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Article

# AI-Generated Drug Innovations and Indian Patent Law: Legal Challenges and Ethical Responses

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**Abstract:** The integration of Artificial Intelligence (AI) into the pharmaceutical sector has redefined drug discovery and development, enabling the generation of novel compounds with enhanced efficiency and precision. However, this transformative progress challenges the foundational tenets of intellectual property (IP) law in India. This paper examines the intersection of AI-generated pharmaceutical compositions and Indian IP laws, with a particular focus on patentability, inventorship, and data exclusivity. The study highlights ambiguities in recognizing AI as an inventor, the complexities of assessing novelty and non-obviousness in AI outputs, and the inadequacy of current legal frameworks in addressing the protection of AI-driven innovations. It argues for a comprehensive overhaul of existing IP laws to include sui generis protections or collaborative inventorship models. Further, it explores international best practices and ethical considerations critical for balancing innovation incentives with public access to essential medicines. The paper concludes by proposing legal, regulatory, and institutional reforms that could empower India to lead globally in responsible and equitable AI-based pharmaceutical innovation.

**Keywords:** AI-generated pharmaceuticals; Indian patent law; inventorship; data exclusivity; drug discovery; intellectual property; Section 3(d); generative AI; legal reform; personalized medicine

## Introduction

The integration of Artificial Intelligence (AI) in the pharmaceutical sector has revolutionized drug discovery and development, offering unprecedented opportunities for innovation. However, this technological advancement also raises complex legal and regulatory challenges, particularly in the realm of intellectual property (IP) laws. This response explores the intersection of AI-generated pharmaceutical compositions and intellectual property laws in India, focusing on key legal frameworks, challenges, and future directions.

### The Role of AI in Pharmaceutical Drug Discovery

AI has emerged as a transformative tool in the pharmaceutical industry, enabling the rapid generation of novel drug compounds and streamlining the drug discovery process. AI algorithms can analyze vast datasets, predict molecular structures, and identify potential drug candidates with high accuracy. For instance, AI can generate pharmaceutical compounds that are not only novel but also exhibit high drug-likeness, making them promising candidates for further development (Shimizu et al., 2023) (Kimta & Dogra, 2024).

### Key Applications of AI in Drug Discovery

- Molecular Generation:** AI can generate molecules with specific properties, reducing the time and cost associated with traditional drug discovery methods (Shimizu et al., 2023).
- Patent Status Verification:** AI can assist in verifying the patent status of generated compounds, ensuring that new drugs are novel and non-obvious (Shimizu et al., 2023) (Chun, n.d.).
- Personalized Medicine:** AI facilitates the development of personalized therapies by analyzing patient-specific data and tailoring treatments to individual needs (Poddar & Rao, 2024) (Kimta & Dogra, 2024).

### *Intellectual Property Challenges in AI-Generated Pharmaceuticals*

The use of AI in drug discovery raises several IP challenges, particularly in relation to patentability, inventorship, and data exclusivity. These challenges are compounded by the lack of clear guidelines in Indian patent law for AI-generated inventions.

#### *Patentability of AI-Generated Inventions*

Indian patent law, governed by the Patents Act of 1970, excludes software and algorithms from patentability unless they demonstrate a technical effect (“Artificial Intelligence and Its Patentability: A Comparative Study Between India,UK, and USA,” 2023) (Bhardwaj & Gupta, n.d.). This creates ambiguity in determining the patentability of AI-generated pharmaceutical compositions, as AI systems often rely on complex algorithms to generate new compounds.

#### **Key Issues:**

1. **Novelty and Non-Obviousness:** AI-generated compounds must meet the criteria of novelty and non-obviousness to qualify for patent protection. However, the lack of clear guidelines for assessing these criteria in AI-generated inventions poses a significant challenge (“Artificial Intelligence and Its Patentability: A Comparative Study Between India,UK, and USA,” 2023) (Bhardwaj & Gupta, n.d.).
2. **Technical Effect Requirement:** Indian patent law requires that software-related inventions demonstrate a technical effect. This requirement may limit the patentability of AI-generated pharmaceutical compositions unless they can be shown to produce a tangible technical outcome (“Artificial Intelligence and Its Patentability: A Comparative Study Between India,UK, and USA,” 2023) (Bhardwaj & Gupta, n.d.).

#### *Inventorship in AI-Generated Inventions*

One of the most contentious issues in AI-generated pharmaceutical compositions is the question of inventorship. Under Indian patent law, only natural persons can be recognized as inventors. This raises concerns about the legal status of AI systems as inventors (“Can Artificial Intelligence (AI) Machine Be Granted Inventorship in India?,” 2023) (Artificial Intelligence and Inventorship Under the Patent Law Regime: Practical Development from Common Law Jurisdictions, 2023).

#### **Key Considerations:**

1. **Legal Recognition of AI as Inventor:** Indian law does not recognize AI systems as legal entities capable of inventorship. This creates uncertainty about ownership rights for AI-generated pharmaceutical compositions (“Can Artificial Intelligence (AI) Machine Be Granted Inventorship in India?,” 2023) (Artificial Intelligence and Inventorship Under the Patent Law Regime: Practical Development from Common Law Jurisdictions, 2023).
2. **Human Intervention:** In cases where AI systems generate pharmaceutical compositions with minimal human intervention, the question arises whether the human operator or the AI system should be considered the inventor (“Can Artificial Intelligence (AI) Machine Be Granted Inventorship in India?,” 2023) (Artificial Intelligence and Inventorship Under the Patent Law Regime: Practical Development from Common Law Jurisdictions, 2023).

*Data Exclusivity and AI-Generated Pharmaceuticals*

Data exclusivity refers to the period during which pharmaceutical companies can exclusively use data generated during the development of a drug. AI-generated pharmaceutical compositions may require new frameworks for data exclusivity, as the traditional rules were not designed to accommodate AI-driven innovations (Kimball & Ragavan, 2022) (Chun, n.d.).

**Key Challenges:**

1. **Scope of Data Exclusivity:** The scope of data exclusivity for AI-generated pharmaceuticals is unclear, particularly in cases where AI systems generate data that is not easily attributable to human inventors (Kimball & Ragavan, 2022) (Chun, n.d.).
2. **Balancing Innovation and Access:** Policymakers must balance the need to incentivize innovation through data exclusivity with the need to ensure access to affordable medicines, particularly in the Indian context (Sabet et al., 2024) (Kimta & Dogra, 2024).

*The Way Forward: Regulatory and Policy Recommendations*

To address the challenges posed by AI-generated pharmaceutical compositions, India must develop a robust regulatory framework that aligns with the rapidly evolving technological landscape. The following recommendations can guide policymakers:

**1. Clarity on Patentability Criteria**

- Indian patent law should provide clear guidelines for assessing the novelty, non-obviousness, and technical effect of AI-generated pharmaceutical compositions (“Artificial Intelligence and Its Patentability: A Comparative Study Between India,UK, and USA,” 2023) (Bhardwaj & Gupta, n.d.).
- The patent office should establish specific criteria for evaluating the patentability of AI-generated inventions, ensuring consistency and predictability in the patent granting process (“Artificial Intelligence and Its Patentability: A Comparative Study Between India,UK, and USA,” 2023) (Bhardwaj & Gupta, n.d.).

**2. Recognition of AI Inventorship**

- India should consider revising its patent law to address the question of AI inventorship. This could involve recognizing AI systems as co-inventors or establishing alternative ownership frameworks for AI-generated inventions (“Can Artificial Intelligence (AI) Machine Be Granted Inventorship in India?,” 2023) (Artificial Intelligence and Inventorship Under the Patent Law Regime: Practical Development from Common Law Jurisdictions, 2023).
- International collaboration and harmonization of inventorship rules can provide valuable insights for Indian policymakers (Poddar & Rao, 2024) (Bharati, 2024).

3. Data Exclusivity Frameworks

- New data exclusivity frameworks should be developed to accommodate AI-generated pharmaceuticals, ensuring that innovation is incentivized while maintaining access to essential medicines (Kimball & Ragavan, 2022) (Chun, n.d.).
- Policymakers should engage with stakeholders, including pharmaceutical companies, researchers, and patient advocacy groups, to develop balanced and equitable data exclusivity rules (Sabet et al., 2024) (Kimta & Dogra, 2024).

4. Regulatory Sandboxes for AI Innovations

- The Indian government should establish regulatory sandboxes to test and refine IP frameworks for AI-generated pharmaceuticals. These sandboxes can provide a safe environment for innovation while minimizing regulatory risks (Poddar & Rao, 2024) (Bharati, 2024).

5. Public-Private Partnerships

- Collaborative efforts between the public and private sectors can accelerate the development of AI-driven pharmaceutical innovations. Such partnerships can also facilitate the creation of standardized datasets and tools for AI-based drug discovery (Kimta & Dogra, 2024) (Sharma, 2020).

Future Prospects for AI in the Indian Pharmaceutical Sector

The integration of AI in the pharmaceutical sector presents immense opportunities for India, particularly in the context of its growing generics industry and commitment to affordable healthcare. However, realizing the full potential of AI-generated pharmaceutical compositions requires addressing the legal and regulatory challenges outlined above.

Key Opportunities:

1. **Global Leadership in Generics:** India's position as a global leader in generic drug production can be further strengthened by leveraging AI for efficient drug discovery and development (Kimta & Dogra, 2024) (Sharma, 2020).
2. **Personalized Medicine:** AI can enable the development of personalized therapies, addressing the diverse healthcare needs of the Indian population (Poddar & Rao, 2024) (Kimta & Dogra, 2024).
3. **Cost Reduction:** AI can significantly reduce the time and cost associated with drug discovery, making it easier for Indian pharmaceutical companies to develop affordable medicines (Shimizu et al., 2023) (Chun, n.d.).

Key Challenges:

1. **Regulatory Uncertainty:** The lack of clear guidelines for AI-generated pharmaceuticals poses a significant barrier to innovation and investment (“Artificial Intelligence and Its Patentability: A Comparative Study Between India,UK, and USA,” 2023) (Bhardwaj & Gupta, n.d.).
2. **Data Security and Privacy:** The use of AI in drug discovery raises concerns about data security and privacy, particularly in the context of patient-specific data (Kimta & Dogra, 2024) (Sharma, 2020).

3. **Workforce Development:** The successful integration of AI in the pharmaceutical sector requires a skilled workforce with expertise in both AI and drug discovery (Kimta & Dogra, 2024) (Sharma, 2020).

Table: Key Aspects of AI in Pharmaceutical Drug Discovery and IP Laws in India.

| Aspect                     | Details                                                                                        | Citation                                                                                                                                                                                                                                                    |
|----------------------------|------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Patentability Criteria     | Indian patent law excludes software and algorithms unless they demonstrate a technical effect. | ("Artificial Intelligence and Its Patentability: A Comparative Study Between India,UK, and USA," 2023) (Bhardwaj & Gupta, n.d.)                                                                                                                             |
| Inventorship Challenges    | Indian law does not recognize AI systems as inventors, creating ownership ambiguities.         | ("Can Artificial Intelligence (AI) Machine Be Granted Inventorship in India?," 2023) (Artificial Intelligence and Inventorship Under the Patent Law Regime: Practical Development from Common Law Jurisdictions, 2023)                                      |
| Data Exclusivity           | AI-generated data raises questions about the scope and duration of exclusivity.                | (Kimball & Ragavan, 2022) (Chun, n.d.)                                                                                                                                                                                                                      |
| Regulatory Recommendations | Clarity on patentability, inventorship, and data exclusivity is essential.                     | ("Artificial Intelligence and Its Patentability: A Comparative Study Between India,UK, and USA," 2023) (Bhardwaj & Gupta, n.d.) ("Can Artificial Intelligence (AI) Machine Be Granted Inventorship in India?," 2023) (Kimball & Ragavan, 2022) (Chun, n.d.) |

AI in Pharma Research

Artificial Intelligence (AI) is significantly transforming the pharmaceutical research landscape, particularly in drug discovery and personalized medicine. AI technologies, including machine learning (ML) and deep learning (DL), are expediting drug discovery processes, optimizing clinical trials, and enabling personalized treatment plans. These advancements are not only enhancing efficiency and reducing costs but also improving patient outcomes by tailoring therapies to individual needs. The integration of AI into pharmaceutical research is poised to revolutionize the industry, although challenges such as data privacy, ethical considerations, and regulatory compliance remain. Below, the key aspects of AI's impact on pharmaceutical research are explored in detail.

AI in Drug Discovery

- AI accelerates drug discovery by identifying potential drug candidates and predicting their efficacy, significantly reducing the time and cost associated with traditional methods (Nihalani, 2024) (Sonia, 2022).
- Machine learning models are used for target identification and validation, virtual screening, and drug repurposing, which streamline the discovery process (Nihalani, 2024) (Acharjee et al., 2023).
- AI-driven algorithms can predict molecular properties and interactions, aiding in the selection of promising compounds for further development (Acharjee et al., 2023) (Amin et al., 2024).

### *Personalized Medicine*

- AI leverages patient-specific data, such as genetic information and clinical histories, to develop personalized treatment plans, enhancing therapeutic effectiveness and minimizing side effects (Nihalani, 2024) (Sonia, 2022).
- Advanced AI models analyze complex biological data to tailor treatments to individual patient profiles, thus improving patient outcomes and reducing adverse reactions (Shah & Shah, 2023) (Halagali et al., 2025).
- AI's role in personalized medicine extends to predicting drug interactions and optimizing treatment regimens based on individual patient characteristics (Serrano et al., 2024) (Suriyaamporn et al., 2024).

### *Clinical Trials and Drug Safety*

- AI optimizes clinical trial design by selecting suitable candidates, managing data, and predicting trial outcomes with greater accuracy, thereby increasing the efficiency of trials (Sonia, 2022) (Mahajan et al., 2024).
- In pharmacovigilance, AI enhances drug safety by enabling real-time analysis of adverse drug reactions and risk assessment, ensuring patient safety post-market (Amin et al., 2024) (Suriyaamporn et al., 2024).

### *Challenges and Considerations*

- Despite its potential, AI in pharmaceuticals faces challenges such as data privacy concerns, ethical considerations, and the need for transparent and interpretable models (Nihalani, 2024) (Sonia, 2022).
- Regulatory frameworks must evolve to accommodate AI technologies, ensuring they are integrated into existing workflows without compromising safety or efficacy (Serrano et al., 2024) (Barua et al., 2024).
- The need for large, high-quality datasets and the high costs associated with AI implementation are additional barriers to widespread adoption (Mahajan et al., 2024).

While AI is revolutionizing pharmaceutical research, it is crucial to address the challenges associated with its integration. Ethical considerations, data privacy, and regulatory compliance are significant hurdles that must be overcome to fully realize AI's potential in drug discovery and personalized medicine. Collaboration among researchers, regulatory bodies, and pharmaceutical companies is essential to navigate these challenges and harness AI's transformative power in the pharmaceutical industry.

### *IP Laws and Pharma Innovation*

Intellectual property (IP) laws play a crucial role in protecting pharmaceutical innovations by providing a legal framework that incentivizes research and development (R&D) in the pharmaceutical industry. These laws ensure that companies can recoup their investments in the costly and risky process of drug development, thereby fostering innovation and economic growth. However, the implementation and impact of IP laws in the pharmaceutical sector are complex and multifaceted, involving a balance between innovation incentives and public health concerns.

### *Incentives for Innovation*

- **Patents as Incentives:** Patents are a primary form of IP protection in the pharmaceutical industry, granting exclusive rights to inventors for a limited period. This exclusivity is crucial for encouraging investment in R&D, as it allows companies to potentially recoup the high costs associated with developing new drugs, which often involve lengthy and expensive clinical trials (Cockburn & Long, 2015) (Gawel, 2016).
- **Economic Growth and Investment:** IP laws, particularly patents, are vital for attracting private investment in high-risk biomedical research. Without these protections, private investment would likely diminish, negatively impacting public funding for fundamental research and slowing down innovation in neglected fields such as rare diseases (Wise, 2014).
- **Facilitating Access to Capital:** A robust patent system is essential for enabling access to capital markets, which is necessary for funding the development of innovative pharmaceutical products. This is particularly important in regions with restricted access to investors (Gawel, 2016).

### *Challenges and Controversies*

- **Access to Medicines:** While patents incentivize innovation, they can also create monopolies that lead to high drug prices, limiting access to essential medicines, especially in developing countries. This tension between patent protection and public health objectives is a significant challenge, as seen in the case of HIV/AIDS treatment, where generic competition drastically reduced prices (Said & Kapczynski, 2012) (Rehan et al., 2024).
- **Balancing Innovation and Public Health:** The monopolistic nature of patents can hinder access to medicines, necessitating a balance between fostering innovation and ensuring affordable access. Strategies such as compulsory licensing and parallel imports are employed to address these issues, aiming to reconcile patent rights with public health priorities (Rehan et al., 2024).

