THE IP PRESS L. REV.
VOL. 1 ISSUE I1, JUNE 2023
ISSN: 2583-7702 (ONLINE)

PATENTS IN MEDICAL PROCEDURES: JUSTIFIED OR NOT?

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ABSTRACT

Patents over medical practices have been a source of controversy for decades. Several nations have outlawed patents on medical procedures, notably diagnostic, surgical, and therapeutic treatments, as a result of the escalating debate over medical treatment claims. This study's research concerns include whether or not patents should be given for medical procedures based on patent policy, and what the possible consequences could be. While some have taken this action, others are still searching for moral and ethical justifications. The predominant argument for this tendency is that medical professionals have a responsibility to disseminate new information and technologies to all other people for the greater welfare of society. Other grounds for the exclusion of medical procedures from patenting include ethical and social issues, unjustified economic gains, licensure, and its implications on the doctor-patient relationship. Using the available data, this research intends to investigate the genesis of medical procedures and their link to patent policies, as well as how medical procedures are situated within patent policies. In the remainder of this work, the author will attempt to comprehend and evaluate the standard shift from its acceptance of medical procedures as patentable to their logical exclusion by dissecting the many arguments for and against this policy.

Keywords: License, Infringement of Patent, PatentEligibility, and New Technologies in Medical Practices.

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1. INTRODUCTION

The patentability of medical procedures has been a topic of debate for many years. Practically, the patentability for medical procedures has gained relevance during the last four decades. According to legal experts mostly in the United States, around 15 medical processes are patented each week. A sudden need arose to validate medical specialists' ability to create and design new treatments. A medical process patent refers to patents that bestow rights over just procedural stages and not medical device inventions. However, this tendency declined as rapidly as it rose. Soon after, prominent medical institutions criticized the practice of issuing patents in medical procedures as unjustified. Subsequently, more than 80 nations lacked confidence in the patentability of most medical procedures, whether surgical, diagnostic, or therapeutic, while others permitted patents exclusively on diagnostic models. It was seen as a threat to the dissemination of knowledge and information about innovative procedures and as being opposed to the altruistic character of the ethics of medical practitioners.

In addition to the exclusion of medical treatments by TRIPS, the practice is also denounced in the 2019 session of the World Medical Association (henceforth "WMA"). The session included both discussions in favour of and against patents. Advocates of patentability emphasized the significance of doctors' private investment in research and development. Opposing states countered with rational arguments, such as ethical issues over the link between medical professionals and innovation, as well as their patients. Patents were avoided since it was unsure if the innovation would be accessible to everyone after its creation. For the benefit of the afflicted, there is a need for standard medical procedures in light of the medical field's development. Keeping these factors in mind, the World Medical Association deemed the sharing of innovative discoveries and scientific information with colleagues to be an ethical obligation considering all significant repercussions on the efficacy of the medicine. Instead, it promotes state-level national medical societies to incentivize the development of novel procedures by doctors.

In addition, some argued that medical technique patents are necessary to maintain exclusivity over them. Due to their monopoly over procedures, inventors may utilize and financially exploit their innovation in whatever way they desired. As a consequence of the lack of limitations, they profited either socially or economically. In addition, the procedures that were granted patent protection at the time were "little employed" and so did not harm the medical industry in general. Regardless, it has been repeatedly criticized for being incorrect due to the absence of a clear distinction between procedures. This means that if fundamental procedures such as open-heart surgery were to become copyrighted and patents for these kinds of procedures were limited, millions of people's health would be jeopardized.

Objective to Protect Medical Procedure:

1. To determine the novation of the patent in a medical procedure.

2. Identifying the idea behind the exclusion of medical, surgical, and therapeutic methods from patentability is itself based on the principles of human rights.
3. Determining the new medical procedure, it turns increases the public good and the quality of the community's health care.

To suggest remedies to overcome the problems regarding patents in medical procedures.

