
INTERNATIONAL JOURNAL OF ADVANCED LEGAL RESEARCH

**PATENTING ARTIFICIAL INTELLIGENCE IN HEALTHCARE:
LEGAL CHALLENGES AND CONSIDERATIONS INVOLVED**- Isha¹**Abstract**

The present article aims at analysing and discussing the use of artificial intelligence in healthcare and the emerging legal issue of patenting the AI technology. The document elaborately explains the meaning of AI in legal sense and briefly describes the types of intellectual property rights including patents. It presents an international aspect as to granting of patents to AI inventions and highlights the challenges involved in the same. Further, the impact of AI in medical care is also dealt with in the present article. Finally, it presents an Indian perspective of the issue as well discussing the landmark judgements and legislations involved.

Introduction

Healthcare, in today's era, is witnessing technological advancement driven by Artificial Intelligence (AI), essentially in the fields of diagnosis and administrative processes. With this advancement, new challenges have also emerged, particularly in intellectual property rights and the patentability of these AI-generated inventions. The present article aims at elaborately discussing the challenges involved in patenting AI, particularly in the area of healthcare and puts forward an international outlook of the same.

What is AI?

Artificial intelligence is a technology that enables computers and machines to imitate human intellect and perform activities like problem solving, solution finding, making decision, finding conclusions etc. It is an ability of a computer to perform tasks which conventionally

¹ Student of B.A. LL.B. (Hons.) at University Institute of Legal Studies, Panjab University, Chandigarh.
For general queries or to submit your research for publication, kindly email us at ijalr.editorial@gmail.com

required human psyche. In other words, AI can be regarded as an ability of a computer to think and learn like humans.

However, there is no universal and comprehensive definition of AI in legal technical terms. It is generally regarded as a combination of software and data whose working is based on algorithms. AI has been defined differently in different jurisdictions. For example:

1. According to 15 U.S. Code § 9401 artificial intelligence is defined as “a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations or decisions influencing real or virtual environments.”²
2. In USA’s draft bill on Fundamentally understanding the Usability and Realistic Evolution (FUTURE) of Artificial Intelligence Act, 2017, AI has been defined as-

“ (A) Any artificial systems that perform tasks under varying and unpredictable circumstances, without significant human oversight, or that can learn from their experience and improve their performance. Such systems may be developed in computer software, physical hardware, or other contexts not yet contemplated. They may solve tasks requiring human-like perception, cognition, planning, learning, communication, or physical action. In general, the more human-like the system within the context of its tasks, the more it can be said to use artificial intelligence.

(B) Systems that think like humans, such as cognitive architectures and neural networks.

(C) Systems that act like humans, such as systems that can pass the Turing test or other comparable test via natural language processing, knowledge representation, automated reasoning, and learning.

(D) A set of techniques, including machine learning, that seek to approximate some cognitive task.

(E) Systems that act rationally, such as intelligent software agents and embodied robots that achieve goals via perception, planning, reasoning, learning, communicating, decision-making, and acting.”³

²Artificial intelligence (AI). (n.d.). LII / Legal Information Institute. [https://www.law.cornell.edu/wex/artificial_intelligence_\(ai\)](https://www.law.cornell.edu/wex/artificial_intelligence_(ai))

³ Soham Bajpal, Artificial Intelligence and its Creation : Who Owns ARTIFICIAL Intellectual Property Rights? (2020) 10 GJLDP (October) 152. <https://www.sconline.com>

For general queries or to submit your research for publication, kindly email us at ijalr.editorial@gmail.com

3. The High-Level Expert group on artificial intelligence of European Commission defined AI in its Report⁴ as-

*“ Artificial intelligence refers to the systems that display intelligent behaviour by analysing their environment and taking actions with some degree of autonomy to achieve specific goals. ”*⁵

It is pertinent to mention here that since AI is a recent development, as a result, not all the states have yet formulated laws in order to regulate AI. For instance, India, even today, has no specific provision that exclusively deals with artificial intelligence and according to the IT Minister Ashwini Vaishnaw, there is no law on AI yet because of the moral and ethical issues concerning the growth of AI in India.⁶

Therefore, it can be concluded there is no uniform definition of artificial intelligence which is accepted by all the states yet, but continuous efforts are being made in order to arrive at one because having a useable definition of AI is essential to formulate laws which cater to the needs of the dynamic society.