### *Legal and Policy Considerations*

- **Regulatory Frameworks:** The legal protection of pharmaceuticals involves compliance with national and international IP laws and treaties. These frameworks are designed to protect pharmaceutical research results and ensure fair distribution of benefits from medical innovations (Lei, n.d.).
- **Impact of IP Policies:** The shaping and implementation of IP policies significantly influence the rate and direction of pharmaceutical innovation. Strong patent laws can undermine access to medicines in developing countries, highlighting the need for policies that balance innovation incentives with access to healthcare (Said & Kapczynski, 2012).

While IP laws are essential for protecting pharmaceutical innovations and driving economic growth, they also present challenges related to access to medicines and public health. The balance between incentivizing innovation and ensuring affordable access to essential drugs remains a critical issue in the pharmaceutical industry. This balance is particularly important in the context of global health crises, where the need for equitable access to medicines becomes even more pronounced.

### *AI in India's Pharma Revolution*

India's relevance as a global pharmaceutical hub is significantly enhanced by the integration of Artificial Intelligence (AI) into its pharmaceutical sector. AI offers transformative potential in addressing longstanding challenges, improving operational efficiency, and reducing costs associated with drug discovery and development. The Indian pharmaceutical industry, already a leader in producing affordable generic drugs and vaccines, stands to benefit immensely from AI's capabilities in various domains, including drug development, manufacturing, and quality control. However, the successful integration of AI requires overcoming several challenges, such as financial limitations, workforce competency, data security concerns, and regulatory complexities. The following sections explore the key aspects of AI's role in India's pharmaceutical sector.

#### *AI in Drug Discovery and Development*

- AI accelerates drug discovery by expediting target identification, virtual screening, and drug repurposing, significantly reducing the time and cost involved in these processes (Nihalani, 2024).
- Machine learning and deep learning algorithms enhance the identification and optimization of drug candidates, predict clinical trial outcomes, and personalize patient treatment plans, thereby increasing the accuracy and efficiency of drug development (Vij, 2024).
- AI-driven techniques facilitate the simulation of physiological conditions and prediction of drug interactions, optimizing research processes and reducing production costs (Halagali et al., 2025).

#### *Manufacturing and Quality Control*

- AI technologies improve manufacturing efficiency and ensure stringent quality control measures, revolutionizing post-market surveillance methodologies (Huanbutta et al., 2024).
- Robotic automation and AI-driven data analytics enhance drug formulation and manufacturing processes, improving pharmacovigilance and drug safety (Nihalani, 2024).
- AI's role in optimizing formulation processes and predicting pharmacokinetics profiles facilitates a more efficient pathway from pilot study to market (Halagali et al., 2025).

#### *Personalized Medicine and Patient Care*

- AI enables precision medicine by tailoring treatments to individual patient profiles, genetics, and environmental factors, maximizing treatment efficacy and minimizing adverse reactions (Das et al., 2023).
- AI-powered applications track and monitor patients' medication schedules, reducing adverse reactions and enhancing treatment effectiveness (Das et al., 2023).
- Personalized drug prescriptions and dosage recommendations minimize medication errors, offering a more patient-centered approach to healthcare (Vij, 2024).

#### *Challenges and Strategic Collaboration*

- The integration of AI in the pharmaceutical sector faces challenges such as financial limitations, workforce competency, data security concerns, and regulatory complexities (Kimta & Dogra, 2024).

- Successful AI integration requires collaborative efforts from the public and private sectors, emphasizing resource allocation for education, infrastructure, regulatory reforms, and workforce development (Kimta & Dogra, 2024).
- Addressing ethical considerations and data privacy concerns is crucial for the responsible and effective utilization of AI in the pharmaceutical industry (Nihalani, 2024).

While AI presents a transformative opportunity for India's pharmaceutical sector, it is essential to consider the broader implications of its integration. The potential for AI to revolutionize healthcare and pharmaceutical practices is immense, but it also necessitates careful consideration of ethical, regulatory, and infrastructural challenges. By investing in AI research, strengthening data infrastructure, and establishing ethical frameworks, India can unlock AI's potential to revolutionize its healthcare landscape, ensuring a healthier and more affordable future for all.

*AI Pharma Patents under Indian IP Law*

The applicability of Indian intellectual property (IP) laws to AI-generated pharmaceutical compositions is a complex issue that intersects with the broader challenges of integrating AI into existing legal frameworks. Indian IP laws, like those in many jurisdictions, are traditionally designed to protect human-generated inventions and creations, which presents challenges when applied to AI-generated outputs. This is particularly relevant in the pharmaceutical sector, where AI is increasingly used for drug discovery and development. The current legal landscape in India does not adequately address the unique aspects of AI-generated works, necessitating a reevaluation of existing laws and the development of new policies to accommodate these technological advancements.

*Challenges in Applying Indian IP Laws to AI-Generated Works*

- **Lack of Legal Recognition for AI as Inventor:** Indian patent law, like many others, requires a human inventor for patent applications. This presents a challenge for AI-generated pharmaceutical compositions, as AI cannot be recognized as an inventor under current laws (Vaish et al., 2023) (Ogwuche, 2023).
- **Ownership and Authorship Issues:** The question of who owns the rights to AI-generated inventions is unresolved. Traditional IP laws focus on human creativity, leaving a gap in protection for works generated autonomously by AI (Munshi & Barai, 2022) (Ahmed, 2025).
- **Patentability Concerns:** AI-generated pharmaceutical compositions may face hurdles in meeting the criteria for patentability, such as novelty and non-obviousness, especially if the AI's processes are not transparent or easily understood (Poddar & Rao, 2024) (Bharati, 2024).

*Opportunities for Legal Reform*

- **Policy Development:** There is a need for policy solutions that address the unique challenges posed by AI in the pharmaceutical sector. This includes considering AI as a tool rather than an inventor, and potentially recognizing the developers or users of AI as the rightful owners of AI-generated inventions (AUTHOR\_ID, 2024) (Makam, 2023).
- **International Comparisons:** Examining how other jurisdictions, such as the US, EU, and China, are addressing AI-generated IP can provide valuable insights for India. These regions are exploring various approaches to integrate AI into their IP frameworks, which could inform India's policy development (Poddar & Rao, 2024) (Ahmed, 2025).
- **Collaborative Approach:** Engaging stakeholders from various sectors, including policymakers, legal experts, and industry players, can help create a stable IP regime that supports innovation while protecting AI-generated works (Poddar & Rao, 2024) (Rusinovich, 2023).

While the current Indian IP framework presents challenges for AI-generated pharmaceutical compositions, it also offers an opportunity to rethink and modernize IP laws to better accommodate technological advancements. The debate over AI's role in IP law is ongoing globally, with no consensus yet on the best approach. Some argue for maintaining the status quo, emphasizing human creativity and inventorship, while others advocate for recognizing AI's contributions to innovation. As AI continues to evolve, the legal landscape will need to adapt, balancing the protection of intellectual property with the promotion of technological progress.

#### *AI and IP Law Challenges*

The intersection of artificial intelligence (AI) and intellectual property (IP) law presents significant legal and ethical challenges, primarily due to AI's ability to autonomously create and modify content. These challenges include issues of authorship, ownership, copyright infringement, and the ethical use of AI technologies. As AI continues to evolve, existing IP frameworks struggle to accommodate the unique characteristics of AI-generated works, necessitating reforms to align these frameworks with technological advancements. This response explores the legal and ethical challenges posed by AI in the realm of IP and proposes potential reforms to address these issues.

#### *Legal and Ethical Challenges*

- **Authorship and Ownership:** Traditional IP laws require human authorship and inventorship, which poses a challenge for AI-generated works. This requirement limits the legal recognition of fully autonomous AI-generated content, creating ambiguity in ownership rights (Oğul, 2024) (Marchenko et al., 2024).
- **Copyright Infringement and Fair Use:** AI's ability to generate content similar to existing works raises concerns about copyright infringement. Determining what constitutes fair use in the context of AI-generated content is complex and requires careful consideration of existing legal standards (Oğul, 2024) (Rusinovich, 2023).
- **Ethical Concerns:** The ethical implications of AI in IP include issues such as privacy breaches, the propagation of deepfakes, and the potential for AI to perpetuate biases. These concerns highlight the need for ethical guidelines and regulations to ensure responsible AI use (Sharma & Sharma, 2024) (Singh, 2024).
- **Liability and Accountability:** Determining liability for AI-generated content is challenging, as traditional legal frameworks do not account for the autonomous nature of AI. This raises questions about accountability and the need for new legal standards to address these issues (Singh, 2024) (Mahingoda, 2024).

#### *Proposed Reforms*

- **New Categories for AI-Generated Works:** Legal frameworks should consider creating new categories for AI-generated works to address the unique characteristics of these creations. This could involve recognizing AI as a co-author or inventor, thereby providing clarity on ownership rights (Marchenko et al., 2024) (Mahingoda, 2024). The criminalization of copyright infringement and persistent judicial backlog in India pose significant challenges to effective IP enforcement (Rahul & Yadav, 2025). The protection of moral rights under Indian copyright law, which ensures creators' attribution and integrity of their work, could inform ownership frameworks for AI-generated pharmaceutical compositions, addressing gaps in recognizing non-human contributions (Yadav, Yadav, Singh, Rajpurohit, & Singh, 2025).

- **Harmonization of IP Laws:** There is a need for greater harmonization of IP laws across jurisdictions to address the global nature of AI technologies. This includes aligning national regulations with international agreements and ensuring consistency in the application of IP laws (Marchenko et al., 2024) (Huda et al., 2024).
- **AI-Powered Enforcement Tools:** Investing in AI-driven tools for monitoring and enforcing IP rights can enhance the effectiveness of IP protection. These tools can help identify potential infringements and streamline enforcement processes (Marchenko et al., 2024).
- **Ethical Guidelines and Global Standards:** Developing ethical guidelines and global standards for AI use can help address ethical concerns and ensure responsible AI deployment. This includes establishing principles for transparency, accountability, and fairness in AI applications (Sharma & Sharma, 2024) (Rotenberg, 2023).

While the proposed reforms aim to address the challenges posed by AI in the realm of IP, it is important to consider the broader implications of these changes. Balancing innovation incentives with public interest considerations is crucial to fostering a legal environment that supports technological advancement while protecting individual rights. Additionally, the rapid pace of AI development necessitates ongoing evaluation and adaptation of legal frameworks to ensure they remain relevant and effective in addressing emerging challenges.

#### *TRIPS Impact on Indian Patent Law*

The Indian Patents Act, 1970, and the TRIPS Agreement have significantly influenced the pharmaceutical industry in India, particularly in terms of patenting practices and access to medicines. The amendments to the Indian Patents Act, driven by TRIPS compliance, have introduced product patents in pharmaceuticals, which has had profound implications for the industry. These changes have been met with both support and criticism, reflecting the complex balance between innovation and accessibility.

#### *Amendments to the Indian Patents Act*

- The Indian Patents Act, 1970, was amended to comply with the TRIPS Agreement, introducing product patents in pharmaceuticals after a 35-year gap. This was a significant shift from the earlier process patent regime, which allowed Indian companies to produce generic versions of patented drugs using alternative processes (Nair, 2008) (Vijayaraghavan & Raghuvanshi, 2008).
- Key amendments occurred in 1999, 2002, and 2005, each aimed at aligning Indian patent law with TRIPS requirements. These amendments extended the patent term to 20 years and introduced provisions for product patents, which were previously not allowed in India (Mathur, 2012) (Nair, 2008).

#### *Impact on the Pharmaceutical Industry*

- The introduction of product patents has led to concerns about increased drug prices and restricted access to medicines. However, the Indian government has implemented TRIPS flexibilities, such as compulsory licensing and Section 3(d), to mitigate these effects (Arora & Chaturvedi, 2017) (Pai, 2015).
- Section 3(d) of the Indian Patents Act restricts patents on new forms of known substances unless they demonstrate significant efficacy, a provision that has been pivotal in cases like Novartis v. Union of India (Pai, 2015) (Ali, 2015).

- Compulsory licensing, as seen in the case of Bayer's drug Nexavar, allows for the production of generic versions of patented drugs under certain conditions, ensuring access to essential medicines (Pai, 2015).

#### *Balancing Innovation and Access*

- The Indian patent regime aims to balance the rights of patent holders with public health needs. This balance is crucial for maintaining India's status as a major supplier of affordable generic medicines globally (Nair & Fernandes, 2014) (Arora & Chaturvedi, 2017).
- The Drug Price Control Order (DPCO) and the National List of Essential Medicines (NLEM) are additional measures to control drug prices and ensure access to essential medicines (Arora & Chaturvedi, 2017).

#### *Challenges and Criticisms*

- Despite the amendments, there are criticisms regarding the narrow focus of patent reforms and the domestic factors influencing these changes. The shared consensus on patent reform has been seen as limiting broader discussions on intellectual property rights (Rangnekar, 2005) (Rangnekar, 2006).
- The Indian pharmaceutical industry has had to adapt to the new patent regime, which has led to increased investment in R&D and a shift in business strategies to comply with international standards (Alam & Rastogi, 2016).

While the amendments to the Indian Patents Act have brought India into compliance with TRIPS, they have also sparked debates about the implications for access to medicines and the pharmaceutical industry's growth. The balance between protecting intellectual property and ensuring public health remains a contentious issue, with ongoing discussions about the effectiveness of current policies and the need for further reforms. The Indian experience highlights the complexities of implementing international agreements in a way that aligns with national interests and public welfare.

#### *TRIPS and Indian Pharma Patents*

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- Compulsory licensing, as seen in the case of Bayer's drug Nexavar, allows for the production of generic versions of patented drugs under certain conditions, ensuring access to essential medicines (Pai, 2015).

### *Balancing Innovation and Access*

- The Indian patent regime aims to balance the rights of patent holders with public health needs. This balance is crucial for maintaining India's status as a major supplier of affordable generic medicines globally (Nair & Fernandes, 2014) (Arora & Chaturvedi, 2017).
- The Drug Price Control Order (DPCO) and the National List of Essential Medicines (NLEM) are additional measures to control drug prices and ensure access to essential medicines (Arora & Chaturvedi, 2017).

### *Challenges and Criticisms*

- Despite the amendments, there are criticisms regarding the narrow focus of patent reforms and the domestic factors influencing these changes. The shared consensus on patent reform has been seen as limiting broader discussions on intellectual property rights (Rangnekar, 2005) (Rangnekar, 2006).
- The Indian pharmaceutical industry has had to adapt to the new patent regime, which has led to increased investment in R&D and a shift in business strategies to comply with international standards (Alam & Rastogi, 2016).

While the amendments to the Indian Patents Act have brought India into compliance with TRIPS, they have also sparked debates about the implications for access to medicines and the pharmaceutical industry's growth. The balance between protecting intellectual property and ensuring public health remains a contentious issue, with ongoing discussions about the effectiveness of current policies and the need for further reforms. The Indian experience highlights the complexities of implementing international agreements in a way that aligns with national interests and public welfare.

### *AI in Drug Discovery and Formulation*

Artificial Intelligence (AI) is playing an increasingly pivotal role in drug discovery, particularly in molecular design and formulation. AI algorithms are transforming traditional pharmaceutical research by enabling the rapid analysis of vast datasets, predicting molecular properties, and optimizing drug formulations. These advancements are not only accelerating the drug development process but also enhancing the precision and efficacy of new therapeutic candidates. The integration of AI in drug discovery is marked by its ability to streamline various stages, from target identification to clinical trials, thereby reducing time and costs associated with bringing new drugs to market. Below, the specific roles of AI in molecular design and formulation are discussed in detail.

### *AI Algorithms in Molecular Design*

- **Target Identification and Lead Optimization:** AI algorithms, particularly machine learning models, are instrumental in identifying novel drug targets by analyzing high-dimensional omics data. These models predict molecular properties and pharmacological profiles, which are crucial for lead optimization (Ozaybi et al., 2024) (Mukherjee et al., 2024).
- **Structure-Based Drug Design:** AI-driven methodologies, such as deep learning, facilitate the design and synthesis of novel drug candidates with enhanced efficacy and specificity. These algorithms explore vast chemical spaces, enabling the discovery of compounds with improved therapeutic potential (Afrose et al., 2024).
- **Predictive Modeling:** AI models predict important aspects of potential drug candidates, including their pharmacokinetic properties and possible toxicity. This predictive capability streamlines the drug discovery process by reducing risks associated with further development (Mukherjee et al., 2024).

### *AI in Formulation and Drug Delivery*

- **Optimization of Drug Formulations:** AI and machine learning techniques are increasingly used to optimize drug delivery systems. They are effective in devising controlled-release formulations and nano-scale delivery platforms, enhancing the durability and efficiency of drug carriers (Dey et al., 2024).
- **Process Parameter Optimization:** AI plays a pivotal role in optimizing process parameters during drug manufacturing. Algorithms enable real-time monitoring and control, ensuring the quality and consistency of drug products. This is achieved through iterative learning and adaptive control, which dynamically optimize manufacturing parameters (Pandey et al., 2024).
- **Personalized Medicine:** AI facilitates the development of personalized treatment plans by integrating multi-omics data sets and predicting drug-target interactions. This approach enhances therapeutic efficacy and reduces side effects by tailoring treatments to individual patient profiles (Afrose et al., 2024).

