the near future, a non-promising scenario where no practical benefit from the generation of such technology is obtained may be expected.

The problem of the anti-commons and the blocking effect of patents over downstream research and commercialization are not broadly accepted as a proven theory. On the contrary, other views propose that patents may encourage parties to enter into negotiations to allow transactions involving technology and operate promoting a bargain effect among patent owners and other players in the market.[58] There are many counter examples to the anti-commons problem, like the case of technology involved in the manufacturing of portable computers, where thousands of patents protecting different portions of the software and hardware are packed in a single device.[59] In spite of this situation, it is clear that no problem has emerged and consumers are allowed to access the product easily and at reasonable prices.[60]

Other arguments in favor of the existence of a patent thicket are those related to the presence of patents covering broad aspects of basic nanotechnological inventions. As discussed, there is a spreading belief that the high potential of nanotechnology combined with its novelty is encouraging many people to rush to the patent offices to get broad protection on basic concepts suitable later to be applied in more specific fields.[61] However, as stated in section II.3, patenting the

55 James Bessen, *Patent Thickets: Strategic Patenting of Complex Technologies*, Boston University School of Law, available at http://www.researchoninnovation.org/thicket.pdf, (last visited September, 2009).

56 *Id.*

57 *Id.*

58 Kieff, F. Scott, *On Coordinating Transactions in Information: A Response to Smith's Delineating Entitlements in Information*, 117 YALE L.J. POCKET PART 101, 2007. Available at http://thepocketpart.org/2007/10/10/ kieff.html, (last visited May, 2009).

59 *Id.*

60 *Id.*

61 *Id. supra* note 51

basic concepts of nanotechnology might face some restrictions, mostly when discoveries and knowledge about the theory behind the operation of nano-technological inventions are involved. It was concluded that general basic knowledge can be considered a patentable invention if it has technical character and industrial applicability is disclosed (in addition to the fulfillment of the other patentability requisites). Furthermore, for complex nanotechnological inventions, applicants might be forced to disclose the scientific fundamentals behind the functioning of the invention, knowledge that cannot be protected by the claims of the patent.

These thoughts may indicate that such broad knowledge on the basic elements of nanotechnology are impossible to be monopolized by patents, and are to a large extent trade secrets which may generate difficulties for the access to knowledge by third parties interested in carrying out research in the same field. This idea is concordant with one of the basic theoretical foundations of the patent system, oriented to promote and incentivize the disclosure of information through the publication of patents in exchange for a limited monopoly. As it was said, in the case of nanotechnological inventions, the patentability requirements may force applicants to disclose more than what is requested in other fields. An example can be found for the case of researchers at universities (one of the institutions accused of monopolization of the basic blocks of nanotechnology). They are not that interested in protecting the result of research through trade secrets, given that secrets may be more difficult to control and license.[62] Moreover, keeping results and inventions under secrecy would be contrary to the interest of the Academy to contribute to the public knowledge for the advance of science.

It is strange that the issue of patent thickets is presented as a problem for the case of nanotechnology at this early stage. The number of patents granted to nano-technological inventions is far from being high when compared with other industries. In other cases like polymers or steel alloys, there exists a flood of patents protecting detailed and limited but complementing aspects of the involved technologies. Even considering the particularities of these industries, these may be further examples where patent thickets are not a real problem for companies agreeing on commercialization of technology protected by scattered patent rights.

At this point, it is necessary to analyze if the concern and critique leveled against the grant of broad patents is based on a problem that arises from patent law and from difficulties in the administrative procedures at patent offices or, on the contrary, whether it is a problem inherent to the general applicability nature of the technology under analysis.

There are arguments to support both views. On one hand what makes this issue more relevant for nanotechnology is the newness of the field and the problems that

62 *Id. supra* note 55.

patent offices are encountering in making a good assessment on patentability due to lack of knowledge or lack of access to relevant prior art to evaluate novelty and inventive step of the inventions and to force applicants to reduce the scope of the claims in view of the prior art. On the other hand, some arguments establish that the general applicability of innovative nanotechnological inventions makes them general in nature and consequently claimed in a general and broad way in a patent specification. This position infers that, due to the early stage of the development of nanotechnological inventions, they are broad and applicable to various fields.

Supporting the idea that the nature of the technology and the inventiveness of the inventor is the only factor regulating the scope of a patent, it has been said that "[I]f [the inventor] has made an invention of general applicability, a generic claim is not the consequence of a verbal skill of the attorney, […], but of the breath of application of the invention".[63]

Even while this may be true in some cases, the common practice carried out by a good patent attorney in drafting a patent application is different.[64] When an inventor comes to a patent professional to ask for the drafting of a patent application, the work of the attorney is to prepare a description and a set of claims protecting not only the invention, but also anything else between the invention and the relevant prior art. Usually, a patent application including a set of claims limited to the embodiments identified by the inventor is not the kind of job expected from a patent attorney. Instead, the final application is merely developed based on the invention. The skills of the attorney are used to extend the scope of the claims, taking care to comply with the patentability requirements and at the same time protecting the invention to the broadest possible extent.[65] In following this practice, the attorney is excluding from the claim any non-essential embodiment in order to avoid potential infringers circumventing the patent, and is providing the patent owner an extended monopoly on the general inventive concept involved in the invention. This is one of the reasons why drafting patent applications is taken so seriously by applicants. The high quality applications are not only easier to be enforced but also more likely to get protection for a wide variety of possible modifications, improvements and other infringing products or methods using such base knowledge.[66] For example, if an inventor comes to a patent attorney asking to get protection for an invention defined as the use of a newly developed nanocomposite material as a coating, the patent attorney will not limit the claims to the use of such material, but will extend the

63 Joseph Straus, *Biotechnology and patents*, 54 CHIMIA, No. 5, 293-298, 2000.

64 *See,* Ronald D. Slusky, *Invention Analysis and Claiming: A Patent Lawyer's Guide*, American Bar Association; May 2007.

65 *Id.*

66 *Id.*

scope to the material itself, to allow the patent owner to get protection for any other use of the invention, even if those uses where not considered by the inventor.[67]

Some other comments make reference to the lack of training, to difficulties in becoming aware of relevant to prior art, and to the patent examiner's individual way of working, making it impossible to cover all the aspects of a multidisciplinary field to which nanotechnology may apply. This is partially true due to the nature of nanotechnology and the failure of patent offices to deal with this kind of invention in the past. Some offices have already tackled these problems, by the creation of a specific classification structure for nanotechnology and teams of examiners specially working on patent applications related to those classes.[68] This initiative will surely improve the quality and the certainty on validity of issued patents, but will not solve completely the problems related to the existence of low quality or invalid patents.

More drastic groups believe that granting companies being with legal monopolies on broad patents for nanotechnological inventions represents a real and specific risk in terms of accessibility to technology for developing countries. The ETC group represents an example of this position.[69] Supporting a view against patentability of nanotechnology, the organization considers that "[…] breathtakingly broad nanotech patents have been granted that cut across multiple industry sectors and include sweeping claims on entire areas of the Periodic Table [...] creating thorny barriers for would-be innovators".[70] Based on these assumptions, they recommend that WIPO "[to] initiate a global suspension of patent approvals related to nanotechnology until South governments and countries-in-transition can undertake a full evaluation of their impacts, and […] to examine the impact of nanotech-related intellectual property on monopoly practices, technology transfer and trade."[71] In line with the ETC Group's position, raising awareness on the issue but without requesting concrete actions, the European Commission considers that "[…] nanotechnology is raising fundamental questions as to what should, and should not, be patentable."[72] These are just a few examples of voices of concern on the role of intellectual property law on the development of nanotechnology. At the moment arguments based on tangible facts to support extreme positions on the inconvenience of granting patents in the field are not available. Nevertheless some specific aspects

67 *See*, for example, patent EP0842967B1 *Composite materials*, filed in 1997.

