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Possibility of Painting the Black-Box White: Patentability and Implementation of Implicit Personalised Medicine

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The birth of Black- box medicine, which relies on complex algorithms and AI to diagnose and treat medical conditions, has sparked significant interest and debate in intellectual property law. As these technologies become integral to modern healthcare, it is important to weigh the upsides and downsides of the technology to protect and regulate them through patents or other IP systems, which is becoming increasingly critical. Algorithms and biological correlations, central to Black- box medicine, face scrutiny under IP protection, especially in patents, due to their potential classification as abstract ideas or laws of nature. The very features that make Black- box medicine innovative and valuable are its reliance on complex algorithms, genetic and biological data, and medical diagnosis and treatment applications. These are the same reasons that render it ineligible for patent protection under the current Indian Patent Regime. Using Black- box medicine also brings significant ethical and social challenges. The lack of transparency in AI systems raises serious concerns about how well we can explain and understand them. This makes it hard to prove they are safe and effective, to interact with them smoothly, and to hold them accountable. Additionally, how different systems work together, how data is shared, and how easily people can access these advanced healthcare solutions must be addressed to avoid widening the Medico-digital divide and to ensure everyone benefits equally from these innovations. Balancing innovation with accessibility, accountability, and fairness will be essential to fully realising the potential of Black- box medicine.

Keywords: Algorithm, Black-Box, Biological Data, Patents, Artificial Intelligence

India's healthcare sector is on a rapid growth trajectory. However, challenges in quality, accessibility, and affordability persist. Shortages in qualified healthcare professionals, infrastructure, and healthcare facilities create significant disparities.[1] AI, the talk of the town solutions, holds immense potential for transforming healthcare. By augmenting the limited workforce, AI can assist with early detection, diagnostics, and decision-making, addressingaccessibility and quality issues.[2] AI-driven solutions are poised to transform this sector, potentially offering more personalised, efficient, and accessible care for millions nationwide.

One such concept under the umbrella of AIis "Black-Box" or "Mystery Medicine". Medicine is transitioning from a one-size-fits-all model to personalised treatments. Doctors consider patient-specific characteristics like age, weight, and genetic or biological markers to make informed decisions. This shift enhances treatment efficacy and patient outcomes. Black Box is many steps ahead of drug repurposing and personalised treatments. Black-box medicine uses AI to analyse massive amounts of health data and identify hidden patterns that humans might miss. This allows for deeper, more precise treatment options that could be more effective. With the integration of AI, treatments could become not just tailored but also predictive, preempting health issues and optimising outcomes based on big data analysis.[3] However, this exciting evolution also brings new challenges.

Legally, Black- box medicine, being mystical in nature, should address issues oftransparency and privacy, as these systems handle a vast amount of sensitive personal health information and patentability, figuring out how to protect the intellectual property of these new technologies. The article begins by examining customised care and delving into the origins and development of personalised medicine. The initial sectionsexplain the importance of personalised approaches in contemporary healthcare and set the stage for legal challenges to Black- box medicine. It covers issues of discrimination, liability, privacy, and patentability. The discussion on patentability is particularly intricate, involving questions of inventorship, patentable subject matter, and the

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requirement for disclosure. This chapter aims to study the convergence of law and logarithms. Finally, the article concludes the discussion by reflecting on the future of protecting Black- box medicine.

Journey from Customised Care to Mystery Medicine

The thought has likely occurred to everyone at some point: why does the same medicine work effectively for one group of individuals but not for another? The inception and development of personalised medicine are deeply rooted in addressing this fundamental question of inter-individual variation. This question has been explored and partially answered through the advent of advanced technologies such as DNA sequencing, proteomics, imaging protocols, and the integration of AI. These technologies have revealed significant differences in how diseases manifest and progress among individuals, underscoring the need for a more tailored approach to treatment.

Personalised medicine is based on the principle that because individuals have distinct and specific characteristics at the molecular, physiological, environmental, and behavioural levels, they require tailored interventions for the diseases they experience.[4] Because of these particular traits, standardised treatments may not always be effective for everyone. Instead, personalised medicine aims to customise interventions to align with each individual's unique profile, ensuring more effective and targeted treatments. Personalised medicine is a term coined to describe the systematic usage of information on individual patients to select and optimise prevention and treatment.[5] It customises healthcare based on individual differences across all phases, from prevention and diagnosis to treatment and post-treatment monitoring.[6] This approach enhances the efficacy of medical interventions and minimises potential side effects, leading to better overall health outcomes.

