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# ARTIFICIAL INTELLIGENCE AND HEALTHCARE IN INDIA: THE ROLE OF PATENT

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## ABSTRACT

Artificial Intelligence (AI) has emerged as a transformative force in healthcare, offering innovative solutions for diagnosis, treatment, improved quality of patient care, and so on. In India, where the healthcare system faces numerous challenges including accessibility, affordability, and quality, AI presents promising opportunities to address these issues. However, the patentability of AI technologies in healthcare is subject to specific requirements outlined by the Indian Patent Office (IPO). The focus of this paper is to explore the patentability requirements for AI in healthcare within the Indian context. This paper starts with a short technical description of what AI is. Then, the paper delves into the applications of AI in the health sector. These include the potential use cases for AI in healthcare. Further, the paper addresses the challenges posed by AI-driven healthcare inventions in meeting the patentability criteria specifically, the statutory provision under the Indian Patent Act, focusing on Section 3 which outlines the criteria for patentability. Furthermore, to have a practical understanding of the scenario a case study has been carried out on AI based healthcare inventions patented in India. Thereby, how the applicants are overcoming the objections they faced during the patent examination process can be understood. In conclusion, navigating the patentability requirements for AI in healthcare presents unique challenges and opportunities in India. By understanding and addressing these requirements, stakeholders can foster innovation, promote access to cutting-edge healthcare technologies, and contribute to the advancement of public health in the country.

Keywords: Artificial Intelligence, Intellectual Property, Patent, Healthcare, India

## **I. Introduction**

The integration of Artificial Intelligence (AI) technology in healthcare has initiated a great revolution, which restructure the landscape of healthcare worldwide. In India, a country handling with the complexities of a vast and diverse healthcare system, AI is showcasing significant promise for addressing longstanding challenges and improving patient outcomes. However, realizing this promise depends not only on technology innovation, but also on the legal and regulatory framework that governs intellectual property, particularly patents.

The Indian healthcare sector has numerous challenges, including accessibility, affordability, and quality of healthcare. With a population of over 1.3 billion people and a healthcare infrastructure that is overburdened, there is an urgent need for new solutions to bridge the gaps in service delivery. In that case AI represents a paradigm shift in healthcare, utilizing data driven insights, innovative solutions for diagnosis, treatments, and improved quality of patient management.

In this context, patents play a critical role in promoting innovation and rewarding investment in AI technology. Patent serves as a cornerstone of intellectual property protection, granting inventors exclusive rights to their inventions and establishing a framework for commercialization, market competition and stimulating progress within the area. In the realm of AI and healthcare, patent plays a critical role in safeguarding novel ideas and technologies, medical equipment, data analytics approaches, and software application that stimulate innovation and improve patient care. Moreover, this collaboration incentivizes research and development efforts by providing a road to commercialization and return on investment, thereby supporting a thriving healthcare innovation ecosystem.

However, the intersection of AI and healthcare presents unique challenges in field of patent law. The dynamic nature of AI algorithms, combined with the complexities of medical data and regulatory compliance, requires a thoughtful approach to patentability. Therefore, this paper delves into the patentability requirements for AI in healthcare within the Indian context.

In order to have a comprehensive understanding on the technological and legal dimensions of AI innovation in healthcare the paper first explain about the technological aspects of AI. Then, in the following the linked between the AI and health sector is drawn by listing and explaining the application of AI technology in the field. Further, the paper navigates the challenges in

patenting AI based healthcare inventions in India. Thereafter, for understanding the practicality in the examination of AI invention in healthcare filed, case study is conducted.

In conclusion, the fusion of AI and healthcare holds immense promise for India's healthcare landscape, offering a pathway to improved outcomes and enhanced efficiency. However, realizing this potential requires a supportive ecosystem that recognizes the vital role of patents in incentivizing innovation and ensuring the availability of cutting-edge healthcare technologies. By addressing the challenges and opportunities at the intersection of AI, healthcare, and patent law, India can pave the way future where technology driven healthcare solution are accessible to all.