AI and Healthcare: a Pivotal Shift

AI has proved to be effectively executing activities that have been conventionally relied on human intellect and required human psyche to be performed, thus, AI has provided an innovative shift in healthcare sector by reducing the dependence and increasing the efficiency.

Within healthcare, artificial intelligence (AI) encompasses using algorithms and machine learning methodologies to scrutinize intricate medical data, generate forecasts, and aid healthcare practitioners in their decision-making endeavours.⁷

⁴ *Ibid*; A Definition of AI: Main Capabilities and Scientific Disciplines

⁵ *Supra*, at 2.; Zhao, L. & City Law School. (2022). Artificial Intelligence and Law: Emerging divergent national regulatory approaches in a changing landscape of fast-evolving AI technologies. In *City Law School Research Paper* [Report]. <https://core.ac.uk/download/548255214.pdf>

⁶ *Laws governing AI in India: Everything You Should Know*. (n.d.). <https://www.legalserviceindia.com/legal/article-13111-laws-governing-ai-in-india-everything-you-should-know.html>

⁷ Chakraborty, D. (2023, November 16). AI (Artificial Intelligence)-Powered health technology, and the role of patents. *New Technology - Technology - India*. <https://www.mondaq.com/india/new-technology/1390152/ai-artificial-intelligence-powered-health-technology-and-the-role-of-patents-#:~:text=AI%20patents%20in%20healthcare%20are%20legally%20recognized%20safeguards,of%20inventors%2C%20and%20foster%20advancements%20in%20the%20sector.>

For general queries or to submit your research for publication, kindly email us at ijalr.editorial@gmail.com

There are different types of AI that are used in the health sector, these include⁸:

1. Machine Learning or ML- It is a training algorithm which uses data to create models that have the ability to perform the tasks such as categorizing information or predicting outcomes. These learning algorithms have the capacity to process large amounts of data and thus, leads to innovations which are effective in improving health of the patients.
2. Deep Learning- It is a species of ML with the difference being that it involves larger amounts of data and layers of ML algorithms in order to produce a neural network which can perform complex tasks.
3. Neural Language Processing or NLP- It involves the use of ML in order to understand the human language which can either be oral or written. It is used to interpret documents or reports.
4. Robotic Process Automation or RPA- It refers to the utilization of AI technology in the computer programs to automate administrative as well as clinical works.⁹

These AI technologies not only provide a time effective and efficient alternative to the conventional healthcare system but also improves the patient experience. The AI is continuously transforming the world of healthcare and medicine in the present era.

AI techniques which are basically used in the field of medicine includes artificial neural networks, fuzzy expert systems, evolutionary computation, and hybrid intelligent system.¹⁰ The use of AI can be found in the following sub-fields of healthcare:

1. Diagnosis- The artificial neural networks are used in clinical diagnosis and image analysis. It can analyse heart waveforms to diagnose conditions such as atrial fibrillation and ventricular arrhythmias.¹¹ For example, the researchers at Stanford University developed a neural network which could classify the skin lesions into benign or malignant groupings and recognises skin cancers.¹²

⁸ Staff, C. (2024, March 19). AI in Health Care: Applications, Benefits, and Examples. Coursera. <https://www.coursera.org/articles/ai-in-health-care?msocid=10a03a76238862ff00132985227a63d6>

⁹ *Ibid.*

¹⁰ Geethu Prakash, *Accrediting the Pharmaceuticals with Artificial Insight*, (2020) 3.1 JIPS 15. <https://www.sconline.com>

¹¹ *Ibid.*

¹² *Supra*, at 8.