68 *Id. Supra* note 6

69 ETC Group, *Nanotech's Second Nature Patents: Implications for the Global South*, Special Report N0. 87, 2005.

70 *Id.*

71 *Id.*

72 *See*, Communication from the Commission, *Towards and European strategy for nanotechnology*, European Communities, available at http://ec.europa.eu/nanotechnology/pdf/nano_com_en_new.pdf, 2004 (last visited September 2009).

of patent law that will be discussed in this Thesis may support the need to assess and track evolution of economical and legal indicators in order to be ready to act if such concerns are proven valid.

III. Novelty

EPC requests novelty for an invention to be patentable.[73] To assess this requirement, EPC defines the state of the art from which the invention needs to differentiate, as "[…] everything made available to the public by means of a written or oral description, by use, or in any other way […]".[74] This means that not only information disclosed in writing or orally may be considered as part of the prior art, but also any substance, material or product containing the invention if it is available to the public before the date of filing of the patent application or the respective priority.

In the following sub-sections we will explore issues related to novelty requirements in light of particularities of nanotechnological inventions.

1. Patenting naturally existing structures

Some of the objects of research in the nanotechnology field have been inspired by morphologies present in nature. Some examples of these structures can be found in the self-cleaning surfaces existing in some vegetables and animals. The wings of butterflies and the leaves of some plats are illustrations of these cases.[75] Maybe the most well-known example is the lotus plant.[76]

With many patents protecting different aspects of their morphology and composition, carbon nanotubes have been proposed as other examples of naturally occurring structures. Carbon nanotubes and multi-walled carbon nanotubes are structures of low energy, i.e. atoms organized in the thermodynamically lowest

73 EPC, Article 54.

74 *Id.*

75 *Emulating nature self-cleaning effects for textiles through nanotechnology*, Mincor TX TT from BASF keeps dirt and water at bay, M2 Presswire, May, 2007. Available at http://www.basf.com (last visited September, 2009). The outside of the seed of the lotus plan are coated by wax crystals around 200 nanometers in size. These crystals prevent the surface from being touched by water or other. This hydrophobic effect is also facilitated by a particular surface morphology, generating an effect of super-hydrophobicity and allowing the plant to keep pores free of dust. The same hydrophobic effect can be seen in other plans such as the nasturtium, reed or ladys mantle.

76 *Id.*

possible energy for that material.[77] Under the laws of thermodynamics, any system tends to its lowest state of energy, and for this reason some researchers have argued that it is possible that carbon nanotubes are present in nature as self generated structures.[78] Nevertheless, as other conditions need to be satisfied to make possible the occurrence of this phenomenon, for example suitable pressure and temperature to make the natural generation of carbon nanotubes not only thermodynamically possible but also kinetically feasible, the natural presence of these structures cannot be demonstrated by a pure theoretical analysis.[79] This does not mean that there is no foundation to say that carbon nanotubes are not present in nature but only that there is not yet factual evidence on the presence of naturally generated carbon nanotubes.[80]

Far from being a new issue, the problem of patentability of substances previously existing in nature appeared in the past in other countries and fields of technology, as biotechnology and pharmaceuticals.[81] However, the discussion in the field of biotechnology was mostly approached in terms of ethical and social aspects in allowing patents protecting forms of life generated by the nature but isolated by humans, raising a debate on why something that was not invented but discovered should be owned by a private entity instead of being part of the public domain. In line with European Directives[82] and decisions of the TBA and the Enlarged Board of Appeal of the EPO (EBA), the EPO solved such problem by modifying the EPC to allow patentability of these kinds of substances provided that the patent is drafted to protect the isolated form of the organism and not the subject matter as present in nature.[83] As a result, a microorganism already present in nature, if the other patentability requirements are fulfilled, is allowed to be patented if claimed in the right way, i.e. claimed as the isolated form of the living being.

The comparison with the case of pharmaceutical compounds may also provide insights capable of extrapolation to nanotechnological inventions. Particularly relevant may be the experience of companies in patenting active chemical

77 Oscar M. Dunens, et al, *Inconsistencies in the Carbon Nanotube Patent Space: A Scientific Perspective*, Nanotechnology Law & Business, Spring 2008, p25-40.

78 *Id.*

79 *Id.*

80 *Id.*

81 *See*, for example, K. D. Raju, *The Debacle of Novartis Patent Case in India: Strict Interpretation of Patentability Criteria Under Article 27 of the Trips Agreement*, November 2007.

82 *See,* Directive 98/44/EC.

83 EPC, Rule 27(a), Patentable biotechnological inventions, "Biotechnological inventions shall also be patentable if they concern: biological material which is isolated from its natural environment or produced by means of a technical process even if previously occurred in nature".

compounds that were not developed by research efforts, but discovered in nature and processed as medicines to cure humans.[84] In many cases, the discovery of the substance is made as a result of cooperation with indigenous communities which have been using the plant containing the active compound to cure the same or different illness for centuries.[85] For similar cases, following the same criteria applied to biotechnological inventions, the TBA indicated that natural occurring substances and substances present in nature are patentable provided that the legal protection is limited to the isolated or purified substance.[86]

In the case of nanotechnological inventions two circumstances need to be differentiated. The first one is when the researcher discovers a structure originated in nature and patents such structure. The second is when an independently generated invention is patented and later declared unenforceable because the discovery of the same structure in the nature. In analyzing these cases, it should be noted that there is no requirement in patent law to disclose the origin or the creative process that gave result to the invention; because of this, examiners or courts are not allowed to distinguish between these two situations. However, in many jurisdictions patent law obliges the applicant to disclose each and every piece of prior art she is aware to the patent office.[87] If the applicant fails to disclose all the information to assess patentability of the invention, the patent may be declared invalid. In this way, the applicant is obliged to refer to the natural substance when describing the state of the art, if known by her, in a way to allow the examiner to perform a complete assessment of novelty taking into account the natural occurring substance.

Bearing in mind the definition of prior art, a substance present in nature should be considered relevant in assessing novelty and inventive step if it is available to the public. Public availability should be interpreted as the hypothetical possibility to have access to the information, without considerations of the reasons or interest of a person to access it or the knowledge of the person about the existence of such information.[88] In this way, even if the existence of the natural occurring substance was unknown to the public, after its discovery the piece of prior art can be used to

84 Jerry I.-H. Hsiao, *Patent Protection for Chinese Herbal Medicine Product Invention in Taiwan,* The Journal of World Intellectual Property, Vol. 10, no. 1, 2007.

85 The case of patents for Naga Jolokia pepper originally from the Naga tribal community used as a medicine or the patent for the energy drink Jeevani produced from a greed plant from Keralaare are examples of patenting modified versions of products that have been present in nature.

86 *See,* for example, T 767/95.

87 For example, according to US law, failing to disclose all relevant prior art that is known by the applicant at the moment of filing and during the prosecution process of the patent application may be considered Inequitable Conduct and make the patent unenforceable according to 37 CFR 1.56.

88 T 444/88.

attack the novelty of the nanotechnological invention. It is important to note that microscopy techniques developed during recent years made the advance of nanotechnology possible by allowing researchers to see the structures by magnifying them up to 2 million times. Many inventions would not be possible without the existence of these techniques. If a court may consider that before the existence of these techniques the natural occurring substances and structures, even present in nature, where not accessible to the pubic because no possibility to observe the subject matter was possible due to the inexistence of that kind of microscope, is a point of uncertainty. If we bear in mind the fundamental reasons for the novelty requirement, we have to consider public availability only after the existence of techniques that made it possible to access the knowledge available in nature.