**Challenges and Considerations:** While AI offers transformative potential in drug discovery and formulation, several challenges persist. Data quality and scarcity, regulatory complexities, and ethical considerations are significant hurdles that need to be addressed. Moreover, the interpretability of AI models and the need for standardized frameworks are critical for the successful integration of AI in pharmaceutical research (Dey et al., 2024) (Abbas et al., 2024) (Ozaybi et al., 2024). Despite these challenges, ongoing advancements in AI technologies and interdisciplinary collaborations hold promise for overcoming these obstacles and fully leveraging AI's capabilities in drug discovery (Ozaybi et al., 2024).

In conclusion, AI is revolutionizing the field of drug discovery and formulation by enhancing the efficiency and precision of molecular design and drug delivery systems. However, to fully realize its potential, the pharmaceutical industry must address existing challenges and foster collaborations across disciplines. This will ensure that AI continues to drive innovation and improve healthcare outcomes.

### *AI-Generated Drug Compositions*

The integration of artificial intelligence (AI) in pharmaceutical research has led to significant advancements in the generation of novel drug compositions. AI-driven methodologies, particularly generative AI, have been instrumental in designing drug-like compounds, optimizing formulations, and ensuring drug safety. These innovations have not only accelerated the drug discovery process

but also enhanced the precision and efficacy of pharmaceutical products. The following sections highlight key case studies and applications of AI-generated pharma compositions.

#### *Generative Drug Discovery*

- Generative AI has enabled the de novo design of drug-like compounds, with several AI-designed molecules entering preclinical and clinical trials. Techniques such as deep learning and novel architectures like Transformers have been pivotal in creating compounds with desirable drug-like properties (Vanhaelen et al., 2024).
- A notable case study involves the use of AI to generate novel molecules that activate the  $\mu$ -opioid receptor and penetrate the blood-brain barrier. Out of 180,000 generated structures, 78% were chemically valid, and 31% met the desired property criteria, showcasing the potential of AI in creating novel therapeutic agents (Wang et al., 2021).

#### *In Silico Formulation Optimization*

- AI has been applied to optimize pharmaceutical formulations, reducing reliance on traditional experimental methods. For instance, a generative AI method was used to digitally create and optimize drug formulations, such as determining the percolation threshold in oral tablets and optimizing drug distribution in HIV inhibitor implants. These AI-generated formulations demonstrated comparable properties to real samples, validating the method's accuracy (Hornick et al., 2024).
- AI-driven formulation design has also been employed to predict drug-excipient compatibility and optimize drug delivery systems, enhancing the efficiency and success rates of pharmaceutical development (Saha, 2024) (Dey et al., 2024).

#### *Patent-Aware Molecule Generation*

- AI has been utilized to generate novel pharmaceutical compounds while considering patent status. By incorporating patent information into the learning process, AI systems can produce drug-like molecules that are both novel and non-infringing, facilitating efficient drug development (Shimizu et al., 2023).

#### *AI in Drug Safety and Pharmacovigilance*

- Generative AI plays a crucial role in pharmacovigilance by enhancing adverse event detection and risk prediction. This application of AI ensures the safety of both new and existing pharmaceuticals, streamlining safety assessments and improving patient outcomes (Mishra & Gupta, 2024).

While AI has revolutionized drug discovery and formulation, it also presents challenges such as data scarcity, regulatory hurdles, and ethical considerations. The integration of AI in drug development raises questions about the quality and safety of AI-generated compounds, necessitating further research and regulatory oversight. Despite these challenges, the potential of AI to transform pharmaceutical research and healthcare outcomes remains significant, promising more personalized and effective therapies in the future.

#### *AI in Drug Discovery*

Artificial Intelligence (AI) is significantly transforming pharmaceutical research by accelerating the discovery of novel compounds and reducing associated costs. This transformation is primarily achieved through AI's ability to predict molecular properties, design new compounds, and optimize

drug development processes. AI technologies, such as machine learning (ML) and deep learning (DL), are instrumental in enhancing the efficiency and precision of drug discovery, thereby reducing the time and financial resources traditionally required. The integration of AI in pharmaceutical research not only speeds up the drug discovery pipeline but also promises to deliver more effective and personalized therapies. Below are the key ways AI is contributing to this transformation:

#### *Accelerating Drug Discovery*

- **Predictive Modeling:** AI models, such as the AI-DTI, are used to predict drug-target interactions, which are crucial for understanding mechanisms of action and identifying potential drug candidates. These models have been successfully applied in rediscovering treatments for diseases like COVID-19 (Bindu et al., 2024).
- **Generative AI:** This technology is used to design novel molecular structures and simulate biological interactions, significantly speeding up the early stages of drug discovery (Gatla, 2020).
- **Bioactivity and Physicochemical Forecasting:** AI systems like AI-D3S utilize advanced algorithms to predict bioactivity and physicochemical properties, which are essential for identifying promising drug candidates (“Advances of AI-Driven Drug Design and Discovery in Pharmaceuticals - Review,” 2024).

#### *Reducing Costs*

- **Optimization of Clinical Trials:** AI enhances the efficiency of clinical trials by predicting failures, personalizing treatments, and optimizing patient recruitment, which reduces the overall cost of drug development (Pereira, 2024).
- **Predictive Toxicology:** By forecasting potential toxicities and side effects, AI reduces late-stage failures, thereby saving costs associated with unsuccessful drug candidates (Patnaik et al., 2023).
- **Streamlining Processes:** AI simplifies labor-intensive processes by analyzing and sorting large data volumes, which helps in identifying the most promising drug candidates more quickly and cost-effectively (Krishnababu et al., 2023).

#### *Enhancing Precision and Personalization*

- **Target Identification and Lead Optimization:** AI facilitates the identification of drug targets and the optimization of lead compounds, which are critical steps in developing effective therapies (Yadav et al., 2024).
- **Drug Repurposing:** AI aids in finding new therapeutic applications for existing drugs, which can be a cost-effective strategy for drug development (Patnaik et al., 2023).
- **Personalized Medicine:** AI's ability to analyze vast datasets allows for the development of personalized therapies, improving patient outcomes and reducing the risk of adverse effects (Ujjwal, 2024).

While AI offers numerous advantages in accelerating drug discovery and reducing costs, there are challenges that need to be addressed to fully realize its potential. Ethical and regulatory issues, such as data accessibility and algorithm interpretability, must be carefully managed to ensure the safe and effective implementation of AI in pharmaceutical research (Pereira, 2024) (Yadav et al., 2024). Additionally, human intervention remains crucial at later stages of the drug development pipeline to validate AI-generated predictions and ensure reproducibility (Hasselgren & Oprea, 2023). Addressing these challenges will be essential for the continued integration of AI in the pharmaceutical industry, ultimately leading to more effective and accessible treatments.

### *Ethics of AI in Pharma and Healthcare*

The integration of Artificial Intelligence (AI) in the pharmaceutical industry and healthcare systems presents significant ethical implications, particularly concerning bias in AI algorithms, transparency and reproducibility of AI-generated results, and public health considerations in India. These issues are critical as AI continues to transform drug discovery, clinical trials, and healthcare delivery, necessitating a careful examination of ethical frameworks and regulatory measures to ensure responsible and equitable use of AI technologies. The following sections delve into these key aspects, drawing insights from the provided research papers.

#### *Bias in AI Algorithms*

- AI algorithms in healthcare and pharmaceuticals can reflect existing biases present in the training data, leading to inequitable healthcare outcomes. This is a significant concern as biased algorithms can perpetuate disparities in healthcare delivery and drug development (Dara & Azarpira, 2025) (Agrawal, 2024).
- To mitigate bias, it is essential to use diverse and representative datasets for training AI models. This approach helps ensure that AI systems provide fair and accurate results across different demographic groups (Bergemann et al., 2024).
- Bias testing and the development of explainable AI (XAI) are crucial strategies to identify and address biases in AI systems, promoting transparency and trust in AI-driven decision-making processes (Jeyaraman et al., 2023) (Bergemann et al., 2024).

#### *Transparency and Reproducibility of AI-Generated Results*

- Transparency in AI decision-making is vital to build trust among stakeholders, including healthcare professionals, patients, and regulatory bodies. The "black box" nature of many AI models poses challenges to understanding and validating AI-generated results (Dara & Azarpira, 2025) (Agrawal, 2024).
- Explainable AI (XAI) techniques are essential to provide insights into how AI models arrive at specific conclusions, thereby enhancing the reproducibility and reliability of AI-generated outcomes (Jeyaraman et al., 2023).
- Regulatory frameworks and guidelines are necessary to ensure that AI systems in healthcare and pharmaceuticals operate transparently and adhere to ethical standards, facilitating the reproducibility of results across different settings (Kang, 2024) (Pitel et al., 2024).

#### *Public Health Considerations in India*

- AI has the potential to revolutionize healthcare in India by enhancing diagnosis, treatment, and healthcare systems. However, ethical considerations such as data privacy, transparency, and bias mitigation are crucial to ensure equitable access to AI-driven healthcare solutions ("AI in Healthcare: Enhancing Diagnosis, Treatment, and Healthcare Systems for a Smarter Future in India," 2023) (Neyigapula, 2023).
- The implementation of AI in Indian healthcare systems requires robust regulatory frameworks to address ethical challenges and promote responsible innovation. This includes ensuring data privacy and security, particularly when handling sensitive health information (Kumar & Velusamy, 2025) (Singh et al., 2023).

- Public health strategies should focus on promoting diversity in AI research and the workforce to address healthcare inequalities and ensure that AI technologies benefit all segments of the population (Jeyaraman et al., 2023).

While AI offers transformative potential in pharmaceuticals and healthcare, it is essential to address the ethical implications associated with its deployment. Ensuring transparency, mitigating bias, and considering public health impacts are critical to harnessing AI's benefits responsibly. Engaging diverse stakeholders, including ethicists, policymakers, and healthcare professionals, is vital to align AI technologies with societal values and promote equitable outcomes. By prioritizing ethical considerations, the pharmaceutical and healthcare sectors can leverage AI to improve patient outcomes and drive innovation while safeguarding human rights and promoting equity.

#### *TRIPS Amendment & Access to Medicines*

The TRIPS Agreement, amended in 2005, significantly impacted the pharmaceutical industry, particularly in developing countries like India. The amendment allowed WTO member states to produce generic pharmaceuticals under compulsory licenses for export to countries lacking production capacity, aiming to improve access to affordable medicines. However, the effectiveness of this mechanism has been debated, as the amendment has not fully resolved the challenges of access to medicines in developing countries (Herget, 2006) (Kennedy, 2010). The Indian pharmaceutical industry, in particular, has navigated these changes by leveraging TRIPS flexibilities and adapting its patent regime to maintain its position as a leader in generic drug production (Nair et al., 2012) (Nair, 2008).

#### *TRIPS Amendment and Compulsory Licensing*

- The 2005 TRIPS amendment was designed to address the needs of countries with insufficient pharmaceutical manufacturing capabilities by allowing them to import generic drugs produced under compulsory licenses (Herget, 2006).
- Despite this, the amendment's implementation has been slow, with fewer WTO members accepting the protocol than required for it to take full effect (Kennedy, 2010).
- Compulsory licensing has been a critical tool for countries like India, enabling them to produce affordable generic medicines and address public health needs during emergencies (Shanmugaiah, 2012).

#### *Impact on Indian Pharmaceutical Industry*

- India's transition to a TRIPS-compliant patent regime has been marked by strategic use of TRIPS flexibilities, such as compulsory licensing and the Bolar provision, to support its generic drug industry (Nair et al., 2012) (Shanmugaiah, 2012).
- The Indian pharmaceutical sector has seen increased R&D investment and a shift towards regulated markets, with a significant number of USFDA and EMA/EDQM approved manufacturing sites (Nair et al., 2012).
- The 2005 Patents (Amendment) Act introduced safeguards against non-meritorious patents, although debates continue over the scope of patentability, particularly concerning New Chemical Entities (NCEs) (Basheer, n.d.).

### *Challenges and Global Perspectives*

- The TRIPS Agreement has been criticized for creating barriers to affordable medicines in developing countries, as it strengthens patent protections that can limit access to essential drugs (Verma, 2011).
- Pharmaceutical multinationals have been resistant to changes that would facilitate the production of generics, impacting technology transfer and access to medicines in poorer countries (Vicente, 2010).
- The debate over whether TRIPS should exclude pharmaceutical patents from extended IP rights protection continues, highlighting the tension between global IP rights and public health needs (Sundaram, 2023).

While the TRIPS amendment aimed to improve access to medicines, its effectiveness remains limited by slow implementation and resistance from pharmaceutical multinationals. The Indian pharmaceutical industry has adapted by utilizing TRIPS flexibilities, but challenges persist in balancing IP rights with public health objectives. The ongoing debate underscores the need for a nuanced approach to IP protection that considers the diverse needs of developing countries.

### *AI as Inventor? Legal & Ethical Debate*

The challenge of defining "inventor" for AI-generated outputs is a multifaceted issue that intersects with legal, ethical, and technological domains. As AI systems become increasingly capable of generating novel inventions, the question arises whether these systems can be recognized as inventors under current patent laws. This debate is exemplified by cases like DABUS, where AI-generated inventions have been submitted for patent protection, challenging the traditional human-centric view of inventorship. The complexity of this issue is compounded by the lack of legal personality for AI, the implications for patent law, and the broader societal impacts of recognizing AI as inventors.

### *Legal Challenges*

- **Human-Centric Patent Laws:** Most jurisdictions, including the European Union, maintain that only humans can be inventors, which excludes AI from being recognized as inventors under current patent laws. This is based on the premise that AI lacks legal personality and the human-centric approach to inventorship (Buzu, 2024) (Matulionytė, 2024).
- **Case Law and Precedents:** The DABUS case and the UK Supreme Court decision in *Thaler v Comptroller of Patents* have reinforced the stance that AI cannot be an inventor, highlighting the gaps in patent law that need addressing as AI technologies evolve (Buzu, 2024) (Matulionytė, 2024).
- **Patentability and Inventorship Criteria:** The current legal framework struggles to accommodate AI-generated inventions, as traditional inventorship criteria emphasize human creativity and conception, which AI lacks (Vaish et al., 2023) (Lamlert, 2020).

### *Ethical and Social Considerations*

- **Incentivizing Human Creativity:** Recognizing AI as inventors could potentially diminish the role of human ingenuity in the inventive process, raising concerns about the future of human creativity and innovation (Matulionytė, 2024).
- **Intellectual Property Rights:** Granting inventorship to AI could lead to broader implications for intellectual property rights, including issues of ownership and liability, which are not adequately addressed by existing laws (Bisoyi, 2022) (Ogwuche, 2023).

- **Spectrum of AI Contribution:** The debate also considers the spectrum of AI involvement in the invention process, from AI as a tool to AI as a primary inventor, which complicates the attribution of inventorship (Nietering, 2022).

#### *Technological Considerations*

- **Autonomy and Inventiveness:** The technological capability of AI to autonomously generate inventions challenges the traditional notion of inventorship, as AI systems can perform the conception step, which is central to inventorship (Geigel, 2022).
- **Machine Learning and Inventive Processes:** The role of machine learning in AI's inventive capabilities raises questions about the criteria for evaluating AI's contribution to inventions and the level of autonomy required for inventorship claims (Geigel, 2022).

While the current legal framework largely denies AI the status of inventor, the ongoing debate suggests a need for new legal solutions to address the challenges posed by AI-generated inventions. This includes exploring dedicated patent laws for AI and considering the ethical and social implications of such recognition. The discussion also highlights the importance of maintaining human involvement in the inventive process to foster creativity and innovation. As AI technologies continue to advance, the legal and societal frameworks will need to adapt to ensure that the benefits of AI are realized without undermining human ingenuity.

#### *AI, Trade Secrets & Trademarks in Pharma*

The integration of artificial intelligence (AI) in pharmaceutical formulations presents unique challenges and opportunities for intellectual property (IP) protection, particularly concerning trademarks and trade secrets. AI's role in drug formulation involves advanced computational methods and predictive modeling, which can significantly enhance the efficiency and effectiveness of drug development. However, this technological advancement also necessitates a reevaluation of existing IP frameworks to adequately protect AI-driven innovations. This answer explores the implications of AI on trademarks and trade secrets within the pharmaceutical industry, highlighting the need for adaptive legal frameworks.

