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Medical Procedures and Patent Policy

The connection between patents and medical procedures has long been a source of contention. Many nations have banned the patenting of medical processes, including surgical, diagnostic, and therapeutic procedures, due to the rising debate about individual claims on medical treatments. The question this paper aims to answer is whether the award of patents in the context of medical operations is legitimate in light of patent policy, and what are the implications? While some have taken this step, others are still searching for a rationale or moral and ethical basis. The most popular reason for this tendency is that medical professionals have a responsibility to share new information and discoveries with all other members of society for the greater welfare. Other grounds for the exclusion of medical processes from patenting include ethical social issues, unjustified economic advantages, licensing, and its implications on doctor-patient interactions, according to previous studies.

Using existing data, this paper aims to investigate the origins of medical procedures and their relationship with patent policies including a comparative study of three countries – India, the United States, and the United Kingdom – and how medical procedures are classified within patent policies in each. By dissecting the various grounds in favour and against this policy, the author will try to comprehend and critically analyse the paradigmatic change from the acceptance of medical operations as patentable to their logical exclusion.

What are Patents?

A patent is a legal document that grants the patentee (the patent holder) the exclusive right to make, use, sell, or offer to sell the subject matter of the patent "claims" to others. For the purposes of this article, medical patents will be defined broadly to include patents relating to pharmaceuticals, their manufacture and use, medical treatment regimens, surgical procedures, medical devices, and health care information technology for hospital and health care management systems (including software for managing hospital bed utilization, care

distribution, medical staff allocation, and cost containment), and combinations of these (for example, a "app" that incorporates the usage of a "medical device," such as an attachment that interfaces with an iPhone to perform a medically relevant function/measurement, such as blood pressure measurement, insulin level monitoring, and so on).

A patent gives the patentee a distinct marketing edge for his or her innovation since others may not be able to utilise any part of the patented subject matter unless a licence or other "right to use" is granted. As a result, a patentee can successfully prevent potential rivals from manufacturing, using, or selling the patented item or method, while also providing a mechanism (e.g., licencing) for collecting the invention's value and development expenses.

An Introduction: Medical Procedures and its relationship with Patent Policy.

For many years, medical techniques and their patentability have been a source of debate. In practise, the patentability of medical techniques has become increasingly important in the past four decades. According to legal experts in the United States, about 15 medical procedures are patented per week.[1] Medical professionals needed to be validated for inventing and innovating new procedures all of a sudden. A medical procedure patent was one that granted rights to solely procedural steps rather than the creation of any medical equipment.[2]

This trend, however, peaked and then petered out. Major medical institutions soon banded together to condemn the process of awarding patents for medical treatments as unjustified. As a result, more than 80 nations are wary of medical procedure patentability, whether surgical, diagnostic, or therapeutic, and some only allow patents on diagnostic models.[3] It was interpreted as a threat to the dissemination of new procedural knowledge and information, as well as a violation of medical professionals' humanitarian character.

[1] Wendy Yang, *Patent Policy and Medical Procedures: The Case for Statutory Exclusion from Patentability*, BOSTON UNIVERSITY JOURNAL OF SCIENCE AND TECHNOLOGY LAW (1995).

[2] WMA - the world Medical ASSOCIATION-WMA statement on PATENTING medical procedures, The World Medical Association, https://www.wma.net/policies-post/wma-statement-on-patenting-medical-procedures/#:~:text=Under%20the%20law%20of%20some,rights%20over%20any%20new%20devices (last visited Aug 7, 2021).

[3] Priyanka Rastogi, *World Wide Legal Status Of Medical Method Patents: An Overview*, (2014).

Types of Medical Patents

Medical equipment, chemical/pharmaceuticals, health care information technology, surgical techniques, and regenerative medicine technologies are the primary categories of “medical patents” mentioned here, however this is not a complete list.

1. Medical Devices

Physical devices used by physicians, hospitals, and other providers are included in this category of medical patents, and include diagnostic instruments, stents, implantable devices (prostheses), surgical instruments, surgical suite gear (sterilisation hoods, patient lifts, patient or monitoring gear), drug and food delivery devices and systems (IV bags, tubing, patient feeding apparatus), and drug and food delivery devices and systems (IV bags, tubing, patient feeding apparatus).

Patented items in this category have lower profit margins (when compared to new pharmaceutical medication products, which are described below), but they are "commercializable" considerably sooner than other types of products included under the "medical patent" umbrella.