A second point in assessing patentability of a natural occurring substance is the possibility for the invention to be rejected by considering it not an invention but a discovery. On this matter the TBA clearly said: ”To find a substance freely occurring is a mere discovery and therefore unpatentable.” [89] Nevertheless, the Board opened the possibility to patent substances present in nature by indicating “Moreover, if the substance can be properly characterized either by its structure, by the process by which it is obtained or by other parameters and it is ”new” in the absolute sense of having no previously recognized existence, then the substance per se may be patentable.”[90] According to this statement, the extra requirement to patent this kind of substance is to characterize it by structure, generation process or any other parameter. The requirement of having no previously recognized existence appears as contrary to the definition of prior art, the existence of which does not need to be known, just available to the public irrespective of the knowledge, intention and actual desire of the public to access it. It is not clear whether the natural substance could not be patented if also its structure, generation process or other parameter used to characterize the invention were accessible to the public. Whatever the case may be, a natural occurring nanomaterial can be patented if the description contains a characterization of an unknown and not previously available to the public parameter or property.

In case it is impossible to find a manner to characterize the invention in a way to fulfill the requirement of the EPO, there is still an option to claim protection not over the substance or structure but over a practical use of it. The Manual for Examiners of the EPO establishes that “If a new property of a known material or article is found out, that is mere discovery and unpatentable because a discovery as such has no technical effect and is therefore not an invention within the meaning of Art. 52(1). If, however, that property is put to practical use, then this constitutes an

89 V 0008/94, 1995, cited in Steven Hildebrand, *Patenting of Human Genes in Europe; Prerequisites and Consequences*, Diploma Paper, Zurich, 2001.

90 *Id.*

invention which may be patentable."[91] According to this rule, a nanomaterial or nanostructure can be patented if the unknown property of such material is used in a practical way. As we can see, the problem of the natural occurring structures can also be approached from the patentable subject matter requirements, but in any case, even if the discovery is considered an invention, it needs to pass the novelty requirement. In this regard, the ambiguity one finds in the foregoing position is that the property, even being unknown, should be considered as part of the prior art. If this is the case, and the property was available to the public, the substance or structure as such could be considered non-patentable.

Yet, the EPO considers that not only the new property of the substance can be patented, but even the substance itself [92], in a way that the use of the property constitutes a patentable invention, and also the matter that has such property.[93] From this case one may infer that in order to keep good chances of patentability under the uncertainties that novelty and subject matter requirements may generate, applicants should seek to claim every aspect of the nanotechnological material, including the matter itself, supported by a description of its use and also the use of such matter in a particular function, taking care to disclose the technical effect produced by the invention. Since the requirement to disclose a technical effect needs to be included in the description of the invention but there is no need to incorporate such use or technical effect in the claims, the scope of protection can still cover the material in general and not its particular use.[94] Furthermore, these requirements may change from country to country, and applicants should take into consideration the differences that may exist with regard to the patentability of discoveries.[95]

91 *See, supra* note 46, Part C IV 2.3.1 Discoveries.

92 *Id.*

93 The EPO Guidelines indicate that "To find a previously unrecognized substance occurring in nature is also mere discovery and therefore unpatentable. However, if a substance found in nature can be shown to produce a technical effect, it may be patentable. An example of such a case is that of a substance occurring in nature which is found to have an antibiotic effect. In addition, if a microorganism is discovered to exist in nature and to produce an antibiotic, the microorganism itself may also be patentable as a feature of the invention."

94 Note that the only explicit reference in EPC to the disclosure of the industrial applicability in a particular technology is made in Rule 29(3), The human body and its elements requires that "The industrial application of a sequence of a gene must be disclosed in the patent application".

95 Different approaches may be present in other countries. For example, the US courts established that "A new mineral discovered in the earth" cannot be patented because is not a human made product. This would bar patenting of any material or structure present in nature. US patent law has been criticized because the lack of consideration of non-written foreign disclosures as prior art to asses novelty or obviousness of patent applications. The law establishes that patents are entitled for a person unless, before the filing on an application, "

As we said, the EPO has introduced a modification to the EPC to explicitly allow patentability of subject mater already present in nature in the case of biotechnological inventions.[96] Strictly speaking, this provision doesn't apply to other fields outside of biotechnological inventions. Two interpretations can be given to this rule when applied to other fields. The first one may consider that the patentability of biological material occurring in nature is an exception to the general criteria of non-patentability of natural occurring substances. The second option may contemplate the view that this specific provision was limited to the field of biotechnological inventions because of the need to comply with the EC Directive on Biotechnological Inventions, and that the same principle may be applied to nanotechnological inventions. If there is some difference among the treatment that should be given to nanotechnological inventions compared with biotechnology, this should be based on both, the particularities of the nature of the technology and policy issues that may force lawmakers to provide further protection for this kind of industry. The implementation of particular patent rules in the biotechnology sector, particularly Directive 98/44/EC, allowed Europe to develop its own biotech industry and to compete with other developed countries in the field.[97] At the moment there is no evidence of a request from the nanotechnological industry for strengthening patent protection and no real evidence has been found on the necessity to increase the patentability requirement for inventions related with natural occurring structures.

[…] the invention […] [is] patented or described in a printed publication in […] a foreign country." Consequently, any knowledge that was not disclosed in writing or in a patent is not valid to be used as prior art. This provision impedes invalidating a patent taking into account non-written prior art, which includes materials and substances present in nature. Other example can be found in the law of some Latin-American countries, for example Argentina, where "live matter and substances preexisting in nature, even if had being isolated, purified and characterized, they continue as discoveries and therefore non patentable." These provisions have been criticized as contrary to TRIPS Agreement. For example, on patentability of nature pre-existing structures Strauss says "From the lack of a definition of the concept of invention under TRIPs Agreement it may not be generally concluded that WTO Members, no matter whether developed or developing countries could legitimately follow a definition of invention that broadly excludes material pre-existing in nature from patentability." In this way, Strauss considers that Art 6g of Argentine patent law under which "any kind of life material or substances already existing in nature," does not constitute an invention, cannot be viewed as being in conformity with Art. 27 of the TRIPs Agreement.

96 *See, supra* note 83.

97 European Commission, *European Life sciences and biotechnology: A strategy for Europe*, 2007.

2. Statistical presence and sub-ranges

A further novelty issue related to materials containing nanotechnological inventions is related to the possibility of invalidation of a patent due to the existence in the prior art of materials containing pure accidental, unplanned and small amounts of the substance claimed as the invention. An example illustrating this situation is found in patents for new steel compositions that claim the presence of nanostructures or nanoprecipitates, like grains or carbides of particular size and distribution that confers the material particular and improved properties over the prior art by the modification of mechanisms of deformation and the control of movement of dislocations.[98] Due to the nature of the manufacturing process, these same structures and carbides can be found in some steels produced in the past, not because the producer intentionally looked for this structure, but because it was impossible to avoid the presence of an small amount of such elements. These products are part of the prior art, even if the presence of such phases were unknown to the manufactures or other parties. As we will see, it is still unclear if such information is relevant to attack the novelty of a patent.

The evaluation of each case will depend largely on the way the applicant drafts the claims of the patent application, and in some cases the presence of traces of these phases containing the nanostructure may clearly anticipate the invention. If the claims are drafted to protect any presence of the phase in the steel, from zero to some value, the invention may not be new. Nevertheless, if the claims are limited to a content far from the small amount found in the prior art, the invention should be considered novel. Even so, the presence of the innovative phases in the prior used steels is usually unknown and it is not always clear how to define the limits of the claims scope to keep the claims of the patent away from this kind of prior art. An alternative solution to the applicants would be to avoid product claims and to assure patentability by claiming the process of manufacturing of the new steel. Even when the scope of protection is much more limited, process claims would give the patent owner more certainty on validity issues. In spite of the validity risks mentioned, in some cases prior art with the mentioned characteristics may not constitute an anticipation of the invention. Such is the case if the prior art doesn't provide enough information to the person skilled in the art to reproduce the invention, where the presence of a phase in a previous manufactured steel may not be considered as a disclosure complete enough to replicate the invention.

98 *See,* for example patent EP0826782B1, *High strength and high toughness steel wires and method for making the same*, filed in 1997.