## II. Understanding AI in Healthcare

### A. Definition and Explanation of AI

Artificial Intelligence (AI) is a field of computer science and engineering concerned with the computational understanding of what is often referred to as intelligent behavior.<sup>1</sup> While the concept of AI is not new<sup>2</sup>, professional in the area have yet to agree on a single definition for it. The first person to use the term 'artificial intelligence', John McCarthy, defines it as "the science and engineering of making intelligent machines".<sup>3</sup> Others have defined it as a program which process information in such a way that the result correspond to how an intelligent human would respond to similar input.<sup>4</sup> Some have described it as the process of creating rational agents that seek to maximize their anticipated benefits based on the knowledge they gain from their surroundings.<sup>5</sup> According to the NITI Aayog's report on National Strategy for Artificial Intelligence it has been stated that "AI refers to the ability of machines to perform cognitive tasks like thinking, perceiving, learning, problem solving and decision making".<sup>6</sup> As a result of prioritizing the generation of outcomes resembling human capabilities numerous formal AI initiatives were launched with an aim of creating machines capable of executing tasks that

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<sup>1</sup> Stuart C. Shapiro, *Encyclopedia of Artificial Intelligence* 54-57 (2nd edn., 1992).

<sup>2</sup> Alan Turing is acknowledge as the pioneer of modern computer science and AI. He coined the "Turing test" to solve the question whether machines can think; A. M. Turing, "Computing Machinery and Intelligence" 59 *Mind* 433-460 (1950).

<sup>3</sup> John McCarthy, *Basic Questions, What is Artificial Intelligence?*, Stanford University, November 12, 2007, available at: <http://www-formal.stanford.edu/jmc/whatisai/> (last visited on Aug.21, 2024).

<sup>4</sup> Raquel Acosta, "Artificial Intelligence and Authorship Rights" JOLT Digest (February 17, 2012), available at: <https://jolt.law.harvard.edu/digest/artificial-intelligence-and-authorship-rights> (last visited on Aug.21, 2024).

<sup>5</sup> Stuart J. Russell & Peter Norvig, *Artificial Intelligence A Modern Approach* 1044 (3rd ed. 2010).

<sup>6</sup> Government of India, "National Strategy for Artificial Intelligence #AIFORALL" 114 (NITI Aayog, 2018)

necessitate human-like creativity.<sup>7</sup> However, artificial intelligence researchers hold different views on the definition of “creativity” in machines.<sup>8</sup> Additionally, the application of AI has expanded across various industries, including healthcare, finance, transportation, education, entertainment, and so on. In many ways, computational creativity entails a machine’s capacity to receive and process input to generate a novel combination of existing ideas and information<sup>9</sup>. This capability is increasingly relevant as we’re entering a time where AI is growing rapidly because computers can handle huge amounts of data and have higher computational power. Regardless of the type of AI employed, every application relies on vast amounts of training data, as AI systems are good at analyzing big sets of data, finding patterns, making predictions based on what they find. Moreover, they continually enhance their performance through exposure to new data or experiences.<sup>10</sup>

### ***B. Types of AI***

AI can be categorized based on their intended purpose and level of capability, resulting in two primary categories: weak AI and strong AI. Weak AI, also referred to as narrow AI, is designed to fulfill specific tasks and lacks the capacity to solve problems beyond its predefined scope.<sup>11</sup> In contrast, strong AI, commonly known as general AI, possesses the capability for independent thinking and reasoning across a wide array of task, resembling human intelligence.<sup>12</sup> This type of AI exhibits cognitive, emotional, and social behaviors comparable to those of humans. While weak AI excels within its specialized domain, general AI aims to mimic the multifaceted abilities of human cognition, enabling it to adapt and tackle diverse challenges beyond predefined tasks.

Additionally, AI encompasses various subfields and technologies that contribute to its development and application. Some of the key subfields and underlying technologies include:

- Machine Learning (ML): It involves algorithms that enable computers to learn from

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<sup>7</sup> Bert-Japp Koops, Mireille Hildebrandt, *et.al.*, “Bridging the Accountability Gap: Rights for New Entities in the Information Society?” 11 *The Minnesota Journal of Law, Science & Technology* 497-561 (2010).

<sup>8</sup> *Supra* note 4

<sup>9</sup> *Ibid.*

<sup>10</sup> Kurt Benke, Geza Benke, *et.al.*, “Artificial Intelligence and Big Data in Public Health” 15 *International Journal of Environmental Research and Public Health* 3 (2018).

