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Economic justification of patents and exceptions to patentability

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Abstract:

The present article is the conclusion of a review of economic justifications for patent rights conducted with the objective of determining whether such arguments are per se capable of sustaining the existence of a different patentability regime for inventions of methods for treatment and diagnostic methods (art.53 (c) European Patent Convention). It starts by exploring the normative background and summarily describes the different types of claims allowed under the current legal framework and their differences. The following sections will apply the principal economic argumentations to inventions of methods for treatment and diagnostic methods, confront those reasoning with contra-arguments and end with the formulation of conclusions extracted from the previous debate.

Introduction:

This article is the result of a review ¹of the mainstream economic justifications for patent rights and addresses the question whether such economic arguments are *per se* capable of sustaining the existence of different patentability regimes applied on the one hand side to inventions of products and apparatus to be used on treatment and diagnostic and on the other

1 As background research for this article a literary survey of works addressing the economic justification of patents and patent scope was conducted. The works consulted include among others: Adam Smith, *An Inquiry into the Nature and Causes of the Wealth of Nations*, ed. Edwin Cannan, 5th ed. (Methuen & Co., Ltd 1904); Adam Smith, *Lectures On Jurisprudence*, ed. R. L. Meek, D. D. Raphael and P. G. Stein, vol. V of the Glasgow Edition of the Works and Correspondence of Adam Smith (Liberty Fund 1982); John Stuart Mill, *Principles of Political Economy with some of their Applications to Social Philosophy*. (William J. Ashley, ed. London; Longmans, Green and Co. 1909); Jeremy Bentham, *The Works of Jeremy Bentham, published under the Superintendence of his Executor, John Bowring* (William Tait 1838-1843), Joseph Schumpeter, *Theory of economic development, transl. Redvers Opie* (Harvard University 1943); Kenneth Arrow, '*Economic welfare and the allocations of resources for invention*', (1962) *Rate and Direction of inventive activity* 609; Joseph Schumpeter, *Capitalism, Socialism, and Democracy*, 3rd ed. (Harper 1975); Edmund W. Kitch, 'The nature and function of the patent System' (1977) 20 *JL & Econ.*; Donald G. McFetridge and Douglas A. Smith, 'Patents, Prospects, and Economic Surplus: A Comment' (1980) 23 *J.L. & Econ.* 197; Frederic M Scherer *Industrial market Structure and Economic Performance*, 2nd ed. (Houghton Mifflin, 1980); Robert P. Merges and Richard R. Nelson, 'On the Complex economics of patent scope' (1990) 90 *Colombia Law Review* 839; Mark F. Grady and Jay I. Alexander, '*Patent Law and Rent Dissipation*', (1992) *Virginia Law Review*, Vol. 78, No. 1, Symposium on the Law and Economics of Intellectual Property 305-350; Richard A. Posner, *Economic Analysis of Law*, 4th ed (Little, Brown and Company 1992); Samuel Oddi, 'Un-Unified economic theories of patents – The not-quite-holy grail' (1996) 71 *Notre Dame law Review* 267; Nuno Pires de Carvalho, *The TRIPS regime of patent rights* (Kluwer Law International, 2002); Clarissa Long, 'Patent Signals', (2002) 69 *U. CHI. L. REV.* 625, 635; William M Landes and Richard A Posner *The economic structure of intellectual Property law*, (Harvard University Press 2003); Robert P. Merges *Justifying Intellectual Property* (Harvard University Press 2011); Robert Cooter and Thomas Ulen, *Law and Economics* (Addison-Wesley 2012).

hand side to inventions of methods for treatment and diagnostic methods. It will be sustained that economic analysis of the structure and justification of patent rights is not capable in itself of providing for convincing arguments for such difference in legal regime and thus, such arguments, if they do exist must be found elsewhere.

Although it appears intuitive that the justification for the exception rests in *ordre public* or morality considerations², reinforced by the growingly popular use of human right discourse concerning limitations to intellectual property rights,³ these ethical justifications are also questionable and should not be taken for granted. Thus the choice of this topic is imposed by the need to research into all the different considerations that can (or cannot) justify the current normative framework in Europe.