#### *Trade Secrets in AI Pharmaceutical Formulations*

- **AI-Generated Information:** AI systems in pharmaceutical formulations generate valuable data, such as optimal excipient combinations and stability profiles, which can qualify as trade secrets. The protection of such AI-generated information is crucial, as it represents a competitive advantage for companies (Sprankling, 2024) (Saha, 2024).
- **Ownership and Protection:** Determining the ownership of AI-generated trade secrets poses a challenge. The legal framework must address whether the AI system, its developers, or the employing company holds the rights to these secrets. This is particularly important as AI systems increasingly contribute to the creation of proprietary information (Sprankling, 2024).
- **Policy Recalibration:** Existing doctrines that limit trade secret protection may need recalibration to accommodate AI's capabilities. This includes considering how AI can potentially terminate certain human-created secrets and how trade secret law can mitigate AI-related risks (Sprankling, 2024).

#### *Trademarks in AI Pharmaceutical Formulations*

- **Trademark Challenges:** The use of AI in pharmaceutical formulations raises questions about trademark protection, especially when AI systems generate new technological achievements.

The current legal framework often struggles to cover these innovations, leading to disputes over trademark rights (Cai, 2024).

- **Training AI Systems:** The use of trademark-protected marks in training AI systems is a contentious issue. The primary function of trademarks is to distinguish products in commerce, and this function may be disrupted during AI training. Legal frameworks need to define the boundaries of trademark protection in this context (Ninković, 2024).
- **Trademark Infringement:** The identification of trademark rights for AI-generated achievements requires improvements in legal provisions. Introducing standards like "confusion possibility" can help determine trademark infringement in AI contexts (Cai, 2024).

While AI offers significant advancements in pharmaceutical formulations, it also presents challenges that extend beyond IP protection. The rapid development of AI technologies necessitates international collaboration and policy reforms to create a stable IP regime that balances robust protection with innovation promotion. This includes addressing issues like AI inventorship, data ownership, and the allocation of AI-related IPRs (Kazimi & Thalwal, 2024) (Poddar & Rao, 2024). Additionally, the evolving landscape of AI in drug formulation highlights the importance of collaboration among policymakers, researchers, and industry players to navigate these complexities and unlock AI's full potential for enhanced healthcare delivery (Gholap et al., 2024) ("Revolutionizing Drug Formulation: Harnessing Artificial Intelligence and Machine Learning for Enhanced Stability, Formulation Optimization, and Accelerated Development," 2023).

#### *AI as Inventor Under Indian Law*

The question of whether AI can be recognized as an inventor under Indian law is a complex and evolving issue. Currently, Indian patent law, like many jurisdictions, does not recognize AI as an inventor. The Indian Patents Act requires an inventor to be a natural person, which excludes AI systems from being named as inventors. However, there is ongoing debate and consideration of whether AI should be granted inventorship status, given its increasing role in the innovation process. This discussion is influenced by global precedents and the unique challenges posed by AI-generated inventions.

#### *Current Legal Framework in India*

- The Indian Patents Act mandates that an inventor must be a natural person, which inherently excludes AI systems from being recognized as inventors ("Can Artificial Intelligence (AI) Machine Be Granted Inventorship in India?," 2023) (Devarapalli, 2019).
- The Supreme Court of India has previously recognized non-human entities as juridical persons in certain contexts, which could potentially be extended to AI systems, but this has not yet been applied to patent law (Ganguli, 2024).

#### *Global Perspectives and Precedents*

- Globally, there is no consensus on AI inventorship. Countries like the USA, UK, and EU have rejected AI as inventors, while Australia and South Africa have recognized AI in this role ("Can Artificial Intelligence (AI) Machine Be Granted Inventorship in India?," 2023) (Mutale, 2024).
- The DABUS case, where an AI was named as an inventor, has been pivotal in sparking international debate. The case highlighted the challenges of recognizing AI as inventors due to the lack of legal personality and the human-centric nature of current patent laws (Matulionytė, 2024) (Engel, 2020).

### *Challenges and Considerations*

- Recognizing AI as inventors raises questions about ownership, liability, and the fundamental nature of inventorship, which traditionally involves human creativity and decision-making (Bisoyi, 2022) (Artificial Intelligence and Inventorship Under the Patent Law Regime: Practical Development from Common Law Jurisdictions, 2023).
- There is a need for a sui generis system or a new legal framework to address the unique challenges posed by AI-generated inventions, ensuring fair treatment and protection of such innovations (Mutale, 2024) (Bisoyi, 2022).

### *Potential for Future Developments*

- The recognition of AI as inventors could encourage innovation and the development of AI technologies, but it also risks diminishing human involvement in the inventive process (Matulionytė, 2024).
- A collaborative approach involving policymakers, legal experts, and industry stakeholders is essential to navigate the evolving intellectual property landscape and to potentially harmonize international standards (Poddar & Rao, 2024).

While the current legal framework in India does not recognize AI as inventors, the ongoing global discourse and technological advancements suggest that this issue will continue to evolve. The potential for AI to be recognized as inventors in the future may depend on the development of new legal frameworks that address the unique challenges posed by AI-generated inventions. This could involve recognizing AI as juridical persons or creating a sui generis system tailored to the needs of AI-driven innovation.

### *Global Patent Office Views on AI Inventions*

The question of how major patent offices like the USPTO, EPO, and UKIPO handle AI-generated pharmaceutical inventions is complex and multifaceted. These offices have been grappling with the implications of AI in the realm of intellectual property, particularly concerning inventorship and patentability. The rulings from these offices reflect a cautious approach, balancing innovation with existing legal frameworks. This answer will explore the perspectives and rulings of these patent offices on AI-generated pharmaceutical inventions, highlighting the challenges and opportunities they present.

#### *USPTO Perspective*

- The United States Patent and Trademark Office (USPTO) has taken a firm stance that AI cannot be listed as an inventor. This decision is based on statutory language that requires an inventor to be a natural person. However, the USPTO acknowledges that AI can assist in the inventive process, provided a human makes a substantial contribution to the conception or reduction to practice of the invention (Engel, 2020) (Hou, 2024).
- The USPTO is also exploring the impact of AI on prior art and the "person having ordinary skill in the art" (PHOSITA) standard, which could affect patentability assessments, particularly in the pharmaceutical sector where AI is increasingly used for drug discovery (Hou, 2024).

#### *EPO Perspective*

- The European Patent Office (EPO) has focused on formal rules, requiring that a human be named as the inventor, even if AI played a significant role in the invention process. This approach is consistent with the EPO's requirement for detailed disclosure of machine learning algorithms

and the characteristics of training data, which are crucial for assessing the technical effect of an AI algorithm (Engel, 2020) (Hou, 2024).

- The EPO's stance reflects a broader European approach that emphasizes the need for transparency and detailed technical disclosure in AI-related patent applications, which is particularly relevant in the pharmaceutical industry where AI is used to optimize drug formulations and manufacturing processes (Huanbutta et al., 2024).

#### *UKIPO Perspective*

- The UK Intellectual Property Office (UKIPO) has considered more substantive aspects of AI inventorship, focusing on the contribution of AI to the inventive process. Like the USPTO and EPO, the UKIPO requires a human to be named as the inventor, reflecting a lack of consensus on recognizing AI as an inventor (Engel, 2020).
- The UKIPO's approach is part of a broader legal landscape in the UK that is adapting to the challenges posed by AI in intellectual property, including the pharmaceutical sector where AI is used for drug discovery and development (Rusinovich, 2023) (Rosati, 2024).

#### *Broader Implications and Challenges*

- The rulings from these patent offices highlight the ongoing challenges in harmonizing international patent laws to accommodate AI-generated inventions. The lack of a universal approach to AI inventorship and patentability could lead to inconsistencies and legal uncertainties, particularly in the pharmaceutical industry where AI is driving significant innovation (Bryukhovetsky, n.d.) (Poddar & Rao, 2024).
- There is a growing recognition of the need for regulatory cooperation and harmonization to address these challenges, ensuring that AI-driven innovations can be effectively protected and commercialized across different jurisdictions (Khan, 2024) (Voitovych et al., 2021).

While the USPTO, EPO, and UKIPO have taken steps to address the challenges posed by AI-generated inventions, their rulings reflect a cautious approach that prioritizes existing legal frameworks. This cautiousness is necessary to ensure that the rapid advancements in AI do not outpace the ability of legal systems to adapt, potentially leading to a more stable and predictable intellectual property landscape in the future.

#### *Section 3(d) and Pharma Patents*

The Indian Patents Act, 1970, particularly through its Section 3(d), plays a pivotal role in shaping the intellectual property framework for pharmaceuticals, including those generated by artificial intelligence. This section is designed to prevent the practice of "evergreening," where minor modifications to existing drugs are patented without significant therapeutic benefits. The provision has been central to India's strategy to balance innovation with public health needs, ensuring that patents are granted only for genuine advancements in drug efficacy. This approach has been both lauded and criticized, reflecting the complex interplay between innovation incentives and access to affordable medicines. Below, key aspects of the Indian Patents Act, 1970, and Section 3(d) are explored in detail.

#### *Key Provisions of the Indian Patents Act, 1970*

- **Section 3(d) Overview:** This section restricts the patentability of new forms of known substances unless they result in enhanced efficacy. It aims to prevent the extension of patent life through

trivial modifications, a practice known as evergreening (Y et al., 2024) (Sohrabji & Maloney, 2020).

- **Impact on Pharmaceutical Patents:** Section 3(d) has been instrumental in rejecting patents that do not demonstrate significant improvements in efficacy, as seen in the high-profile Novartis Glivec case, where the Supreme Court upheld the rejection of a patent application based on this provision (Sohrabji & Maloney, 2020) (Basheer & Reddy, 2008).
- **Compulsory Licensing:** The Act includes provisions for compulsory licensing, allowing generic production of patented drugs under certain conditions, which has been crucial for maintaining drug affordability in India (Y et al., 2024).

*Patentability Criteria*

- **Efficacy Requirement:** The requirement for demonstrating enhanced efficacy under Section 3(d) has been a contentious issue, with critics arguing that it may stifle genuine innovation by setting a high bar for patentability (Goudra, n.d.) (Basheer & Reddy, 2008).
- **Statistical Analysis:** Studies have shown that patent applications with Section 3(d) objections are more likely to be rejected, indicating its significant role in the patent examination process (Sohrabji & Maloney, 2020).
- **Evolving Use:** Over time, the application of Section 3(d) has increased, including its use against primary patent applications, which raises concerns about potential over-utilization and its impact on innovation (Sampat & Shadlen, 2018).

*Challenges and Criticisms*

- **Ambiguity and Interpretation:** The lack of a clear definition of "efficacy" has led to divergent interpretations and application inconsistencies, prompting calls for clearer guidelines and potential amendments to the provision (Goudra, n.d.) (Kant, 2013).
- **International and Domestic Tensions:** The provision reflects broader tensions between national interests in public health and international patent obligations, with debates on whether it aligns with TRIPS standards (Sampat & Shadlen, 2015) (Basheer & Reddy, 2008).

While Section 3(d) has been pivotal in shaping India's pharmaceutical patent landscape, it has also sparked debates about its impact on innovation and access to medicines. Critics argue that the provision may hinder the development of new drugs by imposing stringent efficacy requirements, potentially discouraging investment in pharmaceutical research. However, proponents assert that it is essential for preventing evergreening and ensuring that patents are granted only for genuine advancements, thus maintaining a balance between innovation and public health priorities. As the Indian patent system continues to evolve, ongoing discussions about potential reforms and international alignment will be crucial in addressing these challenges.

*AI Innovation and Section 3(d)*

The intersection of patent eligibility, particularly Section 3(d), and AI-generated incremental innovations presents a complex landscape, especially in balancing innovation with generic drug production. Section 3(d) of the Indian Patent Act is designed to prevent the evergreening of patents by disallowing patents for new forms of known substances unless they significantly enhance efficacy. This provision has significant implications for AI-generated innovations, which often involve incremental advancements. The challenge lies in determining the patentability of these AI-driven innovations while ensuring that the production of generic drugs remains viable and accessible.

### *Impact of Section 3(d) on AI-Generated Innovations*

- **Incremental Innovations:** AI technologies often produce incremental innovations by optimizing existing processes or compounds. Section 3(d) poses a challenge as it requires a demonstration of enhanced efficacy for patent eligibility, which may not always be evident in AI-generated improvements (Poddar & Rao, 2024) (Fabris, 2020).
- **Patentability Challenges:** The inventive step requirement, crucial for patentability, becomes complex with AI-generated inventions. AI can make certain innovations appear obvious, complicating the assessment of non-obviousness, a key criterion for patent eligibility (Ramalho, 2018) (Fabris, 2020).
- **Global Perspectives:** Different jurisdictions have varied approaches to AI-related patentability. For instance, the U.S. and EU emphasize human involvement in the inventive process, which can limit the patentability of AI-generated innovations (Hou, 2024) (Matulionytė, 2024).

### *Balancing Innovation with Generic Drug Production*

- **Generic Drug Production:** Section 3(d) supports the production of generic drugs by preventing the extension of patent life through minor modifications. This is crucial for maintaining drug affordability and accessibility (Poddar & Rao, 2024).
- **AI in Drug Discovery:** AI's role in drug discovery can lead to new formulations or uses of existing drugs. While these innovations can be significant, they must meet the enhanced efficacy requirement to be patentable under Section 3(d), ensuring that only truly novel advancements receive protection (Fabris, 2020) (Kazimi & Thalwal, 2024).
- **Policy Implications:** Policymakers must balance encouraging AI-driven innovation with the need to keep essential medicines affordable. This involves ensuring that patent laws do not stifle innovation while also preventing the monopolization of minor advancements (Kazimi & Thalwal, 2024) (Whalen & Zingg, 2022).

### *AI and Patent Law*

While Section 3(d) aims to prevent the evergreening of patents, it also highlights the need for a nuanced approach to AI-generated innovations. The global patent landscape is evolving, with jurisdictions like the U.S. and EU grappling with the implications of AI on patent law. These regions emphasize human inventorship, which can limit the recognition of AI's role in innovation. However, as AI continues to advance, there is a growing call for international harmonization of patent laws to accommodate AI-driven inventions while ensuring that the benefits of innovation are widely accessible (Hou, 2024) (Schwartz & Rogers, 2022) (Kim, 2020).

### *AI Pharma IP Infringement Challenges*

The challenges in proving infringement for AI-generated pharmaceutical compositions are multifaceted, involving complex legal, technical, and ethical considerations. As AI systems increasingly contribute to drug discovery, the legal frameworks governing patent infringement must adapt to address the unique characteristics of AI-generated outputs. These challenges include determining liability, assessing the originality of AI-generated compositions, and navigating the existing legal frameworks that may not adequately address AI's role in the inventive process. The following sections explore these challenges in detail.

### *Liability and Legal Frameworks*

- **Liability Assignment:** Determining who is liable for AI-generated patent infringements is a significant challenge. Current legal systems often struggle to assign responsibility, as AI systems operate with a degree of autonomy that complicates traditional liability frameworks. The liability could potentially fall on developers, users, or the AI systems themselves, but existing laws like the Digital Millennium Copyright Act (DMCA) are not equipped to handle such cases (Eviani et al., 2024) (Yang, 2024).
- **Patent Law Limitations:** The case of *Thaler v Comptroller of Patents* highlights the limitations of current patent laws, which do not recognize AI as an inventor. This human-centric approach may hinder the development of AI technologies capable of autonomous invention, as it does not accommodate non-human inventors (Matulionytė, 2024).

### *Technical Challenges in Proving Infringement*

- **Similarity and Originality:** AI-generated compositions may closely resemble existing patented drugs due to the nature of AI training processes, which often involve large datasets of existing works. This raises questions about the originality of AI-generated outputs and whether they constitute independent creations or infringe on existing patents (Yang, 2024) (Demir, 2024).
- **Automated Assessment Tools:** Tools like PatentFinder have been developed to address the technical challenges of assessing patent infringement in AI-generated compositions. These tools use advanced algorithms to evaluate molecular structures for potential infringement, offering a more systematic approach to identifying and proving infringement (Shi et al., 2024).

### *Ethical and Policy Considerations*

- **Ethical Implications:** The use of AI in drug discovery raises ethical questions about the balance between innovation and the protection of intellectual property rights. There is a need for legal frameworks that not only address liability but also consider the ethical implications of AI-generated inventions (Shukla, 2024) (Bratajaya, 2024).
- **Policy Development:** There is a call for new legal frameworks and policies that can better accommodate AI-generated content. This includes considering AI as a potential legal author and exploring alternative licensing arrangements to balance the interests of creators, users, and the public (Shukla, 2024) (Rosati, 2024).

While the challenges in proving infringement for AI-generated pharmaceutical compositions are significant, they also present opportunities for legal and technological innovation. The development of new legal frameworks and tools, such as AI guarantee schemes, could provide clearer guidelines and mechanisms for addressing these challenges. These frameworks would need to balance the need for innovation with the protection of intellectual property rights, ensuring that AI technologies can be harnessed responsibly and ethically (Erdélyi & Erdélyi, 2019) (Erdélyi & Erdélyi, n.d.).