2. MEDICAL PROCEDURES AND PATENT POLICY IN INDIA

A procedure patent gave rights to the steps in the process, not to the development of any medical equipment. But this trend reached its highest point and then quickly went away. Because of this, many countries are careful about letting people patent medical procedures, whether they are surgical, diagnostic, or therapeutic. Some countries only let people patent diagnostic methods.[1] This was seen as a threat to the spread of new procedure data and information as well as a violation of the selfless nature of medical professionals.

Therefore, Section 3(i) of India's Patent Act of 1970 excludes any method for the medical or surgical treatment of plants, animals, or humans to render them disease-free or to increase or decrease their economic value. Even though the Patents (Amendment) Act of 2002 declared that any procedure for treating plants is now patentable, therapeutic, and diagnostic procedures remain exempt from patent protection. In Lalit Mahajan's patent application, the issue was whether "a method for detecting the presence of antibodies in human plasma"[2] fell under Section 3 of the Patent Act (i). According to the opposition, this Application's diagnostic element was obscured. According to the Patent Examiner, the disputed invention was a device as opposed to a method or procedure. As a result, it was ruled that the opponent's position was untenable, and Section 3(i) was deemed completely irrelevant[3].

As per a recent decision, the exclusion was deemed inappropriate in the context of a diagnostic device for the rapid detection of antibodies against dengue viral antigens in a human sample. The Patent Examiner determined that a method for locating chemicals suitable for the treatment of obesity is a diagnostic method, and is therefore not patentable under Section 3 of the Patent Act (i). Similarly, in M/s. Applied Research Systems Holding, the question was whether the claim for a 'kit used for the treatment of infertility in women' should be excluded under Section 3 of the

[1] Ruth L Okediji and Margo a Bagley, *Patent Law in Global Perspective* (1st edn, Oxford University Press 2014), page 53.
[2] Rastogi, P. (2014) *World Wide Legal Status of Medical Method Patents: An Overview*. S&A Law Offices. Available at: https://www.mondaq.com/india/patent/311404/world-wide-legal-status-of-medical- method-patents-an-overview.
[3] Promoting access to medical technologies and innovation: Intersection between public health, Intellectual property, and trade, WHO, 2020.

Patent Act (i). Under Section 3 of the Patent Act, it was determined that the claimed invention merely entailed a treatment method (i).[4]

By bringing the pharmaceutical industry under the jurisdiction of patent law, the Novartis case may establish an important precedent for medication accessibility. The decision may serve as a model for how other developing nations interpret and implement the TRIPS Agreement in the future. This case demonstrates how India upholds its global intellectual property obligations while ensuring domestic demands are met by implementing its legal responsibilities following domestic preferences[5].

The decision prioritizes social justice over commercial interests and simultaneously benefits India's indigenous industries. This is the first time that the Indian legal system has been enacted to prohibit drug patents with only minor modifications to existing law. Patenting will henceforth be utilized to protect only truly novel and inventive therapeutics with a substantial therapeutic impact.[6] Based on the preceding decisions, it appears that India has a broader view of the procedure of medical treatment exclusion, resulting in a larger proportion of these innovations being excluded from patentability.

Considerations of public policy are not sufficient to justify discrimination against the patenting of physician-administered medical treatment procedures. Such technologies have the potential to provide relief to a large number of patients; hence, they cannot be considered harmful to public order and morals or "generally uncomfortable." As much as medications, medical gadgets, and cosmetic treatments should be protected by patent law, every argument given against medical treatment technique patents may also be used against a drug, medical device, and cosmetic treatment patent[7].

