



Comparative Analysis of Patentability of Surgical Methods in Pakistan, EU, United States and China

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Abstract

Different Jurisdictions of the world have different, ethical standards, and public policies regarding patentability of their products, Similarly Patentability of Surgical methods are also one of the topics that face different treatment by different international jurisdictions. In this research a thorough comparison of the patent laws affecting surgical techniques in Pakistan, China, the US, and the EU will be provided in. The article will look at how different countries eligibility, reach, and enforcement of surgical technique patents are shaped by their domestic law, case law, and patent office procedures. The paper will highlight important differences, including the EU's categorical exclusion of surgical methods from patent protection, China's restriction on patenting diagnostic and treatment techniques but permission for devices, the United States permissive position with particular enforcement restrictions, and lastly Pakistan's explicit exclusion of surgical methods from patentability under its patent law. The research will conclude with observations on future trends and harmonization issues related to complications. Suitable recommendations will also be presented in the light of the whole research.

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1. Introduction

The complicated and frequent combination of law and medicine, and is represented by surgical procedure patents. In certain jurisdictions of the world, surgical methods and operations are carried out by medical professionals who have also been granted patent protection, despite the fact that patents are typically linked to discoveries like devices or medications.^[1] This article will examine the ethical discussions, legal frameworks, and practical applications related to surgical method patents, emphasizing how they affect patient care and medical innovation. As, one of the most crucial areas of medical innovation is surgical treatments, methods and operations which include cutting-edge techniques that enhance the treatment of patients in a better way. This Research will contribute to the development of patentability of important surgical methods that can be encouraged by the possibility of patentability of these methods. However still, legal traditions, ethical concerns about medical practice, and public health issues all have an ion whether surgical methods are patentable in a given jurisdiction. This article examines the patent laws of the United States, E.U, China, and Pakistan, offering a thorough jurisdictional comparison to help the audience understand this complicated problem in a better way.

¹ Tenvik, Kristin. Patent Protection of Medical Methods: A Comparative Analysis of European and US Law. University of Oslo, 2016.

1.1. Understanding of Surgical Methods

Surgical Methods refer to the several strategies and processes that surgeons employ to identify, treat, or fix medical issues by operative intervention. Depending on the patient's state and the surgical objective, these techniques vary greatly in intricacy and invasiveness.^[2]

The goals of surgical methods are to minimize damage, reduce exposure to foreign materials, and prevent problems like ischemia, or loss of blood supply etc. Methods could include using different equipment like lasers to precisely cut or destroy tissue is known as laser surgery, Extreme cold in cryosurgery to kill aberrant tissue, Electro surgery for cutting and coagulating tissue with electrical currents, Microsurgery which is a process of operating on extremely small structures in the body using microscopes. Examples of surgical methods may include heart bypass, chemotherapy, cataract surgery, biopsy etc.^[3]

2.2. Relation of Surgical Methods with Patent Law

Surgical Methods Surgical and patent law have a complicated interaction that differs greatly between jurisdictions. The medical field contains significant ethical problems, particularly with regard to patient access to care and the free interchange of medical knowledge, even though the purpose of patent law is to encourage innovation by giving exclusive rights but still Novel and non-obvious surgical procedures or techniques are protected by surgical method patents in some countries.^[4] The precise procedures and techniques a doctor utilizes to carry out an operation or therapy are covered under these patents. Surgical method patents concentrate on the procedural side of medical care, as opposed to patents on devices or medications.

In patent law, surgical techniques hold a special and disputed place. Many countries expressly forbid their patentability on the basis of ethics and public health, even though some permit their patenting (with restrictions for medical professionals). Nonetheless, there are ways to safeguard innovation in the surgical industry because related inventions such as medications, surgical instruments, and underlying technology are generally patentable globally. The conflict between intellectual property rights and the core ethical precepts of medicine is brought to light by the current discussion.^[5]

2.3. Role of Patents in Driving Surgical Innovations

Notwithstanding the disputes, patents are essential for the development of surgical techniques and technology for the following reasons:

- **Minimally Invasive Surgery:** Patents safeguard advancements in tools and techniques, such as highdefinition imaging, robotic assistance, and

multipurpose equipment that lessen patient trauma and recovery time. The accuracy and effectiveness of surgery are improved by these proprietary technologies.