For general queries or to submit your research for publication, kindly email us at ijalr.editorial@gmail.com

<https://www.ijalr.in/>

2. Assisting the Physician – AI technology can ask questions to the patient and thus, help in diagnosing the disease and thereby recommending treatment. Baidu, a Chinese search engine, utilizes a chatbot named Melody, when a patient asks a question to the doctor, the chatbot asks appropriate follow-up questions to help learn more about the patient's symptoms so the doctor can make a more informed decision on treatment.¹³ Interventional radiologists at the University of California at Los Angeles have developed a chatbot to assist physicians in providing real-time evidence-based answers to the patient about the next phase of treatment, or information about their interventional radiology treatment.¹⁴

3. Discovering Drugs – The AI algorithms can examine the biological data including genetic information, molecular structures, and clinical trial data. This may assist researchers in the identification of novel targets, the prediction of therapeutic effectiveness, and the optimization of medication formulations.¹⁵

4. Monitoring Patients- AI technology in devices and systems allows for the ongoing surveillance of patients inside healthcare establishments and beyond the confines of their own homes. These gadgets can gather and evaluate data in real-time, encompassing vital signs, activity levels, and sleep patterns, to identify the first indications of deterioration or alterations in an individual's health condition.¹⁶

Therefore, AI can help improve healthcare since it can aid in diagnosis, treatment, drug development, patient monitoring, and administration of patients. It allows better decision making and assists the doctor, while at the same time, optimises healthcare delivery.

Understanding the Intellectual Property Rights

The basic idea behind intellectual property rights is to encourage human creativity and ensuring revenue as a result of commercialisation of work of the creator. It is used by inventors, creators, corporations and other entities in order to prevent and prohibit other from using their inventions. The notion of intellectual property was developed as a response to Article 27 of Universal Declaration of Human Rights which states that everyone has a right to

¹³ Supra, at 8.

¹⁴ Supra, at 8.

¹⁵ Supra, at 6.

¹⁶ Supra, at 6

For general queries or to submit your research for publication, kindly email us at ijalr.editorial@gmail.com

protect the moral and material interests which are the results of his scientific, literary, or artistic production.¹⁷

Due to the recognition of the need of intellectual property at Paris Convention for the Protection of Industrial Policy, 1883 and the Berne Convention for protection of Literary and Artistic Works, 1886, the United International Bureaux for the Protection of Intellectual Property (BRIPI) was established which was later transformed into WIPO or World Intellectual Property Organisation in 1970.

Intellectual property rights can be classified into the following type of rights:

1. Patents – A patent grants the holder an exclusive right over his invention and thereby prevents others from using the invention without permission.
2. Copyrights – In legal terminology, it refers to the rights that the creators have over their literary and artistic work such as books, music, paintings, films etc.¹⁸
3. Trademarks– These are the signs which can distinguish the good and services of one enterprise from the other.
4. Trade Secrets – Trade secrets refer to the IP rights which are exercised over the confidential information which may be sold or licensed, thus, prevents unauthorised disclosure or acquisition of secret information.¹⁹
5. Other kinds of intellectual property rights such as geographical indications, industrial designs etc.

AI and IP law – An Emerging Challenge

AI is not merely a creation but a creator as well. Although when considering AI as a creation, the confusion does not arise because there is a human element involved in the creation and IP law aims at protecting human creations, but AI as a creator poses difficulty in granting intellectual property rights, since AI works independent of any human operation.

With the penetration of generative AI into the domain which was considered to require human creativity, new challenges have emerged in the field of intellectual property rights

¹⁷ United Nations. (n.d.). *Universal Declaration of Human Rights* / United Nations. <https://www.un.org/en/about-us/universal-declaration-of-human-rights>

¹⁸ *What is Intellectual Property (IP)?* (n.d.). <https://www.wipo.int/about-ip/en/>

¹⁹ *Ibid.*

For general queries or to submit your research for publication, kindly email us at ijalr.editorial@gmail.com

<https://www.ijalr.in/>

especially regarding the patentability of the inventions by AI. These challenges emerged essentially due to the 3 basic features of AI, namely:

1. Creativity²⁰ – AI is capable of producing new outcomes which are not existing and can improve the existing processes. It uses the available data to produce new results. Thus, it has the ability to create new designs, produce new drugs and devices.
2. Unpredictable – Unlike traditional algorithms, AI does not work on a specific pattern or process. It has evolving nature and can modify the process in order to achieve the desired results. Machine learning helps AI to improve and evolve. Thus, AI processes data and act in order to generate products, data and processes which are not predicted by the programmers or operators.²¹
3. Autonomous – AI works independent of human interference and accomplishes tasks without any human intervention.

