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Nanotechnology patents in Europe and the methods for treatment and diagnostic exception to patentability[1]

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1. Introduction

Nanotechnology has the potential to profoundly change our standard of living and world economy. Its impact is expected to be deeper than the impact information technology has had over individual and collective lives over the past decades.[2] Worldwide there is a widespread belief among the political and scientific communities that the nanotechnology industrial wave will bring changes to the world development and economic power status quo, as these technologies are expected to grant competitive advantage to the economies that first master them. In this sense, the EU Commission has expressed concerns of losing competitiveness should it fail to keep pace with other economies in the development of nanotechnology. [3]

There is also the perception that direct investment in Nanoscience research is not enough and special attention need to be drawn to intellectual property (IP) rights and especially patent law, as it will play a central role in the outcome of general policies directed towards promoting innovation and technological based economic growth. In this context the patent system is understood as a tool to promote not only innovation and scientific research, but also technology transfer from research entities to industry.[4] However, it can be debated if in practice the current European patent framework is in fact promoting innovation to the full extent of its possibilities. This article focuses on the specific example of nanotechnology inventions and the methods for treatment and diagnosis exception to patentability.

2. Nanotechnology

Nanoscience advances can lead to progress in virtually all technological sectors, and for this reason this scientific field is often characterized as being an *horizontal, key* or *enabling* science. Nanotechnology is also described as a converging technology in the sense that it brings together different areas of science, thus the term is often referred to

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[1] This article is based on the author's thesis '*Nanotechnology Patents in Europe: Exclusions and Exceptions to Patentability'*, written as part of the Master's Programme in European Intellectual Property Law, Stockholm University, 2009. The Author wishes to express her gratitude to Åsa Hellstadius, doctoral candidate at Stockholm University for proofreading this article and for her comments and advice.

[2] Hullman, A. *The economic development of nanotechnology – An indicators based analysis, 2006,* European Commission Unit: Nano S&T – Convergent Science and Technologies. Available at: http://cordis.europa.eu/nanotechnology (November 2009).

[3] See Communication from the Commission to the Council, The European Parliament and The Economic and Social Committee, '*Nanosciences and nanotechnologies: An action plan for Europe 2005-2009'*, Brussels, 7.6.2005 (COM (2005) 243 final).

[4] '*Nanosciences and nanotechnologies: An action plan for Europe 2005-2009'*, Brussels, 7.6.2005 (COM(2005) 243 final).

as an umbrella designation encompassing a vast range of technologies that manipulate matter at nanoscale which means building structures and new materials at an atomic, molecular and macromolecular scale. Any definition of nanotechnology must necessarily be used with caution, being an emerging technological area at the present moment the exact meaning of the term 'nanotechnology' is still subject to intense debate among the scientific community, starting with questioning whether the term should or not be used in the plural form.[5] For the purposes of this article the following definition, issued by the European Patent Office will be used:

> '*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.*'[6]

3. Nano-medicine and the Methods for treatment and diagnostic exception

Nano-medicine research has shown very promising results and an enormous potential to provide solutions in the nearby future to humanise health-care, increase the quality of life, and promote full integration in society of people suffering from long term or incurable medical conditions. The convergence of nanotechnology with biotechnology, biomedicine, and information and communication technologies is expected to lead to great advances in prosthetics, organ replacement and reconstruction surgery, in addition advances provided by nanotechnology will also significantly improve the ability to detect and diagnose disease by introducing small, highly sensitive, inexpensive devices for the manipulation and analysis of cells. Novel nanomaterials and surface modification methods have improved existing techniques that enable scientists to observe and analyse intracellular operations in real time. Such improvement in the study of cellular functions is helping researchers to detect and study diseases at a very early stage, and will prove instrumental to find suitable cures.

Examples of advanced applications of nanotechnology include the use of quantum dots for imaging (visualize alterations in human organs or tissue); the use of carbon nanotube based glucose sensors to monitor diabetes and other diseases, since they change infrared fluorescence according to the glucose level; miniaturised subcutaneous chips continuously monitoring key body parameters including pulse, temperature and blood glucose that could be implanted in patients or even healthy persons in order to achieve early diagnosis; and implantable sensors that can also interface with nanodevices that administer treatments automatically if needed, e.g. drug dispense systems.[7]

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[5] Seear, K, Prof. Petersen, A. and Bowman, D. '*The Social and Economic Impacts of Nanotechnologies:A Literature Review'*, Final Report Prepared for the Department of Innovation, Industry, Science and Research, February 2009, Monash University Victoria, Australia. The authors of this study have identified eighteen substantially different definitions of nanotechnology in relevant sources.