A second point that should be of concern for applicants in the nanotechnology field is the protection of materials by defining particle sizes ranges.[99] If the prior art discloses nanoparticles used as fillers for composites in a range that may overlap with the invention, usually in the range from zero to micrometers, a patent claim intended to protect particles in the range of nanometers could be considered as anticipated by the prior art.[100] For example, patent EP1457509 claims a "Polymeric composition, which contains: a) at least one epoxy resin, b) at least a copolymer also opposite Epoxiden reactive groups and a glass transition temperature Tg of -20 DEG C or less, c) Nano-particles with one by means of neutron small-angle scattering (SANS) of measured average particle size from 5 to 150 Nm." Composite materials made of epoxy resins, a copolymer and reinforcement particles, in the range of micrometers, are well known in the prior art. Usually, patents protecting these concepts disclose particle diameters smaller than micrometers, range that includes nanoparticles even if the invention was originally not intended to cover this kind of reinforcing components. Nonetheless, the referred patent proposes to use particles in the range of 5 to 150 nanometers, features that could make the invention new. EPO has granted the patent, considering that this claim fulfills the novelty and inventive step requirements. The grant was made based on the improved properties obtained by the inclusion of nanoparticles, the criteria usually used in cases of inventions on improvements. Provided that reduction in size of reinforcing particles has been presented in the past as a technique to improve the properties of the matrix, the question arises on how different the result obtained with particles in this range of size should be, compared to microsized particles, to be considered novel.

One possible response to this question can be found in EPO decisions related to "sub-range" inventions. On this matter the TBA indicated that the "selection of a sub-range of numerical values from a broader range is possible when each of the following criteria is satisfied: (i) the selected sub-range should be narrow; (ii) the selected sub-range should be sufficiently far removed from the known range illustrated by means of examples; (iii) the selected area should not provide an arbitrary specimen from the prior art, i.e. not a mere embodiment of the prior description, but another invention (purposive selection)."[101] In claiming sizes in the range of nanometers, the requirements (i) and (ii) seem to be satisfied, as the values are orders of magnitude away from any range in the micro or macro size. The third requirement will be satisfied in case that the properties obtained in the claimed range are far different from what is expected by a person skilled in the art.[102]

99 *See,* Christian Kallinger and Others, *Patenting Nanotechnology: A European Patent Office Perspective*, Nanotechnology Law & Business, Spring 2008, p95-105.

100 *Id.*

101 T 198/84.

102 *See,* EPO Guidelines C-IV 9.8, Novelty: Selection Inventions.

In spite of the aforementioned secondary requirement generated by EPO case law, EPC provisions do not expect improvement of properties as a patentability requirement. The applicant does not need to demonstrate that the invention performs better than relevant prior art, but only to show that the invention is new, non obvious and to provide enough disclosure to allow others to reproduce the invention.[103] If there is no requirement to provide results showing properties of the invention, how can point (iii) of the referred decision can be assessed by the EPO? In this case, the burden of proof may be on the applicant side, and even when there is no requirement to provide such information, she may be obliged to do it to demonstrate patentability over a "sub-range invention". Thus, the applicant may be forced to include examples and to disclose supporting information on this respect that otherwise may be protected by secrecy. Again, we can see that the particularities of nanotechnology requires applicants to take into account practices that would not be needed in other fields, and to disclose information that otherwise would be kept secret, in order to obtain a valid patent.

A further problem identified with inventions that claim a sub-range in size or composition of an equivalent but broader known range, comes from the infringement perspective. The question to answer is whether the user of a nano-technological invention can be considered as an infringer of a prior patent claiming wider ranges; even when at the moment of the filing of the prior patent the nanotechnological invention was unknown and unforeseeable. This issue may have serious consequences for users and manufacturers of nanotechnology, as the universe to check for non-infringement purposes would not only consist of patents in the field of nanotechnological inventions, but also any other kind of patents with scope broad enough to cover a wide range of sizes or compositions. For example, in performing a freedom to operate analysis,[104] third parties would need to take into account patents specifically relevant to the field of the invention and also other patents that even if they were not filed with the intention to cover nanotechnological invention, may cover part or the totality of the technology under assessment. For example, the use of nanoparticles of Silicon Carbide (SiC) as reinforcement in metals may infringe a patent protecting the use of SiC as filler in general —with particles in the range of zero to microsizes— even when the use of these nanoparticles confers exceptional properties to the composite not anticipated by the first applicant. This is an important issue to be taken into account by applicants who many times erroneously confuse patentability with freedom to use. These two

103 *See,* for example T 588/93, Note however, that while improvement or better performance over prior art is not an EPC requirement *per se*, it may provide evidence of inventive step.

104 *Freedom to operate* or *freedom to use* analysis is the common terms used to identify the process of searching and assessing relevant patents in order to verify rights conferred to other patent owners on the technology of interest. The terms *patent clearance* or *non-Infringement* analysis are also used.

concepts are not necessarily related, and patentable technology may still infringe third party patents.

Before evaluating the infringement issue, the case of enforceability of a patent against a product that was not envisaged at the moment of the patent filing will be assessed. Article 83 of EPC requires a patent application to "disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art".[105] This requirement may be a bar for enforcement of a patent against an embodiment unknown at the moment of filing if the disclosure doesn't provide the teaching on how to reproduce such particular embodiment; in this way the patent can be considered invalid to cover such particular feature. In a case that may be applied to this situation, the TBA decided that "[t]he disclosure need not include specific instructions as to how all possible component variants within the functional definition should be obtained."[106] In spite of this, the Board also stated that "[…] any non-availability of some particular variants of a functionally defined component feature of the invention is immaterial to sufficiency as long as there are suitable variants known to the skilled person through the disclosure or common general knowledge, which provides the same effect for the invention."[107] In this way the court affirmed that the invention needs to be disclosed properly, or reproducible by general knowledge by the person skilled in the art, to be enforceable. If the variant —in this case the unforeseeable embodiment— can be reproduced by the common general knowledge of the skilled person in the art, then the patent is valid and enforceable against the nanotechnological invention. However, if the new embodiment was not envisaged and the effect of such new embodiment, in our case the nanotechnological invention, provides a different effect, the patent may not be considered as valid according to article 83 of EPC, mostly if the disclosure doesn't provide enough information to reproduce the invention. As a result, to be enforceable and considered infringed, the description needs to be complete enough to allow the reproduction of the invention and even in cases where the new embodiment was not envisaged, the infringement is possible if the disclosure requirement is satisfied.

In trying to anticipate how a court may construct the scope of the claims of a patent on consideration of an embodiment not foreseeable at the moment of the patent filing, we should refer to decisions in the biotechnology field, where the TBA defined that EPC doesn't requires that "[…] the suggested features in the claims […] may cover an unlimited number of possibilities. It follows that the features may generically embrace the use of unknown or not yet envisaged possibilities, including specific variants which might be provided or invented in the future."[108] Although the

105 EPC, Article 83, Disclosure of the Invention.

106 T 0292/85.

107 *Id.*

108 *Id.*

EPO has no authority to rule on infringement issues, the exclusive responsibility of courts at member states, the decision provides insight on how the issue would be solved at a national level. As an example, in a case related to nanoparticles used as reinforcement in composite materials and in line with the thoughts of the EPO, the District Court of Frankfurt/Main ruled that: “It could be left undecided whether the defendant was right and the amorphous silicon ($SiO2$) used was not known to the average expert at the priority date of the patent in question due to dimensions of its particles within the range of a few (hundred) nanometers. Even fillers unknown at the time of the patent application are within the scope of the patent in question”.[109]

It may be concluded that, in this situation, materials containing previously unknown and unforeseeable characteristics will be probably considered as infringing the referred existing patents, even if such characteristics are considered new and inventive and allowed to be protected by a patent on improvements.

