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Intellectual Property Rights in AI-Generated Medical Innovations: Legal Challenges In India

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Abstract: *The emergence of Artificial Intelligence in gigantic form and recent developments in the same (AI) have led to transformative innovations in every field including the medical arena, resulting in the development of novel diagnostic and surgical tools, treatment plans, and medical devices. However, these AI-generated medical innovations have raised complex legal questions, particularly relating to Intellectual Property Rights (IPR). In India, where the legal framework with respect to Artificial intelligence is not available and is still in progress, the question of how to protect the intellectual property rights of AI-generated medical inventions becomes the need of the hour. This paper explains the relevant Intellectual Property Rights in medical innovations and explores the challenges of applying traditional IPR laws—such as patents, copyrights, and trade secrets—to AI-generated medical innovations. It discusses the issues related to patentability, copyrights, ownership, authorship, and ethical concerns while putting forward the gaps in India's current legal framework. Furthermore, the paper proposes amicable and viable legal reforms and solutions to ensure that India fosters a balanced approach to promoting innovation without compromising ethical standards and public interest.*

Keywords: Artificial Intelligence, A.I Generated Medical-Innovations, IPRs, Patents, Copyrights, Trade secrets

I. INTRODUCTION

As the saying goes, necessity is the mother of invention. Many innovations have been developed to address specific needs, and one of the most significant advancements in the field of automation is Artificial Intelligence (AI). AI has been instrumental in easing and smoothening the life of humans in every field and significantly has reduced the labour of the Human Mind. The labour of the human mind in the present world is recognized and rewarded by the society in form of Intellectual property rights wherein they are given exclusive rights to use it for a set period.[1]

However, after the emergence of AI, innovations have become a major factor in the form of AI and AI-generated innovations are continuously flooding the markets. The challenge comes in front of society as to whom to reward for the innovations done by AI. In India, intellectual property rights exist to protect innovations but when it comes to AI-generated innovations, there is a lot of confusion because the country does not have a legal framework related to IPR and AI-generated innovations. There is a need to reach a viable, acceptable and ethical solution to this problem at the global as well as at local levels.

Artificial Intelligence

The ability to acquire, understand, and apply skills and knowledge is known as intelligence. It may involve cognitive processes such as reasoning, learning, problem-solving, decision-making, memory, and adaptation to new situations. There are widely accepted 9 types of intelligence but these 9 types are related to Humans. However, as the name suggests artificial intelligence is something not natural but a product of Humans. Artificial Intelligence is the field of computer science wherein some algorithm makes the machine works and they work in such a manner analogous to

[1]Cwik, B. (2014). Labor as the basis for intellectual property rights. *Ethical Theory and Moral Practice, 17*(4), 681–695. https://doi.org/10.1007/s10677-013-9471-y

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humans.[2] It might feel as if they have attained cognitive intelligence but that is the sole factor lagging in AI. AI uses data and algorithms to solve problems and even suggest solutions making it look like human intelligence. AI can have various combinations of intelligence. For example linguistic AI helps with proposing sentences in advance and converting it into any language you may desire and it can rephrase things for you in any format the user desires.

AI is playing an important role in improving healthcare by making diagnosis, treatment, and medical research faster and more accurate. AI-powered tools help doctors analyze X-rays, MRIs, and CT scans to detect diseases.

Medical Innovations

The process of evolving new ideas, and methods, and projecting products, or services that bring about positive change or improvement in any field is known as innovations. It usually involves the application of creativity and new thinking to address needs, solve problems, or advance existing systems and procedures. Innovations can be allied, meaning small improvements on existing ideas, or disruptive, which introduce entirely new approaches or technologies that revolutionize industries. Innovations can be seen in every field be it space, defense, education, or the coveted medical field. The medical field is the one that requires the utmost innovations as it life a giving field and everything starts after life.

Innovations made in the field of diagnosis, treatment, drugs, and prevention of disease are referred to as medical innovations. It may involve the development of a machine that might automate the surgery, any drug that can cure certain diseases, or any machine, test that can easily diagnose the disease.[3]

AI-Generated Medical Innovation

Traditionally, innovations were attributed to Human minds and their creativity and labor, However, with the development of Artificial intelligence numerous innovations can be attributed to AI. AI have been very instrumental in medical innovations and has made significant contributions in surgical, pharma and diagnostics field. AI algorithms are increasingly being used to analyze medical images such as X-rays, CT scans, and MRIs to detect conditions like cancer, cardiovascular diseases, and neurological disorders. These AI models can often identify patterns that may be overlooked by human doctors, leading to earlier detection and more accurate diagnoses.[4]

Personalized health plans where AI on the basis of the data provided gives accurate personalized treatment plans and mechanisms to monitor that the plans are executed in proper and chronological order. A similar kind of innovation is wearable devices that timely caution about stress levels, blood pressure, oxygen, and heart rate and provide suggestions to tackle them.