[6] In http://www.epo.org/topics/issues/nanotechnology.html (February 2010).

[7] Nanomedicine Report 2009, chapter 2, available at http://www.observatory-nano.eu/project/ (February 2010).

Nanoparticle delivery systems or nano carriers have many advantages over traditional active agents n particular in the treatment and diagnosis of medical conditions such as cancer, diabetes and HIV/AIDS.

Many of the technologies being developed in the present blur the line between non-patentable methods for treatment and diagnostic methods practiced on the human body on one side and patentable products (substances or compositions) and apparatus used in such activities on the other. Some of these important developments in diagnostics and treatment operate totally *in vitro,* others entirely *in vivo,* some have a combination of phases *in vitro and in vivo,* posing patentability questions concerning the patentability exception for methods for treatment and diagnostic that require careful consideration.

3.1 Nature and ratio of the Exception

Currently, the European Patent Convention (EPC) in its Article 53(c) establishes that:

> *'European patents shall not be granted in respect of: […]methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.'.*[8]

However the exception to patentability of methods for treatment and diagnostic pre-dates the EPC, in fact similar rules existed in a large number of European national jurisdictions even if under general clauses and/or by means of the practice of national patent offices and jurisdictional interpretation.[9] Despite its long existence the ratio of the prohibition has never been consensual as there are several divergent currents of opinion concerning the subject, namely that the prohibition is based on either: (1) general clauses of 'ordre public' and morality; (2) lack of industrial application; (3) lack of an invention in the sense of a technical solution to a technical problem; (4) public interest consubstantiate in public health considerations and the deontological nature of the doctor-patient relation; (5) nature of the medical profession in itself that is exempted from commercial rules such as economic and competition considerations, since the diagnostic and therapeutic freedom should not be hampered by the commercial considerations that are subjacent to IP rights protected subject-matter.[10] In the 1973 EPC the rule was inserted in Article 52 (4), a legal provision devoted to subject-matter that could not be considered as an invention and therefore impossible to patent. The Conference of Munich of 1973, that approved the EPC, adopted the writing proposed by the German delegation based on the opinion of the BGH that considered such methods unsusceptible of industrial application since the medical profession by nature is not a commercial or industrial

[8] Article 53 (c) European Patent Convention (2000).

[9] The subject was debated in particular within jurisdictions with an Anglo-Saxon legal tradition. For a cross-jurisdition comparative history of the prohibition see Marques, J.P Remédio '*A patentabilidade dos métodos de diagnóstico, terapêuticos e cirúrgicos: Questão (bio)ética ou questão técnica? - O actual estado do problema*' in Estudos de Direito da Bioética, vol. II, Almedina, Coimbra, 2008.

[10] Marques, J.P Remédio *op. cit.*.

activity[11] since under German doctrine and jurisprudence such activities are perceived as having as primary goal the profit while the medical professional sole purpose and objective is to serve the public interest (to cure the patient).[12]

This reference to a by default *fictio juris* of lack of industrial application present in the EPC 1973 version meant that such subject–matter had to be considered an invention, but on the other hand the title and body of the Article referred to subject-matter that could not be considered an invention and for that reason non-patentable. This systematization problem raised objections and difficulties of interpretation of the nature of the patentability prohibition. In the EPC 2000 revision this rule was moved to Article 53 (c) and the reference to lack of industrial application deleted. The preparatory documents acknowledge both that the previous exclusion was an artificial legal construction and that these methods should be considered inventions. It is mentioned that the ratio for the prohibition lays in the interest of public health a category pertinent to the general 'ordre public' exemption. In addition, the need to obtain correspondence between the EPC and Article 27 (3) (a) of the TRIPS Agreement is also recognized as a motivation.[13]

3.2 The legal regime of the exception

The scope of the exception does not include all medical methods for treatment, but merely (1) methods of treatment by therapy or surgery and (2) diagnostic methods that are (3) practiced on the human or animal body. Substances or compositions are expressly excluded from the prohibition.[14] Apparatus claims are excluded by nature[15] thus patents may be granted for surgical, therapeutic or diagnostic instruments or any apparatus for use in methods for such.[16]

Therapeutic methods applied to plants, deceased human or animal bodies or applied to prosthetics that are not permanently attached to the body[17] are also not included in this provision. However the exception applies to therapeutic methods applied to prosthetics permanently attached to the body even if the contact with the body is external.[18]

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[11] BGH decision in *Clatzenoperation*, 26/09/1967, in Gewerlicher Rechtsschutz und Urheberrecht, 1968, p. 142.