1. Normative Background and its historical evolution

The TRIPS agreement⁴ is currently the seminal international source of intellectual property law.⁵ Regarding patent rights art 27 TRIPS establishes the general rule that “patents shall be available for any inventions, whether products or processes, in all fields of technology.” It does not contain exceptions to patentability. However art 27 (2) and (3) allow member states to establish two forms of exception: (1) norms that prevent the commercial exploitation of certain inventions considered necessary to protect *ordre public* or morality (art 27 n. 2); (2) norms that restrict the patentability of either, plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes (art 27 n.3 (b)), and diagnostic, therapeutic and surgical methods for the treatment of humans or animals (art 27 n.3 (a)).

The architecture of the provision mirrors the unsettled scholarly debate concerning the nature and ratio of these norms within the jurisdictions that contain them. According to TRIPS diagnostic, therapeutic and surgical methods for the treatment of humans or animals are not

² For background on such debate see Nordberg, A. “Nanotechnology patents in Europe and the exception from patent for methods for treatment and diagnostic methods” N I R., 3/2010, p. 224-238.

³ See Nordberg, A Nanotechnology, Human Rights, Patent Law and the Global South: A brief overview, in “New Technologies and Human Rights: Challenges to regulation” Cunha, M, Andrade, N, Lixinski, L and Lomba, P (eds.), Ashgate (forthcoming)

⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights, contained in an Annex to the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994

⁵ Ratification of the TRIPS has been made condition for accession to the World Trade Organization. The WTO currently has 153 member states.

considered to be a form of *ordre public* or morality exception but an autonomous category. Also, important to bear in mind is that, although the TRIPS recognises and allows these exceptions, not only does it not consider them mandatory, but in fact it restricts the grounds for exceptions to patentability that member states can enact.

The second most relevant source of international patent law in Europe is the European Patent Convention (EPC)⁶. A multilateral treaty instituting the European Patent Organisation (EPO) and providing for an autonomous regional patent system that offers a uniform application procedure which enables applicants to seek simultaneously patent protection in up to 40 European jurisdictions.

The EPC also establishes the general rule that “European patents shall be granted for any inventions, in all fields of technology”.⁷ Although a definition of invention is not provided for, this provision includes a list of subject matter that is not considered to subsume to the concept of invention. Under this rule, most methods, such as “schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers” are not considered to be inventions “as such”, requiring an additional element to confer them “technical character”, methods for treatment and diagnostic methods are no longer mentioned in this provision.⁸ It does follow that such subject matter is not excluded from patentable subject matter, but rather an exception to the general rule prescribing the patentability of all inventions in all fields of technology.

Under the original version of the EPC methods for treatment and diagnostic were mentioned in art 52 (4) and considered an example of excluded subject-matter by lack of the substantive patentability requirement ‘industrial application’. Pursuant to the revision of the EPC in 2000, this norm is now inserted in art 53, a provision devoted to subject matter excluded from patentability for *ordre public* and morality reasons. Also, under its current formulation, the EPC does not preclude the patentability of products used in such methods, as the norm expressively recognizes the patentability of products (whether chemical compounds or apparatus), and even the patentability of new uses of such products.

⁶ Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000.

⁷ Art 52 (1) EPC.

⁸ Before the 2000 revision, methods for treatment and diagnosis methods were considered to lack industrial application, although it was widely held that such was a legal fiction.

The European legislator could have chosen to exclude from patentability all medical and pharmaceutical inventions, or could have taken the option of excluding certain categories of inventions such as chemical compounds or method patents. Although the art 27 TRIPS precludes such option, at the time of the EPC drafting such venue was still possible. In fact, prior to the European patent convention several jurisdictions opted for excluding pharmaceutical products (medicines) or even chemical products altogether.⁹

The existence of exceptions to patentability relating to medicine products, under several different formulations pre-dates both the EPC and the TRIPS agreement, and has longstanding presence in several jurisdictions¹⁰. However it should be noted that the exception from patentability of methods for treatment and diagnosis methods did not appear as such in legal texts before the European patent convention was signed. In fact, prior to the EPC the only European countries with the specific exclusion for methods for treatment mentioned as such in statutory provisions were Czechoslovakia, Poland and Rumania¹¹.