The patenting of medical treatments boosts medical knowledge by stimulating the creation of novel medications and surgical procedures, which in turn improves the common good and, in particular, the overall quality of health care for the population. The researchers assume that the arguable negative impacts of such patenting do not outweigh the benefits, as the patenting of such a

[4] Sundaram J, Pharmaceutical Patent protection and world trade law: The unresolved problem of access to medicine, Routledge, p36, (2018)
[5] Stevens et al, Innovative Approaches to Increase Access to Medicines in Developing Countries, Frontiers in Medicine, (2017).
[6] Ravinder Gabble and Jillian Kohler, "'To Patent or Not to Patent? The Case of Novartis' Cancer Drug Glivec in India'" (https://globalizationandhealth.biomedcentral.com/, 2013) <https://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-10-3>. Accessed October 22, 2022.
[7] Hoen t, Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines, Health Action International, (2016).

treatment does not reduce the availability of healthcare facilities and doesn't create new obstacles distinct from those already present in the medical world or medical procedures.[8]

3. REASONS AND JUSTIFICATION FOR PATENT APPLICABILITY IN MEDICAL PROCEDURES

Because patent law grants inventors an unrestricted legal monopoly, the issue of whether they should be safeguarded when the need to enforce their rights arises. Originally, different patent laws permitted the patenting of surgical, diagnostic, and therapeutic processes based on encouraging innovation and financial rewards, and monopoly over specific operations. All of these are linked to each other. Each invention has two steps in its creation. Both invention and innovation are involved in the patenting procedure.

Patents on medical procedures were initially justified solely on two grounds: enhanced productivity and efficiency. It was performed in the interest of the public, with the intention of rewarding investors. by patenting new methods, ideas, and techniques. It was felt that to make an individual continue with inventing, we must provide the expectation of permanence. Physicians would be more likely to accept a procedure if they thought they would be awarded a patent for it. In economic terms, medical procedure Patents were promoted if demand exceeded the expense of innovations. It seemed reasonable to impose the former on the latter because both patent policy and medical practices are still in their infancy. With the increasing demand for new procedures, the cost of developing new procedures was low. patents with a high price since physicians were ready to pay a larger amount for the invention. Whereas, if the contrary is true, medical process patents are in short supply due to a lack of patentability. Even though some contend that patent costs have no bearing on their utilization, this appears to be inaccurate. The cost of removing polyps from a body, for instance, was so exorbitant that it was not widely available throughout the country.[9]

Technique monopoly implies that innovators may use and commercialize their innovations in any way they see fit. It has been extensively challenged as incorrect due to a lack of clarity in defining different procedures. It means that if basic operations like open heart surgery had to Millions of people would die if these treatments were not patented, and there were only a few patents available. The health of society at large would be compromised.

[8] Katherine Bishop, "How can someone Patent a Medical Procedure" the Legalities of Hair Transplant, Attorney at Law, 2019, https://attorneyatlawmagazine.com/how-can-someone-patent-a-medical-procedure.
[9] Linda Judge (1997) *Issues Surrounding the Patenting of Medical Procedures*. 13 Santa Clara High Tech. L.J. Available at: http://digitalcommons.law.scu.edu/chtlj/vol13/iss1/5.

While there are ethical concerns about patent granting, these considerations do not always exceed the advantages of granting a patent. And besides, without a patent, a physician's only options seem to be to publish the innovation in academic publications, give presentations at a clinical symposium, or retain the innovation a trade secret. The preferred option is to change the current patent laws to require mandatory licensing of patents for medical procedures. However, before moving on to the mandatory licensing option, some additional options are briefly examined.

One of the factors that motivated physicians to patent their medical procedure inventions in the first Their failure to reveal their inventions via scholarly journals It was pointed out that the entire method A patent dispute might be prevented if our profession had provided sufficient credit for innovations and achievements: "If publishing gets difficult for physicians and patent protection is not available, longer feasible, doctors are more likely to maintain their ideas as trade secrets." [10]

A trade secret keeps information out of the general public indefinitely, but a patent explicitly reveals an idea to the public and provides the patent owner the right to prevent anyone else from using or distributing the patented invention for a specified duration as compensation for disclosing information. If somehow the eventual aim of healthcare is to keep information flowing freely, Across the medical profession, the patent system might seem like a preferable option. Moreover, if Patenting is considered an alternative way to address the numerous concerns posed by medical the method of patenting is to update current laws to include mandatory licensing provisions.