[12] German Federal Patent Court in '*Haarwatchstum*' of 27/09/84 in Gewerlicher Rechtsschutz und Urheberrecht, 1985, p.125. According to this ruling commercial or industrial activity is an economic activity that pursues profit. The medical activity while being an economic activity has as final goal to serve public interest – to cure. More recently, in '*Endoprotheseinsatz*' in Gewerlicher Rechtsschutz und Urheberrecht , 2001, p. 321 the lack of industrial application of these inventions was held as reason for patentability refusal., in Marques, J. op.cit..

[13] Special edition n.4 OJ EPO 2001.

[14] Article 53(c) EPC 2000. For simplicity reasons all future references will be used in a large sense including both methods for animal and human treatment.

[15] T-712/93 Joint Medical Products/*Ball and socket bearing for artificial joint* [1997.04.14].

[16] EPO Guidelines Part C, Chapter IV, 4.8.

[17] T-24/91 Thompson/*Cornea*, OJ EPO 1991, 512.

[18] T-1077/93 L'Oreal, OJ EPO 1997, 546.

a) Diagnostic Methods

The meaning of this expression has always been highly debated with particular emphasis in situations where not all phases of the proceeding where practiced in contact with the human body, ultimately leading to opposite currents of jurisprudence within the EPO. On one side was the line of reasoning for the first time proposed in the Brucker case[19] and on the other side the arguments of the leading case Cygnus.[20]

In the Brucker case the EPO Technical Board of Appeal (from hereafter TBA) held a narrow interpretation of the prohibition, ruling that patentability should only be denied for methods where all the steps involved in making a medical diagnosis (making a decision on a particular course of medical treatment) where practiced on the human body. While in the later case Cygnus the TBA departed from this understanding and held that the expression *'diagnostic methods practiced on the human or animal body'* should be considered as to relate to all methods practiced on the human or animal body which related to diagnosis or were of value for the purpose of diagnosis. In light of this decision, in order to fall within the scope of the prohibition it was enough that the claimed method comprised one single step which served diagnostic purposes or related to diagnosis and was to be regarded as an essential activity pertaining to diagnosis and practiced on the living human or animal body.

In the face of conflicting decisions and in the interest of legal certainty the Enlarged Board of Appeal (EBA) was called to pronounce itself over such divergence.[21] In G-1/04 the EBA took a point of view similar to the line of reasoning in Brucker. The EBA held that whilst the surgical or therapeutic nature of a method claim can be established by a single method step, diagnostic methods have an inherent multi-step nature and have to be executed in several steps, cycles or activities in order to be considered as such within the meaning of Article 53(c) EPC.[22] The EBA also acknowledged that methods for diagnostic imply several different phases: (1) examination phase translated in the gathering of data and samples, (2) comparing the data with reference values (3) identifying the existence or not of any significant deviation from reference values, i.e. identifying symptoms (4) relate eventual deviation from reference values (symptoms) with a certain clinical condition. According to the EBA, this last phase is merely deductive and constitutes an intellectual exercise that can not be considered an invention by itself.[23]

According to this understanding, only the first three phases are to be considered under the exception since only those are of a technical nature. It also implies that while examining a claim it is necessary to establish which of the method steps described that have technical character and to ascertain whether an interaction with the human or animal

[19] T-385/86 Brucker/*Non-invasive determination of measure values* [1987.09.25], OJ EPO 1988, 308.
[20] T-964/99 Cygnus/*Device and method of sampling of substances using alternative polarity* [2001.06.29], OJ EPO 2002, 2.
[21] G-1/04 [2005.12.16], OJ EPO 2006, 334.
[22] G-1/04, paragraph 5. Note: This decision pre-dates the EPC 2000 revision and naturally still refers to Article 52(4) EPC.
[23] G-1/04, paragraph 5.2 and 6.4.1.

body takes place.[24] If all the technical phases indispensable to obtain a complete diagnosis (phases 1 to 3) are executed on the living body the method will be unpatentable. On the contrary if one of these technical phases or steps is executed but not in contact with the human body, the method is patentable.

