

Artificial Intelligence and Pharmaceutical Industry: The Transformation in the Technology and Patent System Shaping the Future

Artificial intelligence influences every aspect of our lives and creates revolutionary effects in the pharmaceutical industry as well as in many other sectors. From DeepMind's AlphaGo success to Tempus' personalized approaches to cancer treatment, AI-enabled innovations offer not only scientific achievements, but also wide-ranging advantages such as operational efficiency, cost reduction and risk reduction. However, this technological leap also raises critical questions about the traditional processes of the pharmaceutical industry and the patent system.

According to data from the Tufts Drug Development Research Center, it takes about 10 years for a drug to be developed and put on the market, and it costs \$ 2.558 billion. In particular, clinical trials account for the majority of this cost, while the success rate is below 10%. These challenges cause the pharmaceutical industry to look for more sustainable and rapid solutions.

The discovery of new compounds and molecular design that takes months with traditional methods can be reduced to weeks thanks to artificial intelligence algorithms; clinical trial processes are completed in 20% less time and at a lower cost. For example, BenevolentAI has demonstrated this potential by leveraging artificial intelligence platforms in the rapid discovery of a drug such as Baricitinib in the treatment of COVID-19. It should be emphasized that the contributions of artificial intelligence to the pharmaceutical industry are not limited only to cost and time savings. That is because artificial intelligence also provides a great transformation in areas such as customization of the treatment process, detection of side effects and analysis of patient data. IBM Healthcare's use of artificial intelligence in clinical trial matching is a good example of this.

The increase in the use of artificial intelligence in the pharmaceutical industry also raises new discussions in terms of patent protection and legal grounds; because although the Industrial Property Code No. 6769 ("IP Code") regulates that computer programs are not patentable, there is no regulation in the IP Code on how artificial intelligence-supported inventions will be evaluated in this context.

On the other hand, since Türkiye has been a party to the European Patent Convention since 2000, the European Patent Office's position on the patentability of artificial intelligence-supported pharmaceutical inventions has been binding on Türkiye. Because as one of the conditions for membership in the Convention, Türkiye accepts and undertakes that European Patents decided to be registered by the European Patent Office are deemed to be a national patent registered in Türkiye.

The European Patent Office adheres to conventional criteria when evaluating the patentability of artificial intelligence-supported inventions. For example, using the Problem-Solving approach, it is evaluated whether an artificial intelligence invention has novelty and is not obvious to those skilled in the art. However, whether the problem-solution approach can always be applied in terms of patentability of inventions arising in artificial intelligence and artificial intelligence-supported pharmaceutical development processes is subject to controversy.

Artificial intelligence has taken on a groundbreaking role in the pharmaceutical industry in terms of cost, speed and efficiency. However, this transformation requires a reinterpretation of the traditional patent system and a clearer drawing of the ethical and legal boundaries of technology. The pharmaceutical industry's ability to keep human expertise at the center while embracing the advantages offered by artificial intelligence will be the key to future success. An industry that can achieve this balance will lead not only to more effective treatments for patients, but also to sustainable solutions for the global healthcare system.

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