In this light, it appears somehow extraordinary that the EPC drafting committee considered this to be non contentious matter. During the meetings of the working party of the EPC while debating the need to insert or not a provision of such nature, it was noted that all the national laws of the participant states considered that methods for treatment and diagnostic methods were not patentable, and that none of the delegations had proposed to reverse such principle in European law¹², as a result there was little debate on whether it should or not be part of the convention and why. The debate was instead directed to the legal systematization, as there were different perspectives concerning the ratio and legal classification of the prohibitive norm. This points out in the direction of the conclusion that the origin of such provision in the EPC streams more from long standing national legal tradition of the founding

⁹ Denmark, GB, Iceland, Italy, Luxembourg, Norway, Portugal, Spain, Sweden, Switzerland excluded the patentability of pharmaceutical substances or medicines, in Katzaev's manual and Directory on Industrial Property all Over the world", 7th ed. 1970, Cabinet Katzarov, Geneva, Switzerland.

¹⁰ A. & E. Carpmael *Patent Laws of the World* (Clowes, 1885) quoted by Bentley, Lionel et al. 'Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights' (WIPO 2010), 16.

¹¹ Due to the practical impossibility of accessing all laws in force at the relevant historical moments, for this study were used several guides or directories of patent laws in translation, namely: Berthold Singer *Patent and Trade Marks Laws of the World* (Hammond Press 1911); Konstantin Katzaroff (ed) *Katzaroff's Patent directory: 1931* (self edition,1931); Jan Vojáček *A survey of the principal national patent systems* (Pitman, 1936); Konstantin Katzaroff (ed) *Katzaroff's Patent directory* (Bulgarian Chamber of Commerce 1957.; J.W. Baxter, *World Patent Law and Practice* (Sweet & Maxwell 1968); Katzaroff, 1970, n9; Bentley et al, n8.

¹² Article 52F Travaux Préparatoires (CBE 1973) Resultats de la douzième session du groupe de travail "brevets" qui se tenue à Bruzelle du 26 février au 6 mars 1964 Comptes Rendus, 2632/IV/64-F, 22.

members of the EPC, than any particular study or scientific reasoning. An additional explanation, may reside in the fact that such methods were not considered generally as pertaining to an industrial activity. Traditionally, the medical profession has been considered to be outside the scope of commercial law, being regulated by corporative rules and codes of ethics. The medical profession does not consider itself driven by commercial logic and medical professionals are not allowed to orientate their professional conduct by profit motivations.¹³.

2. Types of claims allowed under the European Patent Convention

The rules in force prescribe that patents are available for all inventions either products or processes.¹⁴ Claims for products encompass both apparatus or mechanical inventions and products *stritus sensus* such as chemical compositions. A method is a type of process. In a purely literal definition, a methods is "a particular way of doing something",¹⁵ thus it implies that a method for treatment by therapy or surgery or a method of diagnosis is a certain particular way or manner of treating or diagnosing a certain condition.

The EPC does not contain a definition of method for treatment and diagnostic methods. Considering the EPO jurisprudence it can be concluded that a method claim is any description of a process that has the purpose of either making a diagnosis for curative purposes or has curative purposes, as opposed to a claim of a method whose purpose is to obtain a product. The method will only fall under the exclusion if it includes interaction with the human or animal body. Neither the nature of the interaction, its intensity, nor the professional qualification of the person who is to perform the method are consequential.¹⁶

The EPC recognizes the patentability of first, second and further medical indications of known substances. Furthermore this legal understanding has evolved into accepting the patentability of dosage regimes. Dosage regimes patents distinguish themselves from the known state of the art by inventing a previously unknown second or further use of a known substance, being that such new use resides merely in quantitative terms. In such patents, the

¹³ "A Physician shall not allow his/her judgment to be influenced by personal profit or unfair discrimination"
"World Medical Association International Code of Medical Ethics, Adopted by the 3rd General Assembly of the World Medical Association, London, England, October 1949 , para 3.