Thus, the understanding of these fundamental features of AI poses a challenge in granting intellectual property rights. Although intellectual property in general faces this difficulty, but the present article focuses only on artificial intelligence in healthcare sector and its intersection with the law of patents.

Requirements to Obtain Patents

As discussed above, patents are the exclusive rights given to the holder over his invention. It means that the patented invention cannot be used or distributed by others unless consent or permission of the owner or the holder of the patent is obtained.

There are a few tests that have to be fulfilled in order to obtain patent for the invention, these tests include:

1. Test of Novelty- Novelty means quality of being new. Therefore, in order to obtain patents, it has to be established that the invention is new and did not exist earlier in its technical filed.
2. Test of Application – It is a requisite to obtain patents that the invention shall have an industrial application, that is, it must be used for some business purpose rather than just being a theoretical concept.

²⁰ Supra, at 2.

²¹ Supra, at 2.

For general queries or to submit your research for publication, kindly email us at ijalr.editorial@gmail.com

<https://www.ijalr.in/>

3. Test of Non-obviousness – It refers to a condition that the invention shall not be obvious. In other words, it should not be of such a nature that ordinarily prudent man could have deduced the same using ordinary skills and knowledge.
4. The Invention must be Within the Scope- It implies that the invention that is being patented shall be accepted as patentable under the law it is being patented. For example, Indian law does not recognise mathematical formulas to be patented.

Apart from the above-mentioned conditions, almost all the countries agree that the invention must have a human element in it for it obtain patent. It means that the invention shall be made by a human. In other words, the test of personhood shall be fulfilled.

How AI poses difficulty in fulfilling these requirement or conditions:

1. AI Fails in the Test of Personhood–Patent law recognises that only a ‘person’ can invent and thus, machines (not being persons) cannot invent. Therefore, AI inventions are non-patentable due to the lack of legal or natural personality.²²
2. AI Fails the Test of Ownership – AI has a dual character; it is both a creation and a creator. Thus, any creation of generative AI is questionable to the extent that is it a creation of AI itself, creator of AI, owner of AI or the operator of AI machine?²³
3. Infringements by AI– The most common argument that is raised against the AI technology is that since AI relies on data to reach its conclusions, it will lead to violation of right to privacy of the individuals. In such cases, the question arises, who will be responsible for such an infringement- AI or the creator of AI or the operator of AI machine?

Due to these challenges, almost all the jurisdictions have ruled against patenting the AI technologies. Some of which are discussed below.

Patent Law and AI: an International Perspective

USA Patent Law and AI:

US patent system recognises only individuals as inventors and not machines.²⁴USlaw has placed certain limitations on obtaining patents over AI produced goods and inventions. The

²² Supra, at 2.

²³ Supra, at 2.

²⁴ Supra, at 8.

For general queries or to submit your research for publication, kindly email us at ijalr.editorial@gmail.com

Supreme court of USA in *Alice corporation v. CLS Bank*²⁵ casted as shadow on the patentability of software because of being 'abstract ideas' which are not patentable. It created a two-part eligibility test in order to be granted patents. The test required the courts to find out if the subject matter of the patent claim was ineligible to be granted patent, for example, abstract ideas and if it was ineligible, then the court had to examine whether other elements of the claim that could make it eligible to be granted patents. The court held that the known ideas are abstract and so is reciting them on a computer, thus, making them ineligible to be granted patents.²⁶

Moreover, in *Health discovery Corp. v. Intel Corp.*²⁷, the federal district court in Texas while implementing the principle laid down in the Alice case held that machine learning technology are not eligible to be patented because they are abstract ideas, thus, failing the Alice patentability test.²⁸

Therefore, it can be concluded that in USA the law does not favour granting patents to the AI inventions since these are considered to be abstract ideas not capable of being granted patents.