2. Chemical Products and Pharmaceutical Drugs

Chemical compounds (vitamins, chemicals used to produce medicines, tissue sterilisation and cleaning agents) and the more sophisticated set of goods classed here as pharmaceuticals are examples of inventions in this area. Pharmaceuticals are materials that will be used to treat an infectious disease (e.g., antimicrobials, vaccinations, antibiotics) or a physical condition (e.g., ageing, chemical/hormonal imbalance, e.g., insulin/diabetes, high blood pressure, dementia, Alzheimer's, Parkinson's disease).

Patents on pharmaceutical medicines and ways of utilising pharmaceutical pharmaceuticals are critical to a pharmaceutical company's and the pharmaceutical industry's overall financial success. Medical patents in these and related categories, among other things, allow businesses to recoup the significant costs of research/development, clinical trials, patent-related expenses, and regulatory approval process costs by allowing patent-protected products to be commercialised for a limited time without competition from other products in the same space as the patentee.

3. Health care Information Technology

Healthcare information technology patents include patents that focus on streamlining the flow of medical history information through electronic medical records, patient data picture archiving, health information exchange systems within or among hospital systems and/or physicians, web-based medical software applications, computerised physician order entry, and digital imaging. In recent years, this category of medical patents has had the most rapid growth, and the number of medical patents in this field is likely to continue to rise.

The desire to create innovative techniques and systems to limit and manage medical expenses more efficiently is driving the exponential increase of medical patents in this area.[4] In this category, medical patents work to lower the administrative expenses of delivering health care while also making medical services more accessible to a larger number of people.

4. Medical and Surgical Methods

Methods and techniques for supplying and executing medical and surgical operations, as well as simplified procedures for administering care or diagnosing a medical condition, whether or not the condition is medically classified as a disease, are all included in this area.[5] This category of medical patents includes surgical procedures for mending a rotator cuff, as well as ways for doing spine surgery without coming into touch with nerves.

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5. Regenerative Medicine

Stem cell therapies and tissue transplant technologies, such as knee cartilage replacement rejuvenation and aesthetic reconstructive operations, are included in this category. Stem cell

[4] Kaiser Permanente, *Using Technology to Improve Health*, (2014).

[5] Patents on Medical Procedures and The Physician Profiteer, FIND LAW (2017), https://corporate.findlaw.com/intellectual-property/patents-on-medical-procedures-and-the-physician-profiteer.html (last visited Aug 5, 2021).

[6] Priyanka Rastogi, *World Wide Legal Status Of Medical Method Patents: An Overview*, (2014).

therapies are widely regarded as the next greatest and most promising medical frontier in human health care. These technologies, like any new medical treatment modality, face not just current regulatory and legislative constraints, but also extra, newly established regulations in many situations (by the FDA and USPTO, for example). Unfortunately, this means that getting these new technology to the public will cost much more money and take longer.

Stem cell therapies have been proposed for the treatment of arthritis, hearing loss, cancer, and other severe diseases for which current medical research provides inadequate therapy options. For a variety of reasons, the United States continues to lag behind other nations in terms of accessible stem cell therapies, one of which being the additional burden of the road to market. The FDA's Center for Biologics Evaluation and Research (CBER), which regulates biological products including stem cell products, has approved a small number of stem cell-related products, and the number of these approved products is expected to grow as more historical clinical data becomes available. Growing social acceptability of these sorts of alternative therapy modalities (among both doctors and patients) has resulted in a greater acceptance of these alternative treatment modalities, with the lack of access to these modalities in the United States leading many to seek treatment overseas.[7]

A. TRIPS and WMA on Patenting Medical Procedures.

A ‘patent', according to the definition, is any ‘invention' that is capable of industrial application and in which the creator has an exclusive right over the invented step for a specified time.[8] All of these aspects are present in medical treatments when they are used. Regardless, most countries advocate for such patents to be excluded. This is drawn from the TRIPS Agreement, [9] which is one of the most significant sources of intellectual property rights. The Agreement expressly authorises member nations to exclude diagnostic, surgical, and therapeutic procedures for the treatment of people and animals from patentable subject matter under paragraph 3 of Article 7. Even though the article expressly specifies that it is a “may” clause, several nations have construed it as a “shall” clause on occasion, mostly due to ethical and societal issues that will be explored later.

[7] Center for Biologics Evaluation and Research, VACCINES, BLOOD & BIOLOGICS U.S. FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/vaccines-blood-biologics (last visited Aug 5, 2021).

[8] Priyanka Rastogi, *World Wide Legal Status Of Medical Method Patents: An Overview*, (2014).

[9] World trade organization, WTO, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm#patents (last visited Aug 5, 2021).