3. Higher degree of purity

In correlation with the higher control of the manufacturing processes, nanotechnology allows the production of materials in a more precise way, in some cases by the production of devices and materials by the manipulation of individual atoms. This permits obtaining materials of higher purity, by controlling the exact composition of what is produced, to give origin to new inventions. While the new manufacturing process can easily fulfill the patentability requirements, the product obtained by that process, the purified material, might lack of novelty. Clarification is necessary to differentiate between cases in which a product with higher purity is in the market and instances where a product, due to description in the written prior art, is the same material with a different content of impurities.

The presence of impurities is usually considered an undesirable effect generated by a technical limitation in the manufacturing processes under use. One must distinguish among impurities and additions of small amount of elements that may indeed cause an effect on the product, like for example the “doping” of silicon to produce solid-state diodes.[110] In some cases, it is the desire of the manufacturer to reduce the content of impurities in order to improve the properties of the material. In other cases, obtaining a material without any impurities may generate new properties

109 *See,* Thorsten Beyerlein, *The Need and Purposes of a “Nanotechnology Act“ in Germany and Europe*, Nanotechnology Law & Business, December 2007, p 545, *supra* note 37.

110 For example patent EP1008157B1 *Thin Film Capacitor Using Diamond-Like Nanocomposite Materials, filed in 1996.*

on the material. These two referred cases, control of impurities and "doping", may bring two different results in assessing patentability.

In principle, it should be noted that if the prior art encourages reducing the level of impurities in order to improve the properties of the material, the absence of impurities might not lead to the generation of a new patentable composition of matter, even if the nanotechnological process under use is new. On the contrary, if the properties obtained by the material free of impurities generate new or radically different effects not disclosed by the prior art, the patentability requirement may be fulfilled.

In a relevant case, the TBA first considered that "a document disclosing a low molecular chemical compound and its manufacture makes available this compound to the public in the sense of Article 54 EPC in all grades of purity as desired by a person skilled in the art."[111] The decision indicates that if a product is in the prior art, with a particular content of impurities, such disclosure anticipates the product with any amount of impurities, including the product free of them. However, in identifying novelty indicators the court said that the product can be considered new "[in those exceptional situations] where it was proved on the balance of probability that all prior attempts to achieve a particular degree of purity by conventional purification processes had failed."[112] By this decision, products of higher purity may be considered new in cases where alternative processes to manufacture the product with such level of purity were unknown, but the burden of proving exceptionality will be on the patentee side.[113] While patentability of a new process capable of manufacturing a known material with a lower level of impurities is not complex to determine, it is not so clear why the EPO considers that the material itself can be patented and not anticipated by the prior art in cases where no additional or disruptive properties are generated.

Alternatively, the case of patentability of high purity materials should be approached from the "unexpected results" view, a concept that has been applied in the past to solve complex patentability issues in the fields of organic and polymer chemistry.[114] Based on this criterion, in assessing novelty of the invention the EPO should evaluate the new properties generated by the absence of impurities in the material and compare those properties with the solution they solve. If such

111 T 0990/96.

112 *Id.*

113 *Id.*

114 US Courts have approached the problem from a different perspective, indicating that a non-purified material doesn't anticipate its pure form. For example, In re Kratz, 592 F.2d 1169, 1174 (CCPA 1979) the court said "stating that a naturally occurring strawberry constituent compound does not anticipate claims to the substantially pure compound", or In re Bergstrom, 57 C.C.P.A. 1240, 427 F.2d 1394, 1401-02 (CCPA 1970) stating that "a material occurring in nature in less pure form does not anticipate claims to the pure material".

properties help to solve a different problem apart from what is disclosed or promoted by the prior art, the invention should be in a better position to be considered new and patentable.

4. The inherent properties

An invention may be anticipated not only by its explicit characteristics but also by the intrinsic or inherent particularities disclosed in the prior art. This premise has been applied in many cases at the EPO.[115]

One of the most relevant cases for the problem of inherent properties is the Mobil Oil III case.[116] Here, the TBA analyzed the relevance in assessing novelty of a prior publication disclosing the use of a compound for a defined purpose (lubricant) on a patent protecting a new use of such compound, where the compound is performing a new purpose (anticorrosive).[117] The court faced the question if the use of the substance inherently anticipated the use as a lubricant.[118] The court ruled that "[…] such new use may reflect a newly discovered technical effect described in the patent. The attaining of such a technical effect should then be considered as a functional technical feature of the claim. If that technical feature has not been previously made available to the public by any of the means as set out in Article 54(2) EPC, then the claimed invention is novel, even though such technical effect may have inherently taken place in the course of carrying out what has previously been made available to the public."[119]

According to this decision, to invalidate a patent based on the presence of inherent properties, the plaintiff needs not only to demonstrate the existence of such inherent property, but also to prove the "availability to the public" of it, according to the definition of Article 54(2) of EPC. In order to be novelty destroying, the prior art must provide a clear, unambiguous and enabling disclosure of the inherent properties.[120] In this way, an inherent feature is considered made available to the public if the feature per se has become part of the state of the art or can be derived by a person skilled in the art.[121] Nevertheless, this is not usually the case with

115 *See,* for example, T 059/87.

116 G 02/88.

117 *Id.*

118 *Id.*

119 *Id.*

120 T 179/01

121 Caroline Pallard, Nederlandsch Octrooibureau, *Novelty of biotechnological inventions and further therapeutic use in Europe*, IP in the life sciences industries 2008, IAM Magazine, 2008, p 35-36.

nanotechnological inventions, as inherent properties present in materials belonging to the state of the art may not be used to attack novelty of new uses of such materials, provided that both, the new use involves a new technical purpose and the inherent property was not available to the public.

Another important aspect of the *Mobil III* decision, upon the question whether the modification of the claims of a patent during an opposition from a product type to a claim of a particular use of such product —action intended to avoid invalidity of the patent when anticipated by inherent properties in the prior art— the TBA defined that "An amendment of a European patent during opposition proceedings simply by way of change of category from a claim to a physical entity per se (e.g. a compound or composition), so as to include a claim to a physical activity involving the use of such physical entity, therefore does not extend the protection conferred by the patent, and is admissible."[122] In this way, in opposition proceedings or during the prosecution of the patent, the strategy of modifying the scope of the claims from a *product* type to a *use* type may be a good alternative to avoid the prior art and get protection for the nanotechnological invention.

As we can see, anticipation of inherent properties is not considered a bar for patentability in all cases. The discovery of new properties even when they were inherently present in the prior art, can provide the basis for patentability, as a second use, of the known material.[123]

The issue may be particularly relevant in assessing patentability of materials with functionalities in the electronic or optical field. Even when some of these materials may be already patented, the understanding, control and manipulation of structures and fillers at nanometer level can give a new world of possibilities to the field. Although these properties where present in those materials from the very beginning, it is now the understanding and control of the relationship among the properties and the matter what generates the new technological development. Nevertheless, patenting a material for a second time because it is possible now to describe the mechanism making those properties possible may not be allowed as those characteristics were implicitly or inherently present in the material since it was used for the first time. Again, the success of the applicant in getting protection on the invention will depend on her ability to draft a claim limited to the new use, the manufacturing process or the method to control such properties.[124]

122 *Id.*

123 *Id*

124 Note the similarities that US case law has with the EPO decisions. The Federal Circuit, in the case Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 631 (Fed.Cir.1987), considered that "A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim". In other example, case Cf., Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373, 1379 (Fed. Cir. 2003), the court indicated "Upon proof that the missing description is inherent in the prior art, that single

IV. Inventive Step

EPC requires an invention to involve an inventive step compared to the state of the prior art to be patentable.[125] The EPO usually uses the "problem-solution" approach to assess patentability over the inventive step requirement. The "problem-solution" approach consists, in the following order, of the identification of the closest prior art to the invention, the evaluation of the technical result obtained by the invention when compared to the prior art, the definition of the technical problem to be solved as indicated in the patent document, and the analysis of the likelihood of a person skilled in the art, taking into account the prior art, to suggest the invention to solve such technical problem.[126]

In the field of nanomaterials we can identify at least two situations of complexity in assessing inventive step requirements. The first one is related to the miniaturization of structures. Miniaturization is the reproduction of a known device, machine, material or any other physical structure in reduced size; in nanotechnology this size is in the order of nanometers. Similarly to the nanotechnology field, other technologies have experienced a process of miniaturization, for example, the electronics industry in the reduction of integrated circuits. Depending on the nature and characteristics of the invention, the new development can be patented or not.

