
PROBLEM AND CHALLENGES TO NOT PATENTING MEDICAL PROCEDURE

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Medical methods, such as medicinal, surgical, and diagnostic treatments, may fail to meet the industrial applicability standards under many patent laws, rendering them non-patentable. This is because of their small industrial impact and emphasis on impacting the human or animal body. Furthermore, medical professional conventions, such as the Hippocratic Oath and medical codes of ethics, prioritize sharing medical information for the benefit of patients over personal gain, which opposes medical process patenting.

Over 80 nations, including some TPP negotiators such as Brunei Darussalam, Chile, Malaysia, Mexico, Peru, Singapore, and Vietnam, expressly ban the patentability of medical treatments. In Canada, medical techniques are not specifically barred from being patented, however, case law prohibits patents on surgical and therapeutic methods while allowing patents on diagnostic methods. Although the patentability of medical techniques is not expressly barred in New Zealand, case law has regularly denied such patents. Despite the fact that the AUSFTA protected the freedom to do so, the Patents Act of 1990 in Australia does not expressly exclude medical operations from patentability, and case law reveals that they are, in fact, patentable.

Economic considerations have always played little influence in the practice of medicine. However, the expansion of managed healthcare systems in recent years, particularly in the United States, has resulted in decreased physician compensation and reduced autonomy in medical decision-making. This shifting landscape has altered the ethical considerations surrounding medical treatment process patenting.

With the development of managed healthcare, the ethical grounds for patenting medical treatment processes have shifted. Because of the economic demands and financial limits imposed by these systems, some stakeholders have advocated for the idea of patenting medical processes to provide financial incentives and rewards for medical advances.

Nonetheless, legitimate issues and challenges exist, affecting both patent and medical

legislation around the world. Problems emerge in particular when surgical approaches are not linked to a specific product and instead represent abstract ideas. In such circumstances, determining the boundaries of patentability becomes complicated since the abstract character of the technique raises issues of novelty, non-obviousness, and industrial application.

As stakeholders battle with balancing economic incentives, ethical considerations, and the overall influence on healthcare practices and patient well-being, these continuous debates and issues continue to shape the junction between patent law and medical legislation.

- Medical technology innovation has the potential to revolutionize healthcare and enhance people's lives all across the world. On the other hand, the problem of patenting medical methods, involves complex arguments. This summary examines the reasons against patenting medical methods.

One important concern is that patenting medical methods may restrict access to critical medical advances. When a process is patented, the inventor or corporation acquires exclusive rights, which might result in exorbitant fees that make certain technology inaccessible. Furthermore, patents might prevent other researchers from developing similar inventions, further limiting access to life-saving therapy. Researchers and clinicians might collaborate to produce innovative technology available to those in need by not issuing patents. Another criticism is that patents on medical methods can stifle scientific advancement. Patents can erect legal barriers and deter researchers from developing new technology, especially if patent holders threaten legal action. Furthermore, patents can lead to secrecy in research and development, hindering the sharing of critical knowledge and slowing the growth of medical technology.

Patenting medical methods raises ethical considerations as well. Medical technologies are frequently created to treat severe diseases or ailments. A company or individual with a method patent may hesitate to share their expertise or work with others to maximize revenues. This poses a moral quandary since the drive for financial gain collides with the necessity to address major medical issues. Many medical professionals are motivated by a desire to help others rather than financial gain, despite claims that patents are required to encourage innovation by offering financial incentives to inventors. In addition, public funding can be used to promote medical research rather than only depending on patents.

- The potential for enhanced knowledge transfer and collaboration among medical professionals is one of the main advantages of not granting patents. Healthcare workers would have improved access to data and information without patents, allowing them to create novel patient care plans and freely share their knowledge. As a result, patient health outcomes may be improved, and the healthcare industry may see an increase in collaboration and innovation. Furthermore, patients may have greater access to vital medical technologies and medicines if medical processes are not patentable. Medical gadgets and treatments are frequently more expensive as a result of patents, making them unaffordable for many people. By removing the financial incentives offered by patents, medical innovations, and treatments can be made more affordable and available to everyone. Another benefit of not issuing patents for medical operations is more transparency and responsibility in the healthcare industry. Medical experts may work together to create new patient care standards and guarantee that every patient receives the best care now that more information and data are available. This may result in a more patient-centered approach to healthcare that places an emphasis on promoting wellness, preventing sickness, and improving patient outcomes.
- The high expense of patented medical treatments, which prevents many people from affording them, is a significant obstacle. People with low incomes and those who live in remote or rural locations with few healthcare options are particularly affected by this. The high cost of purchasing copyrighted medical techniques can also make it difficult for doctors to give their patients the best care possible, which results in healthcare disparities and inequities.

Patents that limit doctors' capacity to collaborate and communicate regarding patient care present another challenge. Patent laws can hamper innovation and make it more difficult for medical professionals to enhance patient outcomes by preventing the exchange of knowledge and data about medical operations. Furthermore, patents might put medical practitioners working to deliver the greatest care in difficult moral and legal situations. If doctors want to adopt a patented medical procedure but are constrained by financial or legal issues, they may be forced to choose less reliable or riskier treatments. In order to balance their duty of care to patients with legal and financial concerns, doctors must traverse difficult ethical situations.

