AI and the New IP Playbook for Biotech-Software Innovators

Technology, Privacy, and eCommerce

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AI’s expanding role in biotechnology

As AI has taken the world by storm over the last few years, companies across diverse sectors have integrated this new technology into their products and workflows. AI use cases have been particularly prevalent in the biotechnology field, where AI has been deployed to accelerate drug discovery, personalize treatment regimens, enhance diagnostics, and analyze genomic and transcriptomic data to drive medical research.

As machine learning and generative AI technologies improve, even more applications in biotechnology are likely to emerge. Future use cases may include AI-driven diagnostic systems that prescribe tailored treatments, virtual clinical trials that streamline the drug development process, and targeted therapeutics for cancer patients that take into account spatial gene expression patterns in tumors.

The IP challenge

Despite the promise of AI in biotech, protecting intellectual property in this space presents unique challenges. First and foremost, it is critical to engage legal counsel who can understand both the

scientific and technical nuances of the invention. This may require working with a firm with expertise spanning both life sciences and software, enabling collaborative efforts between practitioners with complementary backgrounds. At a minimum, it is important to understand the attorney's primary area of expertise so that inventors can fill in the gaps during the drafting process.

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Additionally, companies must implement data protection strategies to safeguard the datasets generated by their AI models. This includes establishing security frameworks, such as encrypting sensitive datasets, limiting access control, and preventing unauthorized access to the data. Moreover, companies should ensure they obtain the rights to any data used for training AI models to mitigate potential downstream IP risks. Otherwise, use of the training data may result in potential liability for copyright infringement.

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It is also essential to perform adequate due diligence before using any third-party AI services or models to ensure that the privacy of the data input into the models is protected. This can reduce the risk of unintentional disclosure and ensure that confidentiality and trade secrets are maintained.

In some instances, the data itself, rather than the method of generating it, may be the most valuable IP.

For example, if a company develops a technique to identify correlations between regional gene expression and therapeutic efficacy, competitors may be more interested in using those correlations as a diagnostic tool than in replicating the process. In such cases, maintaining the

AI model and its associated input/output data as a trade secret may be the better strategy than filing a patent on the process, which likely would require disclosure of the data.

Check out the **ACC AI Center of Excellence for In-house Counsel** for practical guidance and peer-to-peer use cases!

Choosing between patents and trade secrets

When deciding whether to patent biotechnology software or maintain it as a trade secret, companies should consider the likelihood that others could detect or reverse engineer the software. Companies should also consider the possibility that they could detect competitors making similar software.

If the software will be presented publicly, such as in a journal publication or scientific conference, a patent application may be warranted. Conversely, if the AI model is hosted on a back-end server and is unlikely to be discovered, a trade secret may offer stronger, longer-lasting protection.

USPTO guidance and patent eligibility

For companies pursuing patent protection of biotechnology software, recent guidance from the US Patent and Trade Office (USPTO) provides important insights for addressing potential eligibility issues.

The USPTO compared two example claims where the first involved identifying a high-risk patient using an AI model and administering an “appropriate treatment.” The second used the same AI model but specified the treatment as “Compound X eye drops.” The USPTO determined that the second claim was eligible while the first was not, because the second tied the AI model’s output to a practical application.

Demonstrating technical improvements in patent drafting

This highlights the importance of describing how the biotechnology software is being used. Practitioners should identify specific downstream actions, such as administering a particular treatment or therapeutic, correcting sequencing errors, filtering inaccurate data, improving expression profiling, enhancing basecalling, or executing other biologically meaningful tasks.

Practitioners should also include specific speed and accuracy improvements, such as improved accuracy in detecting karyotypes, and any integrations with specific hardware, such as the use of a specialized computer processer (e.g., GPU, FPGA, etc.). These applications can demonstrate that the invention improves a technological field, supporting subject matter eligibility.

Companies should also consider whether copyright can supplement, or fill gaps in, patent and trade secret protection, and provide a layered, more comprehensive protection strategy for biotechnology software. For example, software interfaces (GUIs) and data visualizations may be particularly suited

for copyright protection due to their public-facing nature. And while the copyrightability of datasets generated with the assistance of AI may be unsettled, the arrangement or compilation of that data, particularly when performed by a human as opposed to an AI model, may be sufficiently original to warrant copyright protection.

Securing the future of AI-driven biotech innovation

AI is now a vital tool for biotechnology companies to improve their products and processes. By developing sound data protection strategies, identifying when trade secret protection is appropriate, drafting patent applications that describe technical benefits and specific use cases, and utilizing copyright for applicable works of creativity, biotech companies can position themselves to secure and defend their AI-driven breakthroughs.

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Cameron Pick

Partner

Marshall, Gerstein & Borun LLP

Cameron B. Pick is a partner at Marshall, Gerstein & Borun LLP in Chicago. Drawing on his technical training in electrical engineering and his interest in new and diverse technologies, he guides clients ranging from startups to Fortune 100s in the prosecution of domestic and foreign patents for emerging technologies. Pick can be reached at (312) 474-9565 or cpick@marshallip.com.

Will Hartwell

Senior Attorney — Global Intellectual Property

Illumina

Will Hartwell is a Senior Attorney for Global Intellectual Property at Illumina in Madison, Wisconsin. With extensive experience in patent prosecution and intellectual property strategy, and leveraging his experience as a software developer, he has built a career advising multinational organizations on how to protect high-value software innovations. Will Hartwell can be reached at whartwell@illumina.com.