<sup>11</sup> UK-Ras Network, “Artificial Intelligence and Robotics” 6 (2017)

<sup>12</sup> *Ibid.*

data and make predictions or decisions without being explicitly programmed.<sup>13</sup>

- Deep Learning (DL): It is a subset of ML that involves artificial neural network with multiple layers. Deep learning algorithms are capable of learning complex patterns from large volume of data, making them excel at task such as image and speech recognition, natural language processing, etc.<sup>14</sup>
- Natural Language Processing (NLP): This concept is used to listening and replying, analyzing, speaking, chatting capability given to the machine.<sup>15</sup>
- Computer Vision: It enable computer to understand digital images and videos from the real world. It include task such as facial recognition, object detection, image classification.

These are some of the subfields and technologies, each with its own characteristics, capabilities, and applications which collectively form the foundation of AI driving advancements in various industries and domains, and paving the way for innovative applications and solutions.

### ***C. Applications of AI in Healthcare***

The convergence of artificial intelligence (AI) and healthcare marks the onset of a groundbreaking era, poised to reshape the landscape of human health and medical research. It has the ability to convert extensive patient data into actionable information, improve public health surveillance, expedite health interventions, and streamline research and development processes to be more efficient, faster, and precise.<sup>16</sup> From drug discovery to disease diagnosis, AI is in position to become a game-change, holding immense promise for improving human health and well-being. “With the development of more and more technology and artificial intelligence, healthcare can eventually be delivered at a lower cost because when efficiency is

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<sup>13</sup> Mariette Awad and Rahul Khanna, “Machine Learning”, *Efficient Learning Machines* 1-18 (Apress, 2015).; Brian Wahl, Aline Cossy-Gantner, *et.al.*, “Artificial Intelligence (AI) and Global Health: How Can AI Contribute to Health in Resource-Poor Settings?” 3 *BMJ Global Health* 2 (2018).; *Supra* note 10.

<sup>14</sup> Wolfgang Ertel, *Introduction to Artificial Intelligence* 281 (Springer, Ravensburg, 2nd edn., 2017).

<sup>15</sup> Wahl, *Supra* note at 13.

<sup>16</sup> Wullianallur Raghupathi and Viju Raghupathi, “Big Data Analytics in Healthcare: Promise and Potential” 2 *Health Information Science and Systems* 2-3 (2014).

increased, diagnostics will be more focused.”<sup>17</sup>

***a) Potential use cases for AI in Healthcare in India***

Introducing AI into healthcare holds promise as a solution to major challenges encountered in the field, including diagnosis and screening, therapeutics, preventive measures, clinical decision-making, public health monitoring, complex data analysis. And as time goes on, there could be even more ways AI can help in healthcare challenges in Indian and other countries in the world. Some potential uses cases for AI is mentioned in FIG.1 and explained below:

- *Keeping Well:* AI plays a crucial role in helping individuals maintain wellness by offering personalized fitness programs, monitoring health metrics through wearable devices<sup>18</sup>, providing mental health support via chatbots, assisting in chronic disease management, offering nutrition planning, optimizing sleep patterns, managing stress, an facilitating preventive health screening. By harnessing the power of AI technologies, individuals can access personalized support to make informed decisions about their health and lead a healthy life.
- *Early Detection:* In healthcare, AI analyzes medical images and patient data to identify diseases like cancer or diabetes at their earlier stages, enabling timely intervention. This early detection enables healthcare providers to intervene promptly, offering patients more effective treatments and potentially saving lives.<sup>19</sup> Additionally, AI-driven predictive analytics tools can forecast disease risks based on patient health records, facilitating proactive preventive measures and personalized healthcare plans.

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<sup>17</sup> Rashmi Mabiyan, “How Artificial Intelligence Can Help Transform Indian Healthcare”, *The Economic Times*, May 23, 2018, available at: <https://health.economictimes.indiatimes.com/news/health-it/how-artificial-intelligence-can-help-transform-indian-healthcare/64285489> (last visited on Aug. 25, 2024).