Development of Personalised Medicine

Archibald Garrod and Inborn Errors of Metabolism

Archibald Garrod, an English physician, is considered a pioneer in personalised medicine. His studies, specifically on alkaptonuria, led him to observe that individuals with the disease exhibited unique biochemical markers in their urine compared to those without the disease. Garrod concluded that these diseases were due to specific "altered courses of metabolism", hinting that biochemical processes and disease susceptibility varied between individuals.[7] His work suggested that such metabolic variations were widespread, potentially explaining different susceptibilities and manifestations of diseases among individuals.

Mendelian v *Biometrician Debate*

During Garrod's time, the field of genetics emerged and was influenced by Mendel's principles of "particular inheritance."[8] Researchers like William Bateson and Hugo de Vries, known as Mendelian, emphasised discrete inheritance patterns. Today, we call these discrete units' genes. In contrast, Biometricians, led by Karl Pearson, focused on continuous traits like height and were sceptical of how discrete genetic factors could explain continuous variation. Ronald Fisher resolved this debate by demonstrating that continuous phenotypic variation could be explained by the cumulative effect of multiple discrete genetic factors, paving the way for understanding genetic contributions to complex traits.[7]

Genetic Studies and Personalised Medicine

Modern high-throughput genetic technologies, such as genotyping chips and DNA sequencing, have confirmed that many genes contribute to a person's traits in different ways.[9] Some genes have a significant impact, while others have a smaller one. This discovery has shown that people have millions of genetic differences, leading to wide variations between individuals. As a result, personalised medicine now focuses heavily on genetic information to tailor healthcare to each person's unique genetic makeup.Some of these genetic differences are new mutations unique to an individual.[9] This high level of gene variation helps explain why people differ so much in their traits, disease risk, and how they respond to treatments. Additionally, while personalised medicine is heavily based on genetic information, it also considers other factors like environmental exposures, development, epigenetic changes, and behaviours to determine the best treatment for each person.

As technology advances, the potential for personalised medicine to revolutionise healthcare becomes even more pronounced. By leveraging comprehensive data and sophisticated analytical tools, healthcare providers can develop specialised treatment plans that cater to each patient's unique needs. This represents a significant shift from the traditional one-size-fits-all approach, moving towards a more individualised and precise disease management and prevention method. The applicability of personalised

medicine is not restricted only to treatment options; it caters to disease detection and prevention needs. One of the successful examples of personalised medicine is Imatinib, an anticancer drug. It is specifically designed for patients with chronic myelogenous leukaemia (CML) who harbour a genetic abnormality called the Philadelphia chromosome, producing a mutated enzyme called BCR-ABL tyrosine kinase.[10] Therefore, it is administered selectively based on genetic testing to ensure targeted treatment, which inhibits CML cell proliferation and reverses the cancerous effects of mutation. Warfarin, a blood-thinning medication, interacts differently with individuals based on their genetic makeup. Genetic variants in genes like VKORC1 and CYP2C9 influence how individuals respond to Warfarin. Therefore, the FDA recommends personalised dosing based on genotype to optimise its efficacy and minimise adverse reactions.[4] Immunotherapies, such as cytotoxic T-cell therapies, are tailored to individual cancer patients based on their tumour's unique genetic alterations, known as neo-antigens. This personalised approach harnesses the patient's immune system to target specific tumour markers, improving treatment efficacy.[4]

Personalised medicine has many benefits, such as treatments tailored to individual needs, preventive care, and quicker diagnostics. However, we are not fully using its potential because biological systems are highly complex, making it hard to analyse all the data. Today, medical science often relies on straightforward links, like a specific biomarker directly causing a certain effect. However, biology is rarely this simple. For example, one biomarker could cause multiple effects in combination with other factors.

The factor of ease and commonality in the customised treatment the consumers get is based on their molecular, physiological, environmental, and behavioural characteristics, as discussed in the previous segment of Personalised Medicine. Personalised medicine is about customising treatments based on individual patient differences. Within this, 'Mystery Medicine' or Black Box medicine or explicit personalised medicine uses scientific research to link specific patient traits to treatment outcomes, relying on clear and understandable connections. It creates levels, sub-groups, and strata within the patients based on which medicine would suit what set of patients.[11] While traditional clinical trials provide general results for the average patient, personalised medicine aims to improve health outcomes by focusing on the unique characteristics of each person.