The EBA pointed out that the fact that one step is executed in contact with the body e.g. gathering of samples, does not allow a complete diagnosis. Therefore it can not be considered a method for diagnosis but at best a method of data acquisition or data processing over the physical or psychic condition of (des) equilibrium of the examined individual and is thus patentable as such.[25]

b) Methods of treatment /diagnostic – qualification as such

In a certain line of jurisprudence the qualification of a method of diagnosis has depended on the qualification of the person who was to perform it operate it, i.e. a physician.[26] However in G-1/04 the EBA held that patentability should not be decided on basis of the qualification of the person who is to perform the method. The decision was partly based on the fact that the preparatory works of the Munich conference did not contain any such reference and partly on reasons pertaining to legal certainty. The Board held that the medical profession and medical acts are regulated differently in different jurisdictions and that different legal systems have different solutions regarding what methods and proceedings are reserved to physicians or practiced by nurses, radiologists technicians or other health practitioners. Thus any interpretation that makes patentability dependent on the professional qualification of the person who would/could perform it would ultimately lead to legal uncertainty.[27]

According to this legal reasoning the qualification of the person who is to perform it (medical physician or a veterinary) is indifferent to the qualification of a method as a method for treatment or for diagnosis.

c) Methods of treatment by therapy v. cosmetic methods

Regarding the distinction between what can be considered therapeutic or non-therapeutic, e.g. cosmetic, the EPO jurisprudence has applied a broad concept of therapeutic method.[28] A method is to be considered therapeutic if its execution has the objective of re-establish the physical or psychic equilibrium of a person, even if such method is of prophylactic nature[29] involving the prevention of diseases or any

[24] See also EPO guidelines for examination Part C, Chapter IV, 4.8.
[25] G-1/04, paragraph 6.2.2.
[26] T-385/86 Brucker/*Non-invasive determination of measure values*, OJ EPO 1988, 308.
[27] G-1/04 Paragraph 6.1 and 6.3.
[28] In this sense see Cook, Trevor '*Pharmaceuticals Biotechnology and the Law*', 2 ed., Lexisnexis, London 2009.
[29] T-19/84 Duphar/*Pigs* II [1987.10.15], OJ EPO 189, in this decisions the TBA stated that 'All prophylaxis serves to maintain health and therefore comes under the provision', p. 24.

dysfunction (such as method for removing plaque from teeth[30] or hair loss[31]), the concept also includes any methods destined to relief or suppress pain, physical discomfort[32] or restore any body functions or capabilities[33] even if the diminishing was not caused by a disease.[34] Inventions of process for artificial insemination,[35] contraception[36] and pregnancy termination are not considered therapeutically methods, since pregnancy is a natural state and not a disease. However, methods to prevent or cure any diseases that may occur during the pregnancy but are not intrinsically related to it may be considered therapeutic.

Claims to methods that have both therapeutic and cosmetic features are usually regarded as pertaining to therapeutic methods. Only when it is possible to autonomously dissociate and evaluate the cosmetic effects from therapeutic effects or phases the method will be outside the scope of Article 53(c) EPC. For example, regarding a method to remove body hair[37] the TBA held that it should be considered cosmetic and thus patentable since although excess of body hair could be caused by genetic factors or by an endocrinology disease, it is not a condition by itself that causes pain or discomfort. The only patentable methods are those with technical effects and aesthetic purposes that are totally separated and autonomous from any therapeutic effects that they may have.[38] In a different line of reasoning, in a controversial decision concerning a method for improvement of the physical external appearance of any mammal though administration of a product with appetite suppressing properties, the TBA has held that it was not possible to dissociate the aesthetic effect from the therapeutic effect (obesity treatment) but since the claims only sough to obtain patent protection to the aesthetic method (that could be applied to both healthy and obese persons/animals) patentability should not be denied.[39] However it should be noted that this line of reasoning seems to be an exception to the general trend. The majority view expressed in EPO decisions such as in General Hospital/*Hair removal method*[40] leads to the conclusion that any method claim containing both therapeutic and cosmetic results which can not be separated will be denied

[30] T-290/86 ICI/*Cleaning plaque* [1990.11.13] OJ EPO 1992.
[31] T-143/94 Jutta Mai [1995.10.05] OJ EPO 1996.
[32] T-81/84 Rorer/*Dysmenorrhea* [1987.05.15] OJ EPO 1988.
[33] T-24/91 Thompson/*Cornea* [1994.05.05] OJ EPO 1991.
[34] T-81/84.
[35] T-582/88 Eli Lilly [1990.05.17], OJ EPO, 1991.
[36] T-74/93 British Technology Group/*Contraceptive method* [1994.11.09], OJ EPO 1995, and T-820/92 General Hospital/*Contraceptive method* [1994.01.11], OJ EPO 1995. However the solution will be different if the contraceptive method implies a therapeutic method in the sense that its execution prevents associated side effects, in this sense see T-820/92 General Hospital/*Contraceptive method* [1994.01.11], OJ EPO 1995.
[37] T-383/03 General Hospital/*Hair removal method* [2004.10.01], OJ EPO 2005.
[38] It can be argued that aesthetic imperfections often cause psychic pain and discomfort such as low self esteem and social interaction problems. The essential question lays in obtaining an objective valuation and measurement of such psychic pain and discomfort that ultimately can establish the distinction between enhancement and therapy. Such effects are known to vary to a great extent from individual to individual, the legal criteria adopted so far has been based in subjective notions of reasonability and thus can be criticised for being artificial and lacking scientific grounds.
[39] T-144/83 Du Pont/*appetite suppressant [1986.03.27]*, OJEPO 1986.
[40] T-383/03.