### *Reforming Indian IP for AI-Generated Pharma*

The advent of AI-generated pharmaceutical compositions presents significant challenges to the existing intellectual property (IP) laws in India. As AI technologies increasingly contribute to drug discovery and development, the traditional IP frameworks, which are primarily designed to protect human-generated inventions, face pressure to evolve. This situation is compounded by the unique nature of AI-generated works, which do not fit neatly into existing categories of IP protection, such as patents and copyrights. The implications for India's IP laws are profound, necessitating a

reevaluation of how these laws can accommodate AI-driven innovations while balancing the interests of innovation and public access.

#### *Challenges to Existing IP Frameworks*

- **Patentability Issues:** AI-generated pharmaceutical compositions challenge the traditional criteria for patentability, which include novelty, inventive step, and industrial applicability. The question of inventorship is particularly problematic, as current laws require a human inventor, whereas AI systems can autonomously generate novel compositions without direct human intervention (Munshi & Barai, 2022) (Poddar & Rao, 2024).
- **Data Exclusivity:** AI's role in drug development also raises questions about data exclusivity, a form of protection that prevents competitors from using clinical trial data to gain market approval for generic versions of drugs. The duration and scope of data exclusivity may need to be reconsidered in light of AI's ability to rapidly generate and analyze vast datasets (Kimball & Ragavan, 2022).
- **Copyright Concerns:** While copyright law traditionally protects creative works, its application to AI-generated content is ambiguous. In India, as in many jurisdictions, copyright protection is contingent upon human authorship, leaving AI-generated works in a legal gray area (AUTHOR\_ID, 2024) (Makam, 2023).

#### *Potential Legal Reforms*

- **Redefining Inventorship:** Legal reforms may be necessary to redefine inventorship to include AI systems or to recognize the contributions of AI as part of a collaborative human-AI inventorship model. This could involve creating new categories of IP rights specifically for AI-generated inventions (Rusinovich, 2023) (Bharati, 2024).
- **Policy Solutions for Data Exclusivity:** Policymakers might consider revising data exclusivity laws to account for the unique capabilities of AI in drug development. This could involve shorter exclusivity periods or alternative forms of protection that incentivize innovation while ensuring public access to affordable medicines (Kimball & Ragavan, 2022).
- **International Harmonization:** Given the global nature of pharmaceutical markets, international cooperation and harmonization of IP laws concerning AI-generated works could provide a more consistent and predictable legal environment. This would involve aligning India's IP laws with those of other major jurisdictions, such as the US, EU, and China, which are also grappling with similar challenges (Poddar & Rao, 2024) (Kazimi & Thalwal, 2024).

While AI-generated pharmaceutical compositions pose challenges to existing IP laws, they also offer opportunities for innovation and efficiency in drug development. AI can significantly reduce the time and cost associated with bringing new drugs to market, potentially leading to more rapid advancements in healthcare. However, the legal system must adapt to ensure that these benefits are

realized without undermining the incentives for human creativity and innovation. Balancing these competing interests will be crucial as India navigates the evolving landscape of AI and IP law.

#### *AI Pharma Patents: Indian IP Challenges & Reforms*

The implications of Indian intellectual property (IP) laws on the development and commercialization of AI-generated pharmaceutical compositions are multifaceted, involving challenges and opportunities. The integration of AI in drug development has revolutionized the pharmaceutical industry, enhancing drug discovery and personalized medicine. However, the current IP framework in India, like in many other jurisdictions, struggles to accommodate AI-generated inventions due to traditional notions of inventorship and authorship that emphasize human creativity. This creates a complex legal landscape for AI-driven pharmaceutical innovations, necessitating a reevaluation of existing IP laws to foster innovation while ensuring adequate protection and commercialization opportunities.

#### *Challenges in IP Protection for AI-Generated Pharmaceuticals*

- **Inventorship and Ownership:** Indian IP laws, similar to those in other countries, traditionally require a human inventor for patent applications. This poses a challenge for AI-generated pharmaceutical compositions, as AI systems can independently create novel drug formulations without direct human intervention. The current legal framework does not recognize AI as an inventor, leading to potential disputes over ownership and rights to AI-generated inventions (Ogwuche, 2023) (Makam, 2023).
- **Patentability and Non-Obviousness:** AI's ability to process vast datasets and generate novel compositions may lead to questions about the non-obviousness of these inventions. The traditional standard of a "person having ordinary skill in the art" may not be sufficient to evaluate AI-generated inventions, as AI can produce results that might seem obvious to its computational capabilities but not to human researchers (Fabris, 2020).
- **Data Ownership and Licensing:** The use of AI in drug development involves large datasets, raising issues of data ownership and licensing. Indian IP laws need to address these concerns to ensure that data used by AI systems is legally obtained and that the rights of data owners are protected (Poddar & Rao, 2024) (Pitel et al., 2024).

#### *Opportunities for Legal and Policy Reforms*

- **Sui Generis Rights:** There is a growing recognition of the need for sui generis rights to protect AI-generated outputs. Such rights could provide a tailored approach to IP protection, recognizing the unique nature of AI-generated inventions and ensuring that they are adequately protected under the law (Picht & Thouvenin, 2023).
- **Collaborative Frameworks:** A collaborative approach involving policymakers, industry stakeholders, and legal experts is essential to navigate the complexities of AI and IP. This could lead to the development of a stable IP regime that supports innovation while addressing the unique challenges posed by AI technologies (Poddar & Rao, 2024).
- **International Cooperation:** Given the global nature of AI and pharmaceutical industries, international cooperation is crucial. Aligning Indian IP laws with international standards and practices can facilitate the commercialization of AI-generated pharmaceuticals on a global scale (Napitupulu et al., 2023).

*Ethical and Practical Considerations*

While the legal challenges are significant, ethical considerations also play a crucial role in the development and commercialization of AI-generated pharmaceuticals. Issues such as data privacy, algorithmic bias, and equitable access to AI-driven therapies must be addressed to ensure that the benefits of AI in drug development are realized ethically and inclusively (Pitel et al., 2024). Additionally, the rapid evolution of AI technologies necessitates ongoing adaptation of regulatory frameworks to balance innovation with ethical principles (Moingeon et al., 2024).

In conclusion, the implications of Indian IP laws on AI-generated pharmaceutical compositions highlight the need for legal reforms and international cooperation to address the unique challenges posed by AI technologies. While the current legal framework presents obstacles, it also offers opportunities for innovation and collaboration, paving the way for a more inclusive and effective IP regime.

*Indian Courts and AI Pharma IP*

The role of Indian courts in shaping AI-generated pharmaceutical intellectual property (IP) jurisprudence is pivotal as they navigate the complex intersection of AI technology and IP law. Indian courts are tasked with interpreting existing IP laws in the context of AI-driven innovations, which present unique challenges such as determining inventorship, ownership, and the scope of protection for AI-generated works. This evolving legal landscape requires courts to balance the protection of IP rights with the promotion of innovation, while also considering ethical and societal implications. The Indian judiciary's approach to these issues will significantly influence the development of a stable IP regime that can accommodate the rapid advancements in AI technology.

*Challenges in AI-Generated Pharma IP*

- **Inventorship and Ownership:** AI's role in drug discovery raises questions about who qualifies as an inventor. Traditional IP laws require a human inventor, but AI systems like DABUS challenge this notion by autonomously generating inventions (Choi, 2022). Indian courts must decide whether AI can be recognized as an inventor or if the human developers or operators should hold the rights.
- **Patentability and Protection:** The criteria for patentability, such as novelty and non-obviousness, are complicated by AI's ability to generate vast amounts of data and potential inventions. Courts need to determine how these criteria apply to AI-generated inventions and whether existing laws are sufficient to protect such innovations (Poddar & Rao, 2024) (Choi, 2022).
- **Data Ownership and Exclusivity:** AI systems rely on large datasets, raising issues of data ownership and exclusivity. Indian courts must address how data used by AI in drug development is protected and who holds the rights to AI-generated data outputs (Kimball & Ragavan, 2022).

*Legal Framework and Court Decisions*

- **Current Legal Framework:** India's IP laws, including the Patents Act, do not explicitly address AI-generated inventions, creating ambiguity in legal interpretations. Courts are tasked with interpreting these laws in light of AI advancements, potentially setting precedents for future cases (Pai et al., 2024) (Bratajaya, 2024).
- **Judicial Precedents:** Indian courts have the opportunity to set important precedents in AI-related IP cases. These decisions will influence not only national but also international IP

jurisprudence, as other jurisdictions look to India for guidance on handling similar issues (Solow-Neiderman, 2024).

#### *Ethical and Societal Considerations*

- **Balancing Innovation and Protection:** Courts must balance the need to protect IP rights with the promotion of innovation. Overly stringent IP protections could stifle AI-driven advancements, while too lenient protections might undermine the incentives for innovation (Mahingoda, 2023) (Ni, 2024).
- **Ethical Implications:** The ethical dimensions of AI in pharma, such as accountability and transparency, are critical. Courts must consider these factors when adjudicating cases, ensuring that AI applications in healthcare do not compromise patient safety or ethical standards (Pai et al., 2024).

While Indian courts play a crucial role in shaping AI-generated pharma IP jurisprudence, the broader context involves international collaboration and harmonization of IP laws. As AI technology transcends national boundaries, there is a growing need for a coordinated global approach to address the challenges posed by AI in IP law. This includes developing international treaties and guidelines that can provide a consistent framework for handling AI-generated inventions across different jurisdictions. Such efforts would help ensure that the benefits of AI-driven innovations are realized while maintaining robust IP protections.

#### *Policy Gaps in AI-Driven Pharma under India's AI Framework*

India's Draft National Policy on AI (2019) aims to harness the transformative potential of AI across various sectors, including pharmaceuticals, while addressing ethical and policy challenges. The policy outlines the need for a robust framework to manage AI's integration, focusing on data governance, ethical AI, and regulatory standards. However, gaps remain, particularly in the context of AI-generated pharmaceuticals, where existing frameworks may not fully address the unique challenges posed by AI technologies. This necessitates amendments to ensure ethical and effective AI deployment in drug development.

#### *AI-Generated Pharmaceuticals and Existing Frameworks*

- AI has revolutionized drug discovery and development, offering significant advancements in precision medicine and patient outcomes. However, current regulatory frameworks often fall short in addressing AI's unique characteristics, such as real-time learning and algorithmic transparency (Warokar & Lote, 2024) (Pitel et al., 2024).
- Ethical concerns, including data privacy, algorithmic bias, and equitable access to AI-driven therapies, are critical issues that existing policies must address to ensure responsible AI innovation in pharmaceuticals (Pitel et al., 2024) (Dara & Azarpira, 2025).
- The integration of AI in drug development requires updated regulatory norms to accommodate AI's dynamic nature and ensure patient safety and data protection (Warokar & Lote, 2024) (Mirakhori & Niazi, 2024).

#### *Policy Gaps and Proposed Amendments*

- India's Draft National Policy on AI emphasizes the need for comprehensive data governance and ethical AI practices. However, it lacks specific guidelines for AI in pharmaceuticals, highlighting a gap in addressing sector-specific challenges (Bansal & Jain, 2023).

- Proposed amendments should include clear guidelines for AI validation processes, transparency in AI decision-making, and mechanisms to mitigate biases in AI algorithms (Olorunsogo et al., 2024) (Yu et al., 2024).
- Collaborative efforts between public and private sectors are essential to develop infrastructure, workforce skills, and regulatory reforms that support AI integration in the pharmaceutical industry (Kimta & Dogra, 2024).

*Ethical Considerations in AI-Driven Drug Development*

- Ethical frameworks must prioritize patient data privacy, informed consent, and accountability in AI-driven drug development. Ensuring transparency in AI operations is crucial to maintaining public trust and ethical integrity (Olorunsogo et al., 2024) (Yu et al., 2024). The use of copyrighted academic datasets in AI-driven drug development raises ethical questions about fair use under Indian copyright law, necessitating clear guidelines to ensure compliance with educational and research exemptions (Kumar & Yadav, 2025).
- Intellectual property rights for AI-generated pharmaceuticals present another challenge, requiring updates to existing IP laws to accommodate AI-assisted inventions and creations (Makam, 2023).
- Engaging diverse stakeholders, including ethicists, policymakers, and industry experts, is vital to align AI technologies with societal values and ethical norms (Dara & Azarpira, 2025) (Yu et al., 2024).

While India's Draft National Policy on AI provides a foundational framework for AI integration, it requires further refinement to address the specific challenges of AI-generated pharmaceuticals. The policy must evolve to include sector-specific guidelines, ensuring ethical and effective AI deployment in drug development. This involves updating regulatory frameworks, enhancing transparency, and fostering collaboration among stakeholders to harness AI's potential while safeguarding ethical principles.

*AI Patents, Drug Affordability, and Compulsory Licensing*

The intersection of artificial intelligence (AI) and intellectual property rights (IPR) in the pharmaceutical industry presents both opportunities and challenges for drug affordability and access. AI-driven patents can potentially exacerbate the issue of high drug prices, while compulsory licensing offers a mechanism to mitigate these effects and improve access to essential medicines. This complex dynamic requires a nuanced understanding of how AI innovations and patent laws interact with public health objectives.

*Impact of AI-Driven Patents on Drug Affordability*

- **Increased Efficiency and Innovation:** AI technologies have revolutionized drug discovery and development by enhancing efficiency and reducing costs. This has led to faster R&D processes, which could theoretically lower drug prices. However, the current patent system may not reflect these efficiencies, as it still allows for extended exclusivity periods that keep prices high (Kavusturan, 2020) (Sabet et al., 2024).
- **Patentability Challenges:** AI-generated innovations raise questions about patentability, as traditional patent laws may not adequately address inventions created by AI. This uncertainty can lead to prolonged patent disputes, potentially delaying the entry of affordable generics into the market (Sabet et al., 2024).

- **Exclusivity and Market Dynamics:** The exclusivity granted by patents, even those driven by AI, can lead to monopolistic pricing. This is particularly problematic in developing countries where high prices limit access to life-saving medicines (Li, 2011) (Malmqvist, 2021).

#### *Compulsory Licensing and AI-Generated Pharma Innovations*

- **Legal Framework and Flexibility:** Compulsory licensing (CL) is a legal tool that allows governments to authorize the production of patented drugs without the consent of the patent holder, primarily to address public health needs. This mechanism can be particularly effective in ensuring access to essential medicines in resource-poor settings (Guennif, 2017) (Kuanpoth, 2008). Compulsory licensing remains a critical mechanism in India to enhance access to essential medicines, particularly in the context of AI-driven pharmaceutical innovations, by allowing generic production of patented drugs under specific conditions (Singh, Singh, Prakash, & Yadav, 2025).
- **Impact on Drug Accessibility:** Studies indicate that CL does not negatively impact the availability, affordability, or quality of drugs. Instead, it can enhance access to essential medicines, such as antiretroviral drugs, by bypassing patent restrictions (Guennif, 2017) (Kuanpoth, 2008).
- **Balancing Innovation and Access:** While CL can improve access, it may also discourage innovation if not carefully managed. The challenge lies in balancing the need for affordable medicines with the incentives required for continued pharmaceutical innovation, especially in the context of AI-driven discoveries (Pogge, 2010) (Avallone, 2022).

While AI-driven patents and compulsory licensing offer pathways to address drug affordability, they also highlight the need for systemic reform in the patent system. Proposals such as the Health Impact Fund suggest alternative models that reward pharmaceutical companies based on the health impact of their products rather than sales, potentially aligning incentives with public health goals (Pogge, 2010). Additionally, integrating AI with blockchain and pharmacoeconomics could transform supply chains, enhancing transparency and reducing costs, thereby improving global drug access (Adekola et al., 2022). These approaches underscore the importance of innovative policy frameworks that prioritize both innovation and access, ensuring that technological advancements benefit all segments of society.

#### *Ethical Challenges in AI-Driven Healthcare*

The integration of artificial intelligence (AI) in healthcare, particularly in drug development and medical research, presents both opportunities and ethical challenges. Ensuring equitable access to AI-generated medicines and addressing data privacy in AI-driven research are two critical areas that require robust ethical frameworks. These frameworks must balance innovation with ethical principles to ensure that AI technologies are implemented responsibly and equitably. The following sections explore these challenges and propose strategies to address them.

#### *Ensuring Equitable Access to AI-Generated Medicines*

- **Algorithmic Bias and Inclusivity:** AI systems can perpetuate biases if trained on non-diverse datasets, leading to inequitable access to AI-generated medicines. Ensuring inclusivity in data sets used for training AI models is crucial to prevent biases in decision-making and to promote fair distribution of AI-powered treatments (Pitel et al., 2024) (Yu et al., 2024).