- **New Surgical Techniques:** As a result of continuous advancements in surgical practice, patents have been awarded for innovative techniques such laparoscopic techniques for uterine manipulation and ovarian treatment.^[6]
- **Diagnostics and Therapeutics:** Surgical diagnostic and treatment planning techniques, such as molecular diagnostics and RNA-based medicines for women's health, are also covered by patents.
- **Commercial Incentives:** By encouraging businesses and academic organizations to invest in creating cutting-edge surgical solutions, patents promote competitiveness and technical advancement.^[7]

3. Blems in Patenting Surgical Techniques

3.1. AI and Public Policy Problems

There are serious ethical issues with surgical method patents: There are a number of Ethical and social problems in patenting Surgical methods that may be illustrated as:

- **Access and Affordability:** The basic critic is that patents on medical procedures can limit access to lifesaving therapies and operations by limiting who can perform a surgery or by imposing excessive licensing fees, particularly in poor nations that will be harm to the public.^[8]
- **Interference with Medical Practice:** Secondly patenting of medical procedures has long been opposed by the medical experts, the American Medical Association (AMA), on the grounds that it may conflict with a surgeon's ethical duty to treat patients as best they can and to share knowledge with other medical professionals.^[9]
- **Barrier to Innovation and Dissemination:** Another problem is that some patents on surgical methods might impede the free flow of knowledge and methods amongst medical practitioners, which could distract the development of medical science.
- **Balance between Incentives and Public Health:** The core issue is how to strike a balance between the ethical requirement to guarantee universal and reasonably priced access to healthcare and the necessity to encourage medical research and development if patents were to be granted over surgical methods.^[10]

3.2. Problems in Patenting Surgical Methods

- **Innovation Diffusion:** Surgical information and procedures are often shared freely through collaborations, meetings, seminars and medical

² Litchinko, A., E. Monnard, C. Tappero, and B. Egger. "Role of Lipiodol® Lymphangiography in the Diagnosis and Management of Post-Operative Chylous Ascites." *Frontiers in Radiology*, 2025.

³ MedlinePlus - U.S. National Library of Medicine "Surgery." MedlinePlus, 2022. <https://medlineplus.gov/surgery.html>

⁴ Ní Ghríofa, Eibhlín. *Patenting Practice: A Focus on Medical Methods of Treatment*. University of Turku, 2020. (Discusses how legal traditions, ethics, and patient care concerns affect surgical method patentability in different jurisdictions)

⁵ Pandey, Deepika. "Problem and Challenges to Not Patenting Medical Procedure." *Indian Journal of Law & Legal Research*, vol. 11, no. 2, 2023. https://heinonline.org/hol-cgi-bin/get_pdf.cgi?handle=hein.journals/injlolw11&ion=487

⁶ The Role of Patents in Advancing Minimally Invasive Surgery." Medical Device and Diagnostic Industry, 2023. www.mddionline.com/view/role-patents-advancing-minimally-invasive-surgery

⁷ Patents for New Surgical Techniques, Smith, John. "Innovations in Laparoscopic Surgery: Patent Trends and Impact." *Journal of Surgical Innovation*, vol. 15, no. 2, 2024, pp. 102–115

⁸ Sugarman, Jeremy, and John M. Conley. "Patenting Medical and Surgical Techniques: An Ethical-Legal Analysis." *The Journal of Law, Medicine & Ethics*, vol. 25, no. 3-4, 1997, pp. 253–261

⁹ AMA Position on Medical Patents Detrimental to Both Physicians and Patients." *Journal of Medicine*, 1 Sept. 2024. <https://www.namd.org/journal-of-medicine/1145-ama-position-on-medical-patents-detrimental-to-both-physicians-patients.html>

¹⁰ Kmietowicz, Zosia. "Patent Laws Are Keeping Poor Countries in Poverty." *BMJ*, 14 Sept. 2002

education, so patents on surgical methods may harm this process.