European Union Patent Law and AI:

The European union, at present, consist of 27 European nations and governs their common economic, social and security policies. In EU there are two kinds of patents:

1. National patents which are granted by the nation.
2. The patents that are granted by the European Patent office.

As per the guidelines issued by the European Patent Office, AI algorithms are considered to be of mathematical nature, thus, have to be treated like mathematical methods. Therefore, they can be granted patents if they have a technical nature and provide a technical solution to a technical problem.²⁹ Thus, EU law provides a way to grant patents to AI.

Challenges to Applying Patents to AI in Healthcare

²⁵ 573 U.S. 208 (2014)

²⁶ *Five years after Alice: five lessons learned from the treatment of software patents in litigation.* (n.d.). https://www.wipo.int/wipo_magazine/en/2019/04/article_0006.html

²⁷ 6:22-cv-00356, (W.D. Tex.)

²⁸ Johnson, J., & Waleski, B. D. (2023, January 9). Offensive and defensive IP for AI in health care. Reuters. Retrieved September 21, 2024, from <https://www.reuters.com/legal/litigation/offensive-defensive-ip-ai-health-care-2023-01-09/>

²⁹ Supra, at 2.

For general queries or to submit your research for publication, kindly email us at ijalr.editorial@gmail.com

<https://www.ijalr.in/>

The law of patents seems to be improper when it comes to patenting the inventions by AI since the patents were developed for humans and not humanoids.³⁰ Patent law, conventionally, in all jurisdictions require a human inventor, but, in AI generated inventions this criterion is not fulfilled.

Moreover, in order to obtain patent, a complete and clearly defined scope of what is being patented is required, however, AI technology is dynamic in nature and keeps on evolving, therefore, claim construction in case of AI is challenging and difficult. Since AI technology has an evolving nature, the capabilities differ overtime because of its learning algorithms, thus, even if patented, the technology will keep evolving and so will its scope. This adaptability of AI becomes a challenge while granting patents.³¹

Furthermore, under the patent law, a chain of steps has to be established, that is, there has to be a specific series of process or steps that lead to a particular result, but AI may not always follow the same process in order to achieve the desired result due to its adaptive nature, it may modify and amend the procedures involved, therefore, posing another challenge in getting the AI technology patented.³²

Lastly, there are ethical issues involved in patenting AI technology in the field of medicine and healthcare. Since patents increase the cost of medicine or healthcare devices, the accessibility of the same is negatively impacted, thus, making it difficult for the poor section to reap the benefits of the advancement. Moreover, under WHO, the right to health includes immunization against major infectious diseases, prevention and control of endemic diseases, appropriate treatment of common diseases and injuries, and the provision of essential drugs.³³ Thus, patents in healthcare sector are directly in conflict with the right to health because they reduce accessibility.

The Indian Outlook

³⁰ Aranya Nath and Antara Paral, *Intellectual Property Management in Healthcare innovation During Covid-19 Battle of Granting Patents for AI in Healthcare*, 2.1 DSNLUJ SCI Tech L (2022) 69. <https://www.scconline.com>

³¹ Wenn, A. (2024, March 2). *Intellectual property considerations for AI in healthcare*. <https://www.linkedin.com/pulse/intellectual-property-considerations-ai-healthcare-anthony-wenn-esyec>

³² *Ibid.*

³³ Mirela V. Hristova, 'Are Intellectual Property Rights Human Rights - Patent Protection and the Right to Health' (2011) 93 J Pat & Trademark Off Soc'y 339

For general queries or to submit your research for publication, kindly email us at ijalr.editorial@gmail.com

1. Indian Patent Law and AI:

It is pertinent to mention here that Indian courts have not yet adjudicated on the matter of patentability of AI technology. However, the Indian Patent office prohibits computer programmes or algorithms from being patented, following the Computer Related Inventions.³⁴ The same guidelines are applied to AI inventions as well.

