PATENTABILITY OF METHODS OF MEDICAL TREATMENT IN INDIA

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Abstract

There is exclusion of diagnostic, therapeutic and surgical methods from being patented i.e. medical procedures in India cannot be patented for various reasons. There are criticisms to the exclusion of patentability related to any medical procedure or pharmaceutical or surgical process. The article focuses on why it is restricted in India and will provide reasons as to why it should not undertake a more liberal view and allow said patentability of the medical procedures. The usual justification by countries is that the allowing of medical procedures' patenting will lead to violation of the freedom of the doctors and medical practitioners and hinder their working to help a patient. The doctors must have the freedom to practice and apply the latest medical technology whether patented or not without fear or any infringement. The mindset of the practitioners may not be at par or very different compared to the physicians practicing abroad. The idea of getting a medical procedure patented should be justified and read up upon by the doctors. If patented, many doctors, to prevent infringement might refuse treatment. Further, the differences between the developing and developed countries which permit and prohibit patentability are discussed. A comparative analysis of the countries allowing said patentability and the countries prohibiting said patentability and their reasoning thereof along with the impact of patents on the medical profession shall also be discussed in detail. The lack of judicial interpretation regarding the subject matter of patentability medical a procedure is a factor for not granting the patentability of medical procedures. If there were any judicial decisions or precedents to rely upon the law can be amended but it might be too early for India to amend its law. As for countries like USA and Australia, they have had judicial decisions on the said subject matter and therefore have established the practice but India hasn't had any. IPR in India is still developing and has bloomed wonderfully yet remains the fact that it has to grow and catch on a lot further from where it is now. TRIPS agreement or be it any other international agreement, it should give specific reasons as to why a member state may choose to exclude the patentable matter and if so, it should provide sufficient rational grounds as to why it is doing so that countries when applying such rules can justify their actions, in this scenario, granting/disallowing medical procedures' patentability.

Introduction

Preamble

According to the Indian Patents Act, section 3(i), the section prohibits and excludes medical procedures and methods being patented from the purview of patent eligibility subject matter. The basis therefore being the patents will affect the patients' rights negatively by restricting the access to treatments and also restrict the doctor's freedom to operate. All types of procedures mentioned in section 3 (i) for treating a patient which gets rid of the illness is no invention in the eyes of the Patents Act. Any sort of operations that are performed on the patient, requiring the proficiency and competency of a surgeon is excluded from being patented along with therapy methods practiced on humans.

Interpretation of Section 3(I) Of Patents Act, 1970

The provision doesn't include any invention for the medical or therapeutic use for the treatment of any person or patient or animal. What it does include is the apparatus and devices used in such medical procedures like surgeries and therapies. The said apparatus, if found to be novel (the criteria an author has to satisfy for the acceptance of being granted a patent) will be patentable and their patentability will not be affected by the exclusion and restrictions on patenting the methods of treatment. The scope of the provision hasn't been put to the test judicially.

Ambit of Section 3(I) With Respect to Diagnosis & Detection Methods:

Diagnosis refers to the recognition of the nature of the illness in medical terms; it is summated by the help of the investigation made into the patient's history and previous and current symptoms and also through tests. Diagnosis by a doctor is used to determine the illness or disease a patient is suffering or not suffering from. The said provision does not include detection tests; a screening test is a method of detection of potential diseases in patients who might not show any symptoms of the disease. The primary objective is to detect the anomaly in the body early in order to use preventive or curative medicine. Therefore, the screening tests/ detection tests for detection of illnesses in patients differ from diagnostic methods of treatment.

Trips Agreement & Barring of Patents:

Article 27 of the TRIPS Agreement states the patentable subject matter and exclusions the members may deem fit at their discretion. The subject matter bars are:

(1) The exclusion required to protect the morality, intended to protect human, plant or animal health and life or to also prevent injuries to the environment. The only necessity being the requirement is at stake and not up to the convenience of anyone.