However, personalised medicine focuses on simple relationships that can be clearly defined and validated through scientific processes and clinical trials. This "explicit personalised medicine" approach relies on understanding and verifying straightforward biological connections involving a few patient variables. On the other hand, implicit personalised medicine, or Black-box medicine, aims to expand the scope of personalised medicine by using complex, implicit relationships beyond the reach of current analytical science. It is the next level to Personalised Medicine. Black-box uses opaque computational models to make decisions related to healthcare. They process complex data to reveal hidden patterns and relationships that traditional methods miss. This can improve diagnosis, suggest treatments, and recommend preventive care, which are not possible due to conventional analysis. Also, in drug development, repurposing existing drugs is cost-effective and skips some safety trials. However, issues like patent restrictions make it hard for companies to profit, limiting incentives for drug repurposing. Advanced analytics and AI can help, sifting through health records to find new uses for old drugs, saving time and money.

Difference between Explicit Personalised Medicine and Implied Personalised Medicine

Personalised medicine can be categorised into two main types: explicit and implied personalised medicine.[12] Explicit personalised medicine relies on a narrower range of data or information, making predictions based on simple biological relationships between biomarkers.[12] This approach tends to be more explainable, allowing healthcare professionals to understand the underlying mechanisms behind the predictions. It relies heavily on scientific research and clinical trials to identify and validate these relationships. In contrast, implied personalised medicine utilises a broader set of information, incorporating larger datasets and advanced machine-learning techniques. This enables the prediction of complex biological relationships between biomarkers, though the results are often less explainable due to the intricate nature of the algorithms and the vast amount of data involved.[13] Additionally, implied personalised medicine is generally not susceptible to confirmation through clinical trials, making its validation more challenging.[14]

Personalised medicine stands at the forefront of healthcare innovation, emphasising the customisation of treatments to accommodate the diverse characteristics of each patient. By embracing explicit and implicit

approaches, personalised medicine transcends the limitations of traditional one-size-fits-all methodologies. Explicit personalised medicine leverages scientific inquiry to establish clear connections between patient traits and treatment efficacy. In contrast, implicit personalised medicine harnesses cutting-edge algorithms to navigate vast datasets for predictive insights. Together, these methodologies promise to revolutionise patient care by acknowledging and addressing individual variations, ultimately paving the way for improved health outcomes tailored to each patient's unique needs.

Legal Challenges of Black-Box Medicine

Discrimination

Personalised medicine, be it explicit or implicit, while offering significant potential for targeted treatments and improved health outcomes, raises concerns about genetic discrimination. Discrimination in any field frequently stems from preconceived notions and biases rather than objective assessments of an individual. Discriminatory systems overlook individual qualities such as merit, eligibility, and ability, instead relying on generalised stereotypes.[16] This diminishes the importance of personal achievements and capabilities. Genes determine our unique traits and can also cause genetic disorders that are passed down through families.

Black-box Medicine's outcome would leadto discriminationwhen individuals are treated unfairly based on genetic information, which can have profound economic and social implications. This second type of discrimination is socially acceptable where stratification is allowed, particularly by insurance industries where individuals's genetic makeup will decide the risk associated with providing health insurance and the treatment they can avail.[16] The issue of genetic discrimination becomes particularly pertinent as personalised medicine advances, given its ability to identify even small genomic differences[17] that can influence an individual's health prognosis and responsiveness to treatments. For instance, if genomic data indicates a higher likelihood of developing a serious illness, this could affect an individual's ability to obtain insurance or employment. Genetic discrimination includes charging more, asking for genetic information, and denying coverage, claims, or renewals; in employment, it means not allowing unfair treatment in hiring, pay, promotions, and medical benefits based on genetic information.[18]

Discriminating based on genetic information can lead to social stigmatisation and reduced access to necessary services and opportunities. For instance, individuals with certain genetic markers might be unfairly judged or treated differently in educational, professional, or social contexts. This not only affects their quality of life but also perpetuates social inequalities. To mitigate genetic discrimination, many countries have enacted legislation that restricts the use of genetic information, such as the Genetic Information Non-Discrimination Act, 2008 of the United States of America, in various contexts, particularly in insurance and employment. However, it does not cover life, disability or long-term insurance and has therefore been a subject of criticism. Article 14 of the Constitution of India prohibits discrimination of any kind. This would include discrimination based on the genetic heritage of an individual. The court emphasised the precedent of the Supreme Court in *Consumer Education and Research Centre and* others v *Union of India and others* (1995)[19] which held that the Right to Health has no meaning without the Right toHealthcare.