Miniaturization of the structure of a known material may raise the question whether the invention is obvious when compared to the prior art. In fields outside of nanotechnology it is accepted that miniaturization generally does not allow an invention to pass non-obviousness requirement when compared to a prior known structure or device. For example, reducing the grain size of a metallic microstructure may not be considered as involving an inventive step, as it is known in the field that reducing the size increase resistance and toughness of the material and the prior art suggests following those steps in order to get better properties. At most, what may be seen as an inventive step is the process to reach such grain size, which may not be disclosed by the prior art. On the contrary, when metallic glasses appeared, a kind of

prior art reference placed the claimed subject matter in the public domain". In this way, also in the US the patent owners may face uncertainty regarding novelty of inventions that could be inherently anticipated by the prior art. For other commonly referred cases of inherence see In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977), Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) or Schering Corp. v. Geneva Pharm., 68 USP2d 1760 (CAFC 2003).

125 EPC, Article 56, Inventive Step.

126 European Patent Office, *Case Law of the Boards of Appeal of the European Patent Office*, EPO, 2006.

metallic microstructure characterized by the absence of an organized crystalline structure, they where considered non obvious and patented in view of the prior known metallic microstructures.[127]

Similarly to the aforementioned case, patentability can be assured by showing new properties not present in the prior art.[128] Following this condition, it can be said that patentability of nanotechnological inventions involving the reduction in size of structures is assured when the properties of the material are new, improved or unexpected for the person skilled in the art, provided that these properties are not suggested by the prior art.[129] In assessing inventive step and particularly suggestion in the prior art, case law of the TBA established that it is important to determine "whether a skilled person would have prepared [the invention] with a reasonable expectation that they would successfully solve the technical problem under consideration."[130]

Under this decision, the court said that the "problem-solution" approach requires the invention to be unexpected by the person skilled in the art to solve the technical problem as described in the patent. Therefore, in those inventions where miniaturization allows the material to have different properties, unexpected from the prior art, and those unique properties are used to solve an unknown or known technical problem, the invention is considered in accordance to the inventive step requirement. On the contrary, if the miniaturization to the nanoscale doesn't generate any distinctive property, which cannot be expected from the prior art, the invention will be considered obvious. Thus, two issues need to be considered: whether the prior art suggested the change of properties for miniaturized structures and whether the miniaturization was suggested as a trend to solve the technical problem under evaluation. This train of thought can be seen in a second important decision of the TBA.[131] In this case, the Board clarified that if "miniaturization was something like a trend in the field", and if "a skilled person was thus incited to "pack" known methods into smaller devices", the invention is not patentable under Article 56.[132]

Another example related to a radical change in properties when a structure is miniaturized to the nanometer level may be represented by singe-wall carbon nanotubes. These, when made in a specific configuration, perform like metals and

127 *See*, for example patent GB 1447267, *Amorphous Metal Alloy*, filed in 1973.

128 Nicola Dagg, *The Eurpean Perspective and Regulatory Concerns of the Nanotechnology Movements*, available at http://www.aipla.org/Content/ContentGroups/Speaker_Papers/Spring_Meeting/20045/dagg_nicola.pdf, (last visited May, 2009).

129 *Id.*

130 T 0116/90.

131 T 0070/99.

132 *Id.*

not as semiconductors in terms of electrical conductivity. This property is unexpected for carbon, a material that was not used in the past as an electricity conductor material. Consequently, this characteristic of carbon nanotubes allow them to have an electrical conductivity much higher than normal copper or gold, shifting the material from semiconductor to metallic conduction properties, allowing them to be perfect replacements of electrical connectors in microchips and integrated circuits.[133] Notwithstanding that the exact set of claims is needed to make a more precise assessment of the patentability of the invention, we can predict that patentability would be assured for the use of nanotubes as electrical connectors provided that the prior art doesn't make available the teaching on the use of carbon as electrical conduits, and that the conductivity of the nanotubes is far different from that observed in normal carbon.[134] Other inventions where reduction in size generates different and unexpected properties are composite materials filed with nanoparticles in order to control permeability properties. In absence of prior art indicating a trend in manipulating particles to control permeability at a nanoscale, the skilled person in the art cannot extrapolate the teaching provided by the prior art to the new nanoscale conditions.

Some questions still remain unsolved. How different need the property be with respect of the prior art to make the invention non-obvious? Need it be qualitatively or only quantitatively different from the one observed in the known material? May a difference in 20% of the evaluated property be enough to consider the invention inventive and non-obvious? Until now, the tool used to answer these questions is the "problem-solution" approach, for which we need to define the technical problem that the new developed material is able to solve and to evaluate if such material and property, as a solution for the problem, was already suggested by the prior art. In using this approach, one of the key factors is how the courts will define the person skilled in the art, and the level of inventiveness that will be given to her. Depending on this construction the answers to the questions above will be different. There is no uniform criterion developed yet for all technologies to define this person in all technology fields, as is already quite uniformly defined in other complex areas like biotechnology. This brings uncertainty to validity of nanotechnology related patents, which cannot be fully overcome at the moment. Only a careful strategy followed by applicants can reduce the risk of invalidation by the reach of a good balance among

133 *See,* for example patent US 7,338,915, "Ropes of single-wall carbon nanotubes and compositions thereof", granted in 2008.

134 For an example of modified carbon nanotubes used as conductors in electronic circuits, see patent application EP1575102A1, "Electrical conductor based on proton conducting carbon nanotubes", filed in 2004.

disclosure and full coverage of all allowed type of claims directed to protect all the different aspects of the invention.[135]

In addition to this strategy, to be on the safe side, applicants may decide to claim the invention in a more limited way, including not only product claims in the patent application but also further embodiments, for example, the specific uses and the manufacturing process of the material subject of the invention. Nevertheless, because of the high potential value of patents in nanotechnology, other applicants will decide to take the risk and claim their inventions in the broadest and most general way that is possible. Pure product claims or functional claims may be chosen instead of the more limited version of process claims.

135 In assessing obviousness of miniaturized structures, a similar approach is followed in the US. The United States Patent and Trademark Office (USPTO) has identified several cases that may play a role in the assessment of patentability in nanotechnological inventions, (*see*, Bruce Kiusliuk, Nanotechnology-related issues at the USPTO, USPTO, 2006). Also here, there is no doubt that mere miniaturization of something known is not patentable, provided that such miniaturization doesn't provide any new or unexpected result not proposed by the prior art. For example, case law recognized that "it is well established that the mere change of the relative size of the co-acting members of a known combination will not endow an otherwise unpatentable combination with patentability" (47 C.C.P.A. 795, 274 F.2d 944, 124 U.S.P.Q. 502 (1960)). In line with this decision, other relevant case established that, "dimensional limitations did not specify a device which performed and operated any differently from the prior art" (725 F.2d 1338, 220 U.S.P.Q. 777 (1984)). Even when these cases are not related to nanotechnology, the concepts developed in chemistry, mechanical devices and electronic can be extrapolated to a more recently technology. Because the generation of new or improved properties in materials and the control and manipulation of those properties to adapt them to specific uses characterize nanotechnology, the inventions may not be considered obvious under Section 103, because a difference in size is not the only distinction with the prior art.