¹⁴ Art 27 TRIPS (4).

¹⁵ Cambridge Advanced Learner's Dictionary & Thesaurus, Cambridge University Press, available at <http://dictionary.cambridge.org/>, viewed April 2012.

¹⁶ See for all G1/04 diagnostic methods Official Journal EPO 334 2006.

claims are not directed to the invention of a certain substance (product), nor to a process of obtaining a substance, but rather to a process of obtaining a therapeutic result.¹⁷

3. Economic justification of art 53 (c) EPC

Mainstream scholars that have theorized about the economic justifications for patent rights rarely address the subject of how their theoretical constructions can be reconciled with the existence of exceptions to patentability. In the following section different economic arguments for patent protection will be applied to the exception from patentable inventions for methods for treatment and diagnostic methods. Since exceptions can be understood as either mere qualification of the norm or as having autonomous rationale, the section will be divided accordingly.

3.1. Exceptions as qualification of the norm justified by the rule of free market

Exceptions can be understood as the qualification of the norm, following the reasoning that if inventions are public goods, introducing means to private appropriation by scarcity creation is in itself the exception to the rule. Thus, any rule that restricts the grant of such rights is a mere qualification that re-instates the general principle and rules that condition the functioning of the market.

This line of argumentation implies an understanding of patent rights as artificially created monopolies, and the assumption that a free market operating under perfect competition circumstances is preferable to monopolist or oligopolistic. However, a flaw to this reasoning is that patents are mere entitlements and do not necessarily create monopoly situations. Monopolies will only emerge in the absence of substitute products. Furthermore, such view does not encompass situations where patents are not used in their traditional sense to manufacture and introduce a product in the market.¹⁸

If we understand exceptions as a qualification of the norm, then the reverse argument for justifying the existence of patent rights should validate the existence of exceptions, meaning that exceptions necessarily have to be justified by the absence of a market failure. Under this reasoning, exception would only make sense if the market mechanisms are deemed to provide

¹⁷ G2/08 *Dosage regime* Official Journal EPO 456 2010

¹⁸ Several studies have concluded that the majority of patents are not explored by the patent owners to introduce a product on the market, and often are not explored at all. See Long, n1, 635.

enough incentive as to the production of the optimal level of new methods for treatment and diagnostic methods.

It postulates that the justification for the exception is the general rules that dictate the functioning of a perfect competition market. There is not a sub optimal level of innovation since lead time and demand/offer mechanisms function as incentives. This line of justification is the main argument of patent opponents and if true it should be true to all inventions. Assuming that in patent rights are needs in order to foster investment in the production of new inventions, this economic reverse argumentation could only justify exclusions if a fundamental difference is found between these inventions and the inventions patentable. Products used in medical treatment and diagnosis, either apparatus or chemical compounds are expressly not included on the exclusion. Meaning that in order for this argument to be persuasive, a fundamental difference between these methods and other inventions must exist. Methods are essentially processes, a number of steps that allow a certain result to be obtained. The fundamental difference between a process and product patent is exhaustion, meaning that in a process patent the right is not exhausted when put on the market. Thus, since patents protects against independent creation a method patent can impose a limit on a human activity. However, not all process patents are excluded from patentability. Art 53 (c) EPC does not exclude processes to obtain products used in methods for treatment or in diagnostic methods. Furthermore, first and further medical uses of a known substance are also patentable¹⁹. The provision only excludes from patentability methods performed on the human body for therapeutic or diagnostic purposes. It could thus be sustained that the determinant differentiating factor is the fact that patentability of these methods equal the imposition of a limitation on a human activity performed on the human or animal body for treatment or diagnostic purposes. However, this argument shifts the debate to the field of exercise and enforcement of rights. If any this reasoning would justify the imposition of restriction to the use of the patent right but it does not justify its inexistence.