The court compared the international practices to provide valuable insights into protecting genetic information and ensuring fair treatment in insurance. The Universal Declaration of Human Rights (1948) emphasises medical care as a basic human right. Observing this, the court asserted that health insurance is essential in today's high-cost healthcare system and that it is integral to medical care. The European Convention on Human Rights & Biomedicine bars discrimination based on genetic heritage, permitting genetic testing only for health or scientific research purposes. The Austrian Gene Technology Act (2005) prohibits the use of genetic data for insurance purposes without prior consent, allowing genetic tests only for scientific and educational purposes. Insurance companies do not ask for genetic test results for risk assessment and ensure confidentiality in Finland. France only permits genetic studies for medical purposes or scientific research, and misuse of genetic data is an offence. In Ireland, genetic testing is allowed if not prohibited by law, but genetic data cannot be used for life or health insurance policies. The Constitution of Spain prohibits discrimination based on personal or social circumstances, applicable to both employers and insurers. On the contrary, Sweden's Genetic Integrity Act (2006) permits the use of genetic information in

insurance. The Canadian Life and Health Insurance Association has a voluntary code preventing insurers from demanding genetic testing, but results must be disclosed for high-value policies. Insurance companies in Australia regulate their policies through the Financial Services Council (FSC), requiring customers to disclose genetic test results, which can affect premiums. Different countries have distinct regulations addressing genetic discrimination in insurance. Despite the lack of uniformity, there is a global consensus that discrimination based on genetic heritage is contrary to human rights and needs regulation to protect genetic data and prevent insurance discrimination.

In the Indian context, IRDA's 2013 guidelines led to the exclusion of genetic conditions from insurance coverage due to the lack of a clear definition of genetic disorders. The 2016 guidelines attempted standardisation but did not address the genetic disorder issue directly. The Delhi High Court's ruling in the *United India Insurance* v *Jai Prakash Tayal*[19] brought attention to the vague nature of 'genetic disorder' and urged IRDA to clarify its guidelines.The court highlighted that 'genetic disorder' is a vague term. Genetic conditions can be influenced by various factors like lifestyle, environment, and diet. Detailed genetic testing is essential to determine if a condition is purely genetic.Genetic testing is complex and expensive. Preserving the confidentiality of the data collected is crucial. Without specific testing and clear definitions, excluding genetic disorders from coverage is arbitrary and unfair.

What makes it worse is the fact that insurance companies, like in the present case, have not asked for higher premiums based on a genetic disposition but have completely refused to honour a claim based on a broad understanding (or misunderstanding) of the term genetic disorders.[19]

Pure genetic disorders like Huntington's disease or Down's syndrome might be treated differently in policies, but speculative genetic exclusions should not be permissible.

Insurance companies are free to structure their contracts based on reasonable and intelligible factors, which should not be arbitrary and, in any case, cannot be…exclusionary. Such contracts have to be based on empirical testing and data and cannot be simply on the basis of subjective or vague factors.[19]

The broad exclusion of genetic disorders without reasonableness in insurance contracts is illegal and unconstitutional. In response, IRDA's 2018 notification aimed to protect individuals with genetic disorders from discrimination in health insurance. However, the Supreme Court's stay on the operative part of the Delhi High Court's judgment has maintained uncertainty and continued challenges for individuals with genetic conditions seeking health insurance coverage. The inconsistent and vague guidelines from IRDA have led to a lack of clarity and uniformity in the handling of genetic disorders in insurance policies. While the 2016 guidelines standardised insurance practices, they did not explicitly address genetic conditions, leaving room for continued discriminatory practices by insurance companies. This situation calls for a clear and comprehensive regulatory framework that defines genetic disorders, mandates specific testing protocols, and ensures the protection and confidentiality of genetic data.

Liability

The increasing integration of AI and ML in medicine has raised significant concerns regarding the potential for algorithm inaccuracy to lead to patient injury and subsequent medical liability.[20] Black-box medicine presents a complex landscape of liability concerns involving multiple stakeholders, including developers, manufacturers, healthcare professionals, and health systems.

To determine liability, one should be able to identify parties responsible in the chain from development to application of Black- Box Medicine. There can be two classifications to identify responsible parties: developers of Black- box medicine and healthcare professionals.[21] AI developers are responsible for designing, functionality, and performing AI-personalised medicine. Developers must implement rigorous testing and validation processes to ensure their AI systems perform as expected in real-world healthcare settings, and if it misdiagnoses patients due to biased training data, developers could be held responsible legally for the consequences.

Similarly, healthcare professionals must oversee and interpret AI-generated insights, ensuring that they are used appropriately in clinical decision-making.[21] Professionals must combine the algorithm's outcome with their medical expertise to make informed decisions which adhere to the standard of care with established medical practices. Solely relying on the data generated, either implicit or explicit, will have consequences. Healthcare professionals are ultimately responsible for patient care, including decisions influenced and generated by AI. Legal precedents

indicate that physicians can be held accountable for errors resulting from AI use if those errors lead to patient harm and deviate from the accepted standard of care.[22] If an AI system's recommendation leads to a negative outcome, the professional's liability depends on whether they appropriately validated the AI's input. Allocation of liability impacts both patient redress and the implementation of potentially effective algorithms.[20]

The above discussion of allocating legal liability in healthcare AI becomes significantly more complex when dealing with Black- box models. These models, characterised by their opaque computational processes, present unique challenges in understanding and attributing liability due to their inherent lack of transparency. Black- box models in AI are those whose inner workings are either unknown or cannot be easily understood by humans. These models are trained on data rather than explicitly programmed, making it difficult to explain their outputs or understand the factors they consider important. Lack of transparency complicates the assignment of liability when errors or adverse outcomes occur.