- **Enforcement Restrictions:** It is very challenging for patent holders to directly profit from their inventions because medical professionals are frequently immune from infringement lawsuits generally.
- **Patent Quality and Scope:** It can be difficult to assess if surgical techniques are unique and non-obvious, which might result in disagreements on the validity of patents by patent office.^[11]

4. AI Frameworks of Different Jurisdictions Governing Patentability of Surgical Methods

4.1. Framework of Pakistan on Patentability of Surgical Techniques

The current patent law of Pakistan is the Patent Ordinance of 2000 where Surgical and diagnostic procedures are expressly not protected. According to the ordinance inventions pertaining to surgical, therapeutic, and diagnostic techniques for people or animals are not patentable under Section 7 of the Patent Ordinance.^[12]

Like other countries in Pakistan patent applications also must satisfy requirements for industrial applicability, inventive step, and novelty, regardless of these considerations, surgical techniques are categorically disqualified. Surgical techniques are not covered by the exclusive rights granted to patent holders to stop the unapproved production, use, or sale of patented innovations. Pakistan's official policy to guarantee medical practice and access to healthcare advances is also consistent with this exclusion.^[13]

4.2. Patentability of Surgical Methods in Chinese Legal System

Like the Situation in Pakistan the patent law of China i.e. Article 25.1(3) of the Chinese Patent Law expressly prohibits "methods for the diagnosis or for the treatment of diseases" from becoming patentable. Surgery is a subset of treatment procedures that are also prohibited to be patented.^[14]

However, pharmaceuticals, diagnostic kits, and medical equipment are still patentable. Chinese patent applicants frequently formulate claims as "Swiss-type" claims, which are framed as the use of a substance in the manufacturing of a medication for the treatment of a condition, in order to get around the ineligibility of treatment techniques. Indirect protection of method-related inventions and second medicinal uses is made possible by this technique. As long as the modifications don't go beyond the initial disclosure; China's National Intellectual Property Administration allows changes that convert treatment method claims into Swiss style claims. This adaptability upholds statutory exclusions while promoting patent protection tactics.^[15]

4.3. System of United States for Granting Patents of Surgical Techniques

Unlike Pakistan and China U.S takes a lenient stance when it comes to patentability of surgical methods. Medical treatments techniques, including surgical operations, are all patentable under U.S. patent law 35 U.S.C. § 101 provided they meet the requirements of innovation, non-obviousness, and usefulness under the U.S law. Surgical techniques are not expressly excluded by the U.S patent law.

According to U.S law, surgical method patents cannot be enforced against the doctors who execute the procedure as illustrated in 35 U.S.C. § 287(c). This "safe harbor" clause permits enforcement against producers of equipment or goods used in the patented process but forbid infringement claims against doctors and other healthcare professionals.^[16] Lastly, in situations of infringement, U.S. courts have been known to grant significant damages, remedies and have maintained surgical method patents. For instance, patents pertaining to instruments and techniques used in spinal surgery have led to verdicts worth millions of dollars.^[17]

4.4. Law on Patentability of Surgical Methods

Article 53(c) of the European Patent Convention (EPC), illustrates that the procedures involve surgery or therapy to treat the human or animal body are expressly not patentable. This complete exclusion like Pakistan and China is intended to protect both the public's health and the freedom of practice of medicine.^[18]

Under EU law surgical tools and medical gadgets can be trademarked, but surgical techniques themselves are not protected under I.P law protection. The European Patent Office (EPO) has consistently interpreted the I.P law while granting patents on instruments and devices and refused patents on surgical procedures that result in irreversible tissue damage.^[19]

5. International Regulations and Developments Regarding Patentability of Surgical Methods

International Regulations on Patentability of Surgical Methods

WIPO: WIPO guidelines illustrate that many nations, for ethical and public policy reasons, prohibit the patentability of surgical, medicinal, and diagnostic procedures and techniques. The purpose of this exclusion is to protect surgeon's unrestricted use of these treatments.^[20]

TRIPS: Article 27(3)(a) of TRIPS agreement permits members to exclude from patentability inventions whose commercial exploitation within their borders is required to uphold morality or the public order, including to safeguard the health of people, animals, or plants or to prevent grave environmental harm. Now Although TRIPS do not

¹¹ Nonexcludable Surgical Method Patents." William & Mary Law Review, vol. 57, no. 3, 2016, pp. 621–680

¹² Patents Ordinance, 2000." WIPO Lex, World Intellectual Property Organization, 2000

¹³ Understanding Patent Rights in Pakistan: A Comprehensive Overview <https://osamakhalilaw.com/patent-rights-pakistan-comprehensive-overview/>

¹⁴ Article 25.1(3) Patent Law of the People's Republic of China <https://english.cnipa.gov.cn/col/col3068/index.html>

¹⁵ Strategies for Patenting Personalised Medicine and Companion Diagnostics in China." Managing Intellectual Property, 5 Dec. 2023

¹⁶ 35 U.S. Code § 101 - Inventions patentable." Legal Information Institute, Cornell Law School

