David McCombs, Eugene Goryunov, Dina Blikshteyn and Kalyani Joshi Write About Protecting AI Inventions in Drug Development

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PRACTICES Intellectual Property, Patents, AI and Deep Learning

Artificial intelligence (AI) is a lot more sophisticated today than it was just a few years ago. Its impacts are felt outside of technology applications such as computing, malware, and natural language processing. For example, Google's AI (called DeepMind) recently solved one of biology's greatest problems: It determined a protein's three-dimensional shape from its amino acid sequence. Now, AI is making a foray into drug development processes. Drug development is a risky, expensive, time-consuming, yet often lucrative venture. The costs in time and money are staggering: A drug can take five years to 15 years to develop and commercialize at a cost of hundreds of millions to billions of dollars.

Drug development comprises four major stages: discovery, testing, review, and postmarket-entry safety monitoring. During drug discovery, different exploration methods are used to assess potential drug candidates and predict which of those options will be most successful for treating a given disease. Drug testing involves taking the top candidates from the previous step and evaluating common drug properties such as absorption and toxicity levels. In some cases, animal models are used for testing. Drug review encompasses clinical development time (phase 1–3 clinical trials), in which factors such as drug efficacy and safety are examined through different clinical studies. Finally, during postmarket-entry drug-safety monitoring (phase 4), researchers analyze long-lasting side effects of the drug itself and its administration with other medications. As with many industries, AI-enabled solutions are revolutionizing every stage of the drug development process to accelerate it and improve its efficiency.

Advantages of Using AI

Drug Discovery: Using an AI-enabled approach in drug discovery can be beneficial. An AI system's ability to churn through large amounts of data enables it to identify patterns and more-predictive indicators of potential new drugs. For example, biotechnology company Berg implemented a patient-centric approach in its study of cancer treatments. Company researchers used an AI system with biological and outcomes data from patients to identify key molecules that are generated during cancer metabolism. That enabled the team to discover a new drug candidate, BPM31510, which is now in phase 2 clinical trials as a treatment for different types of cancer.

Clinical Trials: AI can be used to improve clinical trial procedures conducted during drug review. Major steps include finding appropriate patients for a trial and ensuring medication compliance throughout a study. Finding a sufficient number of patients for phase 3 clinical testing can be difficult because patients must meet a specific set of criteria. Those requirements typically are strict and take into account comorbidities and other factors that can exclude some clinical subjects. Industry analysts have estimated that there were more than 300,000 clinical trials taking place at the end of 2020 (1), making it nearly impossible for doctors to be aware of every trial in which a patient would qualify. It is no surprise, then, that the leading reason for trial termination (at 55% of

total trials globally in 2018) is insufficient enrollment (2).

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