V. Industrial Applicability

Industrial applicability of the invention is a further requisite included in EPC to grant a patent.[136] According to this requirement, "an invention shall be considered susceptible of industrial application if it can be made or used in any kind of industry […]".[137] A first evaluation shows that, due to the flexible criteria in the application of the condition by the EPO, the requirement should be one of the easiest to comply with for a nanotechnological invention. However we will see that because of the same difficulties we found in differentiating among scientific discoveries and inventions in the field of nanomaterials and nanostructures, the requirement may be an obstacle to patent the technology at an early stage of development.

To avoid confusion, a differentiation needs to be made between the requirement of a technology to have a technical character in order to be considered an invention and the industrial applicability requirement.[138] Whereas the first condition is defined in article 52 of the EPC and requires the subject matter to have technicality, i.e. a technical character, the industrial applicability requirement, defined in article 57 of EPC, require the invention to be susceptible of industrial application in the sense of being useful for some purpose and subject of a potential commercial gain from the exploitation of such invention.[139] In this way, the words *technical* and *industrial* should not be constructed as synonymous for a patentability analysis, under which an invention may have a technical character but lack industrial applicability.[140] The industrial applicability requirement has been cited by the TBA as a condition related, in cases where the complexity of the invention is high and the practical use can not be considered as implicitly disclosed, to the disclosure requirement.[141] For this reason, it has been indicated that the disclosure requirement may be higher for nanotechnological inventions when compared to other technical fields, including the need to make explicit the industrial applicability of the invention, a practice that does not apply, for example, to inventions in the mechanical field. In other complex technical fields the TBA confirmed the general need to disclose the use of the technology in order to comply with the requirement and at the same time clarified that the mere indication that a product can be produced doesn't necessarily mean

136 EPC, Article 57, Industrial Application.

137 *Id.*

138 T 953/94.

139 *Id.*

140 *Id.*

141 T 718/96.

that the industrial applicability is fulfilled, and stressed the need of disclosure of a profitable use for which the product can be exploited.[142]

The practice at the EPC in connection with the industrial applicability requirement forces the disclosure of one possible application, in any industrial field, to fulfill the requirement. Thus, the disclosure of one example of how the invention can be used at industrial level with useful results is enough to get a valid patent, even if other uses where known by the applicant but not disclosed. Notwithstanding that the applicant needs to identify only or at least one use for the invention, the patent will provide protection for the product itself independently of the disclosed use of such product and a third party may infringe the patent if she makes any use of the invention, in most of cases even if the use was not described or foreseeable by the patent owner. The way in which this requirement is applied to nanotechnology may have a big impact on the patenting strategies followed by applicants (mostly for scientists working in research in basic science). For these kinds of inventions, the requirement of industrial applicability may be even higher than for other nanotechnological inventions, and the applicant may be obliged to develop a detailed and extensive description of one of the uses if the invention presents properties not previously shown by other products. Failing to disclose the use may cause the invention not to fulfill the requirements of industrial applicability and disclosure, a disclosure that needs to be more than pure speculation but supported by real experimentation and tangible results.[143] These testing results that may be necessary to demonstrate the industrial applicability of the invention are usually available only in later stages of the development. This may force the delay in the filing of the patent application thus putting at risk the possibility to generate an early priority and the consequent anticipation of the invention by third parties. While from the applicant perspective such strict applicability of the requirement generates risks for the early patenting of the technology, in the nanotechnological field this may also impact on the rate at which patents for nanotechnological inventions are filed.[144] If this is true, patents would be filed only after the development of a concrete use of

142 T 870/04.

143 T 541/96.

144 Note that particular provisions on the disclosure of industrial applicability have been developed in other fields of technology. An example of this is Rule 29 of EPC “The human body and its elements“, according to which the industrial application of a sequence of gene must be disclosed in the patent application. The requirement doesn’t request to limit the patent claims to the use of such gene, but only to disclose in the description one possible use. This mandatory requirement for specific inventions in the biotechnological field has not correlation in other fields of technology. The concern on the patenting of nanotechnological inventions at an early stage of development and the coverage of broad zones of basic technology may be an indication of the need of development of specific requirements also in the field of nanotechnology.

the invention, and early patenting of general basic knowledge would be more if the applicant has not yet developed a practical industrial use of the invention.

While the industrial applicability requirement has been referred to as an historical evolution of the early patent systems designed to protect objects of manufacture, there is still a disconnection between the requirement and the scope of protection granted by patents.

It was noted that the owner of a patent, for which the claims are directed to the product, is able to stop others from commercializing such product during the patent life. Once the patent is lapsed the product is in the public domain and anybody can make use of the invention. Nevertheless, after the patent expiration there is no guaranty that all uses of the product are free to be exploited or in the public domain. This is because other applicants, or the same patent owner, may file a further patent application to obtain protection of specific new and inventive uses of such product, even when the first patentee already got protection for all possible uses of such product. In this way, some overlapping exists among the first exclusivity right granted for the product and any use of it and the second one granted for one specific use, already included in the universe of protection of the original product patent.

If the patent system requires the applicant to disclose the use and application of industrial level of the product, why is the patent is granted to the product in general and not only to the use or uses disclosed in the patent document? The scope of protection —general use of the product— is wider than the invention developed by the inventor —limited number of uses—and the scope of the exclusivity right goes further to what is requested by the applicant. In the same way as there is no limit for the inventor to include all the developed and foreseeable uses of the technology in the patent claims, protection should be granted only to those uses described in the patent.

Some commentators may argue that a change in the scope of patents, from product to use claims, may be considered as detrimental for the incentives to invent. From this perspective, it should be noted that the inventor or the company financing the development of the invention, make the economical assessment on the convenience of investing and the possibility of recovering on such invention based only on the uses they foresee for the technology during the development of the invention. Any other use that is found in the future extends the value of the patent further from the value the company assigned at the moment of deciding on the investment. In this way, the incentive on research and development on new inventions would not be jeopardized if the scope of the patent is limited to the uses the patentee discloses in order to pass the industrial applicability requirement. In the extreme, since the inventor can get a patent to cover all the uses she developed for the invention and there seems to be no detrimental effects on the incentive for her to invent, there is no need for product patents and only patents covering the use of a product should be granted. Even though this approach may be reasonable to support the idea of limiting the scope of patents in the nanotechnological field, the incentive to innovate is only one of the arguments behind the theory of the patent system. Under other theories this limitation on the scope of patents may have a different impact and would need to be assessed.

VI. Conclusions

Patenting nanotechnological inventions under the EPC may represent some particularities not existing in other fields. This distinctiveness is based on the complex and multidisciplinary nature of the technology, its creation process intimately related to the development of scientific principles and the application of patent law provisions that were developed to deal with more simple inventions.

This Thesis has attempted to cover a list of issues identified as significant for the application of the EPC provisions to nanotechnology and nanoscience. Due to the newness of the field and the absence of a critical mass of cases dealing specifically with nanotechnology, this approach has been made by the analysis of EPO decisions on the application of patentability requirements in other complex technological fields such as biotechnology and chemistry. In implementing the reasoning used in such cases similarities in the challenges faced when patent law was applied in those fields and the problems of today with nanotechnology were identified. In most of the situations, from problems related to patentable subject matter to novelty and inventive step requirements, corresponding cases in other fields assisted in clarifying the uncertainties generated by nanotechnological innovations. No particular problems were found in connection with the need to develop extra pieces of law, and almost all the issues covered by the analysis were answered with existing patent provisions and jurisprudence.

Most complexities related to patenting of nanotechnological inventions are susceptible to be solved by a good, precise and careful drafting of the set of patent claims and the invention description. This practice allows not only to work out problems related to rejections based on subject matter eligible to be patented or to pass the disclosure requirement, but also to avoid later invalidations based on inherence or unknown prior art.

