



Patent protection for medical methods: Ethics Vs. Patent incentives.

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Introduction

The Patent system contributes to human prosperity by promoting the progress of science and technology. It ensures progress by providing incentives to invent, disclose, invest and design around. These incentives assure invention, innovation and efficient use of inventions. Owing to the advantages offered by the patent system, the scope of patentable subject matter has been ever expanding. Its tentacles have spread to every conceivable field of science and technology. The United States Supreme courtⁱⁱ has given an unlimited scope to patentable subject matter by pronouncing that ‘every thing under the sun made by man is patentable’. In addition to the traditional inventions, today’s patentable subject matter includes computer software, business methods, gene sequences, protein sequences, etc. . Efficient use of the patent system by developed countries for economic development, has inspired developing countries like India, Brazil, China and others towards incorporating a patent regime in their legal systems.

Though the patent system has proved to be very useful in promoting the progress of science and technology, its scope has not been extended to methods of medical treatmentⁱⁱⁱ. Most nations have excluded medical methods from the scope of patentable subject matter, by taking into account the ethics inherent in the practice of medicine. This has deprived medical methods of the rapid development provided by the patent system to other fields. Under such a scenario this article examines the possibility and necessity of bringing medical methods under the scope of patentable subject matter.

¹ The views or arguments expressed in this article are that of the author and not the company. Please send your feedback to kalyan@brainleague.com

Part I explores the law with regard to medical method patents in a few selected countries, Part II elaborates the ethical concerns relating to patenting of medical methods, Part III looks at the advantages offered by the patent system to promote progress of medical methods, Part IV pin points the areas of conflict between Ethics and the patent system and proposes possibilities of balancing the conflict and Part V concludes the discussion.

Part I

Law relating to medical method patents

A. Agreement on Trade Related aspects of Intellectual Property Rights (TRIPS).

The Agreement on TRIPS is a part of the Marrakesh Agreement signed by various nations establishing the World Trade Organization. This agreement aims at bringing about uniformity and harmonizing intellectual property laws. Towards this end it mandates certain changes in the municipal laws of its member states. It also aims at providing adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights.

Article 27 of the TRIPS agreement defines the scope of patentable subject matter. Paragraph 1 of Article 27^{iv} states that patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. According to para 1, the scope of patentable subject matter extends to products or processes under all fields, but this provision is subject to provisions under paragraphs 2 and 3. Paragraphs 2 and 3, lay down certain exclusions from the scope of patentable subject matter. Member states are allowed to exclude subjects mentioned in those paragraphs from the scope of patentable subject matter in their municipal laws. Paragraph 3^v permits member states to exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals from patentability. Through paragraph 3 of Article 27 in the TRIPS Agreement, the member states have affirmed the supremacy of ethical concerns over advantages offered by the patent system by allowing non patentability of medical methods.

B. United States of America.

Section 101, Title 35 of the United States Code^{vi} deals with patentable subject matter. The scope of patentable subject matter as per that section is very wide and open. It states that any process, machine, manufacture and composition of matter is patentable if it is new and useful, subject to conditions of Title 35. The statute does not lay down specific exclusions other than the general conditions applicable to all inventions or discoveries in order to be eligible for a patent. The language in Section 101 demonstrates an expansive scope, which has been reiterated by the United States Supreme Court in the case of *Diamond v. Chakrabarty*^{vii}. In that case, the court held that the committee reports accompanying the 1952 Patent Act inform that Congress intended statutory subject matter to include anything under the sun that is made by man^{viii}. A method of medical treatment is a process and is patentable if it is new, unobvious and useful and satisfies other conditions of the patent statute. Therefore, the United States patent law includes medical methods within the scope of its statutory subject matter.

The right to patent a method of medical treatment is available under the statute, but the statute under section 287(c)(1)^{ix} abrogates the remedy available for its infringement, thus nullifying the right to patent. Section 287(c)(1) states that infringement provisions shall not apply to a medical activity performed by a medical practitioner or a related health care entity^x. The term medical activity has been defined in the same section to include performance of any medical or surgical procedure^{xi}. These provisions were added to the statute in the year 1996 through an Omnibus Consolidated Appropriations Act. They deny the patentee a remedy for infringement of a medical or surgical procedure.