- **Regulatory Frameworks:** The dynamic regulatory environment poses challenges to equitable access. Continuous adaptation of regulatory frameworks is necessary to ensure that AI-driven therapies are accessible to all, regardless of socioeconomic status (Pitel et al., 2024).
- **Global Health Equity:** AI has the potential to improve global health equity by making advanced medical treatments more widely available. However, this requires a concerted effort to address existing health disparities and ensure that AI technologies do not exacerbate them ("Ethical Challenges and Opportunities in AI-Driven Healthcare," 2025).

#### *Addressing Data Privacy in AI-Driven Research*

- **Data Privacy and Security:** The integration of AI in healthcare raises significant concerns about patient data privacy and security. Theoretical models and practical approaches, such as the 'Integrated Security and Ethics Model,' are essential to mitigate risks and enhance protections (Gawankar et al., 2024).
- **Informed Consent and Transparency:** Traditional informed consent models are inadequate in the context of large-scale data environments. Evolving these models to include AI-powered oversight processes can help maintain privacy, equity, and trust among patients (Evans & Bihorac, 2024).
- **Regulatory Compliance:** Compliance with regulations like the Health Insurance Portability and Accountability Act (HIPAA) and the General Data Protection Regulation (GDPR) is crucial to address liability in cases of AI errors and to protect patient data (Yu et al., 2024) (Momani, 2025).

#### *Ethical Frameworks and Governance*

- **Ethical Frameworks:** Developing robust ethical frameworks is essential to guide the development and implementation of AI technologies in healthcare. These frameworks should focus on transparency, fairness, and accountability to uphold patient rights and ensure responsible AI integration (Gunawan & Wiputra, n.d.) (Eacersall et al., 2024).
- **Stakeholder Engagement:** Engaging diverse stakeholders, including policymakers, healthcare providers, and AI developers, is crucial for aligning AI development with ethical norms and addressing practical clinical needs (Yu et al., 2024).
- **Explainable AI:** Developing explainable AI systems can foster trust and transparency, allowing healthcare professionals and patients to understand AI-driven decisions and their implications (Journal, 2024).

While AI holds tremendous potential for revolutionizing healthcare, its success depends on addressing both technical and ethical challenges. Ensuring equitable access to AI-generated medicines and safeguarding data privacy are critical components of this endeavor. By developing comprehensive ethical frameworks and engaging diverse stakeholders, the healthcare sector can harness AI's benefits while maintaining ethical integrity. This balanced approach is essential to foster innovation and trust in AI-driven healthcare systems.

#### *Global Approaches to AI Inventorship and Patentability*

The intersection of artificial intelligence (AI) and intellectual property (IP) law presents a complex landscape, particularly concerning AI inventorship and patentability. Different jurisdictions, including the US, EU, and others, have adopted varied approaches to these issues, reflecting their unique legal traditions and policy priorities. This analysis explores these approaches and considers lessons for India's IP regime.

*Approaches to AI Inventorship and Patentability*

- **United States:** The US patent system currently does not recognize AI as an inventor. The case of *Thaler v. Iancu* highlighted this limitation, where the court ruled that only natural persons could be recognized as inventors under US law (Mutale, 2024). The US does allow patents for software that demonstrate a technical effect, which can include AI-based inventions, provided they meet the criteria of novelty, non-obviousness, and utility (Bhardwaj & Gupta, n.d.).
- **European Union:** Similar to the US, the EU does not recognize AI as an inventor. However, the EU has a more flexible approach to software patents, allowing them if they provide a technical contribution beyond a mere computer program (Mutale, 2024). The EU's approach emphasizes the technical character of the invention, which can facilitate the patenting of AI-related innovations ("Intellectual Property Rights for Software, Artificial Intelligence and Computer Related Inventions: A Comparative Analysis," 2024).
- **Other Jurisdictions:** In South Africa, there is a growing discourse on the need for a *sui generis* system to address AI inventorship, given the limitations of current patent laws in recognizing AI-generated inventions (Mutale, 2024). This reflects a broader trend in some jurisdictions to consider new legal frameworks tailored to the unique challenges posed by AI technologies (Kazimi & Thalwal, 2024).

*Lessons for India's IP Regime*

- **Current Challenges:** India's patent law explicitly excludes software and algorithms from patentability, which poses a significant barrier to AI-based inventions (Bhardwaj & Gupta, n.d.). This exclusion reflects a more conservative approach compared to the US and EU, potentially stifling innovation in AI technologies.
- **Potential Reforms:** To foster innovation, India could consider revising its patent laws to allow for the patentability of AI-based inventions that demonstrate a technical effect, similar to the approaches in the US and EU ("Artificial Intelligence and Its Patentability: A Comparative Study Between India, UK, and USA," 2023). This would involve developing clear guidelines for assessing the novelty and non-obviousness of AI-generated inventions (Artificial Intelligence and Inventorship Under the Patent Law Regime: Practical Development from Common Law Jurisdictions, 2023).
- **Inventorship Considerations:** India could also explore the possibility of recognizing AI as a co-inventor or developing a *sui generis* system to address the unique challenges of AI inventorship. This would require a careful balance between protecting human inventors' rights and acknowledging AI's role in the invention process ("Emerging Technologies and Intellectual Property Rights: A Cross-Jurisdictional Examination of AI and Patent Laws in India and the USA," 2023) (Mutale, 2024).

While the current legal frameworks in the US, EU, and other jurisdictions present challenges in recognizing AI as inventors, they also offer valuable insights for India. By adopting a more flexible approach to software and AI patentability, India could enhance its innovation ecosystem. However, any reforms must carefully consider the implications for human inventors and the broader public interest. As AI continues to evolve, ongoing dialogue and international collaboration will be crucial in developing effective IP regimes that support innovation while ensuring fair protection for all stakeholders.

### *TRIPS, AI, and Indian Pharma*

The TRIPS Agreement has significantly influenced Indian intellectual property (IP) laws, particularly in the pharmaceutical sector, by mandating minimum standards of IP protection that align with global norms. This has led to substantial changes in India's patent system, including the introduction of product patent protection. However, the harmonization of these laws with international standards, especially concerning AI-generated pharmaceutical innovations, presents unique challenges. The integration of AI in drug discovery and development raises questions about inventorship, data ownership, and the applicability of existing IP frameworks. These challenges necessitate a nuanced approach to harmonization that balances innovation with public health needs.

#### *Influence of TRIPS on Indian IP Laws*

- **Implementation of Product Patents:** The TRIPS Agreement required India to transition from process patents to product patents in pharmaceuticals, which was implemented in 2005. This shift aimed to align India's IP laws with international standards, fostering innovation and foreign investment ("The Effect of TRIPS Implementation on Indian Patent Law: A Pharmaceutical Industry Perspective: With Special Reference to Healthcare Industry," 2022) ("Whether Indian Patent Act TRIPs Compliant for Pharmaceutical Business: A Case-Based Approach," 2023).
- **Section 3(d) of the Indian Patents Act:** This provision, which restricts patents on new forms of known substances unless they significantly enhance efficacy, has been contentious. It reflects India's attempt to balance TRIPS compliance with public health priorities, as seen in the Novartis case (Ali, 2015) (Khader, 2008).
- **Data Exclusivity:** India's lack of data exclusivity regulations allows generic manufacturers to use clinical trial data without conducting new trials, promoting drug affordability but raising compliance issues with TRIPS norms (Anuritha & -, 2024).

#### *Harmonization Challenges for AI-Generated Pharma Innovations*

- **Inventorship and Ownership:** AI's role in drug discovery complicates traditional notions of inventorship, as AI systems can independently generate novel compounds. Current IP laws, including those influenced by TRIPS, do not adequately address AI-generated inventions (Poddar & Rao, 2024).
- **Data Ownership and Licensing:** The cross-border nature of AI data flows presents challenges in harmonizing data protection and ownership laws, which are crucial for AI-driven pharmaceutical innovations (Khan, 2024).
- **Regulatory Divergence:** Different interpretations of TRIPS provisions by member countries, including India, create inconsistencies in patentability criteria and enforcement, complicating the global harmonization of AI-related IP laws (Maria, n.d.) (Kapczynski, 2009).

While the TRIPS Agreement has facilitated a more uniform global IP framework, it has also been criticized for imposing stringent IP protections that may hinder access to essential medicines in developing countries. Critics argue for differentiated IP protections for life-saving drugs versus non-essential medications, suggesting that such an approach could better balance innovation incentives with public health needs (Subhan, 2020). Additionally, the rapid advancement of AI technologies necessitates a reevaluation of existing IP frameworks to ensure they remain relevant and supportive of innovation in the pharmaceutical sector.

## Conclusions

The integration of artificial intelligence (AI) in pharmaceuticals is revolutionizing the drug discovery process, reducing timelines and costs. However, India's existing intellectual property (IP) framework remains anchored in human-centered inventorship and outdated patentability criteria. Three fundamental legal and ethical challenges arise from AI-generated pharmaceutical compositions: ambiguity surrounding AI as an inventor under the Indian Patents Act, difficulties in meeting patentability standards for AI-generated outputs, and inadequacy of data exclusivity frameworks in recognizing AI-driven research. Ethical concerns such as algorithmic bias, transparency in AI decision-making, and equitable access to medicines further complicate this landscape. India's continued leadership in the global pharmaceutical industry depends on modernizing its legal and regulatory systems. A multi-pronged reform approach is advocated, including recognizing collaborative human-AI inventorship models, refining Section 3(d) to evaluate incremental AI innovations, introducing sui generis protections for AI-generated data, and establishing regulatory sandboxes to safely pilot legal frameworks. International comparative insights highlight the need for harmonized global standards that align innovation incentives with public health goals. India must balance innovation with accessibility, competitiveness with equity, and legal certainty with technological adaptability. By developing robust regulatory frameworks, fostering stakeholder collaboration, and investing in workforce development, India can unlock the full potential of AI in the pharmaceutical sector.

## References

- Abbas, M., Rassam, A., Abunora, R., Karamshahi, F., & Abouseada, M. (2024). The Role of AI in Drug Discovery. *ChemBioChem*. <https://doi.org/10.1002/cbic.202300816>
- Acharjee, P. B., Ghai, B., Elangovan, M., Bhuvaneshwari, S., Rastogi, R. P., & Kumar, P. (2023). Exploring AI-driven approaches to drug discovery and development. *The Scientific Temper*. <https://doi.org/10.58414/scientifictemper.2023.14.4.48>
- Adekola, A. D., Kassem, R. G., & Mbata, A. O. (2022). Convergence of AI, blockchain and pharmacoeconomics in building adaptive pharmaceutical supply chains: A novel paradigm shift for equitable global drug access. *International Journal of Scientific Research Updates*. <https://doi.org/10.53430/ijrsru.2022.4.1.0142>
- Advances of AI-driven Drug Design and Discovery in Pharmaceuticals - Review. (2024). *Journal of Angiotherapy*. <https://doi.org/10.25163/angiotherapy.819488>
- Afroze, N., Chakraborty, R., Hazra, A., Bhowmick, P., & Bhowmick, M. (2024). AI-Driven Drug Discovery and Development. <https://doi.org/10.4018/979-8-3693-3629-8.ch013>
- Agrawal, K. (2024). *The Ethics of Computing in Pharmaceutical Research*. <https://doi.org/10.69613/x7we5074>
- Ahmed, T. (2025). A Comparative Legal Analysis of Copyright and Patent of Outputs Generated by Artificial Intelligence: In Search of Possible Approaches for Bangladesh. *Deleted Journal*. <https://doi.org/10.1177/2753412x241312077>
- AI in Healthcare: Enhancing Diagnosis, Treatment, and Healthcare Systems for a Smarter Future in India. (2023). *Advances in Bioengineering and Biomedical Science Research*. <https://doi.org/10.33140/abbsr.06.10.02>
- Alam, T., & Rastogi, R. (2016). Pre TRIPS, Post TRIPS Patent Regime and the Indian Pharmaceutical Industry: An Empirical Study. *Indian Journal of Science and Technology*. <https://doi.org/10.17485/IJST/2016/V9I9/79662>
- Ali, F. (2015). Transcending Differences: The Challenge for Pharmaceuticals in the Post-TRIPS Indian Patent Regime. *Social Science Research Network*. <https://doi.org/10.2139/SSRN.2566170>
- Amin, A., Chowdhury, I. Q., Abyaz, R., Alom, S., Siam, S. A., Imran, A., Lia, F. S., & Azad, P. A. K. (2024). Artificial Intelligence in Pharmacy: Innovations, Applications, and Future Emerging Challenges. *Indian Scientific Journal Of Research In Engineering And Management*. <https://doi.org/10.55041/ijrsrem40335>
- Anuritha, A., & -, J. D. (2024). The Impact of TRIPS-Driven Data Exclusivity on Pharmaceutical Innovation in India: Balancing Patent and Public Health. *International Journal For Multidisciplinary Research*. <https://doi.org/10.36948/ijfmr.2024.v06i06.32114>
- Arora, S., & Chaturvedi, R. (2017). *Impact of TRIPS on Providing Easy Access to Affordable Medicines in India*.

- Artificial Intelligence and Inventorship Under the Patent Law Regime: Practical Development from Common Law Jurisdictions.* (2023). <https://doi.org/10.2478/vjls-2023-0002>
- Artificial Intelligence and its Patentability: A Comparative Study Between India, UK, and USA. (2023). *International Journal For Multidisciplinary Research.* <https://doi.org/10.36948/ijfmr.2023.v05i03.3666>
- AUTHOR\_ID, N. (2024). Intersection of generative artificial intelligence and copyright: an Indian perspective. *Journal of Science & Technology Policy Management.* <https://doi.org/10.1108/jstpm-08-2023-0145>
- Avallone, S. (2022). *Compulsory Patent Licensing and Access to Medicines: A Silver Bullet Approach to Public Health?* by Van Anh LE. London, New York Shanghai: Palgrave Macmillan 2022. xiii + 184 pp. Hardcover: €84.99, E-Book: €71.68. doi.10.1007/978-3-030-84193-5. *Asian Journal of International Law.* <https://doi.org/10.1017/s2044251322000388>
- Bansal, S., & Jain, N. (2023). A Comprehensive Study Assessing the Transformative Role of Artificial Intelligence in India's Governance Policy Framework. *International Journal For Science Technology And Engineering.* <https://doi.org/10.22214/ijraset.2023.54973>
- Barua, R., Das, D., & Biswas, N. (2024). *Revolutionizing Drug Discovery With Artificial Intelligence.* <https://doi.org/10.4018/979-8-3693-2238-3.ch004>
- Basheer, S. (n.d.). *Limiting the Patentability of Pharmaceutical Inventions and Micro-Organisms: A Trips Compatibility Review.* <https://doi.org/10.2139/ssrn.1391562>
- Basheer, S., & Reddy, P. (2008). The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d). *Social Science Research Network.*
- Bergemann, R., Sharma, S., Vanderpuye-Orle, J., & Poirrier, J. (2024). PP25 Artificial Intelligence In Healthcare Decision-Making: Addressing Challenges, Ethical Considerations, And Bias. *International Journal of Technology Assessment in Health Care.* <https://doi.org/10.1017/s0266462324001983>
- Bharati, R. K. (2024). AI and intellectual property: Legal frameworks and future directions. *International Journal of Law, Justice and Jurisprudence.* <https://doi.org/10.22271/2790-0673.2024.v4.i2c.141>
- Bhardwaj, I., & Gupta, E. (n.d.). *Artificial Intelligence And Its Patentability: A Comparative Study Between India, UK, And Usa.*
- Bindu, Ch. H., Babu, R., Bhimana, S., Babu, M. K., Devadas, Ch., & Marri, J. (2024). *Revolutionizing Pharmaceutical Sciences. Advances in Medical Technologies and Clinical Practice Book Series.* <https://doi.org/10.4018/979-8-3693-6597-7.ch008>
- Bisoyi, A. (2022). Ownership, liability, patentability, and creativity issues in artificial intelligence. *Information Security Journal: A Global Perspective.* <https://doi.org/10.1080/19393555.2022.2060879>
- Bratajaya, M. M. A. (2024). A Legal Protection Study of Intellectual Property Rights Infringement Committed by the Artificial Intelligence. *SHS Web of Conferences.* <https://doi.org/10.1051/shsconf/202420407009>
- Bryukhovetsky, I. V. (n.d.). *Legal Aspects of Protection of Rights to Intellectual Property Created by Generative AI.* <https://doi.org/10.18572/1811-1475-2024-7-41-43>
- Buzu, I. (2024). The Inventorship Paradox within Generative AI. *Intillectus.* <https://doi.org/10.56329/1810-7087.24.1.03>
- Cai, N. (2024). Research on the Trademark Protection of Artificial Intelligence Generation Technology Achievements. *Advances in Economics and Management Research.* <https://doi.org/10.56028/aemr.12.1.502.2024>
- Can Artificial Intelligence (AI) Machine be Granted Inventorship in India? (2023). *Journal of Intellectual Property Rights.* <https://doi.org/10.56042/jipr.v28i2.1268>
- Choi, D.-J. (2022). The Patent System and the Legal Status of So-called 'AI-generated Inventions'- Interpretation of Current Laws and Suggestions of Legal Principles for the AI Era -. *Beobhag Nonjib - Ihwa Yeoja Daehaggyo.* <https://doi.org/10.32632/elj.2022.27.1.267>
- Chun, M. (n.d.). Artificial Intelligence for Drug Discovery: A New Frontier for Patent Law. *Social Science Research Network.* <https://doi.org/10.2139/ssrn.4566014>
- Cockburn, I. M., & Long, G. (2015). The importance of patents to innovation: updated cross-industry comparisons with biopharmaceuticals. *Expert Opinion on Therapeutic Patents.* <https://doi.org/10.1517/13543776.2015.1040762>
- Dara, M., & Azarpira, N. (2025). Ethical Considerations Emerge from Artificial Intelligence (AI) in Biotechnology. *Avicenna Journal of Medical Biotechnology.* <https://doi.org/10.18502/ajmb.v17i1.17680>