patentability under the rule of Article 53 (c) EPC. It is also apparent that the delimitation of the concept of therapy is an artificial legal creation not fully based in scientific criteria and often dependent on circumstantial factors such as the actual phrasing of the claims.[41]

d) Methods for surgery

Taking into account the previously mentioned considerations regarding the *ratio legis* and nature of this legal provision, the prohibition concerning surgery methods should not be understood as absolute, meaning that the nature of this patentability exemption does not seem to imply a prohibition *per se* of all chirurgical methods, but rather only of those that pursue or have as a result therapeutic goals.[42]

The EPO guidelines for examination still maintain that *'Surgery defines the nature of the treatment rather than its purpose. Thus, for example, a method of treatment by surgery for cosmetic purposes or for embryo transfer is excluded from patentability, as well as surgical treatment for therapeutic purposes.*'[43] However in light of the EBA decision on G-1/04 where the EBA held (while defining the interpretation of ought to be considered diagnostic methods) that chirurgic methods in the meaning of the EPC are any methods that imply physical interventions on the human or animal body, *'in which maintaining the life and health of the subject is of paramount importance*'[44] the provision should be understood has only encompassing surgery methods with a therapeutic objective or effect such as prevention of diseases or any dysfunction and re-establishing the physical or psychic equilibrium of a person (including relief/suppress of pain and physical discomfort and restore any body functions/capabilities even if the diminishing was not caused by a disease). Only such interpretation is compatible with the ratio of the legal rule, understood has the protection of the freedom of practice of non commercial/non industrial activities in the field of human and veterinary medicine.[45]

3.3 Applying the general rule to Nanotechnology inventions

Nanotechnology inventions due to their interdisciplinary nature are likely to experience all the patentability difficulties previously felt in more classical technological fields, that is to say that a nanotechnology invention combining different technological fields such as for example biotechnology, biomedicine, and information and communication technologies will likely experience all and the same patentability issues relevant in those technological field that it encompass. On the other side, there is also good news for inventors seeking patent protection: nanotechnology inventions' hybrid

[41] See in this sense Cook, Trevor, op. cit.
[42] In this sense Marques, J. op. cit.. See also Bentley, L and Sherman S., *'Intellectual Property Law'*, Oxford University Press, 2001 and Bentley, L and Sherman S., *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 6 ed. Sweet & Maxwell, London, 2007.
[43] EPO Guidelines 2009 Part C, Chapter IV, 4.8.1.
[44] G-1/04 paragraph 6.2.1. In the same sense see T-35/99 Georgetown University/*Pericardial access* [1999.09.29], OJ EPO 2000, and T-789/96 Ela Medical/*Méthode thérapeutique [2001.08.23]*, OJ EPO 2002.
[45] G-6/83 Pharmuka/*Indication médicale* [1984.12.05], OJ EPO 1985.

nature means increased flexibility in patent claim drafting and thus increased patent strategic options to maximize patent protection and circumvent exclusions and exceptions to patentability, for example often it will be possible to describe an invention both as an apparatus and a compound.[46]

In theoretical terms, applying the general orientation of the EPO to nanotechnology will lead to the conclusion that nanotechnology inventions of a therapeutic nature that can only be described as a method claim in principle can be patentable. Patentability will not be barred as long as the phases of the method that operate in contact with the body do not allow identifying the presence of a symptom but merely intermediate results. However this requirement may be difficult to fulfil due to the particular nature of nanotechnology.