¹⁷ Anderson, Jonas. "Nonexcludable Surgical Method Patents." William & Mary Law Review, vol. 61, no. 3, 2020, pp. 637–700

¹⁸ European Patent Office. "Article 53 – Exceptions to Patentability." European Patent Convention, 1 Apr. 2024, www.epo.org/en/legal/epc/2020/a53.html

¹⁹ Trade mark protection for medical devices and digital health products." Taylor Wessing, 14 Sept. 2022

²⁰ World Intellectual Property Organization. "Patentability Criteria and Exceptions: Exclusion of Surgical, Therapeutic and Diagnostic Methods." WIPO, 18 Aug. 2003

specifically address surgical methods, many nations interpret the morality and public health exclusions to bar the patenting of surgical, therapeutic, and diagnostic procedures in order to protect patients and medical practice.^[21]

Latest Innovative Trends on Patentability of Surgical Methods Internationally

With significant advancement in robotic assistance, AI integration, and enhanced imaging technologies, the global patent landscape for surgical techniques particularly minimally invasive and laparoscopic surgery is changing

quickly. These developments, which seek to enhance surgical accuracy, patient outcomes, and procedural efficiency, are fueling a global spike in patent applications.^[22]

Patent filings pertaining to robotic-assisted surgical systems and multifunctional surgical instruments are dominated by major industry players like Intuitive Surgical Inc., LSI Solutions, Covidien LP, and Endochoice Inc. With 3,500 laparoscopic device patents and more than 800 minimally invasive surgical device patents, the US leads the world in artificial intelligence and robotics.^[23]

6. Parative Analysis of the Law of China, Pakistan, E.U and U.S on the Issue

Table 1: Comparison with Regard to Matter Protectable or Not in Domestic Laws

Jurisdiction	Patentability Status & Legal Basis
Pakistan	(Explicitly Not Patentable) Regardless of novelty, non-obviousness and practical application, surgical, therapeutic, and diagnostic techniques are not patentable.
China	(Excluded under treatment methods) Swiss-style claims and device patents are permitted under Article 25.1(3), but diagnosis and treatment techniques are not patentable.
U.S.	(Patentable) Surgical methods are patentable in US patent law, while practical exclusion rights are limited by enforcement immunity for medical practitioners; there is no legislative exclusion.
E.U.	(Not patentable) Medical gadgets are patentable while, surgical procedures, methods and techniques are not patentable under Article 53 EPC.

Table 2: Comparative Analysis with Regard to Enforcement and Infringement Issues

Jurisdiction	Enforcement & Infringement Dynamics
Pakistan	No issues related to enforcement arise as surgical methods are not patentable in Pakistan in any way.
China	Enforcement on targets devices and drugs, direct method claims are not enforceable.
U.S.	Enforcement against practitioners is barred; manufacturers and suppliers can be sued for contributory infringement.
E.U.	No infringement claims possible on surgical methods; enforcement focuses on devices and not methods.

7. Conclusion and Recommendations

7.1. conclusion

At the nexus of ethics, medicine, and law, surgical procedure patents hold a special and complicated place. They present serious ethical and practical issues in addition to providing enormous incentives for creativity and technology improvement in surgery. The question of whether surgical techniques can be patented is complex and varies by jurisdiction. Strong public health goals are reflected in China's and Pakistan's explicit exclusion of surgical techniques from patent protection. In order to balance innovation and access, the US allows certain patents but restricts enforcement against medical professionals. While permitting equipment patents, the EU continues to explicitly exclude surgical techniques. For inventors, attorneys, and legislators navigating the international patent landscape in medical technology, it is imperative that they comprehend these distinctions. This dynamic nexus of innovation, medicine, and law will probably continue to evolve in the future. Different ways to striking a balance between these issues are reflected in jurisdictional differences. In the future, utilizing the advantages of surgical technique patents while preserving patient access and the independence of medical practice would require sophisticated regulations and well-defined legal frameworks.

7.2. Recommendations

- Use the US's more lenient approach to patent surgical techniques (enforcing against manufacturers) while honoring Europe's exclusion by concentrating on devices and formulations.
- Improve the Patent Specifications i.e add more specifications to for broadening claims and accommodate various patent standards, include alternate embodiments and thorough disclosures.
- Create a balance between Innovation and Ethics in a way to promote innovation without limiting patient access or medical freedom, and maintain openness to minimize legal concerns.

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