The differences between products, traditional processes and method claims do not sustain arguments for differential treatment from an economic perspective. On the contrary, according to the arrows information paradox²⁰ since the invention of a method is both easier to copy and

¹⁹ Art 54 (4) (5) EPC

²⁰ Arrow n1, 609

easier to keep secret than other types of invention then the need for legal protection is greater. Furthermore, this view of exceptions as mere qualification of the norm although compatible with classical justification of patents, such as the reward theory and early incentive theories, does not encompass a notion of the function of the patent system as providing incentive to innovation, understood as a process.

3.2 Exceptions as autonomous norms

Exceptions to the general norm of patent availability have a restrictive field of application and follow a reasoning that is different from the general considerations that justify the main norm. Understanding exceptions as autonomous norms may entail not only the danger of interpreting the norm beyond its intended reach but also of losing a systematic perspective leading to the application of different logic to similar realities and thus introducing disruptive elements into the system. However, understanding exclusions as autonomous norms, eradicates the need to justify the exception by using the reverse argument that imposes the general rule sustaining the absence of the conditions that determine the justification of the general norm and allows autonomous justification. While patents as a legal institute have been for a long time justified by economic reasoning, exceptions as autonomous norms so far have been mostly justified based on specific private moral reasoning. However, it is still possible to search for autonomous rational for exceptions outside the field of ethical considerations.

3.2.1 Absence of market failure

If we take into consideration that exceptions are for the most part considered justified by moral reasoning, then in economic terms it is possible to sustain that the exception exists because the subject-matter considered are not economic goods, but rather '*bads*', or something that the society does not want to be produced or will commit resources to dispose off. Pursuant to this reasoning there is no need to provide for incentive to innovation in order to correct a market failure where such market failure does not exist. If any, there is a need to disincentive the allocation of societal resources to the production of '*bads*' (non-ethical conforming inventions) and provide incentive to the production of goods (innovation in ethical conforming inventions).

The 'general' exception to patent grant of art 53 (a) has a pure ethical *ratio legis*: these are subject matter whose commercialization violates the core values and ethical principles of our civilization.

A patent is a mere administrative concession of a right to exclude third parties from exploring the invention, not a regulatory authorization to market a product. In this sense the grant of a patent *per se* is not susceptible of violating any ethical values, it is the commercial exploitation of the patent that may or not have such effect. The EPC legislator chose to ignore the possibility of addressing the subject in regulatory framework, and chose to make the grant of patents conditional on the observance of the concept of human dignity in the commercialization phase. One possible argument is that the grant of a patent creates on the patent holder the legal expectation of being able to explore the invention commercially, and that the grant of a patent may appear to be on the eyes of the public as a sign of administrative endorsement of such non-ethical conforming inventions.

Still, despite of being based on ethical considerations, it is possible to justify the exclusion from patentability of subject-matter encompassed in 53 (a) EPC based on the fact that such subject matter is not an economic good, an item destined to satisfy a societal need.²¹ However, concerning methods for treatment and diagnostic methods such considerations do not apply, since it is difficult to sustain that the normal commercialization of a treatment of diagnostic method would *per se* violate ethical principles.²² It could be argued that the commercialization of health care is unethical since health is a basic human right founded in a notion of dignity of the human life. Such would be a valid argument in a global system that provided universal medical care and pharmaceutical products for free, and where all stages of the medical innovation process were conducted directly by public or state subsidised institutions and completely subtracted from the logic of a free market economy. However such reasoning does not apply in a market economy where medical and pharmaceutical innovation is privately funded and products used on medical treatment are market goods.

Another recurrent argument is linked with the nature of the medical profession. Traditionally the medical profession has not been considered a commercial or industrial activity, and medical acts are not acts of commerce. It is argued that the medical profession

²¹ This notion does not preclude the existence of demand for such detrimental or unethical products or services.

²² Absent any specific circumstances of exclusionary abuse that should be subject to competition rules.

does not follow market logic of profit and prices are not governed by offer and demand considerations, since the medical profession, although not barred from making a living from medicine practice, should have as higher objective the interest of the patients.

The ethical rules that guide the medical profession are irrelevant; a non profit activity is not synonym of non economic. Law and economics scholars have since long proved that any human activity can be studied by in economic theory even non commercial activities can be submitted to a cost/benefit analysis and obey to the supply/demand paradigm.