<sup>18</sup>Farida Sabry, Tamer Eltaras, *et.al.*, “Machine Learning for Healthcare Wearable Devices: The Big Picture” 2022 *Journal of Healthcare Engineering* (2022).

<sup>19</sup> Simarjeet Kaur, Jimmy Singla, *et.al.*, “Medical Diagnostic Systems Using Artificial Intelligence (AI) Algorithms: Principles and Perspectives” 8 *IEEE Access* 228049-228069 (2020).

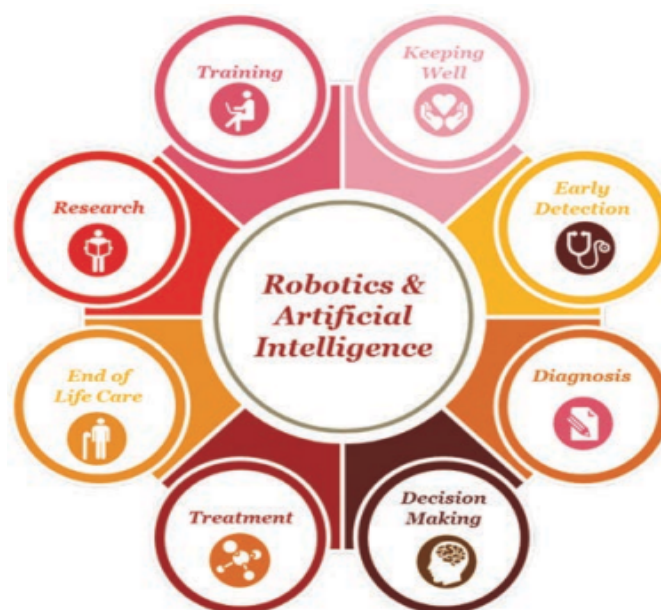


FIG 1: AI is transforming every aspect of healthcare in innovative ways<sup>20</sup>

- **Diagnosis:** AI is revolutionizing diagnosis in healthcare through its ability to rapidly analyze complex datasets and identify subtle patterns and anomalies indicative of various medical conditions at their earlier stages<sup>21</sup>. From interpreting medical images like X-rays and MRIs to analyzing patient records and genetic data, AI enables healthcare professional to identify diseases such as cancer, heart disease, and neurological disorders much earlier than traditional methods allow. Furthermore, AI-driven diagnostic tools can enhance efficiency by streamlining the diagnostic process, reducing wait times, and optimizing resource allocation within healthcare system. In 2016, IBM's Watson identified a rare leukemia in a misdiagnosed patient by analyzing genetic data and 20 million cancer research papers in just 10 minutes, ultimately saving her life.<sup>22</sup>
- **Decision Making:** It provide decision making by leveraging patient data to offer tailored insights for diagnosis and treatment. Through advanced algorithms, AI predicts disease

<sup>20</sup> Jon Arwidson, Jan Von Zweigbergk, *et.al.*, "No Longer Science Fiction: Artificial Intelligence", *Pharma Industry*, Nov. 13, 2017, available at: <https://www.pharma-industry.se/wp-content/uploads/2017/11/artificial-intelligence.pdf> (last visited on Aug. 25, 2024).

<sup>21</sup> Milad Mirbabaie, Stefan Stieglitz, *et.al.*, "Artificial Intelligence in Disease Diagnostics: A Critical Review and Classification on the Current State of Research Guiding Future Direction" 11 *Health and Technology* 693–731 (2021).

<sup>22</sup> Jon Fingas, "IBM's Watson AI Saved a Woman from Leukemia", *Engadget*, Aug. 07, 2016, available at: <https://www.engadget.com/2016-08-07-ibms-watson-ai-saved-a-woman-from-leukemia.html> (last visited on Aug. 25, 2024).

risks, recommends personalized care plans, and optimizers resource allocation within healthcare systems. This results in improved patient outcomes and cost efficiencies across the board.