4. TRIPS AND WMA

A 'patent', as per the terminology, is any 'innovation' that is capable of industrial uses and in which the creator has an exclusive right over the invented process for a limited amount of time. Each of these components is included in medical treatments when they are used. Nevertheless, many countries push for these kinds of patents to be excluded. This is drawn from the TRIPS Agreement, which is among the most powerful sources of intellectual property rights. The Agreement expressly enables member nations for excluding methods for medical treatments from patents under paragraph 3 of Article 7. Even though the article expressly indicates it is a 'may' clause, several nations nevertheless construed it as a 'shall' clause occasionally, mostly due to ethical and social considerations.[11]

In contrast to TRIPS' exclusion of medical methods, the World Medical Association (WMA) 2019 has criticized the practice. Patents were debated both in favor and against throughout the session. Doctors benefit from private investment in research and development, according to proponents of

[10] Linda Judge (1997) *Issues Surrounding the Patenting of Medical Procedures*. 13 Santa Clara High Tech. L.J. Available at: http://digitalcommons.law.scu.edu/chtlj/vol13/iss1/5.

[11] Gopakumar KM, Twenty years of TRIPS agreement and access to medicine: a development perspective, 55(3), Indian Journal of International Law, p.390, 367–404 (2015).

patentability. Opposition states countered with rational arguments such as moral considerations about medical professionals' relationships with the invention and their patients. Patents have been discouraged due to the uncertainty as to whether or not an innovation would be accessible to the general public after it is invented.[12]

With advancements in medicine, there is a need for standardized medical practices to help individuals who are suffering. With all of these considerations in mind, the WMA stated that sharing breakthrough discoveries and knowledge along with colleagues is a moral duty that must be balanced against all major effects on medical efficacy. Instead, it promotes state-level medical societies to incentivize physicians to create new techniques for treatment.

4.1 The Importance of Patenting Medical Procedures

There are several grounds for patenting medical procedures. Early medical procedures were copyrighted to increase productivity. In essence, it was assumed that production efficiency would benefit the public. This was because innovators were financially encouraged to innovate medical procedures via patenting. In turn, such monetary prizes would fund more research and development, which is essential for the development of breakthrough medical procedures. According to economic theory, assuming medical procedures are still not legally covered by patents, market competition may cut prices to the point where the inventor has no motivation and is only rewarded for opportunity costs. This may ultimately lead to a decline in innovation, which would be detrimental to the general population. Furthermore, the demand-supply law had a significant impact on the frequency with which medical procedures were patented. In the past, medical procedures were copyrighted if their demand outweighed the expense of their discovery. Additionally, medical procedure patents assist maintain a product's exclusive status. Patenting a medical procedure would essentially prevent other companies or inventors from duplicating the procedure and profiting from it commercially. This would turn the inventor's monopoly into a profitable enterprise.

4.2 Patenting Medical Procedures Has Disadvantages

Licensing is one of the worst drawbacks connected with the patenting of medical procedures. The costs of the procedures are greatly increased by licensing fees and royalties. This would prevent everyone from having access to healthcare. In addition, transaction expenses associated with the drug may make it very challenging to implement such medical procedure patents. Several opponents of the patenting of medical procedures claim that the public's right to health should take precedence over the economic advantages that might be derived from medical procedure patents. It is also argued that the quality of public health must always be prioritized by increasing the

[12] Sanya Bhatia, 'Medical Procedure and Patent Policy: Comparative Study In US, UK And India' (SSRN, 2021) <https://poseidon01.ssrn.com/delivery.php?ID>

accessibility of medical procedures. To make medical procedures more affordable, it is essential that they not be patented. Lastly, many have claimed, from an ethical standpoint, that the patenting of medical procedures could compromise the physician-patient relationship. This stems from the fact that, because of patents, a physician's diagnostic and treatment options for a patient are highly restricted. In conclusion, the patenting of medical procedures may often impede universal access to healthcare.[13]