The amendment was made after Pallin, an ophthalmologist, had sued Singer and Hitchcock for performing hundreds of surgeries which infringed his patented method of making an incision in the eye which would be self healing in a cataract surgery^{xii}. The American Medical Association and the doctors being dissatisfied with Pallin's acts expressed a need for a legislation to protect the doctors from such suits, as they would have a devastating affect on medical science. In response to this President Bill Clinton signed the Act in the year 1996.

After the passage of the Act in the United States, the right to patent medical and surgical procedures exists but the right to enforce those rights or to sue for infringement does not exist. Consequently, the right to patent medical methods is effectively nullified by depriving the right to enforce. Therefore, in United States even if the right exists it is a nullity.

C. Europe

The conditions for patentability under the European Patent Law are different when compared to the United States Law. Article 52(1)^{xiii} of the European Patent Convention states that patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step. Clause (4) of the same article excludes methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on humans from the scope of patentable subject matter^{xiv}. So, in Europe, methods of medical treatment by surgery or therapy and diagnosis are not patentable.

The law relating to patentability of medical methods has been elaborated by decisions of the EPO board of appeals and other national boards. These decisions have laid down certain guidelines to be followed while deciding upon the patentability of surgical, therapeutic and diagnostic methods.

Surgical methods: There is no conflict in the decisions of various boards with regard to patentability of surgical methods. The term "surgery" has been held to include not only invasive operations, but also non-invasive procedures such as repositioning^{xv}. Performing a surgical on dead body of an animal was held to be patentable as the prohibition to patentability exists only against living organisms^{xvi}.

Therapeutic methods: Therapeutic methods are not patentable if they involve a therapy on human or animal body. The term "therapy" has been defined to include anything that relates very broadly to the treatment of a disease in general or to a curative treatment as well as to the alleviation of the symptoms of pain and suffering^{xvii}. The patentability of a 'therapy' depends upon the nature of the treatment^{xviii}. Generally cosmetic methods are

patentable in EPO, however if they include a therapeutic method they are not patentable^{xix}.

Diagnostic methods- Diagnostic methods are of two types: *In vivo* and *In vitro*^{xx}. *In vivo* methods are barred from patentability but *In vitro* methods are patentable^{xxi}.

In a decision by the appeal board of EPO^{xxii}, it was held that a diagnostic method involves four steps:

- (1) A first examination phase, during which data is gathered,
- (2) a comparative phase, in which the data gathered is compared with normal values,
- (3) the recording of a significant deviation from the normal values when the comparison is made,
- (4) and lastly, the attribution of the deviation to a particular clinical picture.

If any of these steps are not present then it is not a diagnostic method and therefore it can be patented. The Swiss Federal Court^{xxiii}, tightened the strings on patentability of diagnostic methods by holding that a method shall be considered a diagnostic method even if the final step of medical judgment is missing.

The German Federal Patent Court in *Mitt* held that an invention directed towards collection of data, which will be helpful for diagnosis, is a diagnostic method, therefore, making it not patentable. The French court^{xxiv} "Court d'Appel de Paris" decided otherwise by holding that a method for determining heart function involving collection of data to be patentable.

Hence, in Europe, if the claims in a patent application contain at least one element, which involves a surgical or a therapeutic or a diagnostic method, then it is not patentable.

D. Japan

The law relating to patentability has been laid down under section 29 of Japanese Patent Law, which talks about patentability of inventions. Section 29(1) states that an invention must be Industrially applicable in order to be patentable^{xxv}. Part II of the Examination Guidelines for Patent and Utility Model under Section 2.1 lay down that a method of medical treatment is an Industrially Inapplicable Invention. It excludes methods for

treatment of the human body by surgery or therapy and diagnostic methods^{xxvi} from patentability. A method of treatment by using a patentable medical instrument and pharmaceutical product is also considered as an industrially inapplicable invention^{xxvii}. However, Methods for treatment of samples that have been removed from the human body and methods of gathering information from them are not considered methods of treatment and are therefore not excluded from patentability^{xxviii}. On the other hand, if the sample is returned to the human body, it is a medical method and is therefore excluded from patentability^{xxix}.