In addition to TRIPS' exclusion of medical methods, the practise was denounced in a session of the World Medical Association (hereafter referred to as "WMA") in 2019. Patents were debated both in favour and against throughout the session. Physicians benefit from private investment in research and development, according to proponents of patentability.

Opposing states countered with logical explanations such as ethical concerns about medical professionals' relationships with the invention and their patients.[10] Patents were discouraged because to the uncertainty of whether or not the innovation would be available to the general public once it was invented. With advancements in medicine, there is a need for standardised medical procedures to help individuals who are suffering. With all of these considerations in mind, the WMA determined that sharing breakthrough innovations and scientific information with colleagues is an ethical obligation that must be balanced against all significant repercussions on medical efficacy. Instead, it promotes state-level medical societies to incentivize physicians to create innovative techniques.

B. Initial Reasons for patentability of medical procedures.

Medical treatments have been a hot topic since the beginning of patent law. Because patent law grants inventors an unrestricted legal monopoly, the general concern is whether physicians who reveal their innovations should be protected. Individual claims on medical procedures have led to the prohibition of medical process patenting in several nations. Initially, different patent laws allowed for the patenting of surgical, diagnostic, and therapeutic processes on the basis of encouraging creativity and innovation, economic advantages, and exclusivity over certain operations. All of these are linked to one another.

Every discovery has two steps to it's creation. Both invention and innovation are involved in the patenting process. While invention relates to the realisation of the creator's concept, innovation refers to the model's functional operation. Patents on medical treatments were originally justified only on these two grounds: improved productivity and efficiency.[11] This was done in the name of "public interest," with the assumption that patenting innovative

[10] WMA - the world Medical ASSOCIATION-WMA statement on PATENTING medical procedures, THE WORLD MEDICAL ASSOCIATION, https://www.wma.net/policies-post/wma-statement-on-patenting-medical-procedures/#:~:text=Under%20the%20law%20of%20some,rights%20over%20any%20new%20devices (last visited Aug 7, 2021).

[11] Wendy Yang, *Patent Policy and Medical Procedures: The Case for Statutory Exclusion from Patentability*, BOSTON UNIVERSITY JOURNAL OF SCIENCE AND TECHNOLOGY LAW (1995).

methods, ideas, and techniques would provide a financial incentive to investors. As a result, two economic models – the 'invent-to-invention' and 'invent-to-innovate' theories – were created to encourage invention and innovation. The first model's promoters thought that in order for an inventor to continue innovating, a model must be in place that generates the expectation of permanence. Physicians would be more likely to follow a technique if they knew they would be granted a patent for it if they knew they would be given one. Another aspect of this was the system's economy. It was believed that if the innovator is not provided such protection, market competition may push prices so low that the creator bears no incentive and merely recovers the opportunity cost.[12] The result might be a loss of creativity or innovation in general. The second idea, on the other hand, proposed that businesses encourage investment or other advantages. Independent incentives to create without patent monopolies, such as research funding and publications, are among them. For example, a research institute may invest in additional research into how pacemakers operate and even recommend changes to make them more efficient.

In terms of economics, medical procedure patents were promoted if demand outweighed the expense of inventions. It made logical to put the former on the latter because both patent policy and medical practises were still in their infancy. The cost of developing new techniques was cheap, and demand for patents with a high price was strong since physicians were prepared to pay a higher price for the patent. If the reverse is true, medical process patents are in short supply due to a lack of patentability.[13] Although some contend that patent costs have no impact on their usage, this appears to be incorrect. The cost of removing polyps from a human body, for example, was so costly that it was not widely available in the United States.[14]

Some have emphasised the necessity of medical process patents in order to maintain monopoly over them. Monopoly over methods meant that innovators may utilise and commercialise their innovation in any way they wanted on the market. They benefitted both socially and economically as a consequence of the lack of constraints. Furthermore, the procedures that were granted patent protection at the time were "rarely used," and so had no negative impact on the medical sector.[15] Regardless, this has been extensively criticised as false due to a lack of clarity in defining the separation of procedures. This means that if fundamental treatments

[12] Ibid.
[13] Ibid.
[14] Ibid.
[15] Ibid.

like open heart surgery were to be copyrighted and patents for such procedures were limited, millions of people may die and their health would be jeopardised.

II. Opposition to inclusion of medical procedures as patents.

Medical technique patents were not only warmly welcomed, but also scorned. Opponents of such patents highlighted a slew of ethical and social issues, from society concerns to human rights issues. The majority of them were focused with doctors' ethical responsibilities and their influence on patients.