In the case of Black- box models, developers may not fully understand why their systems produce certain outputs. This makes it challenging to hold them accountable for specific errors or adverse outcomes, as they themselves may not know the underlying reasons for the AI's behaviour.[23] However, developers still have a duty to ensure that their models are thoroughly tested, validated, and free from biases that could compromise patient safety.When using Black- box models, healthcare professionals face the dilemma of relying on AI outputs that they cannot fully explain or understand. This raises concerns about their ability to meet the standard of care. Suppose an AI-generated recommendation leads to patient harm. In that case, the professional might still be held liable if their reliance on the AI is deemed inappropriate or failed to apply their judgment adequately.

This can be particularly challenging when the algorithm's recommendations diverge from established medical knowledge or practice. For example, suppose a Black- box AI model suggests a novel treatment that deviates from established medical practices but is highly effective for a particular patient group. Despite its effectiveness, the treatment is not widely accepted or understood. If this novel treatment improves outcomes, the doctor who adopts it may face legal challenges for deviating from standard care practices. Professionals might argue that the positive results justify the deviation. In this case, the question of liability becomes complex, as it involves balancing adherence to established standards with the potential benefits of innovative AI-driven approaches.However, Black- box models' opaque nature makes it difficult to align AI-generated decisions with established medical care; what would happen in this kind of scenario is still a matter of research. Choosing to use a particular black-box algorithm is a complex decision for doctors. Still, due to its opaque nature, they cannot fully understand or verify the recommendations made by black-box algorithms.This lack of transparency means that physicians must decide whether to trust the algorithm's outputs without being able to scrutinise the underlying logic.[23] Enhanced transparency, robust validation, and clear guidelines on shared responsibilities can help address these challenges and ensure a fair and effective allocation of liability.

Privacy

Black- box medicine, which relies on opaque algorithms, raises significant privacy concerns. The vast data used in these models may make individual identification less likely, but the sensitivity of health information demands robust privacy protections. Sensitive information is particularly vulnerable during collection, storage, and transmission. As per the ethical guidelines[2], AI technologies should ensure privacy and data protection at all development and deployment stages for our discussion of black-box models. Trust is essential in healthcare, where data misuse can harm patients and lead to discrimination, even if unintended.[24] Cybersecurity is a major concern, especially given past incidents like the 2016 data leak from a diagnostic lab in Maharashtra, India.[24] Ensuring the security of massive health datasets is a significant challenge[25], particularly preventing unauthorised access and breaches.

Adjacent to privacy is confidentiality; informed consent from the patients is also crucial.[15]Obtaining genuine consent from patients is difficult, especially when they may not fully understand the extent of data usage and potential privacy implications while at the same time not 'undermining their consent'.[25] Black-box medicine uses far more information than traditional healthcare applications, requiring comprehensive access to health information and generating new health data. The extensive data requirements of Black- box medicine can lead to

losses of patient privacy and affect patient autonomy and decisional privacy.[26] Patients might feel their personal health information is no longer under their control, leading to reluctance to share vital information with healthcare providers. The protection of informational health privacy is vital to prevent harm to individuals, ensure high-quality healthcare, and safeguard public health.[15] Four classes of privacy harms can arise from privacy violations in Black- box medicine: Objective, Subjective, Dignity and Autonomy, and Behavioural Changes Harm.[27]

Objective Privacy Harms

Financial Consequences include if patients' records indicate a costly illness, they might face insurance denial, job rejection, or scams. Non-Financial Consequences Disclosure of sensitive conditions can damage reputation and family relations. For example, a patient with a mental health condition might avoid seeking treatment due to privacy concerns, leading to worsening of their condition and potentially more severe health outcomes.[15]

Subjective Privacy Harms

Psychological Impact- Individuals may suffer discomfort, embarrassment, or mental distress due to privacy breaches, especially with sensitive health information. For example, if a patient's HIV status is disclosed without consent, they may face social stigma and discrimination in various aspects of their life.[15]

Dignity and Autonomy Harms **Loss of Autonomy**

Privacy violations can erode individual autonomy, dignity, and personal decision-making capabilities, which are essential for leading autonomous lives. Patients might feel their personal health information is no longer under their control, leading to reluctance to share vital information with healthcare providers.