The examination guidelines explain the patentability of surgical, therapeutic and diagnostic methods by dealing with each method of treatment individually. Methods for treatment of the human body by surgery^{xxx} include Surgical operations and drawing blood, cosmetic methods for surgical operations whose purpose is not therapeutic or diagnostic and preparatory treatment for surgery, such as anesthetic treatment. These methods are industrially inapplicable and therefore not patentable.

Methods for treatment of the human body by therapy^{xxxi} include the following: (i) methods of giving or injecting medicine, or giving physical treatment to a patient for cure or restraint of a disease; (ii) methods of transimplanting or implanting substitute organs such as artificial internal organs or artificial limbs; (iii) methods of preventing a disease and methods of treatment for the maintenance of physical health and (iv) Preparatory methods of treatment by therapy or methods for nursing associated with the treatment. These methods are not patentable as they are industrially inapplicable.

Diagnostic methods^{xxxii} means methods of gathering different kinds of data by measuring structures or functions of each organ in the human body by physicians (or persons directed by them) for the medical purposes such as detecting diseases or recognizing or judging the physical condition of the human body, or methods of judging the condition of diseases based on the said data. These include: (i) methods of measuring the shape or size of internal organs or the conditions of the interior or exterior of the human body for the medical purposes of detecting diseases or recognizing or judging the physical condition of the human body and (ii) preparatory methods for diagnosis. It is to be noted that methods per se for measuring structures or functions of the human body whose purposes are other than medical ones such as detecting diseases or recognizing or judging the

physical condition of the human body are not deemed as “methods for treatment of the human body by diagnostic methods.”

So, in Japan the general rule is that methods of treatment by surgery or therapy and diagnostic methods are not patentable and clear guidelines have been laid down to determine their patentability.

E. Australia

Section 18 of the Patent Act, 1990 provides that an invention is a patentable invention if the invention is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies^{xxxiii}. Section 6 of the Statute of Monopolies states in part that a patent shall not be granted if the invention is generally inconvenient^{xxxiv}. Hence, a method of medical treatment is denied patentability only if it is generally inconvenient. The Patent Act in general does not prohibit patents on medical methods. There is a provision which excludes human beings, and the biological processes for their generation from the scope of patentable inventions^{xxxv} but methods of medical treatment do not fall under the scope of this provision because that provision excludes only human beings and processes to generate them but not processes to treat them.

The judiciary in its decisions has affirmed the intention of the legislature to allow patentability of medical methods.. In *Bristol-Myers Squibb Co v F H Faulding & Co Ltd*^{xxxvi}, the FEDERAL COURT OF AUSTRALIA while dealing with petty patents claiming a method of administering anti-cancer drug, taxol, opined that a method of medical treatment is patentable according to the statute. The court observed that there is no reason to exclude a method of treatment from patentability when a product for treatment is being allowed^{xxxvii}. It also observed that the parliament did not intend to exclude methods of medical treatment from the scope of patentability as it would have done it explicitly if it wanted to when it passed the 1990 Patent Act^{xxxviii}. In its opinion the court reversed the decision of the lower court, which held that patenting methods of medical treatment was generally inconvenient under section 6 of the Statute of Monopolies^{xxxix}.

Earlier in *Anaesthetic Supplies Pty Ltd v Rescare Ltd*^{xli} the court had stated that there is no statutory provision in Australia prohibiting the grant of a patent for a process of medical treatment, and that it was noteworthy that Parliament had the opportunity to exclude methods of treating the human body when it enacted the 1990 Act, but that the limit of the exclusion was only human being and biological processes to generate human beings which does not include a method of treating the human body^{xli}. In the light of the statutory provisions and Judicial decisions, it can be concluded that methods of medical treatment are patentable in Australia.

F. India

Chapter II of the Indian Patent Act^{xlii} lays down a list of inventions that are not patentable. All inventions or discoveries listed under Section 3 of Chapter II are not inventions within the meaning of the Patent Act and are therefore not patentable. Section 3(i) states that any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products is not patentable^{xliii}.

This provision rules out the patentability of methods used for treatment of human beings, animals and plants. In order to fall outside the scope of patentability the method should be for Medicinal, surgical, prophylactic, curative or other treatment. By including the words “or other treatment” after prophylactic, this clause has been given a wide scope which means that any method for any sort of treatment shall be considered to be unpatentable under the Indian Law. Thus, India has a very strong exclusion clause for medical methods.