Regarding some of the nanotechnology inventions previously mentioned such as nanoparticles delivery systems introduced in the blood stream with the mission to identify and repair or destroy, e.g. cancer cells, any inventors IP strategy will most likely encompass attempts to obtain patent protection covering as many aspects and components of the invention as possible. Such may include attempts to claim the nanoparticles delivery system in itself and/or drafting claims for: (1) the nanoparticle (that can take many shapes, be composed of different materials such as polymers, lipids, carbon nano-tubes or ceramic materials and offer different features that may be patentable); (2) the active agent; (3) the targeting moiety (usually small molecule or peptide-based).[47] In addition nanoparticles delivery systems can be used by patent holders in order to extend the life or revitalise patents of active agents by means of second medical use patents claims due to nanoscale related advantages over the original active agent. Special attention to claim drafting will be required as to avoid both the surgery and therapeutic methods prohibitions, in particular while claiming the nanoparticles delivery system as a whole.

In general, substance or compositions claims and apparatus claims should present a safer option as to avoid the patentability exception. While method claims will remain particular difficult to obtain in Europe due to the need to circumvent the '*practiced* on *the human body*' prohibition, in light of the EPO jurisprudence as described previously in principle nanodevices or substances if claimed as such should be patentable. A patent is merely a monopoly right to commercially explore the invention, e.g. manufacturing and making available in the market and does not include the use of the invention by medical practitioners, thus patentability of apparatus or substances can not hamper the freedom of diagnosis and pursuing a selected medical treatment.

Outside the scope of this prohibition are also cosmetic methods, but the distinction between what is still therapeutic even if only prophylactic and what can be considered cosmetic is not clear, and as observed previously the EPO decisions on the matter show some degree of inconsistency. Nanotechnology is expected to add further

[46] Zech, Herbert, '*Nanotechnology – New Challenges for Patent Law?'*, 2009 6:1 *SCRIPTed* 144, available at http://www.law.ed.ac.uk/ahrc/SCRIPT-ed/vol6-1/zech.asp (February 2010)

[47] Follett, Angela D. and Lavoie, Teresa A. *'Delivering macro-quality IP protection for nanosized therapeutics*', 5 Nanotechnology L. & Bus. 163, 2008.

difficulties since many of the on-going research will lead to inventions that not only are meant to restore natural functions and abilities but have the potential to enhance them.

In general terms, nanotechnology inventions concerning methods for enhancing natural human capabilities (e.g. improving the sense of vision, smell or earring) or introduce abilities, functions characteristics not provided by nature in the present evolutionary state (e.g. telepathic and telekinetic abilities) should not find objections under this provision as it has been interpreted by the EPO. As long as such methods can not be considered therapeutic, they should be treated in an analogical way as cosmetic methods and thus outside the scope of the prohibition.[48]

In practice in borderline situations it may prove difficult to assert what is enhancement and what is restoration of human abilities and functions since those tend to vary from individual to individual, possible criteria could be the medical tables for subnormal values that implies a medical diagnosis of a certain medical condition e.g. lack of vision, anything above those values could be considered enhancement and therefore non therapeutic. However the difficulty will remain since under these criteria the same invention would be considered either therapeutic or non-therapeutic depending on its intended user. Implants in the nervous system that allow the user to communicating wireless with computers and exchange nerve signals with other persons is an example of a technology being researched that if applied to an individual with mobility and communication capability severely reduced it will have as primary objective and effect to restore the ability to communicate and interact with the surrounding environment and thus it will have to be considered restoration/replacement of natural abilities and thus therapeutic, but the same technology when applied to subjects without such impairments it will have as effect the introduction of telepathic abilities and will have to be considered enhancement. Ultimately patentability will be dependent to a large extent on the creativity applied in patent drafting, something that is not new in the patent system but nonetheless raises objections from a legal science point of view.

4. Methods for treatment and Diagnosis and the reform of the patent system

The interdisciplinary nature of nanotechnology appears to advice against specific patent legislation, something that could prove difficult in light of the TRIPS Agreement and could only be achieved by introducing a Nanotechnology Directive or a similar legal instrument clarifying concepts and patentability issues. Furthermore, to introduce such legislation would be premature at this point since the technology is still emerging.[49] However, such does not exclude the fact that nanotechnology due to its nature requires the revaluation of this exception to patentability, nor that its overall increasing social-economic relevance cannot be overlooked and will became a contributing factor for such need.

[48] However, it is not excluded objections raised under the general 'ordre public' and morality exception to patentability of Article 53 EPC. See for further analysis Nordberg, A. *'Nanotechnology patents in Europe: Exclusions and Exceptions to patentability'*, Stockholm University, Jan.2010. Available at: http://www.juridicum.su.se/juruppsatser/2010/ht_2010_Ana_Rita_Nogueira_de_Sousa_Branquinho_Nordberg.pdf (February 2010).

[49] In this sense Zech, H. op.cit.