While there might be other ethical arguments capable of sustaining the exception, those are not capable of transforming from an economic view point these inventions into unwanted goods or '*bads*'. Neither the distinction between process or product patents and its implications dictates the validity of the argument that denies the economic incentive provided by the grant of patents to unwanted or non-useful goods.

3.2.2 There is a market failure corrected by alternative forms of incentive

The main justification for patent rights existence is derived from being the optimal mean to correct a market failure. We need to consider if there is a market failure in the case of methods for treatment and diagnostic methods.

If the theory is correct it should be valid to all inventions: products and processes. A method, in its essence can be qualified has a type of process – a way to achieve a result. However methods differ from other processes since the result is not a physical but rather an immaterial product: restoration of health or detection of a certain health condition.

On general terms, the patentability of processes collides with the difficulty of considering them to be an invention. Ideas and scientific theories are not inventions. Methods are a sequence of pre-established steps, and mental steps or ideas can not be patentable as such. However, a well determined sequence of steps of a technical nature can be patentable, since it is no longer considered to fall under the concept of non-invention of art 52 EPC.

A recurrent argument is that incentive for innovation concerning methods for treatment and diagnostic methods provided by patents is not necessary, since such incentive is provided by alternatives means, i.e. a system relying on other forms of incentive that include research grants, career progress, public recognition, good will for the hospital/practitioners involved, a perceived ethical duty of sharing knowledge and other similar non-monetary incentives. It

remains to be determined if such system provides for a more efficient allocation of resources. Answering this question with empiric data does not appear to be a feasible task. While innovation has not ceased in Europe in the absence of patents it is impossible to compare the actual level of innovation with an eventual level of innovation should patents for these inventions had been available. Furthermore, a comparison with the EUA where method patent are issued, would not provide useful empirical data. Not only the innovation processes is not fully known and has many determinant concurring factors, but also any conclusions would be tainted by the fact that once patented the information is public and the invention can be practiced in Europe without any restrictions.

The mere argument, above, necessarily implies that the need for incentive to innovation, as to correct a market failure does exist in the medical sector. However, such argument states that inventors of methods for treatment and diagnostic methods respond primarily to alternative incentives, rather than to patents. Such might be true if we use a justification for patents based on reward/incentive to invent paradigm. Under such justification, inventions are typically produced during the normal course of the medical activity in the attempt to improve existing methods, and thus other mechanisms of incentive/reward such as professional recognition are enough to provide society with the optimal level of inventions. Furthermore, resort to trade secret is precluded since medical practitioners are bound by the deontological obligation of sharing knowledge with other medical professionals.²³ Thus patents are not needed either as incentive/reward to disclosure.

However, currently it is doubtful that inventions of methods of treatment or diagnostic are the product of research conducted mainly by medical professionals. The link between the medical practitioner and these inventions is becoming thinner as technology evolves. The mere qualification of an invention as treatment or diagnostic applied on the human body is problematic. Under current practice of the EPO the qualification of a method invention as treatment or diagnosis does not rely on the qualification of the person who performs it.²⁴ Likewise the application of the exclusion is completely independent of the characterization of the inventor or patent applicant. The patent applicant can be and often is a commercial

²³ References to the Hippocratic oath and the norm of sharing medical knowledge adopted by the American Medical Association code of ethics are common in literature. However, it should be noted that a similar rule is not found explicitly in the World Medical Association International Code of Medical Ethics.

²⁴ G1/04 *diagnostic methods* Official Journal EPO 334 2006; G1/07 *medi-physics* Official Journal EPO **130** **2011?**

company or a privately funded research institution, instead of an individual. Even when the inventor(s) are simultaneously the patent applicant(s), they are not necessarily medical practitioner(s). In the case of the most advanced technologies such as nanomedicine, research is done typically by teams of scientists with multidisciplinary scientific backgrounds. Medical diagnosis and treatment research is no longer necessarily conducted by medical practitioners in the course of their practice.

In conclusion, if we move beyond the classical notion of invention and the reward/incentive to invent arguments for patent protection, and use the notion of innovation the necessary conclusion is that those alternative forms of incentive only operate for inventions resulting from personal medical practice and not inventions created and developed into market product in complex industrial settings.