G. China

Chapter II of the Patent Law of the People’s Republic of China deals with the requirements for the grant of a patent. It states that in order to be patentable an invention must possess the characteristics of novelty, inventiveness and usefulness or practical

applicability^{xliv}. Article 25 of the same chapter provides the list of subjects excluded from patentability. Clause (3) states that no patent right shall be granted to the method for diagnosis or for the treatment of diseases^{xlv}. Thus the Chinese Patent Law provides a broad ban on patentability of methods of medical treatment of diseases and diagnosis methods.

Summation

Medical methods are not patentable in all above mentioned countries with the exception of United States of America and Australia. Though medical methods are patentable in United States, the right to enforce those patents is not available thus making such patents futile. Thus, effectively medical are patentable only in Australia.

Developed countries like Japan and certain countries in Europe have put together a set of guidelines through statutes, guidelines and judicial decisions in order to guide an examiner and the judge while determining the patentability of medical methods. They have emphasized on determining and defining the scope of surgical, therapeutic and diagnostic methods in order to determine patentability. If a method falls outside the scope of their definition it will be held to be patentable else it will not be patentable. On the other hand developing countries like India and China have laid a blanket prohibition on medical methods through their wide statutory provisions. This difference between the developed and developing countries can be attributed to the social conditions and ideologies followed by those countries.

Part II

Ethical concerns.

Most countries have excluded medical methods from patentability by taking into consideration, the ethics inherent in the practice of medicine. The American Medical Association (AMA) has elucidated the ethical issues involved in patenting medical

methods in an article published in the Food and Drug Law Journal^{xlvi}. The AMA in that article advocates exclusion of medical methods by arguing that allowing their patentability would undermine the traditional obligations of the medical profession, make economics rather than health care the primary concern of doctors, restrict access to the patented methods, increase financial burden and damage patient confidentiality and privacy.

The medical profession has an obligation to share information, knowledge and research. Their primary concern is health care of the patient. Patenting medical methods with its emphasis on individual rewards, selective sharing and ownership would promote withholding of information, knowledge and research for personal gain, thus undermining the sanctity of the profession. Furthermore, medical method patents will elevate economic goals above those of patient health by making the doctor holding the patent a business man selling methods of treatment rather than a professional sharing and disbursing quality health care.

Patenting a medical method restricts access of that method to the patient because the physician conditions application of the method upon acquisition of a license. The patentee may restrict the number of licenses or may even deny licenses when required. A doctor's medical judgment about the appropriate method will be influenced, as the doctor might prefer to adopt an inferior method rather than licensing the patented method or referring the patient to a licensed doctor. Moreover, a doctor's freedom to use advanced medical methods will be seriously affected due to fear of liability for unlawful infringement of a patented method. This restricts access to advanced methods and prevents evaluation of new methods.

Patenting a method restricts peer review of the method resulting in a decrease in quality and safety of new methods. Students and researchers will not be able to get access to the method as use of a patented invention for academic and research purposes is not allowed in some countries like USA.

Patenting a medical method might lead to an increase in financial burden over the patients as the licensing fee and litigation possibilities will add up to the fee paid by the patient. After a patent is granted, it is not easy to monitor the use of the patented method by the physician. Determining whether a doctor has used a patented method would result

in violation of privacy rights of the patient as it would involve searching and examining patient records.

For the aforementioned reasons, the AMA concludes that it is unethical for physicians to secure and enforce patents on medical methods.

Part III

Advantages of patenting medical methods.

Extending patent protection to medical methods would promote the progress of medical science by providing incentives to invent and innovate new and useful methods. In addition to the incentives to invent, invest, design around and disclose, patenting a method of medical treatment provides the following advantages:

A. Rapid development of new and better methods of treatment

Though new methods of treatment are being developed in the absence of patent protection, the pace of development of new medical methods would increase dramatically if they are made patentable. By offering financial rewards to the inventor for developing a new method, the patent system, instills an inventive spirit in the minds of the doctors, which results in an increase in research and development, thus spurring the development of new medical methods. Patenting medical methods will increase investment in research and development as investors consider patents as a good source of revenue and are today considered as very valuable assets. Increase in investment for research will in turn boost the rate of development of new methods.