If the nature, ratio and maintenance of this prohibition have long been subject to intense debate, such interrogations are becoming increasingly important and accurate in light of the recent scientific advances in fields such as nanomedicine and nanobiotechnology.

Among European scholars, many do not favour the maintenance of this exception to patentability in its current formulation,[50] and legal practitioners have since long used creative claim drafting to avoid an entire industry to fall into the scope of the prohibition,[51] which from a legal science perspective is always a sign of de-synchronization between law and the social reality.

The issue is complex due to the delicate nature of the interests being balanced and thus further research and public debate is needed in this field and the projected reform of the patent system that recently shown some progress[52] can provide an excellent opportunity for both.

The act of attributing a patrimonial right (e.g. patent) is in nature different and should not be confused with the act of attributing (or denying) effective and un-restricted economic and industrial exploitation of such patrimonial right. The patent right should be understood as a mainly neutral legal institute, in the sense that it is outside its scope regulating the development of certain research activities, or the possibility and forms of commercial and industrial exploitation of an invention.

Patent law ultimate goal and primary function should be to promote and reward scientific research and technological and industrial innovation by determining which inventions can be commercially and industrially explored in a regimen of monopoly for a certain period of time (currently twenty years). In this sense exceptions to patentability should be narrowly constructed, carefully accompanying the evolution of the legal system and in close connection with scientific progress and social evolution. Allowing patent protection, i.e. a monopoly right for commercial exploitation, provides incentive

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[50] See among others Beier, Freidrich-Karl, '*Future Problems of Patet Law*' in International Review of Industrial Property and Copyright Law, 1972; Bergmans, Bernhard, *'La Protection des Innovations Biologiques- Une Etude de droit comparé*, Maison Larcier, Brussels 1991; Moufang, Rainer, *'Methods of medical treatment under patent law'* in International Review of Industrial Property and Copyright Law, Vol. 24 No 1/1993; Thums, Doris, *'Patent Protection for Medical Treatment a distintion between patent and medical law'*, International Review of Industrial Property and Copyright Law, Vol. 27, No. 4/1996; Domeij, Bengt '*Pharmaceutical Patents in Europe'*, Norstedts Juridik, Stockholm 2000; Thomas, Daniel X. '*Patentability Problems in Medical Technology'*, in International Review of Industrial Property and Copyright Law, 2003; Marques, J.P. Remédios, *'A patentabilidade dos Métodos de diagnóstico…'* op.cit.; Cook, Trevor '*Pharmaceuticals Biotechnology and the Law*' op. cit.

[51] A known example is the use of *Swiss-type* claims *'Use of a substance or composition X for the manufacture of a medicament for treatment of disease or condition Y'* in order to obtain patent protection for pharmaceuticals.

[52] Recently, during the Swedish Presidency of the EU a breakthrough in negotiations was achieved pursuant to the 2982nd Competitiveness meeting of the EU Council that concluded over the *creation of a European and EU Patents Court (EEUPC), an EU patent, including the separate regulation on the translation […], an Enhanced Partnership between the European Patent Office and central industrial property offices of Member States and, to the extent necessary, amendments to the European Patent Convention'* , and the accession of the EU to the EPC. See Council of the European Union *'Conclusions on an enhanced patent system in Europe*' 2982nd Competitiveness (Internal market, Industry and Research) Council meeting, Brussels, 4 December 2009, paragraph 4.

not only for further research but also and most relevantly in this complex technological field provides incentive for the disclosure of the invention.

Given the above mentioned function of the patent system, the patentability exception of Methods for treatment and Diagnosis has always been difficult to justify. The exception was initially constructed has an exclusion based in a lack of industrial application, and later was framed in Article 53 (c) pursuant to the EPC Revision in 2000 and as discussed previously, its nature and *ratio legis* is still largely debated. Currently the *ratio legis* of this prohibition is anchored in the need to protect and assure therapeutic freedom to medical practitioners, and the universal right to access medical care. The main argument, still subsisting as justification for the prohibition is that allowing the patentability of such methods would imply that medical practitioners would be forced to pay royalties and thus hampering their therapeutic freedom. However, such does not seem convincing as it has been for long considered acceptable to pay the patent holder royalties included in the price of pharmaceutical products and apparatus for clinical use such as machines and instruments, without the patentability of those apparatus ever being doubted for 'ordre public' and morality reasons.[53] Further one has to take into consideration that the prohibition does not exist in all patent systems and such international patent law lack of harmonization creates difficulties and legal uncertainty. For example, in the USA patent law there is no correspondent patentability prohibition of therapeutic and diagnostic methods, medical practitioners are exempted from patent infringement as long as the performance of the patented method occurs during the exercise of a medical activity[54] and notably litigation opposing patent holders for therapeutic and diagnostic methods and health care professionals is relatively uncommon. Leading to consider from a *de jure condendo* perspective, whether it should not be preferable to erase this exception to patentability and introduce either a similar solution or other correction mechanisms to protect the interest of public health such as (a) compulsory license mechanisms;[55] (b) Establish a experimental use exception; or (c) Use public regulatory instruments such as market authorizations similar to those existing for pharmaceutical products to maintain accessibility to these products.