- *Treatment:* AI is instrumental in transforming treatment strategies beyond patient identification. Through advanced algorithms and predictive analytics, AI enables clinicians to adopt a holistic approach to disease management. It enables the coordination of personalized care plans and empowers patient to better manage and adhere to long term treatment programs. One of an example in this is ‘AiCure’ which is an application monitor’s patient with long term conditions, ensuring medication adherence through visual recognition technology that confirms ingestion and send relevant data to care providers or pharmaceutical companies.
- *End of Life Care:* These introduce robots capable to help individuals maintain their independence for longer period and decrease reliance on hospitalization, caregivers, and are homes by performing tasks like monitoring vital signs and providing medication reminders. Moreover, advancements in AI and humanoid design enable these robots to engage in conversations and social interactions, thereby promoting cognitive stimulation and alleviating feelings of loneliness and isolation among aging individuals.
- *Research:* In healthcare research, AI is a game change, recently finding advancements in drug research and discovery, where it significantly accelerating the pace of innovation<sup>23</sup>. It has emerged as a powerful tool in drug research and discovery, offering innovative solutions to streamline processes and reduce costs. By harnessing the latest advances in AI, researchers can expedite drug discovery and repurposing efforts, ultimately cutting both the time to market and associated expenses for new medications. AI algorithms analyze vast datasets to identify potential drug candidates, predict their efficacy, and optimize treatment regimens. This transformative approach holds promise for accelerating medical breakthroughs, bring novel therapies to patients more rapidly, and addressing unmet healthcare needs effectively.

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<sup>23</sup> Diana Gina Poalelungi, Carmina Liana Musat, *et.al.*, “Advancing Patient Care: How Artificial Intelligence is Transforming Healthcare” 13 *Journal of Personalized Medicine* 1-13 (2023); Reuters, “AstraZeneca Taps AI for Drug Discovery in Deal with Berg”, *Reuters*, Aug. 28, 2017, available at: <https://www.reuters.com/article/business/astrazeneca-taps-ai-for-drug-discovery-in-deal-with-berg-idUSKCN1B81G7/> (last visited on Aug. 27, 2024).



- *Training:* AI enhances learning with realistic simulations and convenient mobile access. By utilizing natural speech technology and vast databases, AI creates lifelike scenarios for trainees. Mobile devices with capabilities offer flexibility for on-the-learning. Additionally, AI seamlessly integrates with virtual reality<sup>24</sup>, providing accurate simulations that boost understanding and memory retention. Through these advancements, AI simplifies and improves healthcare education for professionals.

Overall, AI has the potential to transform healthcare by enhancing diagnostic accuracy, personalizing treatment approaches, improving patient access and engagement, and driving innovation across the entire healthcare ecosystem. However, alongside these great promises come challenges, ethical considerations, and issues related to patents rights.

### III. Patent and AI-Based Healthcare Inventions in India: The Challenges

Patents are essential drivers of growth and progress in the healthcare sector, particularly in the realm of AI. The patent system aims to incentivize innovation, yet there remains uncertainty regarding the need for incentivizing automated inventions.<sup>25</sup> While AI doesn't require any incentive to innovate, some observers contend that extending the patent system to cover AI inventions is crucial. They argue that extending patent protection would offer the essential incentives needed to encourage developers working on AI technologies.<sup>26</sup> Through the granting of exclusive rights to AI-driven health tech inventions, patent incentivize investments in research and development, propelling continuous advancements in healthcare technologies. Furthermore, patents facilitate collaboration among stakeholders, fostering an environment conducive to knowledge sharing and technology transfer. By safeguarding novel ideas and enabling disclosure in public documents, patent not only protect against unauthorized use but also contribute to the dissemination of knowledge, allowing others to build upon existing innovations.

Creating AI enabled healthcare inventions involves employing a combination of mathematical models, methods, and algorithms throughout the processes of training, testing, validation, and

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<sup>24</sup> Ambreen Usmani, Manal Imran, *et.al.*, "Usage of Artificial Intelligence and Virtual Reality in Medical Studies" 38 *Pakistan Journal of Medical Sciences* 777-779 (2022).

<sup>25</sup> Erica Fraser, "Computers as Inventors – Legal and Policy Implications of Artificial Intelligence on Patent Law" 13 *SCRIPTed* 311 (2016).