Intellectual Property Rights

Intellectual Property Rights (IPR) area bundle of rights in the form of legal protections granted to individuals or organizations for their creations or inventions, which are the result of the labor of human minds. These rights provide the creators with exclusive control over their intellectual property, allowing them to protect their ideas, creations, and innovations from unauthorized use or duplication or use for commercial purposes. IPR encourages innovation by offering creators incentives such as recognition, control, and financial rewards for their work. Intellectual Property Rights (IPR) safeguard creations of the mind, promoting innovation and economic growth. They grant legal protection to intangible assets like inventions, artistic works, trademarks, and designs. Key types include patents, copyrights,

[2] E & ICT Academy. (2024, October 14). *What is artificial intelligence?* IIT Kanpur. https://eicta.iitk.ac.in/knowledge-hub/artificial-intelligence/what-is-artificial-intelligence/

[3] EMJ Innovations. (2017, January 10). *What do we mean by innovation in healthcare?* EMJ Reviews. https://www.emjreviews.com/innovations/article/what-do-we-mean-by-innovation-in-healthcare/

[4] Open MedScience. (n.d.). *About Open MedScience*. Open MedScience. https://openmedscience.com/about-open-medscience/

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trademarks, industrial designs, geographical indications, and trade secrets, ensuring creators' exclusive rights while fostering creativity and fair competition.[5]

Intellectual Property RightsAnd Their Relevance In Medical Innovation In India

Patents: A patent is a right in the form of a document, issued, upon presenting an application for grant of patent, The Office of the Controller General of Patents, Designs and Trade Marks (CGPDTM), which describes an invention and creates a legal situation in which the patented invention can normally be exploited only with the authorization of the owner of the patent. The exploitation can be in the form of manufacture, use, sale or import. Invention means a solution to a specific problem in the field of technology. A patent may be given for a product or a process. The protection conferred by the patent is for a limited time. Generally, it is for 20 years[6]

Patentability in India- to qualify for a product or the process for grant of patent, it must be novel (not known to public), must be of Public utility, and innovative. Mere little improvement in existing product will not qualify for the patent. Also the grant of patent is subjected to Section 3 and 4 of Indian patent Act 1970, which exclude patenting of natural existing process, mathematical formulaes, frivolous oatent, something against the public policy and "any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products."[7]

Copyrights: Copyright grants creators of original works such as literary, artistic, musical, or software works, the exclusive right to use and reproduce their creations. Copyright protection ensures that authors or creators are not deprived of the benefits of their work, especially in creative fields.[8] In medicine, copyrights might apply to medical textbooks, research articles, software applications for medical use, or artistic representations. Copyrights are incentive to the artistic creation of humans and rewarding to them of their labour.

Trademarks: A trademark is a recognizable sign, design, or expression that distinguishes products or services from another and ensure the originality of source desired. Trademarks protect branding elements such as logos, names, and slogans.[9] In the healthcare industry, trademarks play an essential role in protecting brand identity, especially for pharmaceuticals, healthcare products, and medical institutions. Often we see Puma, Nike trademarks

Trade Secrets: Trade secrets refer to confidential and proprietary information that provides a business with a competitive advantage. This could include formulas, processes, or techniques that are not publicly disclosed.[10] In the medical field, trade secrets could involve proprietary manufacturing processes, pharmaceutical formulas, or research data that companies wish to keep confidential to maintain an edge in the market.

Industrial design: Design rights protect the unique visual design or appearance of a product, such as the shape, configuration, or ornamentation.[11] In medical innovations, design rights could apply to the aesthetic features of medical devices or the user interface of medical software.

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[5]Jyoti Rattan, *Intellectual Property Rights: Covering Copyright Act, Patents Act, Trademarks Act*, Vol. 1 (Bharat Law House, New Delhi, Year), p. 18.

[6]Office of the Controller General of Patents, Designs & Trade Marks (CGPDTM), *Organizational Structure of Office of CGPDTM* (Government of India, n.d.), p. 2.

[7]*The Patents Act*, No. 39 of 1970, § 3(i) (India).

[8] Copyright Office of India, *Handbook of Copyright Law* (Government of India, n.d.), available at https://copyright.gov.in/documents/handbook.html.

[9] Office of the Controller General of Patents, Designs & Trade Marks (CGPDTM), *Trademark FAQs* (Government of India, n.d.), available at https://ipindia.gov.in/faq-tm.htm.

10World Intellectual Property Organization (WIPO), Trade Secrets (n.d.), available at https://www.wipo.int/en/web/trade-secrets.

[11] Office of the Controller General of Patents, Designs & Trade Marks (CGPDTM), *Designs* (n.d.), available at https://ipindia.gov.in/designs.htm.

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Legal Challenges in India for IPR In Ai-Generated Medical Innovations

Thereare numerous challenges with respect to IPR for AI-generated medical innovations faced globally and they are analogous to the legal challenges in India. Challenges range from personification to ethical standards, ownership to possession, and control to the originator.

Absence of Legal Framework with respect to AI

India has been discussing legal frameworks concerning the regulations of AI and AI-generated content. However, no concrete and apparent regulations have been tabled till now regarding AI. There are loopholes and as AI has been advancing, the power to anticipate the advancement and accordingly law-making bodies are lagging. In the absence of any clear rules and regulations it would be very difficult to protect the intellectual property rights of AI-generated medical innovations.