- One worry is that paying license fees for medical procedures that are protected by

patents may sway doctors' decisions about what is best for their patients. It is crucial to remember that doctors have a professional obligation to advise their patients of all available treatment options, even those that are not protected by patents. In the *Moore v. Regents of the University of California* case, the conflict of interest issue between a doctor's study for a patent and the patient's right to know about the doctor's objectives was brought up. Rules and ethical guidelines, however, are in place to avoid these conflicts and guarantee that physicians take their patients' interests first.

Instead of charging them fees for using copyrighted techniques, one possible solution to this issue is to give doctors a tiny royalty for each procedure or treatment they do. This strategy can encourage patient access to healthcare while making sure that physicians receive fair compensation for their contributions to medical advancement.

- In the healthcare sector, patient privacy is a critical factor, and not issuing patents for medical treatments may have an impact on patients' expectations of privacy. Although refusing to grant patents encourages openness and accessibility in healthcare, it can cause patients to worry about their privacy and ownership over their medical information. Patients have a reasonable expectation of privacy regarding their health-related information and procedures. It might be difficult to control access to medical procedures and the information produced by their usage without patent protection. Patients who value their privacy could be concerned about their medical information being used or shared without their permission or being unauthorized. Furthermore, the lack of patent protection for medical procedures may impede the creation of cutting-edge treatments and technology. Investment in research and innovation is frequently fueled by the financial incentives given by patents. Without these incentives, companies and researchers could be less inclined to invest in the development of novel medical procedures, potentially impeding the development and expansion of the healthcare sector. It is necessary to balance the advantages of not issuing patents and safeguarding patient privacy to allay these worries. To resolve privacy concerns, rigorous privacy laws and regulations that provide people authority over their medical information can be implemented. Without primarily relying on patents, the development of novel medical treatments and technologies can be supported by looking into alternate financing sources, such as government grants or philanthropic donations.

- The argument over granting patents for medical treatments heavily weighs the question of cost. Critics claim that because businesses must charge for using copyrighted procedures to recoup their investments, patents can result in increased healthcare costs. Without patents, there is no cost associated with using the procedure, which may reduce the incentive for businesses to invest in the creation of novel medical techniques. The lack of patents, however, can also lead to a lack of competition, which may raise prices. Patents promote competition and the creation of comparable technology at lower costs, which may result in more inexpensive medical care. The refusal of medical method patents might also have an effect on research and development. The high expenses of medical research may deter businesses from making investments without the assurance of patent protection, so limiting the accessibility of novel medical technologies and therapies.

Remembering that patenting medical inventions is not a perfect answer is crucial. Patents can be expensive, and because of this, patients may have to pay more for their care. Additionally, if businesses withhold medical treatments and technologies to protect their rights, patents may limit access to them.

- Concerns about a potential conflict with the Hippocratic Oath, a cornerstone of medical ethics, are raised by the idea of not granting patents for medical methods. The patenting of medical procedures can affect the accessibility and price of healthcare, limiting patients' access to the most up-to-date treatments and equipment, especially for those from low-income families or in distant places. This is a dilemma for physicians because they could be forced to make choices that are influenced by things other than what is best for the patient, such as financial limitations. The Hippocratic Oath's primary tenet—that the patient's health comes first—is in direct conflict with this.

Conclusion

The development of intellectual property rights (IPR) in India is still ongoing, though it has advanced significantly. However, there is still a need for improvement and comprehension, notably with regard to the Indian Patents Act's section 3(i) and the patentability of medical devices and non-patentable items like medical processes. The particular requirements for medical patentability may not be well-known in India by many people, including practitioners. Practitioners may unintentionally seek patents for medical procedures that may be rejected for

legitimate reasons due to a lack of expertise and comprehension. It is crucial for doctors to educate themselves about the justification and effects of acquiring a patent for medical practice because the thinking of practitioners in India may differ from those working elsewhere. If a procedure is patented, some doctors could refuse to treat patients out of concern for possible infringement. Practitioners may unintentionally seek patents for medical procedures that may be rejected for legitimate reasons due to a lack of expertise and comprehension. It is crucial for doctors to educate themselves about the justification and effects of acquiring a patent for a medical practice because the thinking of practitioners in India may differ from those working elsewhere. If a procedure is patented, some doctors could refuse to treat patients out of concern for possible infringement.

BIBLIOGRAPHY

BOOKS

- Intellectual Property Law (by P. Narayanan – 3rd edition)
- Law relating to Intellectual Property Rights (by Dr. V.K Ahuja – 3rd edition)
- The law of Patents- with a special focus on Pharmaceuticals in India: Dr.S.R Myneni 2022
- Asia’s Patent Right Creation and Registration (Law of Patent): Dr. S.R Myneni
- Law of Intellectual Property 11th edition 2022: Dr.S.R Myneni

Journals

- Are Medical Methods Patentable

Tydskrif vir Hedendaagse Romeins - Hollandse Reg (Journal for Contemporary Roman - Dutch Law) Vol. 32, Issue 3 (1969) , pp. 242-262
- Prometheus Laboratories v. Mayo Clinic's Gift to the Biotech Industry: A study of patent - eligibility of Medical Treatment and Diagnostic Methods after Bilski
Northwestern Journal of Technology and Intellectual Property, Vol. 9, Issue 7 (spring2011), pp.457-476 Hoang, Dan
- Medical Methods, Risk to Public Health, and Exclusion from Patentability
European Journal of Risk Regulation, Vol . 1, Issue 2 (June 2010), pp. 154-156 Bonadio, Enrico