<sup>26</sup> Ryan Abbott, "I Think, Therefore I Invent: Creative Computers and the Future of Patent Law" 57 *Boston College Law Review* 1104 (2016). (asserting that allowing patent protection to inventions generated by AI would "encourage innovation under an incentive theory")

integration into software solutions. This entails subjecting vast amounts of healthcare data, such as electronic health records and medical images, to the machine learning pipeline to develop and validate models capable of real-world healthcare applications.

However, like any other invention, the patent evaluation of AI related healthcare inventions is important. In India, there are no rules or guidelines specifically talks about AI or applied to AI-related inventions. But as AI inventions found their basis in mathematical methods or algorithms the inventions relating to AI are examined under the guidelines for the examination of computer related inventions (CRIs).<sup>27</sup> As per the guidelines, computational models and algorithms are categorized as abstract ideas or mathematical method. Although all AI and machine learning systems are fundamentally rooted in mathematical methods, their applications vary widely. Consequently, while some of these applications may not meet the patentability criteria in the system, others remain eligible for patent protection.

The major challenges raised globally in the patentability of AI related inventions includes the legal definition of inventorship, interpretation of the patent eligibility standards, standard of obviousness, and addressing the need for incentivization.<sup>28</sup> Even though all these are hot debating issues, this paper aims to focus on the patentability criteria specifically, the statutory provision under the Indian Patent Act, focusing on Section 3 which outlines the eligibility criteria for obtaining a patent.

#### ***A. Patent Eligibility of AI-based healthcare inventions in India***

While examining patent applications of AI related inventions in medical field, the examiners often raise objections under Section 3(k) and Section 3(i) of the Indian Patent Act 1970. Section 3(k) of the Indian Patent ACT, 1970, pertains to the exclusion of certain subject matters from patentability, specifically regarding computer programs. Section 3(k) states that:

*3) The following are not inventions within the meaning of this Act:*

*(k) a mathematical or business method or computer programme per se or algorithms;*

This provision aims to prevent the monopolization of purely abstract or algorithmic idea,

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<sup>27</sup> Revised Guidelines for the Examination of Computer Related Inventions (CRIs), 2017

<sup>28</sup> Office of the Federal Register, *Request for Comments on Patenting Artificial Intelligence Inventions*, 84 FR 44889 (August 27, 2019).

ensuring that patents are granted only for inventions that involve technical advancements and practical applications. However, as per the CRI guidelines, which define “hardware” as “the physical and electronic parts of a computer, rather than the instructions it follows,” claims associated with the operational method of a hardware device employing an AI model generally encounter no objections.

When examining AI-based healthcare inventions, it is crucial to emphasize the technical contribution/effect of the invention to successfully prosecute it. For example, emphasizing the processing speed and efficiency of an AI system is crucial, particularly in the healthcare setting requiring real-time decision making capabilities. Furthermore, effective utilization of memory and database resources is essential for managing substantial data processing demands. By demonstrating the AI system’s ability to compress data efficiently without compromising accuracy, inventors can highlight its potential to enhance data transmission and analysis efficiency. Additionally, advancements in user interface design and radio signal transmission not only enhance the usability of AI system but also enable remote monitoring and analysis of patient data, particularly in underserved areas with limited healthcare access.

Even if the subject matter of AI-related invention in healthcare relates to a method of diagnosis, then came into picture Section 3(i) of the Indian Patent ACT, 1970. Section 3(i) states that:

*3) The following are not inventions within the meaning of this Act:*

*(i) 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;*

Accordingly, this section excludes certain subject matters from patentability specifically regarding any process for the medicinal, surgical, curative, diagnostic, and therapeutic or processes for the treatment of human beings or animals shall not be granted a patent. This provision aims to ensure that medical treatments and procedures remain accessible to public without hindrance from patents, thereby safeguarding public health and welfare.

As a result, AI-driven healthcare innovations may face objections under this section. However, in such circumstances, it is possible to present arguments asserting that the application of AI

in these inventions are tools which perform a function on the collected samples or process images that provide the patient's health status, without engaging in interaction with human beings or animals.

#### IV. Case Study

This case study section is to understand the practical scenario of examination pattern followed by Indian Patent Office (IPO) in the examination of AI-based healthcare inventions. The pilot study is based on granted Patents in India. A keyword search using both artificial intelligence and healthcare related term on Orbit Express, a patent database, was carried out to find relevant patents, using data from the past 6 years (from 2018 to 2023). Multiple strategies were adopted to arrive at the relevant result.