Investment and production in the drug industry is largely spurred by the availability of patents for drugs. Most pharmaceutical companies are largely dependant on their patent rights. The rapidity of invention in drugs and medical implements can largely be attributed to the incentives offered by the patent regime. The same rapidity in the invention of new methods of treatment can be achieved by applying the patent system to medical methods.

B. Integration of new technology with methods of treatment

Novel methods of treatment integrating technology can be developed only with large investments. Methods like Surrogate Embryo Transfer have been the result of intensive research involving huge amounts of money. Such methods will not be developed without an incentive to invest in their development. Such an incentive is provided by the patent system by granting exclusive rights to exploit the invention for a limited period of time. So, the patent system promotes the development of medical methods that integrate technology.

C. Development of alternative curative methods

Patentability of medical methods will encourage development of alternative curative methods such as Ayurveda, Homoeopathy, Chakra therapy, music therapy, magnetotherapy, unani and so on, which have proved to be very efficient and useful in treatment of diseases where conventional methods of treatment have failed. Sufficient attention is not given to learning, practicing and researching on these alternative methods of treatment because there are no incentives to develop those fields. In order to encourage their development incentives have to be provided and that is possible by extending the patent system to medical methods .

Development of alternative curative methods with little or no side affects will improve the efficiency of medical treatment by giving more latitude to the doctor while deciding upon the most appropriate treatment for a particular disease.

D. Disclosure of patented medical methods

The patent system grants exclusive rights to the inventor for a limited period in exchange for the inventor's disclosure of his invention. An inventor has a duty to describe and enable the invention in order to get a patent for it. So, in order to patent his medical method a doctor has to disclose his method of treatment, this will prevent secret

medical practices for financial gain and will inspire spread of information and knowledge.

Part IV

Balancing the conflict

The debate regarding patentability of medical methods revolves around the conflict between ethics inherent in the practice of medicine and the economic incentives offered by the patent system. The lawmakers have resolved the conflict in favor of ethics by excluding medical methods from the scope of patentability. Though the issue seems to have been put to rest, the remarkable advantages offered by the patent system makes us wonder about the possibility of allowing medical method patents by balancing the conflict.

There are possibilities of balancing the conflict between ethical concerns and patent incentives. All the concerns enunciated by the AMA have alternatives that can be employed to balance the conflict. The issue of a doctor being guided by an economic motive while treating a patient can be partially neutralized by fixing royalty rate on licenses based on the importance of the medical method employed. For example, a method of treating cancer can have a lower royalty when compared to a method of performing a plastic surgery. Furthermore, a compulsory licensing scheme can be enforced to ensure broad practice of the method. The duty of a doctor to disclose information will not be affected because the patent system mandates disclosure of information in order to obtain a patent. The AMA's concern that patenting a medical method impedes clinical and educational access is not true because the patent system does not restrict access; it makes it conditional on obtaining a license. This condition is also only temporary, as the method will fall into the public domain after the patent term expires at which time access is available to all.

Academic access is not affected because exemptions have already been provided in the patent laws of most nations for academic use and research. The disadvantage to the

patient who may have to pay a high fee to get access to the patented medical method can be neutralized by government action. The government may subsidize payments to patients who cannot afford the treatment. Further, this concern of the AMA is not completely true because invention of a new method reduces the overall cost of treatment. Dr. Pallin's self-healing incision saved 17 dollars per stitch that was required in the absence that method. (Point made by senator Hatch of the United States Congress while opposing the medical procedures reform legislation).

Patient confidentiality can be protected by conducting in camera proceedings when privacy issues are involved. Finally, the concern of physician autonomy can be balanced by mandating payment to the patent holder in the form of a running royalty i.e. making royalties payable after the patented method is practiced on the patient. The doctor who practices a method for his selfish financial interests can be controlled by severe disciplinary or other legal sanctions for violating ethical norms. Thus, all concerns cited by the AMA except the first can be neutralized.