Nanotechnology inventions blur the already thin line between what can and what can not be considered for legal purposes of the patentability exception a method for treatment and diagnosis applied to the human body. Nanotechnology inventions including those that could fit into the prohibition, unlike traditional therapeutic/diagnosis methods are no longer a by-product of the medical praxis, a result of 'accidental' findings by a single medical practitioner, but rather require considerable investment in specialized equipment and the full time work of scientific multidisciplinary research teams. Nano-medicine research activities consume considerable time and financial resources and the inventions in this field are the result of prolonged research frequently conducted by multidisciplinary teams meaning that professional and scientific acknowledgment, e.g.

[53] Domeij, Bengt '*Pharmaceutical Patents in Europe'*, 2000, Chapter 1.
[54] §287 (c) (1) (4) USA Patents Act.
[55] Compulsory licences are already established in general terms in the projected European patent regulation, see Article 21(2) Revised *proposal for a Council Regulation on the Community patent',* Brussels, 7.04.2009.

through publishing the findings in scientific publications, is no longer a suitable incentive for an enabling disclosure. Under this line of reasoning the patentability exclusion not only is no longer achieving its objectives of promoting the development of new medical methods of treatment and providing for universal accessibility to state of the art medical care, but is in fact becoming a hampering factor.[56]

As mentioned it remains a matter for discussion if the solution adopted in the European patent system is in fact the most appropriate to accomplish in simultaneous the objectives of: (1) protecting the freedom of the medical practitioner to perform on their patients all known (state of the art) methods for treatment and diagnosis that they deem appropriate; (2) the right of the patient to receive any methods for treatment and diagnosis available, appropriate and efficient for his/her condition and; (3) the need to promote innovation and scientific research, i.e. though an adequate reward system.

The argument, that allowing the patentability of such methods would imply that medical practitioners would be forced to pay royalties and thus hampering their therapeutic freedom is not convincing if we consider that: (a) It has been for long considered acceptable to pay the patent holder royalties included in the price of pharmaceutical products and apparatus for clinical use such as machines and instruments, without the patentability of those apparatus ever being doubted for 'ordre public' and morality reasons; and (b) The evidence found in the example of other patent systems where such prohibition does not exist reinforces the conviction that other legislative solutions are in fact possible. Another recurrent argument lays in the protection of public interest: it is often commented in the political rhetoric that lifting the patentability prohibition would increase the cost of the health care systems and further increase the financial burden that public health care systems imposes on public finances. Such argument losses credibility if corrective legislative measures, such as for example the ones mentioned above, are introduced simultaneously with lifting the prohibition.

Conclusions:

At this point to maintain a general prohibition clause that leads to artificial legal constructions in order to (continue to) keep outside the scope of the provision the pharmaceutical industry, something that may become increasable difficult as scientific advances further blur the line between what may or not fall under the exception, appears to be incompatible with the general objectives of improving the competitiveness of European industry, promoting scientific research and industrial innovation, and strengthen the mechanisms and dynamics of transforming scientific advances into new products available in the market that can benefit the overall society by providing for universal accessibility to state of the art medical care.

The projected reform of the patent system and the introduction of a European patent provide for a forum for debate and an opportunity for re-thinking this patentability issue and consider whether it should not be preferable to allow patentability and simultaneously introduce legal mechanisms to either: (1) Exempt medical practitioners from patent infringement as long as the performance of the patented method occurs

[56] In similar sense regarding biotechnological inventions Domeij, B. op. cit.

during the exercise of a medical activity; (2) Make use of compulsory license mechanisms; (3) Establish a experimental use exception; and/or (4) Use public regulatory instruments such as market authorizations similar to those existing for pharmaceutical products to maintain accessibility to these products.

The projected reform of the patent system so far has not contemplated any changes concerning this exception to patentability, however this is a complex and most important issue as any legislative option (including maintaining the current formulation) needs to maintain a balance between delicate and most relevant public interests, such means that these matters need to continue to be object to public debate and further legal science research.