Moreover, the Indian Patents Act, 1970 bars business methods, programs, or mathematical formulas from being patented.³⁵ The section-6 the Act requires that an application for patenting an invention can be made only by first true inventor or any other person so assigned by him. Here, although it is not specified that ‘inventor’ means a human inventor or a natural person, however, it is implied that first inventor is always a natural person.³⁶

Therefore, it can be implied that Indian law does not recognise granting patents to AI technologies or inventions.

2. Patent and Healthcare:

Right to health is considered to be a facet of right to life within the ambit of article 21 of the Indian Constitution.³⁷ Moreover, the Article 25(1) of Universal Declaration of Human rights states that everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing, and medical care.³⁸ Therefore, accessibility of healthcare facilities is an ambit of right to health itself.

However, a patent system results in an inverse relationship between the cost of such healthcare products and affordability of access.³⁹ As a result, the Indian Patents act, 1970 only recognises process patents and not product patents.⁴⁰ Further, Indian law allows ‘compulsory licensing’ in respect of the product patents under the patent law. Compulsory licensing refers to the involuntary contract between the willing buyer and an unwilling seller

³⁴Artificial Intelligence and Intellectual Property Rights [Brought to you by Chadha & Chadha] | Asian Legal Business. (2019, May 22). <https://www.legalbusinessonline.com/news/artificial-intelligence-and-intellectual-property-rights-brought-you-chadha-chadha/77741>

³⁵Prachi Mishra and Virendra Singh Thakur, *Intellectual Property Rights in the Age of Artificial Intelligence: Challenges and Perspectives*, 14 RMLNLUJ (2022) 236. <https://www.scconline.com>

³⁶*Ibid.*

³⁷State of Punjab v. M.S. Chawla

³⁸Supra, at 15.

³⁹Indulia, B. (2020, July 14). *Pharmaceutical Patents and Healthcare: a legal conundrum* | SCC Times. SCC Times. <https://www.scconline.com/blog/post/2019/09/03/pharmaceutical-patents-and-healthcare-a-legal-conundrum/>

⁴⁰*Ibid.*

For general queries or to submit your research for publication, kindly email us at ijalr.editorial@gmail.com

<https://www.ijalr.in/>

which is imposed by law, that is, the government is empowered to grant the license to use the patent without the permission of the patent holder.⁴¹ It has been done to provide healthcare to public and also fulfil the constitutional obligation of right to life as envisaged under Article 21.⁴²

Moreover, the section-3(d) of Patents Act, 1970 prevents evergreening which is an act of getting extensions on the patent period by getting minor innovations in the patented product patented again. It was held by the hon'ble Apex Court in *Novartis AG v. Union of India*⁴³:

“Section 3(d) was introduced to prevent evergreening, to provide access to the life-saving drugs and to discharge their constitutional obligation of providing good healthcare to its citizens.”

Therefore, it can be concluded that India has tried to use the flexibility granted under the TRIPS agreement in order to ensure accessibility to healthcare facilities to the public since it is an important constituent of right to health within the meaning of right to life under article-21.

Conclusion

In conclusion, the use of artificial intelligence in the healthcare sector can be regarded as a profound shift towards more efficient healthcare, especially in the fields of diagnosis, treatment, and monitoring of the patients. However, with this advancement a new challenge has emerged in the arena of law as to the patentability of these inventions. Although law is supposed to be dynamic in nature and adaptive in the sense that it accommodates the needs of a changing society, but even today, there are no established rules or principles governing the issue of AI. It is pertinent to mention here that in spite of any legislation, almost all the jurisdictions are unanimous that AI inventions are not eligible to be patented due to the major challenges involved in the same as has been discussed in the present document.

⁴¹ *Ibid.*

⁴² *Bayer Corp. v. Union of India*, 2014 SCC OnLine Bom 963; *Ibid.*

⁴³ (2013) 6 SCC 1

For general queries or to submit your research for publication, kindly email us at ijalr.editorial@gmail.com