5. ISSUES AND FUNDAMENTAL RIGHTS VIOLATIONS

Critics of these patents claimed plenty of moral and sociological issues, from societal problems to human rights violations. Some of these are;

Medical practitioner's ethical responsibilities- Many governments refuse medical procedure patents based on moral and rational considerations instead of scientific or technological considerations. The most concerning aspect of granting patents is that several people cannot afford them, whereas others will not grant permission to use the copyrighted process in dispute. As a consequence, there is no flexibility in information and knowledge transmission. A Hippocratic oath is one that a doctor takes before beginning his or her career. They are said to gain additional incentives for their scientific breakthroughs, such as publication in journals, presenting new knowledge at seminars, and so on. Physicians get respect and recognition for their efforts, and data is made available to the whole medical profession, making it a win-win situation for everybody. A limitation on medical procedure patents could hurt inventors' earnings, but it's important to remember that they can be motivated in other ways than money.

Relations between the doctor and the patient- Medical procedure opponents argue that allowing patents will have a detrimental effect on the doctor-patient relationship in certain situations. Usually, a doctor would use their better judgment to treat people, but with the presence of medical procedure patents, the doctor's inclination could be influenced by the patented procedures nature. This places an additional force on the patient, who must not only pay a major financial cost but also be subjected to discriminatory treatment[14].

Licensing- Applying licensing fees or royalties to exclusive monopolies increases the financial burden. Certain cases are subjected to modified therapy and have become a source of extra income. Unjustified monetary benefits- It is frequently alleged that inventors and private firms invest in situations wherein medical process patents are almost expected to be awarded. Doctors must

[13] Gopakumar KM, Twenty years of TRIPS agreement and access to medicine: a development perspective, 55(3), Indian Journal of International Law, p.390, 367–404 (2015)
[14] Hoen t, Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines, Health Action International, (2016).

undoubtedly be rewarded for their innovations, but not just financially. Even when a demand-supply model exists, the expenses must not be too high that it is unsustainable.
Fear of violation or infringement- The fear of violation, especially in emergencies, is among the most serious concerns stated by critics of medical procedure patents. Doctors who performed a patented medical treatment in an emergency will be protected under the current equitable principle of necessity. It is indeed difficult to envision a doctor refusing to perform an emergency procedure out of fear of infringement of the patent. Therefore, it is exceedingly doubtful anybody would want to patent an emergency method in the first place, considering that the law of necessity will render it invalid. The issue is that when it comes to the patentability of non-emergency operations, the "fear of infringement" argument holds little significance on its own[15].

6. SUGGESTIONS

A mandatory licensing scheme would allow a physician who patents a medical technique invention to obtain fair financial compensation while also assuring that other physicians who desire to utilize the copyrighted method are not precluded from using it. Mandatory licensing will make it illegal for a doctor to charge an unreasonable fee for using an invention. Since more people may get accessibility to the invention, this may lead to less biased reporting. This means that more people will be able to reveal whether or not the inventor acted illegally during the application procedure. Finally, it could eliminate the need for a physician to violate a patent to use a medical procedure, resulting in a reduced number of patent infringement cases. As a result, fewer infringement cases may result in fewer investigations into patients' medical records, reducing patient privacy breaches and, reducing any unfavourable influence on the physician-patient relationship.

To address the problems related to patents in medical procedures, here are some remedies that can help overcome these challenges:

Legislative Reforms: The Indian government can consider amending the Patents Act to provide more explicit guidance and criteria for the patentability of medical procedures. These reforms can ensure that patents are granted only for genuinely innovative and non-obvious approaches, avoiding overly broad patents that impede future research and accessibility.

Patent Examination Guidelines: The Indian Patent Office can develop comprehensive examination guidelines specific to medical procedure patents. These guidelines can clarify the patentability requirements and set standards for assessing novelty, inventive steps, and sufficient disclosure of the procedure.