Behavioural Changes

Altered Interactions- Lack of privacy can hinder cooperation, trust, and confidence, leading individuals to avoid beneficial interactions, thus harming societal well-being. For example, an individual with a contagious disease might not seek medical help, increasing the risk of spreading the disease to others.[15]

The dual nature of Health Information is the primary factor for privacy violations in Black- box Medicine, as health information is both sensitive and valuable, creating a tension between privacy demands and the need for access.[28] Privacy violations stem from massive data collection, comprehensive health information, broad distribution of health information and creation of new health information.[29] The massive aspect deals with large quantities of data from numerous individuals and many data points per individual to identify subtle correlations; comprehensiveness takes care of the qualitative aspect. Data must be comprehensive and inclusive of all patient categories to avoid errors.[30] Sharing and combining data from various providers into central repositories increases the risk of data breaches during transmission. Further, Health information needs to be distributed to various stakeholders, including doctors, hospitals, laboratories, developers and researchers.[30] This broad distribution was not required in traditional health care, increasing the potential for privacy violations. Also, black-box models create new health information, such as inferences about disease risks and treatment susceptibilities.[27] This new information can lead to privacy issues, similar to traditional health data, by influencing financial decisions or causing non-financial harms like embarrassment and stigma. Solutions to these privacy challenges must balance the need for data to achieve the benefits of Black- box medicine with the imperative to protect patient privacy and maintain trust in the healthcare system.

Patentability

While personalised and Black- box medicine holds great promise for improving healthcare, they also present significant challenges in terms of patent law and intellectual property rights. Patents play a crucial role in incentivising innovation and investment in Black- box medicine, but they also raise complex legal issues regarding inventorship, patentability of the subject matter, and disclosure. AI can analyse vast datasets, identify patterns, and generate new insights that can lead to inventions. This capability enhances the inventive process by providing tools that surpass human analytical capacities. Secondly, AI systems can autonomously generate inventions, creating outputs that may not be directly attributable to human inventors. Should the legal frameworks surrounding patents be adapted to address inventorship, accountability, and disclosure issues in Black- box Medicine, or is there a need for an altogether new legal framework?

Inventorship of Patent

Traditional patent systems require a named human inventor. Determining inventorship when AI is involved is complex, as AI systems can be created without direct

human intervention. AI systems can develop patentable subject matter, but it remains unclear if AI can be considered an inventor and be eligible for patent protection.[31] Historically, people have claimed patents for AI-generated inventions since the 1980s but have not disclosed AI's role, often listing themselves as inventors on legal advice.[32] Most jurisdictions require patent applications to list a natural person as the inventor to protect and acknowledge human inventors' rights. This requirement ensures due credit for human inventors, even though ownership can be transferred to businesses or employers.[32] Recognising AI as an inventor when it functionally invents protects the integrity of human inventorship. Allowing humans to claim credit for AI-generated work could devalue genuine human inventorship, as it equates the work of someone who merely instructs an AI with that of a true inventor.[32] Inventorship in AI-made inventions concerns the actual creators of the invention, while ownership pertains to patent holders who enforce their rights.[33] AI lacks the capacity for legal obligations like infringement or compensation, preventing recognition as inventors despite their creative role.[33] Listing an AI as aninventor is not about granting rights to machines but rather about protecting the moral rights of human inventors and the integrity of the patent system.[31] The goal is to incentivise innovation through patent protection without undermining the moral rights of human inventors.Australia, the UK, the US, and South Africa exhibit different stances inrecognising AI as an inventor. Australia supports AI inventorship from a procedural standpoint. In supporting this notion, Justice Beach posed a profound question: "We are both created and created. Why cannot our own inventions be created?" He distinguished between ownership of a patent and who can be an inventor, arguing that these are separate issues.[32] The UK acknowledges AI's inventive capabilities but maintains that only natural persons can be inventors.[32] The US strictly limits inventorship to natural persons based on statutory language.[32] South Africa uniquely granted a patent to an AI inventor, although its patent system's lack of formal examination may invite future challenges.[32] These varying approaches underscore the need for international consensus and potentially new legal frameworks to address AI inventorship in patents.Adapting legal frameworks to recognise AI's role in inventorship while preserving human inventorship integrity is essential for fostering innovation and upholding the patent system's credibility.