The first concern of the AMA, which deals with economic motive involving medical sanctity and professionalism cannot be completely balanced. On one hand, medical sanctity and professionalism among doctors encourages sharing of information and cooperation thus resulting in good health care. While on the other hand, the patent system promotes development of new medical methods, increases investment in research and mandates disclosure of information, as a result, improving medical care. Both ethics and the patent system ultimately result in developing health care, therefore in resolving the conflict the issues boils down to which is more beneficial to the society? (Ethics or Patent system). Though ethics relating to medical sanctity and professionalism still remain in books, they have since long been ignored by the medical profession. Medical practice has become a business with the growth of corporate hospitals, preservation of medical methods as trade secrets and soaring costs of medical treatment, thus making economic motives the basis of medical practice. Under such a scenario, the society would be better off with patents on medical methods as that would give better medical care by rapidly developing new and efficient medical methods with a slight increase in the already very high costs. It would also encourage disclosure of new medical methods, thus promoting sharing of information. The advantages offered by the patent system to the

society outweigh the ethics in this issue, leading us to the conclusion that the society would be more benefited if patents are allowed on medical methods.

Permitting medical method patents is better for the society, but applying the general rules of patentability might not suit them because it would result in grant of trivial and frivolous patents. The line for regulating medical method patents should be drawn somewhere between a blanket prohibition and free grant of patents. A patent will be granted to a process or a method if the method is new or novel, useful, nonobvious, sufficiently described and enabled. These requirements should be applied strictly in case of medical methods to avoid trivial and frivolous patents.

Part V

Conclusion

The legislatures of the world have unanimously decided to exclude medical methods from the scope of patentability by giving importance to the ethics inherent in the practice of medicine, thus depriving the society of the advantages that can be provided by the patent system to progress of medical science. As pointed out in part IV, the patent system provides more benefits to humanity when compared to the ethics of medical practice and most ethical concerns can be neutralized by alternatives. Therefore, in the light of advantages offered by the patent system and possibilities of neutralizing ethical concerns, governments should consider amending their patent laws to extend patent protection to medical methods. India is highly renowned in the world for its traditional curative methods like ayurveda, naturopathy, unani medicine, etc., which have proved to be very effective where conventional methods of treatment have failed. The Indian government in particular should seriously consider allowing medical methods to be patented in order to promote progress and development of their traditional curative methods.

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ⁱⁱ [Diamond v. Chakrabarty, 444 U.S. 1028 \(1980\)](#).

ⁱⁱⁱ The term methods of treatment or medical methods used in this article shall mean surgical, therapeutic, diagnostic, prophylactic and other curative methods except methods of administering drugs.

Surgical method: ‘Surgery’ is defined in the Meriam Webster Medical Dictionary as, “1 : a branch of medicine concerned with diseases and conditions requiring or amenable to operative or manual procedures... 3 a : the work done by a surgeon b : OPERATION. Operation has been defined in the same dictionary as, “a procedure performed on a living body usually with instruments for the repair of damage or the restoration of health and especially one that involves incision, excision, or suturing.” (<http://www.intelihealth.com/IH/ihtIH/WSIHW000/9276/9276.html>, © 2003 by Meriam-Webster, Incorporated). Any medical method that includes a surgery as defined above is called a surgical method.

Diagnostic method: ‘Diagnosis’ is defined by the Meriam Webster Medical Dictionary as, “1 a : the art or act of identifying a disease from its signs and symptoms...” Any medical method that includes diagnosis as defined above is called a diagnostic method.

Therapeutic methods: ‘Therapy’ is defined by the Meriam Webster Medical Dictionary, as a “remedial treatment of mental or bodily disorder.” Any medical method that includes a therapy as defined above is called a therapeutic method.

Prophylactic method: ‘Prophylaxis’ is defined by the Meriam Webster Medical Dictionary as, “measures designed to preserve health and prevent the spread of disease: protective or preventive treatment.” Any medical method that includes prophylaxis as defined above is called a prophylactic method.

Other Curative methods: Meriam Webster Medical Dictionary defines curative as, “relating to or used in the cure of diseases...” There are lots of such curative methods. Some of such methods are: Acupressure, Acupuncture, Alexander Technique, Aromatherapy, Ayurveda, Biofeedback Training, Chakra Therapy, chiropractic, Color Therapy, Emchi, Homeopathy, Magnetotherapy, Music Therapy, Nature Cure, Osteopathy, Pranic Healing, Unani etc.

^{iv} Article 27 Paragraph 1: “Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”

^v Article 27 Paragraph 3: “Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;”

^{vi} “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title”.Section 101, Title 35 (2003).

^{vii} [Diamond v. Chakrabarty, 100 S.Ct. 2204\(1980\)](#)

^{viii} [Id.](#) at 2208.