(2) Secondly, it talks about the methods of treatment of humans or animals or plants which may be diagnostic or surgical. The agreement states that the products used during treatments are patentable in their own right, the reasoning behind it being that they don't fall under the category of methods of treatment.[1]

It is still debated whether the patenting system present in countries allow for more efficient ideas and to what extent.[2]The underlying question here is whether the countries would benefit more from the exclusions rather than the enabling clauses. India being a developing country has adopted wide interpretations of the exclusions, showcasing their national considerations. In India, patentability not just identifies with the progressions and the developments but the idea of access to the technological goods i.e. the pharmaceuticals and public wellbeing.[3] It is the duty of the state of a developing nation to stabilize the inconsistent issues of patent rights, *ordre public* (morality), social standards and the fundamental rights of the constitution.[4] The issue here is whether one is to protect the patent rights or the right to health. A common ground has to be evolved, a concept that connects the distance between the two.

Exclusion of Medical, Diagnostic & Therapeutic Methods:

The goals of medical law and patent law are different from each other, which is giving rise to the conflict that we know of. It has become a complicated issue because medical law is based on the concept of the Hippocratic *Oath* and thee goal being preservation of human life. Patent law on the other hand, its objective is to motivate and encourage inventors by rewarding them, the end goals are too distinct when compared to each other. The issue here becomes of a public policy kind as so as to guarantee the most ideal treatment to the patient, physicians should consistently be free in their decision of treatment.[5] The reason for the exclusion of said procedures is based on the principles of human rights. The fundamental right to life to be given the most attention and is of the highest priority. The right of any person to get sufficient and genuine methods of treatment in case of an illness is the top priority of the doctors and it is the benchmark of medicine. The reason behind said exclusion is to make sure that the patents would never effect or influence the doctors from performing

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[1] O. Mitnovetski & D. Nicol, *Are Patents for Methods of Medical Treatment Contrary to Order Public and Morality or "Generally Inconvenient"?* 30 J. OF MED. ETHICS 470, 477 (2004).

[2] Hall Bronwyn H, *Patents and Patent Policy*, 23 (4) OXFORD REV. ECON. POLICY 568, 587 (2007)

[3] Hestermeyer Holger, *Human Rights and the WTO: The case of patents and access to medicines*, 20 (1) EUROPEAN JOURNAL OF INTERNATIONAL LAW 236, 236 (2009).

[4]Basheer Shamnad, et al., *Patent Exclusions that Promote Public Health Objectives*, WIPO REPORT 1,5 (2010), https://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex4.pdf.

[5] Pila J, *Methods of Medical Treatment within Australian and UK Patents Law*, 24 (2) THE UNIVERSITY OF NEW SOUTH WALES L. JOURNAL 421, 462 (2001).

their jobs and executing their duties properly.[6] Since the TRIPS agreement has given the freedom of exercising the exclusion at the country's discretion, the interpretation of the idea for the exclusivity having a capitalist outlook has an outcome where some countries are divided on allowing said methods to be patentable and some countries prohibiting said methods from being patentable and India is one of them. The international and domestic legislation referring to the exclusion clauses from patenting, medical procedures in particular, many developed nations haven't provided patentability prohibitions to medical and therapeutic procedures.

Patentability of Medical Procedures; Comparative Analysis of Countries:

India

Indian Patents Act, 1970 prohibits the patentability of medical, surgical, curative, prophylactic, diagnostic or therapeutic treatments of humans or animals[7] to render them free of disease or illness they might be suffering from. The nature of interpretation is strict; meaning the literal rule of interpretation is applied. The importance of public health and welfare in reference to improvement in biotechnology and in general highlighted in the constitution are thrown a light upon and shown relevance in the exclusion clause of the act.