3.2.3 Patent rights as (not) necessary conditions to induce investment in innovation in methods for treatment and diagnosis

As a rule companies will invest in research that may lead to products or services that can be marketed in conditions as to recovers their opportunity costs (either by using patents or trade secrets to do so). Inventions that either can be market under trade secret, or are accidental inventions that require small investment and have a high benefit-cost ratio will not be induced by the patent system,²⁵ and thus the patent system is not a necessary condition to their existence.

Some of the arguments for denying patentability for methods rest on the notion that typically methods are accidental inventions or by-products of the medical practice. However, even in the absence of definitive empirical data such does not appear compatible with the complexity of contemporaneous medicine. Furthermore, most inventions in the medical sector tend to fall into what the patent-induced theory would classify as revolutionary²⁶, due to the nature of the field and the need to satisfy strict regulatory constraints. Once a medical invention is available in the market all it needs is to have a therapeutic advantage to render all other options redundant. After all a physician is barred by professional deontological rules from prescribing a therapeutically inferior product or use a less efficient method for treatment

²⁵ Scherer n1, 443- 450 and Oddi n1, 278

²⁶ Revolutionary inventions are those that produce a “spectacular technical contribution” and are patent induced. Scherer, n1 443

or diagnostic. Resort to outdated or less efficient treatments will only be acceptable in case of unavailability of such resources.

A contra argument could be raised, by arguing that innovation has not cease in the absence of these methods patents in Europe. However, such argument would be overthrown by the evolution of medicine. Until recently, it could have been sustained that there was a clear distinguishing between methods and product inventions, and methods were either accidental inventions or developed in public research entities, such as hospitals and universities in a setting where the incentive provided by patents was not determinative.

3.2.4 Patents as prospects

According to the prospect theory the function of the patent system is defined as a means to provide reward for investment in the development of a technological prospect after the patent has been granted. The prospect is defined as "a particular opportunity to develop a known technological possibility"²⁷. Under this vision of the patent system, the patentability of methods for treatment is justified, even for those that may be accidental inventions. If we accept that patent rights function as an incentive to prospect or to develop the invention, then arguments such as the existence of other forms of incentive related with the medical professional would be completely void. Even if we accept that inventions can be supplied without the need of patent rights incentive, the same can not be said for ulterior phases of the innovation process.

3.2.5 Market signals

Patents, as other IP rights, are currently understood by the different market agents (investors, entrepreneurs, scientists, decision makers, opinion makers and consumers) as signalling a complexity of characteristics and functions. A patent today, as evolved into a signal of potential for further technological development, an investment security, a business asset, a basic commodity for downstream industries, a guarantee of quality, exclusivity and originality to the consumer.

Although the patent rights were not created in order to convey information about the invention beyond the disclosure of technical information, currently ownership of patents

²⁷ Kitch n1, 266.

transmits a variety of signals to the market and has become to venture investors an important element in assessing opportunity costs in the decision making process. Patents have become a form of meter other not so readily accessible attributes of companies.²⁸ Additionally, patents convey information to consumers and are seen as a sign of prestige, a guarantee that the good is innovative, and a token of quality and safety.²⁹

Understanding patents not only as incentive/reward providers, but as holding an additional signalling function whether as “as means of credible publicizing information”³⁰ or as an accurate manner of metering inventions,³¹ implies questioning whether such function would exist or not in the case of medical methods and whether the availability of this signalling function is more efficiently achieved by patents or by alternative means.

The signalling function operates independently of the type of claim, and thus it would provide an additional tool of dissemination of information regarding novel methods for treatment and diagnostic methods. Furthermore, patent right holders have incentive and tend to invest considerably in reinforcing the information function with marketing efforts directed to specially targeted audiences. Traditional alternative forms of incentive/reward require an individual effort in obtaining information and thus are less efficient. Furthermore, a race to publish, compared with a race to patent produces more incentive to publication of early research results than to publish better researched subject, undermining the information function.