Even so, some problems have been identified in two specific topics. The first area is related to the exclusion from patentability of some basic knowledge developed during the research process. In this regard we found that patenting nanotechnological inventions at an early stage of development could be difficult in terms of fulfilling requirements related to disclosure and industrial applicability. The second area is related to the scope of rights granted by a patent. It was shown that limiting the scope of patents protecting nanotechnological inventions to the specific use or uses described in the specification may improve the correspondence between the scope of the invention and the scope of rights granted by the patent. From this it was concluded that this would contribute to development of a more certain scenario for users of nanotechnological inventions and for patent right owners in terms of enforceability and freedom to use.

List of Works Cited

Books, Journal Articles and Statutes (In Order of Appearance)

Jeremy J. Ramsden, *What is nanotechnology?*, Nanotechnology Perceptions 1, p3–17, 2005.

Allhoff, Fritz, Nanotechnology & Society: Current and Emerging Ethical Issues, Lin, Patrick, 2008.

Principles for Nanotech Oversight, ICTA, AFL-CIO, FoE, IUF, ETC Group, Third World Network, Loka Institute, July 2007.

Dan L. Burk and **Mark A. Lemley**, *Is Patent Law Technology-Specific?*, UC Berkeley Public Law Research Paper No. 106; and Minnesota Public Law Research Paper No. 02-14, 2002.

Convention on the Grant of European Patents (European Patent Convention), 13th Edition, 2007.

Jane Calvert and **Ben R. Martin**, Changing Conceptions of Basic Research? Science and Technology Policy Research, University of Sussex, 2001.

Hans Poser, *On Structural Differences Between Science and Engineering*, PHIL & TECH 4:2, 1998.

D. R. Basset, *Nanoscience and Nanotechnology: an Overview*, Center for Workforce Development, University of Washington, 2006.

G. Binasch, **P. Grünberg**, **F. Saurenbach**, and **W. Zinn**, *Enhanced Magnetoresistance in Layered Magnetic Structures with Antiferromagnetic Interlayer Exchange*, Phys. Rev. B 39, 4828, 1989.

T. Yoshida et al., *Magnetoresistance effect of InAs deep quantum well structures grown on GaAs substrates by molecular beam epitaxy*, 1997 International Conference on Solid-state Sensors and Actuators, Chicago, June 16-79, 1997.

Regulation (EC) No 726/2004.

M. Correa, The International Dimension of the Research Exception, AAAS, 2005.

Dr. Bernhard Hertel Bernhard, Class lecture, Max Planck Innovation GmbH, Course Science, IP & Start Ups, Munich Intellectual Property Law Center, Munich, Germany, at MIPLC, Germany, April, 2008.Bayh-Dole Act, 35 U.S.C. § 200-212.

Mowery, David C., **Nelson, Richard R**., **Sampat, Bhaven N**. and **Ziedonis, Arvids** A., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, Research Policy, Vol. 30, pp. 99-119, 2001.

Wagner, R. Polk, *Of Patents and Path Dependency: A Comment on Burk and Lemley*, Berkeley Technology Law Journal, Vol. 18, p. 1341, 2004.

Commission de l'Ethique de la Science et de la Technologie, Ethic, Risk and Nanotechnology: Responsible Approaches to Dealing with Risk, 2008.

David M. Berube, *Intuitive Toxicology: The Public Perception of Nanoscience, Nanotechnology and Society: Current and Emerging Ethical Issues*, F. Alloff, P. Lin, 2008.

ETC, Principles for the Oversight of Nanotechnologies and Nanomaterials, 2008.

Guidelines for Examination in the European Patent Office, European Patent Office, December 2007.

F. Scott Kieff, *IP Transactions: On the Theory & Practice of Commercializing Innovation*, Stanford Law and Economics Olin Working Paper No. 311, October 2005.

F. Scott Kieff and **Troy A. Paredes**, *Engineering a Deal: Toward a Private Ordering Solution to the Anticommons Problem*, Stanford Law and Economics Olin Working Paper No. 330, November 2006.

James Bessen, *Patent Thickets: Strategic Patenting of Complex Technologies*, Boston University School of Law, March 2003.

F. Scott Kieff, *On Coordinating Transactions in Information: A Response to Smith's Delineating Entitlements in Information*, 117 YALE L.J. POCKET PART 101, 2007.

Mark Lemley, *Patenting Nanotechnology*, Stanford Law School, John M. Olin Program in Law and Economics Working Paper No. 304, June 2005.

Joseph Straus, *Biotechnology and patents*, 54 CHIMIA, No. 5, 293-298, 2000.

ETC Group, *Nanotech's Second Nature Patents: Implications for the Global South*, Special Report N0. 87, 2005.

Communication from the Commission, Towards and European strategy for nanotechnology, European Communities, 2004.

Oscar M. Dunens et al., *Inconsistencies in the Carbon Nanotube Patent Space: A Scientific Perspective*, Nanotechnology Law & Business, p25-40, Spring 2008.

K. D. Raju, *The Debacle of Novartis Patent Case in India: Strict Interpretation of Patentability Criteria Under Article 27 of the Trips Agreement*, November 2007.

Directive 98/44/EC.

Steven Hildebrand, *Patenting of Human Genes in Europe; Prerequisites and Consequences*, Diploma Paper, Zurich, 2001.

Christian Kallinger and others, *Patenting Nanotechnology: A European Patent Office Perspective*, Nanotechnology Law & Business, p95-105, Spring 2008.

Thorsten Beyerlein, *The Need and Purposes of a "Nanotechnology Act" in Germany and Europe*, Nanotechnology Law & Business, p 545, December 2007.

Caroline Pallard, Nederlandsch Octrooibureau, *Novelty of biotechnological inventions and further therapeutic use in Europe*, IP in the life sciences industries 2008, IAM Magazine, p 35-36, 2008.

Case Law of the Boards of Appeal of the European Patent Office, European Patent Office, 2006.

Nicola Dagg, The Eurpean Perspective and Regulatory Concerns of the Nanotechnology Movements, 2004.

Court Decisions (In Order of Appearance)

V 0008/94 "HOWARD" (OJ EPO, 1994 388).

T 0619/02 "Odour selection/QUEST INTERNATIONAL" (OJ EPO 2006).

T 0870/04 "BDP1 Phosphatase/MAX-PLANCK" (OJ EPO 2005).

G 0002/88 "Mobil Oil III" (OJ EPO,1990 093).

In re Cortright, 165 F.3d 1353 (Fed. Cir. 1999).

T 0356/93 "PLANT GENETIC SYSTEMS" (OJ EPO, 1995 545).

T 767/95 "Interleukin 1/IMMUNEX CORPORATION" (OJ EPO 2000).

T 444/88 "Japan Styrene Paper" (EPO CLBA 1996).

T 198/84 "Hoechst" (OJ EPO ,1985 209).

T 0292/85 "Genentech" (OJ EPO, 1989 275).

T 0990/96 "Erythro-compounds/NOVARTIS" (OJ EPO 1998).

In re Kratz, 592 F.2d 1169, 1174 (CCPA 1979).

In re Bergstrom, 57 C.C.P.A. 1240, 427 F.2d 1394, 1401-02

T 0218/02 "Sputter coated glass article/GUARDIAN" (OJ EPO 2006).

Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 631 (Fed.Cir.1987).

Cf., Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373, 1379 (Fed. Cir. 2003).

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

Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

Schering Corp. v. Geneva Pharm., 68 USP2d 1760 (CAFC 2003).

T 0116/90 "Beecham-Wuelfing" (EPO CLBA 1996).

T 0070/99 "Analytical devices/UNIVERSITY OF PENNSYLVANIA" (OJ EPO 2003).

47 C.C.P.A. 795, 274 F.2d 944, 124 U.S.P.Q. 502 (1960).

725 F.2d 1338, 220 U.S.P.Q. 777 (1984).

T 953/94 "functional analysis/BREDFORD" (OJ EPO 1996).

T 179/01 "Herbicide resistant plants, MONSANTO" (OJ EPO 2005).

T 718/96 "Safety Cap System" (OJ EPO 1998).