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*Short communication*

# Artificial intelligence and intellectual property in the pharmaceutical industry: legal, ethical and regulatory challenges

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## Introduction

Pharmacy has long occupied a central position in debates surrounding the development and enforcement of intellectual property law, primarily due to the highly regulated and innovation-driven nature of the pharmaceutical industry (Cockburn, 2006). In recent years, however, the rapid advancement of artificial intelligence has introduced a new layer of complexity, fundamentally challenging traditional legal concepts such as inventorship, ownership, and patentability.

Despite a growing body of academic literature addressing the intersection of artificial intelligence and intellectual property, a significant research gap remains. Existing studies often examine these issues in isolation, without adequately considering the specific regulatory, ethical, and market-related implications within the pharmaceutical sector, particularly in the context of the European Union and emerging legal systems such as North Macedonia.

Against this background, this paper seeks to critically examine whether current intellectual property regimes can accommodate AI-driven innovation in the pharmaceutical industry. It further explores the extent to which traditional legal doctrines should be adapted, reinterpreted, or supplemented to address questions of ownership, inventorship, and responsibility for AI-generated inventions. The study ultimately aims to contribute to the ongoing debate by proposing balanced and pragmatic solutions that reconcile innovation incentives with ethical considerations and public health objectives.

## Materials and methods

This paper employs a qualitative, doctrinal legal research methodology, complemented by comparative, conceptual, and normative analysis, to examine the challenges posed by artificial intelligence to the protection of intellectual property rights in the pharmaceutical industry.

The core method applied is doctrinal legal analysis, consisting of a systematic examination of primary and secondary sources of law relevant to artificial intelligence–driven innovation in the pharmaceutical sector. This includes the analysis of legal norms governing patent law, copyright law, and the protection of trade secrets, with particular emphasis on concepts such as inventorship, ownership, patentability criteria, and the role of human contribution in inventive activity.

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A comparative legal method is further employed to identify convergences, divergences, and regulatory gaps across selected jurisdictions. This comparative perspective enables a critical evaluation of the coherence and adaptability of EU and Macedonian intellectual property law within a global innovation ecosystem (Cockburn, 2006).

Finally, the methodology includes a policy-oriented normative assessment aimed at formulating reform proposals. On the basis of the doctrinal and comparative findings, the paper evaluates the need for adaptation of existing intellectual property frameworks and explores alternative or complementary protection models for AI-generated inventions.

## Results and discussion

The results of the analysis indicate that the current intellectual property framework, particularly within the European Union, but also the legal regulations in North Macedonia, is only partially capable of addressing the challenges posed by artificial intelligence generated inventions in the pharmaceutical industry. Existing legal regimes remain firmly rooted in anthropocentric assumptions, most notably the requirement that inventive or creative activity be directly attributable to a natural person (Kumar, 2025).

In the pharmaceutical context, the findings suggest that legal uncertainty surrounding AI-generated inventions may undermine incentives for innovation or encourage strategic behavior that prioritizes formal compliance over substantive inventiveness. At the same time, an overly expansive reinterpretation of inventorship risks diluting the original rationale of patent protection, which is closely tied to human intellectual contribution. (Hosseini, 2024).

While copyright law also relies on authorship and originality linked to human creativity, trade secret protection offers a more technology-neutral form of legal security for AI-related assets, such as algorithms, training data, and proprietary models (Pradhan, 2026). Nevertheless, the analysis highlights that an increased reliance on trade secrets in pharmaceutical innovation presents significant drawbacks. In particular, secrecy may conflict with regulatory transparency obligations, clinical trial disclosure requirements, and broader public health objectives embedded within the regulatory framework.

## Conclusion

The findings demonstrate that while existing intellectual property regimes continue to play a central role in incentivizing pharmaceutical innovation, they are increasingly challenged by the growing autonomy and complexity of AI-driven inventive processes. Traditional, human-centered legal concepts such as inventorship, authorship, and ownership prove insufficient when applied to inventions generated with substantial or autonomous involvement of artificial intelligence systems.

In response to these challenges, this paper argues against radical departures from existing intellectual property frameworks and instead supports incremental, carefully calibrated reform. Ultimately, the study concludes that the effective regulation of AI-driven pharmaceutical innovation requires an integrated approach that balances innovation incentives with ethical responsibility and public health objectives, ensuring the continued legitimacy and sustainability of intellectual property protection in the age of artificial intelligence.

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