Problem of Personhood

One of the most discussed topics in all the IPR and AI-related forums is about granting person hood to AI. Every IPR law provides protection either to a natural person like Humans or an artificial person like a company but the root inventor or the creator is always the human be it in an individual capacity or a Professional capacity.

Dr. Stephen Thaler, an AI researcher, filed a patent application in the United States for an invention created by an AI system named DABUS (Device for the Autonomous Bootstrapping of Unified Sentience). DABUS generated two innovations: a food container designed to be more efficient and a flashing light system for improving emergency signaling.In the patent application, Dr. Thaler listed DABUS as the inventor, instead of a human. However, the USPTO rejected the application, arguing that only a human can be recognized as an inventor under U.S. patent law.[12] Even the U.S. Court of Appeals for the Federal Circuit upheld the decision, agreeing that the patent could not list an AI as the inventor, reaffirming the traditional requirement that inventors must be human.

Who is the owner or the author?

A question with respect to the ownership or the authorship of the creation of AI dribbles the legal minds and have been a greater challenge. The content generated by AI can be attributed to the owner of AI or the one who made the AI. Disputes will arise as to ownership of the innovation as there is lack of clarity due to absence of rules and regulations it would be difficult to decide the ownership and accordingly the granting of IPR will become a spear-walk.

Is it the actual creation?

One of the topics which is actively been debated is whether the innovation made by AI is actually the invention or not. AI generates the product on the basis of data provided to it and based on the algorithm, thus it is always contended that AI does it only with the available data and does not create data or innovate it. Further, it is also contended that most of the time data involved may itself have copyrights or other IPR concerns. Thus it becomes difficult to put the creation in the basket of innovation or the creation, or to consider it mere a smart work of available arrangement of permutations and combinations.

Ethical Challenge

Altough ethical challenges do not fall directly under the ambit of legal challenges but they are incidental to it. Ethical challenges involve the testing of the AI-generated innovations and its effects on the public. AI-generated medical innovations will lack the cognitive ability and consequently all those values which are required for a medical field like empathy, cognition of pain and pleasure etc. Humans are always preferred over Robots, the events of malfunctions of AI would be fatal and thus it may come as hurdle to get seek acceptance in the society.

[12] *Thaler v. United States Patent and Trademark Office*, 558 F. Supp. 3d 238 (E.D. Va. 2021).

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The Way Out

Every riddle has a way and every puzzle has a answer. Similarly the problem of IPR in AI generated medical innovation is undoubtedly a complex one but few solutions can be suggested such as,

Granting Of Personhood

Granting the status of person-hood to the AI would ease the complex entangled threads,As there have been instances of denying the IPR to AI generated innovation on the basis of AI not being a Human being. Once the status of personhood is granted to AI, IPR rights can be filed on behalf of AI as an artificial person. A smoothening will be there in evaluating the applications considering the AI as artificial person.

Agreement Between the Stake-Holder

The IPR catalogue can be enriched by an agreement between the stake-holders like the owner of AI and the maker of AI as to who will be the author/owner of AI generated innovations and this will easily solve the problems of ownership of innovations.

A way analogous to the employee and employer relationship can be maintained between the owner and AI, as when an employee does an invention the patent goes to the company he serves similarly when the AI will do innovation the patent will go the owner of AI or the one who gave the command to AI, in context of individual capacity.

Subjected To IPR Laws

There can be instances wherein AI-generated innovations are already known to the public but in different forms, all such innovations shall be excluded from IPR as done in Patent Laws. The Intellectual property rights of AI-generated medical innovations will remain subject to all traditional laws of IPR like patent and copyright acts. This will enhance the accountability and ensure the public interest is not hampered and ethical standards are maintained.

II. CONCLUSION

India faces significant legal challenges in regulating IPR for AI-generated medical innovations, with many of these issues being analogous to global concerns. The absence of a clear legal framework for AI makes it difficult to protect intellectual property rights, as existing laws are not designed to address AI's evolving role in innovation. The debate around personhood for AI remains a central issue, as AI cannot currently be recognized as a legal entity or inventor, which complicates patenting and ownership rights.

The ownership and authorship of AI-generated creations also remain unclear, with disputes arising over whether the creator of the AI or its user should hold the rights. Further, there is uncertainty about whether AI's output qualifies as a true innovation or simply a recombination of existing data, raising questions of originality and copyright concerns.

Ethical challenges, while not directly legal, also pose a significant barrier to AI acceptance in fields like medicine. AI lacks essential human qualities such as empathy and judgment, which are crucial in medical settings, and concerns about potential malfunctions can hinder trust.

The legal framework surrounding IPR for AI-generated medical innovations is undoubtedly complex, but by adopting innovative solutions such as granting AI personhood, formalizing stakeholder agreements, and applying existing IPR laws to AI creations, the challenges can be addressed. These approaches would not only simplify the patent process but also protect public interest, foster accountability, and ensure ethical standards are upheld in the development of AI-powered medical technologies. By thoughtfully integrating AI into the IPR system, India and other nations can unlock the full potential of AI in healthcare while ensuring that legal and ethical issues are appropriately managed.

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