United Kingdom

As accepted practice with reference to the prerequisite for a patent was that an invention should be industrially applicable and was also stated that medical treatments practiced on a human or animal is not industrially applicable therefore not patentable. In 2004, the Patents Act of UK amended the act of 1977, introducing Section 4(A) with reference to the European Patent Convention, it focused on the implementation of patentability but not through the patentability of medical methods with industrial applicability. These provisions allow the patentability of the medical usage of an officially recognized substance.[8]

Republic Of Korea

The patenting of medical, therapeutic and medical procedures have been interpreted as actions that could potentially fetter and hinder public health, according to the Article 32 of

[6] Kanakanala Kalyan C, *Diagnostic Method Patent Model- Patent Incentives and Socio Ethical Concerns*, 12(1) J. INTELLECT. PROP. RIGHTS 104, 110 (2007).
[7] The Patents (Amendments) Act, 2002, § 3(1)(b), No. 38, Acts of Parliament, 2002 (India).
[8] The Patents Act, 2004 of UK, art 4(A).

the Korean Patent Act that regulates that any action or patent that shall violate the public order or prove to be injurious to public health and morale shall be non-patentable. [9]

Germany

The German Patent Act, 1981 allows patentability for inventions that are genuine and new, have a factor of inventive steps embedded and are industrially applicable. Methods for medical procedures on human or animals are not considered inventions that are in any way vulnerable to industrial application.

Malaysia

Malaysia prohibits the patentability of medical procedures on humans and animals as according to Section 13 (d), which states that the procedures involving the treatment of human or animals by any means practiced are hereby not patentable. The Malaysian Patents Act, 1983 states the usual requirements for granting a patent like novelty, industrial application, and genuine idea, inventive in nature under Part IV.

United States of America

The scope of the subject matter relating to patentability in the USA according to the Section 101, Title 35 of the United States Code "is very wide as it states that any invention is patentable if it is genuine, novel and has utility, keeping the conditions of Title 35 in mind." The provision doesn't lay down any sort of prohibitions or said exclusions with regard to medical procedures. But under the *Morton doctrine*, the practice was banned in the country even though no statute bars the practice of patenting medical procedures. [10] In *Morton v. New York Eye Infirmary* the doctrine was reinforced and was stated that said procedures are not patentable. In the *Pallin case*, where the *Omnibus Consolidated Appropriations Act* for the protection of doctors and physicians relying on patented procedures to treat patients was drawn up by the US government. The current law doesn't restrict the patentability of medical procedures instead states the exception for the doctors and physicians in situations where patented procedures that are violated, is restricting the imposition of patent rights on medical procedures. In summation, the US concept of exclusions from patentability of medical procedures is very indifferent as they grant patents to the medical methods but they limit the scope of the said patents by engaging certain defenses in favor of doctors who have the patent.[11]

Australia

[9] The South Korean Patent Act, 2005, art 32.
[10] Morton v. New York Eye Infirmary, 17 F.Cas. 879 (1862).
[11] Pallin v. Singer, 36 USPQ 1050 (1995).

The High Court in *Joos v The Commissioner of Patents* in 1972, "which was regarding the restorative and cosmetic method for treating bald patients with a hair weaving procedure, awards of patents have been accessible for procedures for medicinal treatment. The first case where a court needed to judge whether this contention was right was in the Federal Court case, *Anaesthetic Supplies Pty Ltd v Rescare Ltd (Rescare)*, which was regarding an invention for treating snoring disorders in patients and a procedure as well, for its treatment. From the outset occurrence, the judge held that it was not generally inconvenient that such innovation is given a patent. The court was of the opinion that the outcome would be illogical if the products used to treating humans were patentable and the method of treating humans weren't Sheppard J disagreed, contending that awarding a patent for a method/procedure of treatment would be "generally inconvenient" by quoting Section 6 of the Statute of Monopolies. Following the Rescare case, patents for methods of treatment were awarded consistently.

At that point, in the instance of *Bristol Myers Squibb Co v F H Faulding and Co Ltd* the issue was brought again up for a case including two patents for a procedure for regulating the medication Taxol in the treatment of cancer. Heerey J of the Federal Court of Australia didn't feel bound by the decision in the Rescare case, thinking of it as not to be ratio decidendi however just an obiter. Heerey J concurred with Sheppard J in Rescare and pursued his disagreeing judgment. Thus, the protection of the method in the issue was viewed as "generally inconvenient" for public policy reasons and the two patents were held to be invalid." "On appeal, notwithstanding the dissents, the Full Court unanimously overruled Heerey's judgment by following the majority in Rescare case that patentability of procedures for medicinal treatment was not "generally inconvenient." Therefore, Australia considers methods of medical treatment as patentable subject matter.[12] The Australian Law Reforms Commission never encouraged exclusion from patentability of procedures of medical treatment rather the commission is concerned with the ill-effects it would have on the biotechnology investment, healthcare and innovation and research & development operations. In summation, the Australian Law Reforms Commission never encouraged the restrictions on the patentability of medicinal methods instead the commission is focused on the ill-effects it would have on the biotechnology investment, healthcare and innovation and research &

