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Short communication

Intellectual property and pharmaceutical innovation in the era of artificial intelligence

Katerina Smilevska[1*], Aleksandra Grozdanovska[2], Zoran Sterjev[2], Katerina Anchevska-Netkovska[2]

[1]*Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje, Republic of North Macedonia*
[2]*Faculty of Pharmacy in Skopje, Mother Teresa Str. No. 47, 1000 Skopje, North Macedonia*

Introduction

Artificial intelligence (AI), particularly deep learning and generative models, is reshaping drug discovery and development. From therapeutic target identification and de novo molecular design to clinical trial optimization and post-marketing surveillance, AI offers the potential for a faster, more systematic and data-driven approach to innovation. However, in the highly regulated pharmaceutical industry, these advancements bring significant challenges related to intellectual property (IP), regulatory compliance, legal and ethical standards. Addressing these challenges is essential to ensure safety, credibility and public trust.

Challenges to intellectual property in the age of artificial intelligence

Intellectual property (IP) is essential for promoting innovation and protecting investments in pharmaceutical research and development. The reliability and transparency of AI systems depend on the availability, quality and traceability of training data, while AI-generated outputs raise complex questions regarding authorship, ownership and accountability (Poddar and Rao, 2024).

The concept of inventorship under artificial intelligence

The classical concept of inventorship defines innovation as the result of human intellectual and creative activity. According to the European Patent Convention (EPC) and the practice of the U.S. Patent and Trademark Office (USPTO), only natural persons may be recognized as inventors. However, the growing role of AI blurs the boundary between a tool and a potential autonomous creator, challenging this traditional model. (Poddar and Rao, 2024) World Intellectual Property Organization (WIPO) highlights the need to adapt existing legal concepts to ensure legal certainty, promote innovation and protect public interest. (World Intellectual Property Organization, 2019). Consequently, the degree and nature of legally relevant human contribution in AI-assisted innovation may require redefinition.

Patentability and ownership of AI-generated innovations

The patentability of AI-generated outputs raises both technical and legal challenges. Many AI systems operate on “black-box” models, where decision-making processes are difficult to explain. This lack of transparency complicates the identification of the technical contribution, the distinction from prior art and demonstration of non-obviousness. Therefore, detailed documentation of

*katanasovska@alkaloid.com.mk

AI use, including researcher-defined parameters, constraints and key decisions, is essential for establishing inventorship and ensuring patent validity. Legal ownership is also complex, with potential claims by the AI developer, system owner or authorized user. In the pharmaceutical industry, clear documentation of human contribution and well-defined contractual arrangements are critical for legal certainty and sustainable innovation (Poddar and Rao, 2024).

Regulatory perspectives on artificial intelligence in the European Union and the United States

Regulatory systems in the EU and the US recognize and support the use of AI provided that algorithmic transparency, scientific validation and human oversight are ensured. In the EU, the Artificial Intelligence Act (AI Act) and the European Medicines Agency (EMA) Reflection Paper, establish an integrated, risk-based regulatory framework requiring documentation, traceability and explainability. (European Parliament and Council of European Union, 2024; European Medicines Agency, 2023) This approach enhances legal predictability and harmonization, but increases tensions between transparency requirements and protection of algorithms, model architectures and data as trade secrets.

In contrast, the U.S. approach relies on iterative, interactive and context-specific oversight, using the concept of "model credibility" to establish trust. (U.S. Food and Drug Administration, 2021) Rather than requiring predefined disclosure, it focuses on demonstrating that AI systems are fit for their intended purpose. This provides greater regulatory flexibility and enables hybrid IP strategies combining patents and trade secrets.

Ethical challenges of artificial intelligence in pharmaceutical innovation

The use of artificial intelligence (AI) in pharmaceutical innovation raises ethical challenges related to data quality and privacy, algorithmic bias, transparency, accountability and equitable access to innovation. The World Health Organization (WHO) outlines recommendations for responsible AI use through rigorous real-world testing, transparent protocols and international standards for safety and efficacy (World Health Organization, 2024).

Conclusion

Artificial intelligence has the potential to transform drug discovery and development by improving efficiency and reducing development risks. However, current European and U.S. patent frameworks recognize only humans as inventors and responsible parties. Consequently, transparent documentation of human contribution remains essential for patent protection, regulatory acceptance and public trust.

References:

European Medicines Agency, 2024. Reflection Paper on the Use of Artificial Intelligence in the Medicinal Product Lifecycle. European Medicines Agency, Amsterdam. https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-use-artificial-intelligence-ai-medicinal-product-lifecycle_en.pdf

European Parliament and Council of the European Union, 2024. Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence. Off. J. Eur. Union L, 2024/1689. https://eur-lex.europa.eu/eli/reg/2024/1689/oj

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. Front. Artif. Intell. 7, 1372161. https://doi.org/10.3389/frai.2024.1372161

U.S. Food and Drug Administration, 2021. Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device Action Plan. U.S. Food and Drug Administration. https://www.fda.gov/media/145022/download

World Health Organization, 2024. Benefits and Risks of Using Artificial Intelligence for Pharmaceutical Development and Delivery. World Health Organization, Geneva. https://www.who.int/publications/i/item/9789240088108

World Intellectual Property Organization, 2019. WIPO Technology Trends 2019: Artificial Intelligence. World Intellectual Property Organization, Geneva. https://doi.org/10.34667/tind.29086