- Das, S. K., Maheshwari, R., Chakraborty, J., Roy, S. D., & Shil, D. (2023). Enhancing drug related problem (DRP) management in Indian healthcare through AI integration: An insight view. *Intelligent Pharmacy*. <https://doi.org/10.1016/j.ipha.2023.08.006>
- Demir, M. S. (2024). AI-Induced Copyright Infringement: Application of Legal Neutrality Based on the Qualitative Similarity Criterion. *Social Science Research Network*. <https://doi.org/10.2139/ssrn.4689391>
- Devarapalli, P. (2019). Patent Inventorship and Ownership Issues on Inventions Developed by Humans Using Artificial Intelligence (人工知能を用いて人が生み出した発明についての 発明者適格と権利帰属問題). *Social Science Research Network*.
- Dey, H., Arya, N., Mathur, H. D., Chatterjee, N., & Jadon, R. S. (2024). Exploring the Role of Artificial Intelligence and Machine Learning in Pharmaceutical Formulation Design. *International Journal of Newgen Research in Pharmacy & Healthcare*. <https://doi.org/10.61554/ijnrph.v2i1.2024.67>
- Eacersall, D., Pretorius, L., Смирнов, И. Е., Spray, E., Illingworth, S., Chugh, R., Strydom, S., Stratton-Maher, D., Simmons, J., Jennings, I., Roux, R., Kamrowski, R., Downie, A., Thong, C. L., & Howell, K. A. (2024). Navigating Ethical Challenges in Generative AI-Enhanced Research: The ETHICAL Framework for Responsible Generative AI Use. <https://doi.org/10.48550/arxiv.2501.09021>
- Emerging Technologies and Intellectual Property Rights: A Cross-Jurisdictional Examination of AI and Patent Laws in India and the USA. (2023). *Journal of Intellectual Property Rights*. <https://doi.org/10.56042/jipr.v28i5.399>
- Engel, A. (2020). Can a Patent Be Granted for an AI-Generated Invention?<https://doi.org/10.1093/GRURINT/IKAA117>
- Erdélyi, O. J., & Erdélyi, G. (2019). The AI Liability Puzzle and A Fund-Based Work-Around.*arXiv: Computers and Society*.
- Erdélyi, O. J., & Erdélyi, Z. (n.d.). The AI Liability Puzzle and A Fund-Based Work-Around. <https://doi.org/10.48550/arxiv.1911.08005>
- Ethical Challenges and Opportunities in AI-Driven Healthcare. (2025). *Journal of AI-Powered Medical Innovations*.<https://doi.org/10.60087/japmi.vol.03.issue.01.id.007>
- Evans, B. J., & Bihorac, A. (2024). Co-creating Consent for Data Use — AI-Powered Ethics for Biomedical AI. *NEJM AI*. <https://doi.org/10.1056/aipc2400237>
- Eviani, N. Y., Maskun, M., & Faqi, A. F. (2024). Legal Challenges of AI-Induced Copyright Infringement: Evaluating Liability and Dispute Resolution Mechanisms in Digital Era. *Jambura Law Review*. <https://doi.org/10.33756/jlr.v6i2.24459>
- Fabris, D. (2020). From the PHOSITA to the MOSITA: Will “Secondary Considerations” Save Pharmaceutical Patents from Artificial Intelligence? <https://doi.org/10.1007/S40319-020-00953-8>
- Ganguli, P. (2024). Recognising generative and autonomous AI as a ‘juridical person.’ <https://doi.org/10.69554/ayhz2687>
- Gatla, T. R. (2020). Generative ai applications in drug discovery: accelerating innovation in pharmaceuticals. <https://doi.org/10.26662/ijiert.v7i12.pp260-271>
- Gawankar, S., Nair, S. N., Pawar, V., Vhatkar, A., & Chavan, P. (2024). Patient Privacy and Data Security in the Era of AI-Driven Healthcare. <https://doi.org/10.1109/iccube61740.2024.10775004>
- Gawel, C. R. (2016). Patent protection as a key driver for pharmaceutical innovation. *Pharmaceuticals, Policy and Law*. <https://doi.org/10.3233/PPL-160431>
- Geigel, A. (2022). Machine learning AI systems and the virtue of inventiveness.*AI and Ethics*. <https://doi.org/10.1007/s43681-022-00197-x>
- Gholap, A. D., Uddin, M. J., Faiyazuddin, Md., Omri, A., Gowri, S., & Khalid, M. (2024). Advances in artificial intelligence for drug delivery and development: A comprehensive review. *Computers in Biology and Medicine*. <https://doi.org/10.1016/j.combiomed.2024.108702>
- Goudra, H. V. (n.d.). Balancing Innovation and Access: Examining the Need to Amend Section 3(D) in India. *Social Science Research Network*. <https://doi.org/10.2139/ssrn.4679882>
- Guennif, S. (2017a). Is compulsory licensing bad for public health: some critical comments on drug accessibility in developing countries. *Research Papers in Economics*.

- Guennif, S. (2017b). Is Compulsory Licensing Bad for Public Health? Some Critical Comments on Drug Accessibility in Developing Countries. *Applied Health Economics and Health Policy*. <https://doi.org/10.1007/S40258-017-0306-1>
- Gunawan, A., & Wiputra, R. (n.d.). *Ethical Implications of Generative AI in Medicine: A Systematic Review of Current Practices and Future Directions*. <https://doi.org/10.1109/icspc63060.2024.10862569>
- Halagali, P., Nayak, D., Seenivasan, R., Manikkath, J., Rathnanand, M., & Tippavajhala, V. K. (2025). Artificial Intelligence Revolution in Pharmaceutical Sciences: Advancements, Clinical Impacts, and Applications. *Current Pharmaceutical Biotechnology*. <https://doi.org/10.2174/0113892010356115241224104018>
- Hasselgren, C., & Oprea, T. I. (2023). *Artificial Intelligence for Drug Discovery: Are We There Yet?* <https://doi.org/10.1146/annurev-pharmtox-040323-040828>
- Herget, G. (2006). *WTO approves TRIPS amendment on importing under compulsory licensing*.
- Hornick, T., Mao, C., Koynov, A., Yawman, P. D., Thool, P., Salish, K., Giles, M., Nagapudi, K., & Zhang, S. (2024). In silico formulation optimization and particle engineering of pharmaceutical products using a generative artificial intelligence structure synthesis method. *Nature Communications*. <https://doi.org/10.1038/s41467-024-54011-9>
- Hou, S. M. (2024). International Patent Office Guidance on Artificial Intelligence Inventions. *Social Science Research Network*. <https://doi.org/10.2139/ssrn.4843648>
- Huanbutta, K., Burapapadh, K., Kraisit, P., Srimornsak, P., Ganokratana, T., Suwanpitak, K., & Sangnim, T. (2024). The Artificial Intelligence-Driven Pharmaceutical Industry: A Paradigm Shift in Drug Discovery, Formulation Development, Manufacturing, Quality Control, and Post-Market Surveillance. *European Journal of Pharmaceutical Sciences*. <https://doi.org/10.1016/j.ejps.2024.106938>
- Huda, M., Awaludin, A., & Siregar, H. K. (2024). *Legal Challenges in Regulating Artificial Intelligence: A Comparative Study of Privacy and Data Protection Laws*. <https://doi.org/10.59613/g8dc9v94>
- Intellectual Property Rights for Software, Artificial Intelligence and Computer Related Inventions: A Comparative Analysis. (2024). *Journal of Intellectual Property Rights*. <https://doi.org/10.56042/jipr.v29i1.703>
- Jeyaraman, M., Balaji, S., Jeyaraman, N., & Yadav, S. (2023). Unraveling the Ethical Enigma: Artificial Intelligence in Healthcare. *Cureus*. <https://doi.org/10.7759/cureus.43262>
- Journal, I. (2024). Generative AI for Healthcare: Applications, Challenges, and Ethical Considerations. *Indian Scientific Journal Of Research In Engineering And Management*. <https://doi.org/10.55041/ijsrem39600>
- Kang, H. S. (2024). *AI and pharma: Transforming the paradigm, embracing the new era*. <https://doi.org/10.36922/aih.2973>
- Kant, A. (2013). *An Attempt at Quantification of "Efficacy" Factors under Section 3(d) of the Indian Patents Act*.
- Kapczynski, A. (2009). Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector. *California Law Review*. <https://doi.org/10.15779/Z38K11P>
- Kavusturan, E. (2020). Reforming U.S. patent law to enable access to essential medicines in the era of artificial intelligence. *Northwestern Journal of Technology and Intellectual Property*.
- Kazimi, J., & Thalwal, H. (2024). *Intellectual Property Protection in AI-driven Innovations: A Comparative Analysis*. <https://doi.org/10.1109/tiacomp64125.2024.00060>
- Kazimi, J., & Thalwal, H. (2024a). *Intellectual Property Protection in AI-driven Innovations: A Comparative Analysis*. <https://doi.org/10.1109/tiacomp64125.2024.00060>
- Kazimi, J., & Thalwal, H. (2024b). *Legal Implications of Artificial Intelligence and Machine Learning Algorithms in Intellectual Property Protection: A Comparative Analysis*. <https://doi.org/10.1109/gtsd62346.2024.10675218>
- Kennedy, M. (2010). When will the Protocol Amending the TRIPS Agreement Enter into Force. *Journal of International Economic Law*. <https://doi.org/10.1093/JIEL/JGQ016>
- Khader, F. A. (2008). *Transcending Differences: The Challenge for Pharmaceuticals in the Post-TRIPS Indian Patent Regime*.
- Khan, A. (2024). The intersection of artificial intelligence and international trade laws: challenges and opportunities. *IIUM Law Journal*. <https://doi.org/10.31436/iiumlj.v32i1.912>
- Kim, D. (2020). 'AI-Generated Inventions': Time to Get the Record Straight? <https://doi.org/10.1093/GRURINT/IKAA061>

- Kimball, J., & Ragavan, S. (2022). AI (Re)Defining Pharmaceutical Exclusivities. *Biotechnology Law Report*. <https://doi.org/10.1089/blr.2021.29257.sr>
- Kimta, A., & Dogra, R. (2024). *Artificial Intelligence in the Pharmaceutical Sector of India: Future Prospects and Challenges*. <https://doi.org/10.61440/jbes.2024.v1.21>
- Kimta, A., & Dogra, R. (2024). *Artificial Intelligence in the Pharmaceutical Sector of India: Future Prospects and Challenges*. <https://doi.org/10.21203/rs.3.rs-3878145/v1>
- Krishnababu, K., Kulkarni, G. S. and S., R. Y., & Paarakh, P. M. (2023). *Revolutionizing the Pharmaceutical Industry with Artificial Intelligence*. <https://doi.org/10.55529/jaiml.34.26.37>
- Kuanpoth, J. (2008). Give the Poor Patients a Chance: Enhancing Access to Essential Medicines through Compulsory Licensing. *Journal of Generic Medicines*. <https://doi.org/10.1057/JGM.2008.26>
- Kumar, R., & Yadav, A. (2025). Academic Use and Academic Writing: Copyright Law, Digital Transformation, and Educational Fair Use in India. Preprints. <https://doi.org/10.20944/preprints202506.0721.v1>
- Kumar, R. K. S., & Velusamy, S. (2025). Harnessing Artificial Intelligence for Enhanced Pharmacovigilance: A Comprehensive Review. *Indian Journal of Pharmacy Practice*. <https://doi.org/10.5530/ijopp.20250145>
- Kumar, R., & Shahi, S. K. Introduction to the Concept of originality under Copyright Law in India.
- Lamlert, W. (2020). *Problems of Patentability and Inventorship for Inventions Created by Artificial Intelligence*. <https://doi.org/10.18178/IJKE.2020.6.1.125>
- Lei, G. (n.d.). *The Apply of Intellectual Property Protection in New Drug Research and Development of Medical Research institutes*. <https://doi.org/10.3969/j.issn.1674-4721.2013.12.083>
- Li, Y. (2011). Intellectual property and public health: two sides of the same coin \*. *Social Science Research Network*.
- Mahajan, B. S., Mahale, B. S. P., Pawar, A. R., Patil, V. V., Patil, P. S., & Songire, J. (2024). A Review on Artificial Intelligence in Pharmacy. *Research Journal of Science and Technology*. <https://doi.org/10.52711/2349-2988.2024.00020>
- Mahingoda, C. B. (2023). *Intellectual Property Rights in the Era of Artificial Intelligence: Navigating the Challenges and Expanding the Boundaries*. <https://doi.org/10.54389/voaf9040>
- Mahingoda, C. B. (2024). Challenges and Frontiers in Intellectual Property Rights Amidst the Rise of Artificial Intelligence. *Humanities and Sciences*. <https://doi.org/10.4038/sjhs.v4i2.55>
- Makam, G. (2023). AI-Generated Creations: Navigating Legal Implications and Crafting Effective Policy Frameworks. *Social Science Research Network*. <https://doi.org/10.2139/ssrn.4520938>
- Malmqvist, E. (2021). *Global Health Impact: Extending Access to Essential Medicines*, Nicole Hassoun . Oxford University Press, 2020, xv + 301 pages. *Economics and Philosophy*. <https://doi.org/10.1017/S0266267121000134>
- Marchenko, V., Dombrovskaya, A., & Prodaivoda, V. (2024). Comparative analysis of regulatory acts of the eu countries on the protection of intellectual property in the conditions of the use of artificial intelligence. *Public Administration and Law Review*. <https://doi.org/10.36690/2674-5216-2024-3-44-66>
- Maria, C. C. (n.d.). *Trade Related Aspects of Intellectual Property Rights*. <https://doi.org/10.1093/law/9780198707219.001.0001>
- Mathur, V. (2012). Patenting of Pharmaceuticals: An Indian Perspective. *International Journal of Drug Development and Research*.
- Matulionytė, R. (2024). 'AI is not an Inventor': *ThalervComptroller of Patents, Designs and Trademarks* and the Patentability of AI Inventions. *Modern Law Review*. <https://doi.org/10.1111/1468-2230.12907>
- Mirakhori, F., & Niazi, S. K. (2024). *Harnessing the AI/ML in Drug and Biological Products Discovery and Development: The Regulatory Perspective*. <https://doi.org/10.20944/preprints202410.2510.v1>
- Mishra, H. P., & Gupta, R. (2024). Leveraging Generative AI for Drug Safety and Pharmacovigilance. *Current Reviews in Clinical and Experimental Pharmacology*. <https://doi.org/10.2174/0127724328311400240823062829>
- Moingeon, P., Garbay, C., Dahan, M., Fermont, I., Benmakhlouf, A., Gouyette, A., Poitou, P., & Saint-Pierre, A. (2024). *[The revolution of AI in drug development]*. <https://doi.org/10.1051/medsci/2024028>
- Momani, A. (2025). *Artificial Intelligent Implications on Health Data Privacy and Confidentiality*. <https://doi.org/10.48550/arxiv.2501.01639>