[12] The Australian Patents Act, 1990, §18(2).

development operations. The following table shows the countries allowing and prohibiting the patentability of medicinal methods:[13]

JURISDICTION	CLAUSE	STATUS
INDIA	SECTION 3(I)	NOT ALLOWED
EUROPIAN UNION	ARTICLE 53(C)& 52(4)	NOT ALLOWED
USA	CLASS 128, 239, 897 & 899	ALLOWED
JAPAN	ARTICLE 29(1)	NOT ALLOWED
CHINA	ARTICLE 25.1(3)	NOT ALLOWED
EGYPT	ARTICLE 2	NOT ALLOWED
KOREA	ARTICLE 32	NOT ALLOWED
NEW ZEALAND	SECTION 2(1)	ALLOWED FOR NON HUMAN
PAKISTAN	SECTION 7(4)(C)	NOT ALLOWED
SOUTH AFRICA	SECTION 25(A)	NOT ALLOWED
THAILAND	SECTION 9(4)	NOT ALLOWED
AUSTRLIA	SECTION 18(1)(A)	ALLOWED
CANADA	SECTION 2	NOT ALLOWED
SINGAPORE	SECTION 16(2)(2)	NOT ALLOWED

Impact of Medical Patents on Medical Profession & Public Policy

Rationale of the law

The practice of providing protection for patents relating to medical apparatus, cosmetic surgery and drugs for human beings and they're not considered against the public policy or violating any societal standards. Then the question that arises that is why patents for medical methods are excluded? For example any drug curing an autoimmune condition is patentable, what is the explanation for refusal to patent a procedure to administer said drug? The EPC denies the claims of patents where the medical procedure is in anyway therapeutic. What is the reason one can give with respect to legal and logical standpoints to claim that medical methods produce a cosmetic result or an operative result instead of a curative result that the latter is not patentable and the earlier is? The court in *Wellcome Foundation v. Commissioner of Patents*[14]held that the differences have been viewed without a specific distinction and stated that law should live up to the requirements of the modern era as the society is not static but dynamic.

Reluctance to Perform a Patented Procedure

[13] Lalit Ambastha & Shruti Kaushik, *Method of Treatment; A Patent Perspective*, PATENTWIRE (Oct. 31, 2019, 3:30 PM), https://www.patentwire.co.in/wp-content/uploads/2019/05/Method-of-Treatment.pdf.
[14] Wellcome Foundation Ltd v Commissioner of Patents, [1983] FSR 593.

Medical practitioners may refuse or hesitate to conduct a procedure that is patented to prevent infringement. The equitable doctrine would naturally protect the physicians who opted to apply a patented method in an emergency, for example. But in India, if filed for a suit the practitioner may be left empty handed as under the Hippocratic Oath they are bound to serve the patient.

Increasing Healthcare Expenses

The increase in the costs as to the medical procedures patents is an issue. [15] The prices of drugs and the medical apparatus' used in treating are expensive. Expenditure in costly new treatment may bring about decreased medical services costs in the long haul, on account of shortened emergency hospital stays, less intensive care and proficiency.[16] A patented procedure can be less expensive than the unpatented one, henceforth.

Harm to the Doctor/Patient Relationship

An issue that involves a patient's case being fully confidential with the doctor, the confidentiality clause that some doctors serve could be butting heads with the filing of an application for a patent. If a case is filed against the doctor having a patent then the patient being treated by said doctor, his/her right to privacy may be violated as the court may order for an enquiry into the case through the medical records including the patient's medical history.