^{ix} 35 USC Sec. 287 (2002).

^x Section 287(c)(1) reads, “With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of section 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

^{xi} The term 'Medical activities' are defined in 35 USC 287(c)(2)(A) as "the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a

composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent"

^{xiii} *Pallin v. Singer*, 1995 WL 608365 (D.Vt.,1995.).

^{xiii} European Patent Convention, Article 52(1): Patentable Inventions: "European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step."

^{xiv} Article 52(4): "Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods."

^{xv} T182/90 (OJ 9/94, 641)

^{xvi} **T182/90**

^{xvii} **T144/83 (OJ 1986/301)**.

^{xviii} **T144/83 (OJ 1986/301)**

^{xix} Patenting Inventions in the Field of Medical Technology by Dr. Axel von Hellfeld WUESTHOFF & WUESTHOFF.

^{xx} ***In vivo* methods are methods performed on a human or animal body and *in vitro* methods are methods that don't involve human or animal body.**

^{xxi} Patenting Inventions in the Field of Medical Technology by Dr. Axel von Hellfeld WUESTHOFF & WUESTHOFF.

^{xxii} T 385/86, Bruker Medizintechnik, OJ 1988, 308

^{xxiii} GRUR INT. 83, 316

^{xxiv} PIBD, no. 329, II-189

^{xxv} **Section 29. Patentability of inventions : "(1) Any person who has made an invention which is industrially applicable may obtain a patent..." Section 29, Japan Patent Law(2003).**

^{xxvi} **See 2.1 Industrially Inapplicable Inventions: (1)Methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body. Examination guidelines for patents and utility models in Japan-Part II-Chapter 2 (2002).**

^{xxvii} **Id.**

^{xxviii} **Id.**

^{xxix} **Id.**

^{xxx} See 2.1" ... 1) Methods for treatment of the human body by surgery practiced on the human body. Examination guidelines for patents and utility models in Japan-Part II-Chapter 2(2002).

^{xxxi} See 2.1 ... 2)Methods for treatment of the human body by therapy. Examination guidelines for patents and utility models in Japan-Part II-Chapter 2 (2002).

^{xxxii} See 2.1 ... 3) Diagnostic methods. Examination guidelines for patents and utility models in Japan-Part II-Chapter 2(2002).

^{xxxiii} PATENTS ACT 1990,-SECTION 18 - Patentable inventions: "(1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim: (a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies;..."

^{xxxiv} Section 6 of the Statute of Monopolies, 1624 provides that no declaration contained in the statute shall extend:

" ... to any letters patent and grants of privilege for the term of fourteen years or under, hereafter to be made, of the sole working or making of any manner of new manufactures within this realm to the true and first inventor and inventors ...which others at the time of making such letters patent and grant shall not use, so as also they be not ... generally inconvenient;"

^{xxxv} Se Patents Act, 1990, Section 18(2)

^{xxxvi} **Bristol-Myers Squibb Co v F H Faulding & Co Ltd, [2000] FCA 316 (22nd March, 2000)**

^{xxxvii} **Id.**at para 15

^{xxxviii} Id. at para 16

^{xxxix} Id. at para 7

^{xl} Anaesthetic Supplies Pty Ltd v Rescare Ltd, (1994) 50 FCR 1 (Rescare) at para 77.

^{xli} Section 18(2) reads, "Human beings and the biological processes for their generation, are not patentable inventions" Section 18, Patent Act, 1990.

^{xlii} See Chapter II of the Indian Patent Act, 1970.

^{xliii} See Section 3 clause (i), Chapter II of the Indian Patent Act, 1970.

^{xliv} Article 22: Inventions and Utility Models: Substantive Requirements of Patentability: "Any invention or utility model for which patent right may be granted must possess novelty, inventiveness and practical applicability." Patent Law of the People's Republic of China (1984).

^{xlv} Article 25: Subject Matters Excluded from Patentability: "For any of the following, no patent right shall be granted: ... (3) methods for the diagnosis or for the treatment of diseases;" Patent Law of the People's Republic of China (1984).

^{xlvi} American Medical Association, Council on Ethical and Judicial Affairs, ETHICAL ISSUES IN THE PATENTING OF MEDICAL PROCEDURES, 53 FOODDLJ 341 (1998).