Patentable Subject Matter

While patents are crucial for incentivising innovation, their effectiveness in fostering progress in Black- box medicine is undermined by challenges in meeting the written description requirement and issues of patent eligibility. Patent eligibility hinges on whether an invention qualifies as statutory subject matter. Algorithms and biological correlations, central to Black- box medicine, face scrutiny due to their potential classification as abstract ideas or laws of nature. This categorisation renders them ineligible for patent protection under current legal and judicial interpretations. The Supreme Court of the United States's jurisprudence, particularly in *Mayo* v *Prometheus*[34], establishes rigorous criteria for patent eligibility. The Court has identified three judicial exceptions: laws of nature, natural phenomena, and abstract ideas.[34] Patents on Black- box medicine potentially fall under all these prohibitions due to their reliance on complex algorithms and biological correlations.The Supreme Court ruled that medical diagnostic processes, which involve laws of nature, are not patentable. This decision set a precedent against patents that primarily rely on natural phenomena.[34] The Court emphasised that merely appending conventional steps to laws of nature, natural phenomena, or abstract ideas does not render them patentable. The invention must demonstrate a genuine application of these concepts.[34] Black- box medicine inventions often involve algorithms and data analytics that may be categorised as abstract ideas. Furthermore, correlations drawn between biological data and medical conditions could be seen as natural phenomena. The Court's stance implies that combining diagnostic methods with routine, conventional activities (such as standard medical practices) does not suffice to justify patentability. The focus remains on whether the invention provides a genuine application or transformation beyond the natural laws or phenomena it utilises.

Further, the *Association for Molecular Pathology et al*. v *Myriad Genetics*[35] case significantly narrows the path to patentability for innovations in Black- box medicine that depend on natural products and biomarkers. The Court ruled that isolated DNA sequences, when extracted from the human body, are products of nature and thus not eligible for patent protection.[35] This directly affects Black- box medicine, where genetic testing and diagnostics heavily rely on identifying and analysing specific

DNA sequences and biomarkers.The decision casts doubt on the strategy of using patents to protect natural biomarkers essential for diagnostic tests in Black- box medicine. Biomarkers, similar to isolated DNA, are considered natural products, making it difficult to secure patents that provide exclusivity over their use in diagnostic technologies.

Adding to this, *Alice Corp*. v *CLS Bank International*.[36] The decision reinforced that merely implementing abstract ideas, such as algorithms or mathematical formulas, on a computer does not make them eligible for patent protection. This directly affects innovations in Black- box medicine that rely heavily on complex algorithms and software to analyse and interpret medical data. The decision emphasised the need for inventions to integrate abstract ideas into something more transformative and practical.[36] In the context of Black- box medicine, this means that patent applications must demonstrate how algorithms and software lead to concrete improvements in diagnosing or treating medical conditions beyond just computational implementation.

Analysing the Indian Patent Act of 1970 in the context of Black- box medicine reveals similar challenges for patentability. The specific exclusions in the Act highlight the complexities and limitations of protecting such innovations under the current patent framework. Clause (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.[37] Black- box medicine, which heavily relies on advanced algorithms and AI to diagnose and treat medical conditions, falls squarely within this exclusion. The rationale behind this exclusion is to ensure that essential medical treatments remain accessible to all and are not hindered by patent restrictions. However, this also means that the innovative processes and methodologies integral to Black- box medicine cannot be patented, potentially disincentivising investment and innovation in this field.

Clause (j) plants and animals in whole or any part thereof other than micro- organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.[38] While this section may seem less relevant at first glance, it does have implications for Black-box medicine, particularly when considering the biological data and genetic information often utilised in these AI-driven processes. For instance, if Black-box medicine involves the use of genetic data from plants or animals to develop treatment algorithms, these components would not be eligible for patent protection. This exclusion aims to prevent the monopolisation of natural biological entities, but it also complicates the patent landscape for innovations that intersect with biological data.

Clause (k) a mathematical or business method or a computer program per se or algorithms.[39] This exclusion is particularly pertinent to Black-box medicine, which relies on sophisticated algorithms and AI-driven computer programs. These algorithms analyse vast medical data to uncover patterns and make diagnostic or therapeutic recommendations. Under this provision, the core technological innovations that power Black- box medicine are ineligible for patent protection. This presents a significant barrier to securing intellectual property rights for the developers of these technologies, potentially limiting the commercialisation and widespread adoption of black-box medical solutions.