Judicial Precedents: Indian courts have the authority to interpret patent laws and establish legal precedents. Courts can play a crucial role in shaping the landscape of medical procedure patents

[15] Ibid 11

by considering factors such as public interest, access to healthcare, and equitable distribution of benefits. Judicial decisions can influence patent law jurisprudence and guide future cases.

Narrower Patent Eligibility Criteria: The Indian patent law (The Patents Act, 1970) already includes provisions that restrict the patentability of specific subject matters, such as methods of treatment or diagnostic methods. To address the issue of patents in medical procedures, the Indian Patent Office can ensure strict examination of patent applications, granting patents only for truly novel and non-obvious medical procedures.

Exemptions for Research and Non-Profit Use: To promote medical research and ensure access to necessary procedures, exemptions can be established to allow researchers and non-profit organizations to use patented medical procedures without infringing on the patent holder's rights. This would encourage collaboration and open sharing of knowledge, fostering further innovation and driving down costs.

Compulsory Licensing: Compulsory licensing allows governments to grant licenses for patented medical procedures to third parties, even without the patent holder's consent. This approach ensures that essential medical procedures remain accessible and affordable, particularly in cases where the patent holder is unwilling to make the procedure available or demands exorbitant prices.

Patent Pools: Patent pools involve aggregating patents from multiple holders and making them available under a single license. This approach promotes cooperation and collaboration among inventors, inspiring intellectual interchange and the development of improved procedures. It also simplifies the licensing process, reducing administrative burdens and costs.

Periodic Patent Reviews: Implementing regular reviews of medical procedure patents can help ensure that they continue to meet the criteria for granting a patent. This process would evaluate patents' ongoing validity and relevance, considering factors such as medical advancements, public health needs, and the impact on affordability and access to care.

Differential Pricing and Licensing: To address the issue of affordability, patent holders can adopt differential pricing strategies, offering lower prices or licensing agreements specifically tailored to the economic conditions of different countries or regions. This approach enables more comprehensive access to medical procedures while still allowing patent holders to recoup their investments and incentivizing further innovation.

Open Source and Collaborative Research: Encouraging open-source initiatives and collaborative research efforts can foster innovation and knowledge sharing within the medical community. By openly sharing procedures, data, and findings, researchers can collectively work towards improving medical practices without relying heavily on proprietary patents.

International Cooperation and Harmonization: Addressing the challenges of medical procedure patents requires international cooperation and harmonization of patent laws. This ensures consistent patent eligibility, licensing, and enforcement standards, promoting fairness and accessibility across different jurisdictions.

These treatments are potential solutions to the problem of patents in medical processes. The implementation and effectiveness of these solutions may vary depending on legal frameworks, cultural contexts, and the interests of different stakeholders. Balancing the incentives for innovation and the need for affordable access to medical procedures requires careful consideration and ongoing exchange of ideas among policymakers, healthcare professionals, inventors, and patient advocacy groups.

7. CONCLUSION

Exclusions of medical operations, particularly medicinal, surgical, and diagnostic techniques, continue to remain a difficult notion to comprehend in the patentable domain. The subject is so complex, with so many varying interpretations and grounds for inclusion and exclusion, that it causes more complexity than it addresses. On the global front, it is past time for some clarity so that a unified position can be taken. The arguments for incorporating medical processes in patentability outweigh the advantages, and many governments have already done so. The gap must be bridged by creating a model based on the TRIPS agreement and WMA meetings, so that a considerable mechanism can be established, and member states may effectively balance public health and social gain of inventors on an equal footing. We cannot avoid the truth that physicians and medical associations want to own and profit from their ideas. It also is unrealistic to believe they won't find a means to do so even if they can't get a patent. Any reform in the law or policy aimed at addressing this issue should encourage transparency. Efforts need to be made to establish a unified, well-defined framework. Compulsory licensing should also be necessary in circumstances where a procedure is essential to save lives or improve the effectiveness of a process. Any compulsory license must ensure that the patentee is fairly compensated. It is critical to have a solid business strategy in place to promote access to innovative treatments, particularly when there is no current remedy to a medical issue.