Conflict of Interest

The issue regarding the conflicts of interest being a possible outcome as if the doctors who have incurred costs such as license fees for the patented procedure, while opting for the correct treatment for the patient, their decision and judgment might be hampered and inclined.[17] The said argument negates the issue that the physicians have an obligation to let the patient know of all the alternatives available to him/her to treat the disease or condition. A conflict among the physician's research for a patent and the right of the patient to be informed about the physician's motives were discussed in *Moore v Regents of University of California.*[18]The medical negligence and malpractice laws considered with the ethical duty of a doctor/physician are strong agents to prohibit doctors in performing dangerous or unneeded medical procedures and actions taken against the best interest of the patient. It is

[15] Gocyk-Farber B, *Patenting Medical Procedures: a search for a compromise between ethics and economics*, 18 CARDOZO LAW REV. 1572, 1573 (1997).
[16] Anderson S, *A Right without a Remedy: The Unenforceable Medical Procedure Patent*, 3 MARQ INTELL. PRO. L. REVIEW 117, 153 (1999).
[17] Meier B., *The New Patent Infringement Liability Exception For Medical Procedures*, 23 JOURNAL OF LEGISLATION 265 (1997).
[18] Moore v. Regents of University of California, 793 P2d 479 (1990).

recommended that instead of demanding a fee by the physicians, they could ask for a small royalty to be given to them per procedure and operation.[19]

Patenting Medical Procedures- A Complicated Issue

The usual justification by countries is that the allowing of medical procedures' patenting will lead to violation of the freedom of the doctors and medical practitioners and hinder their working to help a patient. The doctors must have the freedom to practice and apply the latest medical technology whether patented or not without fear or any infringement. In India, the scope of patents with regard to the said subject matter is not wide as it lacks judicial opinions by the courts. If one considers that the procedure is patentable throughout its life then the people in the country may reap the advantages of medical procedures that don't have patentable or profit-making apparatus'. That being said the individuals will have to incur costs like increased expenses, accessibility issues, enforcement issues, and the patient-doctor relationships will be fettered. The society does not need said hindrances and is better if the medical procedures are excluded. Public health should be and is the main priority in India and that is a good step. The patent rights and the well-being of people, between them, clearly the priority should be the public health as increasing accessibility of medical innovations is a priority.

Recommendation

Clarity in the International Regime of Patents

TRIPS agreement or be it any other international agreement, it should give specific reasons as to why a member state may choose to exclude the patentable matter and if so, it should provide sufficient rational grounds as to why it is doing so. The principle behind the exclusions is to be interpreted in such a way that justifies the exclusion. Their objective should be to examine the loopholes in the existing provisions legalizing exclusions of medical procedures and eventually look for remedies to the issues at hand. The different approaches taken by various countries of developing or developed nature can be understood and a rational system will be established in the patent regime. Ultimately, it will promote the priority of social and public benefit by improving quality in the healthcare sector. In summation, a constructive interpretation of the TRIPS agreements and the countries' reasons to prohibit the patentability of medical procedures will definitely benefit the patent regime.

Conclusion

[19] Chartrand S., *Why Is This Surgeon Suing? Doctors Split Over Patenting of Their Techniques*, NEW YORK TIMES, (Jun. 8. 1995).

IPR in India is still developing and has bloomed wonderfully yet remains the fact that it has to grow and catch on a lot further from where it is now. People in India who do not have an idea about the patentability of medical apparatuses and non-patentable subject matter like medical procedures u/s 3(i) should know what it is first. The practitioners without any prior knowledge may apply for a patent but it may be rejected on valid grounds. The mindset of the practitioners may not be at par or very different compared to the physicians practicing abroad. The idea of getting a medical procedure patented should be justified and read up upon by the doctors. If patented, many doctors, to prevent infringement might refuse treatment. It might be too early for India to make exclusions of medical procedures invalid as of now. Another major reason being the lack of judicial interpretation regarding the subject matter of patentability medical a procedure is a factor. If there were any judicial decisions or precedents to rely upon the law can be amended but it might be too early for India to amend its law. As for countries like the USA and Australia, they have had judicial decisions on the said subject matter and therefore have established the practice but India hasn't had any.