“Method and system for determining total count of red blood cells in peripheral blood smear”.<sup>29</sup> The present disclosure relates to a method and system for determining Total Count (TC) of RBCs in a Peripheral Blood Smear (PBS). The application is an Indian Patent with Application No. 201841013568, filed April 9, 2018.

As per the description of the invention, the system receives numerous images from the monolayer of the PBS. Subsequently, it utilizes deep learning models to extract, segment, and identify RBCs within each of these images. For every image, the system calculates a value for each variable within a defined set of variables. This set encompasses foreground non-pallor area, RBC density, cell count, cell count ratio, foreground area, and filled foreground area. Moreover, the system computes statistical parameters for each variable across the entirety of the images. These statistical parameters serve as input for a supervised learning model, aiding in the determination of RBC total count (TC). In essence, this TC estimation system offers an effective and robust approach to estimating RBC TC by leveraging multiple images of the PBS.

During examination, the examiners raised objection under Section 3(i) and 3(k) on claims 1-16 of the invention<sup>30</sup>. While the prosecution, to address the objection raised under Section 3(i)

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<sup>29</sup> See prosecution history of Indian patent IN323817.

<sup>30</sup> See prosecution history of Indian patent IN323817, First Examination Report (FER):

1. These claims mentions about "method for estimating Total Count of Red Blood Cells in a blood smear" which is a diagnostic method and isn't patentable as per Section 3(i) of Indian Patent Act, 1970 as the act says "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".

the stated that Claims 1-16 of the method in question do not pertain to treatments or processes intended to eliminate diseases in humans or animals. Instead, this method utilizes various image processing techniques to analyze multiple images of PBS. It involves extracting image patches containing RBCs and computing values for a set of variables associated with these images. Moreover, the method's focus on determining RBC total count (TC) does not indicate whether the human or animal is disease-free. Additionally, they also took the dictionary meaning of "Diagnosing" and specified that the claims 1-16 shall not be considered as a method of diagnosing. As the reply to the FER was not satisfied a hearing was conducted. The clarification during the hearing by the applicants highlighted that the subject matter of the claims 1-16 is a technical process use for estimating total count of RBCs in a given blood sample and a physician must review and analyze the outcome of the claimed invention in order to diagnose a condition. Thus, overcome the objection under Section 3(i) under Indian patent act, 1970.

Further, to address objection under Section 3(k) the applicant highlighted that the invention provides an automated method for estimating the TC of RBC based on an analysis of values of a set of variables, corresponding to the blood smear, with enhanced accuracy, which is a practically implementable solution to a technical problem.

## V. Conclusion

AI-driven healthcare innovations and products are revolutionizing the healthcare landscape, offering expedited, precise, and economical diagnostics and treatments to enhance patient outcomes significantly. These advancements represent a paradigm shift in healthcare delivery, empowering clinicians with cutting-edge tools to diagnose ailments swiftly and administer targeted therapies, thereby improving patient care and quality of life.

In the realm of Indian patent practice, potential objections may arise under sections 3(k) and 3(i) of the Indian Patent Act, 1970, alongside standard concerns regarding novelty, inventive step, and industrial applicability. However, proactive measures and strategic approaches outlined in this discourse can effectively mitigate these challenges. By leveraging comprehensive strategies tailored to address context-sensitive objections, innovators can

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2. Claims 1-16 are directed towards a mathematical method for estimation of blood components using computer program. Such claims are not allowed as per section 3(k) of the Act.

navigate the patent landscape with confidence and secure robust protection for their AI-based healthcare inventions.

While securing patents for AI-driven healthcare innovations may pose hurdles, these obstacles are resolvable through the presentation of compelling arguments and tangible demonstrations of the transformative impact of these technologies on healthcare outcomes. By emphasizing the tangible benefits and societal value of innovative healthcare solutions, patent applicants can overcome challenges, paving the way for the widespread adoption and integration of AI-driven technologies in healthcare delivery. In conclusion, the convergence of AI and healthcare holds immense promise for revolutionizing patient care, and by navigating patent challenges effectively, we can accelerate the realization of this transformative potential.