A. Ethical responsibility of medical practitioners.

Many nations reject medical procedure patents based on ethical and logical considerations rather than scientific or technological considerations. The most concerning aspect of permitting patents is that many people cannot pay them, while others may not be granted permission to utilise the copyrighted technique in issue. As a result, there is no mobility in knowledge and information sharing.

1. Doctor's Hippocratic Oath and Other Incentives. A Hippocratic oath is one that a doctor takes before beginning his or her career. This oath binds doctors to execute their duties to the best of their abilities for the welfare of their patients while maintaining patient privacy, imparting the secrets of medicine to other physicians, and so on.[16] The oath establishes a bond between the practitioner and his or her patients, which cannot be maintained if medical procedure patents are imposed. This is because some innovators may choose to use their innovations exclusively, denying other practitioners the option to exploit them. As a result, proponents of excluding patenting ideas base their arguments on the traditional Oath, which states that physicians have a responsibility to share their knowledge and abilities.[17] Furthermore, physicians are said to have other incentives for their discoveries/inventions, such as publishing in journals, presenting new knowledge at conferences, and so on. Physicians get respect and recognition for their efforts, and information is made available to the whole medical community, making it a win-win scenario for everybody. It is also suggested that prohibiting

[16]Peter Tyson, THE HIPPOCRATIC OATH TODAY PBS (2001), https://www.pbs.org/wgbh/nova/article/hippocratic-oath-today/ (last visited Aug 5, 2021).

[17] Joel J. Garris, *The case for patenting medical procedures*, 22 AMERICAN JOURNAL OF LAW & MEDICINE 85–108 (1996).

medical procedure patents will reduce innovators' earnings, despite the fact that physicians can be incentivised in other ways and not only salary.

2. Effect on Patients Health. Traditionally, medical practitioners strive to provide the best possible treatment to their patients. This is the broader objective that everyone strives for, but what happens when the transmission of knowledge about new methods is restricted? Patients suffer because their physicians are unable to offer them with the necessary therapy, especially when the inventor decides to utilise the patent solely or market it just to a specific region/people. Some patients may also suffer as a result of the increased costs associated with excessive demand. The Surrogate Embryo Transfer method, which was to be trademarked in the United States, is a notorious example of this. No one else could be treated with the treatment unless their doctor obtained a licence to do so if this was followed.
3. Effect on Doctor-Patient Relationship. Opponents of medical procedure patents argue that allowing patents will have a detrimental influence on the doctor-patient relationship in some situations if they are permitted. Normally, a doctor would use their best judgement to treat patients, but with the existence of medical procedure patents, the doctor's tendency might be influenced by the patented process's tilted nature.[18] This places an external load on the patient, who must not only face a significant financial expense but also be subjected to discriminatory treatment. A cardiologist, for example, may utilise a balloon catheter to embolize the heart rather than open heart surgery, even if the latter is more appropriate, just because she has a licence to do so.

B. Other Reasons

1. Societal Concerns. Patents have a considerably bigger overall impact on medical operations than in any other discipline. The field is surrounded by serious worries about both cost and restricted accessibility. Because of a restricted monopoly to exploit the patent, nearly all patent regimes fail to stimulate creativity and innovation. There is a belief that limiting use diminishes the societal advantages that an innovation generally provides, resulting in no 'public benefit.'[19]

[18] Patents on Medical Procedures and The Physician Profiteer, FIND LAW (2017), https://corporate.findlaw.com/intellectual-property/patents-on-medical-procedures-and-the-physician-profiteer.html (last visited Aug 5, 2021).

[19] Supra at 11.

2. Licensing. Adding licencing fees or royalties to exclusive monopiles increases the financial burden. Regardless, some patients are subjected to manipulative and inefficient therapy, and they become a way for investors to make extra money. Furthermore, transaction expenses exacerbate the difficulty of enforcement.

3. Unwarranted economic benefits. It is frequently stated that inventors and private businesses invest in situations where medical procedure patents are almost guaranteed to be obtained. Physicians should undoubtedly be rewarded for their innovations, but not just financially. Even if a demand-supply model exists, the prices should not be so high that it is cost prohibitive.

4. Human Rights Dimension. It is believed that the right to health should be given first priority on humanitarian grounds. Public health and well-being should take precedence over patent rules and their complexity, and access to them should be improved. Outside of economics and patent laws, invention and innovation should be encouraged.