Disclosure

The patent system is designed to balance the inventor's right to exclude others from making, using, or selling their invention with the public's right to learn about and build upon new technologies. This is doneby requiring detailed disclosures, the system promotes cumulative innovation. The written description requirement ensures that the scope of the patent claims is commensurate with the Inventor's contribution to the art. This helps prevent overly broad claims that could stifle competition and innovation. Black-box medicine, which relies heavily on complex and often opaque algorithms, faces unique challenges in meeting the written description requirement. As discussed earlier, no transparency in Black-box algorithms, by definition, operate in ways that are not easily interpretable or transparent, even to their developers. This opacity makes it difficult to describe the invention in a way that meets the statutory requirements. It has complex and implicit knowledge.[40] Many algorithms used in Black- box medicine involve complex machine-learning models and AI systems. These models often rely on vast amounts of data and intricate training processes that are difficult to document comprehensively.[41] Further, algorithms can evolve and improve over time based on new data inputs and refinements. Given the complexity and non-transparency of black-box algorithms, inventors may struggle to provide a

written description that is sufficiently detailed to enable a Person having ordinary skill in the art (PHOSITA) to practice the invention.[41] This difficulty can result in rejected patent applications or patents that are vulnerable to invalidation.Capturing the full scope and future potential of these evolving systems in a patent application is inherently challenging. Under the Indian Patent Regime,

Sub-Section (4) says-Every complete specification shall(a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed; (b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and (c) end with a claim or claims defining the scope of the invention for which protection is claimed; (d) be accompanied by an abstract to provide technical information on the invention.[42]

As discussed in earlier parts as well, lack of transparency complicates compliance with clause (a)[42], which requires a detailed description of the invention. Secondly, in Black- box medicine, the best method often involves complex algorithms that are not easily interpretable. Primarily, disclosing these algorithms is difficult to do without revealing trade secrets or compromising competitive advantage, which poses a substantial challenge. Black-box models frequently evolve over time as they learn from new data. This dynamic nature makes it difficult to define the scope of the invention clearly, as required by clause (c). The evolving algorithms may alter the performance and operation of the invention, complicating the claims made in the patent application. Given the difficulties in meeting current disclosure requirements, there may be a need to adapt or create new legal frameworks that accommodate the unique nature of Black- box medicine.

Trade secret protection can be a viable alternative to patents. It offers flexibility by covering a broad range of subject matter, including raw data, algorithms, and processes. However, trade secret law provides relatively weaker protection compared to patents. Its enforcement is limited to cases of misappropriation, and it offers no protection against independent discovery or reverse engineering. A hybrid IP strategy may act as a pragmatic solution. Innovators can consider using patents for tangible, verifiable inventions such as medical devices, diagnostic kits, or software interfaces, where disclosure fosters regulatory approval and public trust.[43] Conversely, trade secrets may be better suited to protect proprietary algorithms, training methodologies, or high-value data sets, where patent eligibility is unclear or where disclosure would compromise competitive advantage.

Conclusion

Black-box medicine represents a paradigm shift in healthcare, offering immense potential for personalised treatment and improved patient outcomes. However, it raises critical concerns surrounding genetic discrimination, liability, and privacy, necessitating a clear and robust framework for implementation. Also, its integration into the intellectual property regime poses intricate legal challenges. Patent eligibility and disclosure requirements complicate the landscape for black-box medicine. Algorithms and biological correlations, essential components of Black Box innovations, often fail to meet the eligibility criteria under current legal standards. Additionally, the non-transparent and evolving nature of black-box algorithms presents significant obstacles in meeting the disclosure standards essential for public knowledge and subsequent innovation. Indian Patent System mirrors these challenges; while these provisions aim to ensure accessibility and prevent monopolisation, they also risk disincentivising investment in this transformative field.

As IP protection plays a vital role in encouraging innovation by granting exclusive rights that enable innovators to recoup research and development costs**,** there is a growing argument for developing a new IP regime tailored to the unique characteristics of Black-box medicine. This calls forreassessing existing patent frameworks to ensure they remain effective in fostering innovation while upholding the principles of fairness and equity. This could involve creating provisions for partial disclosure and protecting proprietary algorithms while ensuring sufficient transparency. While there is a push to grant intellectual property (IP) protection to Black- box medicine technologies to spur innovation, this approach may inadvertently undermine the need for a balanced liability framework. The opaque nature of black-box technologies hinders transparency and accountability, allowing errors, biases, or adverse outcomes to go unchecked. Moreover, algorithms trained on biased data risk perpetuating inequalities, while the extensive use of sensitive patient data raises serious privacy concerns. Prioritising IP protections over theseconsiderations may incentivise innovators

to focus on market dominance while neglecting their responsibilities toward patient welfare and public trust. This imbalance not only jeopardises patient safety but also hampers the ethical development of transformative technologies.By aligning innovation incentives with legal and ethical safeguards, stakeholders can harness the full potential of black-box medicine while upholding public trust, protecting patient welfare, and ensuring fairness in healthcare systems.

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