3.2.6 Rent dissipation

Although rent dissipation theory, as proposed by Grady and Alexander has been justly criticised³² and is not intended to be a patent justification theory, its basic premises can be used to assert the justification of exclusions to patentability. According to the rent dissipation theory any subject matter, even those falling under art 52 and 53 EPC could be patentable. Discoveries and scientific theories could be patentable since they often open a race for finding the first patentable invention or what Grady and Alexander call improvements.

²⁸ Long n1, 646.

²⁹ Such holds true even if such information is an illusion at best. A patent does not guarantee that an invention is a preferable technical solution, but it does attest that it's a new solution, and it works as claimed.

³⁰ Long n1, 625.

³¹ Carvalho n1, 1.

³² Landes and Posner n1, 352.

Similar reasoning can be applied to exceptions to patentability including methods for treatment and diagnostic methods applied to the animal or human body. Even if it is accepted the argument that incentive for the invention is provided not by the availability of patent rights but by alternative means (e.g. research grants, prestige, sense of duty). Alternative means of incentive also have an economic cost, and races to be the first to publish and be credit for scientific achievement also produce rent dissipation.

Medical methods are clearly inventions whose signalling potential is enormous. Survival is the most basic instinct; there is nothing more valuable than health and nothing more prestigious than finding a new method of treatment. With the exception of a few cases of self contained perfect solutions, any new method would trigger a race for improvement, leading to rent dissipation. In this sense the grant of patents for methods for treatment would be justified by the need to limit rent dissipation in post-grant phases. Patents are more efficient in preventing rent dissipation than the incentive and reward provided by research grants and moral and reputation related rewards due to the fact that patents are granted to one applicant only and in a processes conducted by one single entity – the relevant patent office. Research grants and other incentives potentially can be simultaneously provided by an unlimited number of entities to a considerable number of researchers.

3.2.7 Race to invent

Opponents of broad patent scope, such as Merges and Nelson claim that empirical evidence proves that coordinated development by a single entity is less efficient than open competition.³³ Thus, the patent system should provide incentive to induce a race-to-invent by narrowing the scope of pioneer patents. Arguably, this reasoning provides arguments that impose stricter application of exclusions and exceptions to patentability. Regarding the methods exception it should be said that this understanding can be extended to alternative means of incentive/reward. A race to invent is a race to reap a reward, monetary or not it can always be measured in economic terms. Likewise it is of little consequence if such race is fuelled either by a race to patent or a race to publish: human behaviour dictates that the economic man innovates to seek a competitive advantage (even if such advantage is the sense of fulfilling a mere moral command of contributing to progress and the good of mankind). In

³³ Merges and Nelson n1

this sense, Merges and Nelson conclusion that competition fosters innovation is not contradicted. However, restricting incentive to pioneer inventions overlooks the fact that such would decrease incentive to disclosure information, since postponing patentability to a more mature phase of the innovation process would delay even more the publication of knowledge. Also reducing incentives to basic research corresponds to investment swift from basic research to product development, and such can have unwanted overall social effects.

Conclusion:

Economic reasoning applied to the art 53 (c) EPC does not provide convincing arguments for the justification of the exclusion from patentability of methods for treatment and diagnostic methods applied on the human or animal body. In fact, this exercise shows that this exception to patent protection not only is not compatible with currently known economic justifications of patent rights, but in fact economic reasoning applied to art 53 (c) appears to reinforce the general principle that patents should be available for any inventions, either processes or products. The absence of an economic justification for this exception leads to the following logic conclusions. Firstly, if economic justifications are not able to explain the existence of this exception, then economic reasoning can not be used as the sole framework for justification of patent rights but rather as an approach that needs to be complemented by the use of other methodologies of analysis. Secondly, in the absence of economic justifications the existence of the provision must be justified by other considerations, namely ethical arguments such as protection of public accessibility to state of the art health care and of the professional freedom of medical practitioners. Thirdly, if either such ethical justifications were also to be found flawed in particular when confronted with the latest scientific and technical developments in emerging technologies or were found unable to promote the attainability of the values it intends to protect, then there is room for further research and debate concerning possible alternative legislative options.