III. Medical Procedures and Patent Policy in India, US and UK.

1. India

By virtue of Section 3(i) of the Indian Patents Act, 1970,[20] India excludes surgical, therapeutic, and diagnostic techniques of treatment for humans and animals from the scope of patentable subject matter as a result of the TRIPS agreement. Previously, this included plants, but with the passage of The Patents (Amendment) Act, 2002, this was changed.[21] The non-industrial use of medical treatments was one of the main grounds for their exclusion from patenting, which is an important criterion for patent appraisal and issuance. A precise technique of giving medications, diagnosing a medical issue, or performing surgery are all examples of medical procedures.[22] Diagnostic techniques for exterior tissues or fluids, on the other hand, may be patentable. Furthermore, in the instance of Lalit Mahajan's patent application pertaining to a 'device for detection of antibodies to HIV and p24 antigen of HIV1 in human serum or plasma,' the grey area between patentability of a device and diagnostic/therapeutic technique was clarified.[23] The opponents argued that because the apparatus in question lacked diagnostic characteristics, it was not patentable under Section 3(i). The Patent Examiner recognised the

[20] The Patents Act 1970, No. 39, Acts of Parliament, 1970 (India)

[21] Supra at 8.

[22] Priyank Gupta, SECTION 3(I) OF INDIAN PATENT ACT, 1970: PATENT ELIGIBILITY OF "METHOD OF TREATMENT CLAIMS" STRATJURIS.COM, https://www.stratjuris.com/section-3i-of-indian-patent-act-1970-patent-eligibility-of-method-of-treatment-claims/ (last visited Aug 7, 2021).

[23] Rachna Bakhru, A review of recent patent opposition cases Managing Intellectual Property (2015), http://rnaip.com/wp-content/uploads/2015/09/a-review-of-patent-opposition-cases.pdf (last visited Aug 5, 2021).

inventive step, but pointed out that the invention was a device rather than a diagnostic technique. Similarly, the question in M/s. Applied Research Systems Ars Holding, Netherland was whether a 'kit for the treatment of infertility for women receiving numerous doses of FSH …' may be excluded under Section 3 I of the Act.[24] Because the product was only being utilised as a medical treatment, the decision was positive. While the first application did not meet the method's requirements for an industrial application, the second did.

2. United States of America

Any technique, machine, manufacturing, or composition of matter is patentable if it is innovative and beneficial, according to the law. While inventors are free to obtain medical procedure patents, they are not given with any recourse in the event of infringement, as the legislation does not offer any explicit exemptions. This implies that, while they may have an autonomous monopoly, there is no way to enforce it. After a sequence of three instances – Ex parte Brinkerhoff, Ex parte Scherer, and lastly the Pallin case in 1992 – this was clarified. The first two instances in the contentious Pallin case, in which a surgeon sued his colleagues for patent infringement of a cataract removal surgical procedure, were reversed by US courts.[25] Following the initial infringement lawsuit, the U.S. The Court was the first to develop a notion of exclusions from patentability for medical, surgical, and therapeutic procedures, implying a higher duty to strike a balance between public health and societal benefit.[26]

3. United Kingdom

The necessity of 'industrial use/application' as a key condition for granting patents to any invention, methods, or designs has been evident from the establishment of patent law in the United Kingdom. Medical procedure patents were expressly excluded owing to their lack of industrial application. The previous practise has also been criticised as a breach of professional ethics. The British Parliament updated the Patents Act of 1977 to bring it into line with the European Patent Convention, but it still prohibits medical procedure patents for diagnostic, therapeutic, and surgical procedures.

[24] Supra at 8

[25] Patents on Medical Procedures and The Physician Profiteer, FIND LAW (2017), https://corporate.findlaw.com/intellectual-property/patents-on-medical-procedures-and-the-physician-profiteer.html (last visited Aug 5, 2021).

[26] E Asif, EXCLUSION OF DIAGNOSTIC, THERAPEUTIC AND SURGICAL METHODS FROM PATENTABILITY NOPR (2013), http://nopr.niscair.res.in/handle/123456789/18370 (last visited Aug 5, 2021).

IV. Conclusion

Exclusions of medical treatments, including medicinal, surgical, and diagnostic approaches, remain a difficult notion to grasp in the patentable domain. The subject matter is so complex, with so many different interpretations and grounds for inclusion and exclusion, that it causes more difficulty than it answers. On the international front, it is past time for some clarity so that a unified position can be taken. Clearly, the arguments against include medical perations in patentability outweigh the benefits, and most nations have already done so. The gap must be bridged by creating a model based on the TRIPS agreement and WMA meetings, so that an effective mechanism can be established and member states may effectively balance public health and social benefit of inventors on an equal footing.