- Mukherjee, D., Sharma, T. K., Lunawat, A. K., Awasthi, A., Kurmi, B. D., Kumar, M., Gupta, G. D., & Thakur, S. (2024). Advancement of Artificial Intelligence in Drug Discovery: A Comprehensive Review. *Current Artificial Intelligence*. <https://doi.org/10.2174/0129503752322569241104114248>
- Munshi, Md. O. F., & Barai, S. (2022). IP Rights to AI-Generated Works: Barriers Presented by Existing Law and Reforms Needed. *Canadian Journal of Business and Information Studies*. <https://doi.org/10.34104/cjbis.022.037046>
- Mutale, C. (2024). Crossing Frontiers: A Comparative Exploration of AI Inventorship and Ownership in Patent Law. *International Journal of Research in Social Science and Humanities*. <https://doi.org/10.47505/ijrss.2024.11.5>
- Nair, G. G. (2008). *Impact of TRIPS on Indian Pharmaceutical Industry*.
- Nair, G. G., & Fernandes, A. (2014). *Patent Policies and Provisions Relating to Pharmaceuticals in India*.
- Nair, G. G., Fernandes, A., & Parmar, K. R. (2012). *Post-TRIPS Thrust Triggers for Indian Pharmaceuticals in the IP Context*.
- Napitupulu, P. A., Sinaga, C. A. F., & Hasugian, A. L. P. (2023). The Implication of Generative Artificial Intelligence towards Intellectual Property Rights (Examining the Multifaceted Implications of Generative Artificial Intelligence on Intellectual Property Rights). *West Science Law and Human Rights*. <https://doi.org/10.58812/wslhr.v1i04.330>
- Neyigapula, B. S. (2023). *AI in Healthcare: Enhancing Diagnosis, Treatment, and Healthcare Systems for a Smarter Future in India*. <https://doi.org/10.22541/au.169108923.36325496/v1>
- Ni, J. (2024). Intellectual Property Protection Dilemmas and Legal Response Strategies Under the Perspective of Generative Artificial Intelligence. *Journal of Education, Humanities and Social Sciences*. <https://doi.org/10.54097/8q8mfm80>
- Nietering, P. (2022). *Why Artificial Intelligence Shouldn't Be a Patent Inventor*. <https://doi.org/10.2458/azlawjet.5510>
- Nihalani, G. (2024). Applications of Artificial Intelligence in Pharmaceutical Research: An Extensive Review. *Bioequivalence & Bioavailability International Journal*. <https://doi.org/10.23880/beba-16000231>
- Ninković, M. J. (2024). *Korišćenje žigom zaštićenih oznaka prilikom „treniranja“ naprednih sistema veštačke inteligencije*. [https://doi.org/10.51204/internet\\_dijalog\\_2408a](https://doi.org/10.51204/internet_dijalog_2408a)
- Oğul, S. (2024). Intellectual Property in the Age of Machine Creativity. *Advances in Human and Social Aspects of Technology Book Series*. <https://doi.org/10.4018/979-8-3693-7235-7.ch013>
- Ogwuche, P. (2023). Artificial Intelligence: The Legal Implications of Intellectual Property Rights for AI-generated Inventions. *Social Science Research Network*. <https://doi.org/10.2139/ssrn.4589323>
- Olorunsogo, T., Adeniyi, A. O., Okolo, C. A., & Babawarun, O. (2024). Ethical considerations in AI-enhanced medical decision support systems: A review. *World Journal of Advanced Engineering Technology and Sciences*. <https://doi.org/10.30574/wjaets.2024.11.1.0061>
- Ozaybi, M. Q. B., MADKHALI, A. N. M., Alhazmi, M., Faqihi, H., Alanazi, M. M., Siraj, W. H. Y., Zalah, A. H. A., Khormi, M. M. A., Salem, A., Mashragi, T. Q. M., Alotaibi, A., Naji, A., Bagal, R. M. A., Maswadi, A. M. M., & MARWEE, H. A. A. (2024). The Role of Artificial Intelligence in Drug Discovery and Development. *Egyptian Journal of Chemistry*. <https://doi.org/10.21608/ejchem.2024.337877.10835>
- Pai, S. N., Jeyaraman, M., Jeyaraman, N., & Yadav, S. (2024). Doctor, Bot, or Both: Questioning the Medicolegal Liability of Artificial Intelligence in Indian Healthcare. *Cureus*. <https://doi.org/10.7759/cureus.69230>
- Pai, Y. (2015). The Growing Irrelevance of a TRIPS Challenge to India's Patent Law. *Social Science Research Network*.
- Pandey, P., Likhariya, M., Bhadoria, J., Vinchurkar, K., & Jain, P. (2024). *Role of Artificial Intelligence in Drug Product Design and Optimization of Process Parameters*. <https://doi.org/10.2174/9789815305753124010011>
- Patnaik, S. K., Sahu, M., Padmasri, B., Damarasingu, P., Nayak, D., Haque, M. A., & Panigrahi, S. K. (2023). *Transforming Drug Discovery and Development: The Impact of Artificial Intelligence*. <https://doi.org/10.52783/jchr.v13.i4.1303>
- Pereira, A. da S. (2024). *A transformação da indústria farmacêutica pela inteligência artificial: impactos no desenvolvimento de medicamentos*. <https://doi.org/10.69849/revistafar10202410082124>
- Picht, P. G., & Thouvenin, G. (2023). AI and IP: Theory to Policy and Back Again – Policy and Research Recommendations at the Intersection of Artificial Intelligence and Intellectual Property. *International Review of Intellectual Property and Competition Law*. <https://doi.org/10.1007/s40319-023-01344-5>

- Pitel, E., Leașu, F., Nicolau, A., & Rogozea, L. (2024). Ethical aspects in the use of artificial intelligence in the process of drug development | [Aspecte etice în utilizarea inteligenței artificiale în procesul de dezvoltare a medicamentelor]. *Jurnal Medical Brașovean*. <https://doi.org/10.31926/jmb.2023.2.8>
- Poddar, A., & Rao, S. R. (2024). Evolving intellectual property landscape for AI-driven innovations in the biomedical sector: opportunities in stable IP regime for shared success. *Frontiers in Artificial Intelligence*. <https://doi.org/10.3389/frai.2024.1372161>
- Pogge, T. (2010). *Incentives for Global Public Health: The Health Impact Fund: better pharmaceutical innovations at much lower prices*. <https://doi.org/10.1017/CBO9780511750786.008>
- Rahul, S. K., & Yadav, R. K. (2025). The Copyright Quandary: Criminalization and Judicial Backlog in India. *Journal of Intellectual Property Rights (JIPR)*, 30(2), 188-196.
- Ramalho, A. (2018). Patentability of AI-generated inventions: is a reform of the patent system needed? *Social Science Research Network*. <https://doi.org/10.2139/SSRN.3168703>
- Rangnekar, D. (2005). *No Pills for Poor People? Understanding the Disembowelment of India's Patent Regime*.
- Rangnekar, D. (2006). No pills for poor people. *Economic and Political Weekly*.
- Rehan, H., Asghar, M., & Geetha, K. T. (2024). Intellectual property rights. *I-Manager's Journal on Economics & Commerce (JECOM)*. <https://doi.org/10.26634/jecom.4.1.20931>
- Revolutionizing Drug Formulation: Harnessing Artificial Intelligence and Machine Learning for Enhanced Stability, Formulation Optimization, and Accelerated Development. (2023). *International Journal of Pharmaceutical Sciences and Medicine*. <https://doi.org/10.47760/ijpsm.2023.v08i08.003>
- Rosati, E. (2024). Infringing AI: Liability for AI-Generated Outputs under International, EU, and UK Copyright Law. *European Journal of Risk Regulation*. <https://doi.org/10.1017/err.2024.72>
- Rotenberg, M. (2023). *Human Rights Alignment: The Challenge Ahead for AI Lawmakers*. [https://doi.org/10.1007/978-3-031-45304-5\\_38](https://doi.org/10.1007/978-3-031-45304-5_38)
- Rusinovich, K. (2023). The Intersection of AI and Intellectual Property Law: Navigating Legal Frontiers. *International Journal of Science and Research*. <https://doi.org/10.21275/sr231128214222>
- Sabet, B., Eslamitabar, S., Lame, E., & Anvar, F. (2024). Challenges of the Intellectual Property System in Pharmaceutical Innovations Resulting from Artificial Intelligence. *Journal of Pharmaceutical Care*. <https://doi.org/10.18502/jpc.v12i2.16191>
- Saha, G. (2024). *Artificial Intelligence (AI) in Formulation Development*. <https://doi.org/10.69613/tkh3gv85>
- Said, M. E., & Kapczynski, A. (2012). *Access to Medicines: the Role of Intellectual property Law and Policy*.
- Sampat, B. N., & Shadlen, K. C. (2015). Drug patenting in India: looking back and looking forward. *Research Papers in Economics*.
- Sampat, B. N., & Shadlen, K. C. (2018). Indian pharmaceutical patent prosecution: The changing role of Section 3(d). *PLOS ONE*. <https://doi.org/10.1371/JOURNAL.PONE.0194714>
- Schwartz, D. L., & Rogers, M. (2022). Inventorless Inventions? The Constitutional Conundrum of AI-Produced Inventions. *Social Science Research Network*. <https://doi.org/10.2139/ssrn.4025434>
- Serrano, D. R., Luciano, F. C., Anaya, B. J., Ongoren, B., Kara, A., Molina, G., Ramirez, B. I., Sánchez-Guirales, S. A., Simón, J. M., Tomietto, G., Rapti, C., Ruiz, H. K., Rawat, S., Kumar, D., & Lalatsa, A. (2024). Artificial Intelligence (AI) Applications in Drug Discovery and Drug Delivery: Revolutionizing Personalized Medicine. *Pharmaceutics*. <https://doi.org/10.3390/pharmaceutics16101328>
- Shah, P. N., & Shah, R. P. (2023). Artificial Intelligence in the Paradigm Shift of Pharmaceutical Sciences: A Review. *Nano Biomedicine and Engineering*. <https://doi.org/10.26599/nbe.2023.9290043>
- Shanmugaiah, K. (2012). *The impact of TRIPS Agreement on access to medicines in developing countries: Legal challenges faced by the pharmaceutical industry particularly in India*. <https://doi.org/10.32890/UUMJLS.3.2012.4549>
- Sharma, A. K., & Sharma, R. (2024). Generative Artificial Intelligence and Legal Frameworks: Identifying Challenges and Proposing Regulatory Reforms. *Kutafin Law Review*. <https://doi.org/10.17803/2713-0533.2024.3.29.415-451>
- Sharma, R. (2020). *Artificial Intelligence & Intellectual Property Related Issues in India: Need for Proper Regulatory Framework*.

- Shi, Y., Li, S., Zhang, T., Fang, X., Wang, J., Liu, Z., Zhao, G., Zhu, Z., Gao, Z., Zhong, R., Zhang, L., Ke, G., Weinan, E., Cai, H., & Wang, X. (2024). *Intelligent System for Automated Molecular Patent Infringement Assessment*. <https://doi.org/10.48550/arxiv.2412.07819>
- Shimizu, Y., Ohta, M., Ishida, S., Terayama, K., Osawa, M., Honma, T., & Ikeda, K. (2023). AI-driven molecular generation of not-patented pharmaceutical compounds using world open patent data. *Journal of Cheminformatics*. <https://doi.org/10.1186/s13321-023-00791-z>
- Shukla, Ms. M. (2024). *Artificial intelligence and copyright law: navigating the challenges of ownership, infringement, and ethics in the age of ai-generated content*. <https://doi.org/10.58532/nbennurdch13>
- Singh, H. (2024). Legal Aspects of Digital Ethics in the Age of Artificial Intelligence. *Advances in Human and Social Aspects of Technology Book Series*. <https://doi.org/10.4018/979-8-3693-3334-1.ch005>
- Singh, S., Kumar, R., Payra, S., & Singh, S. K. (2023). Artificial Intelligence and Machine Learning in Pharmacological Research: Bridging the Gap Between Data and Drug Discovery. *Cureus*. <https://doi.org/10.7759/cureus.44359>
- Singh, S., Singh, A., Prakash, R. C., & Yadav, R. K. (2025). Contemporary Stance of Compulsory Licencing in the Indian Pharmaceutical Industry. *Journal of Intellectual Property Rights (JIPR)*, 30(3), 361-375.
- Sohrabji, N., & Maloney, K. (2020). *Section 3(d) and Pharmaceutical Patents in India*.
- Solow-Neiderman, A. (2024). Do Cases Generate Bad AI Law? *The Columbia Science and Technology Law Review*. <https://doi.org/10.52214/stlr.v25i2.12764>
- Sonia, D. F. ul ain. (2022). Healing horizons: ai and ml innovations in pharmaceuticals. *ShodhKosh Journal of Visual and Performing Arts*. <https://doi.org/10.29121/shodhkosh.v3.i2.2022.2241>
- Sprankling, J. G. (2024). *Trade secrets in the artificial intelligence era*. <https://doi.org/10.2139/ssrn.4847813>
- Subhan, J. (2020). Scrutinized: the TRIPS agreement and public health. *McGill Journal of Medicine*. <https://doi.org/10.26443/MJM.V9I2.445>
- Sundaram, J. N. (2023). *World Trade Law and Access to Medicines: Reassessing Protection of Pharmaceutical Patents Under the TRIPS Agreement*. <https://doi.org/10.59019/asrs6775>
- Suriyaamporn, P., Pamornpathomkul, B., Patrojanasophon, P., Ngawhirunpat, T., Rojanarata, T., & Opanasopit, P. (2024). The Artificial Intelligence-Powered New Era in Pharmaceutical Research and Development: A Review. *Aaps Pharmscitech*. <https://doi.org/10.1208/s12249-024-02901-y>
- The Effect of TRIPS Implementation on Indian Patent Law: A Pharmaceutical Industry Perspective: With Special Reference to Healthcare Industry. (2022). *Journal of Pharmaceutical Negative Results*. <https://doi.org/10.47750/pnr.2022.13.s03.150>
- Ujjwal, A. (2024). The Integration of Artificial Intelligence in Drug Discovery and Development: Novel Approach. *International Journal of Scientific Research in Science and Technology*. <https://doi.org/10.32628/ijrst24116175>
- Vaish, K., Bahuguna, R., Kathuria, S., Joshi, K., Yadav, R., & Gehlot, A. (2023). *The Challenge of Recognizing Artificial Intelligence as Legal Inventor: Implications and Analysis of Patent Laws*. [https://doi.org/10.1007/978-981-99-7216-6\\_25](https://doi.org/10.1007/978-981-99-7216-6_25)
- Vanhaelen, Q., Aliper, A., & Zhavoronkov, A. (2024). *Generative Drug Discovery*. <https://doi.org/10.1201/9781003399346-3>
- Verma, S. K. (2011). *TRIPS Agreement and Access to Medicines*.
- Vicente, I. P. (2010). *Análisis Económico del Sector Farmacéutico: Efecto de los TRIPS en la difusión de la innovación farmacéutica en países en vías de desarrollo*.
- Vij, P. (2024). Pharma in The Digital Era: The Role of Artificial Intelligence in Drug Development. <https://doi.org/10.52783/cana.v32.2259>
- Vijayaraghavan, B., & Raghuvanshi, P. (2008). Impact of the Amended Indian Patent Act on the Indian Pharmaceutical Industry. *Journal of Generic Medicines*. <https://doi.org/10.1057/PALGRAVE.JGM.4950102>
- Voitovych, P., Bondarenko, K., Ennan, R., Havlovska, A., & Shliienko, V. (2021). *Objects of intellectual property rights created by artificial intelligence: international legal regulation*. <https://doi.org/10.46398/CUESTPOL.3968.32>

- Wang, Y., Michael, S., Huang, R., Zhao, J., Recabo, K., Bougie, D., Shu, Q., Shinn, P., & Sun, H. (2021). Retro Drug Design: From Target Properties to Molecular Structures. *arXiv: Biomolecules*. <https://doi.org/10.1101/2021.05.11.442656>
- Warokar, P., & Lote, S. (2024). *Ethical and Regulatory Consideration in AI-Assisted Drug Development*. <https://doi.org/10.1109/idicaiei61867.2024.10842700>
- Whalen, R., & Zingg, R. (2022). Innovating under Uncertainty: The Patent-Eligibility of Artificial Intelligence after Alice Corp. v. CLS Bank International. *Social Science Research Network*. <https://doi.org/10.2139/ssrn.4099290>
- Whether Indian Patent Act TRIPs compliant for Pharmaceutical Business: A Case-based approach. (2023). *Journal of Intellectual Property Rights*. <https://doi.org/10.56042/jipr.v28i3.1006>
- Wise, J. (2014). Protecting intellectual property is vital for medical innovation, says UK report. *BMJ*. <https://doi.org/10.1136/BMJ.G1238>
- Y, L. T. D., Raghava, D., & K, N. R. (2024). A Review on Evolution and Challenges of Pharmaceutical Patent Protection in India. *Journal of Pharma Insights and Research*. <https://doi.org/10.69613/qkswa210>
- Yadav, A., Yadav, R. K., Singh, V. P., Rajpurohit, G. S., & Singh, S. (2025). Recognition to Implementation: Bridging the Gap in Moral Rights Protection under Indian Copyright Law. *Journal of Intellectual Property Rights (JIPR)*, 30(3), 295-303.
- Yadav, S., Singh, A., Singhal, R., & Yadav, J. P. (2024). *Revolutionizing drug discovery: The impact of artificial intelligence on advancements in pharmacology and the pharmaceutical industry*. <https://doi.org/10.1016/j.ipha.2024.02.009>
- Yang, Y. (2024). The Study of Copyright Infringement Liability of Generative Artificial Intelligence. *Lecture Notes in Education Psychology and Public Media*. <https://doi.org/10.54254/2753-7048/34/20231893>
- Yu, S., Lee, S., & Hwang, H. (2024). <https://doi.org/10.7180/kmj.24.140>

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