# Patenting AI/ML Life Sciences and TechBio Innovations – How Much Disclosure Is Sufficient?

# By Hanna Kim and Terri Shieh-Newton

In recent years, the rapid advancement of artificial intelligence (AI) and machine learning (ML) technologies has sparked a wave of innovation across various sectors, particularly in life sciences. ML technologies have increasingly been incorporated into medical devices, leading to the U.S. Food and Drug Administration (FDA) approval of approximately 950 AI-enabled medical devices.<sup>1</sup> Machine learning is also being used today in drug discovery, patient care, preclinical and clinical testing, as well as drug validation studies. However, as the patent landscape for these technologies expands, a critical issue has come to the forefront: the sufficiency of disclosure in AI/ML patents: How much detail is enough to meet legal standards and foster innovation while protecting intellectual property?

# The Growing Need for AI/ML Life Sciences Patent Disclosure

The core of the patent system is the balance between encouraging innovation and ensuring public benefit. Inventors receive rights to exclude others from practicing their inventions for at least a statutory 20-year period in exchange for sharing enough details to allow others to understand and practice the invention. However, in the case of ML inventions, particularly in the life sciences, this balance is difficult to strike due to the inherent complexity and abstract nature of these technologies.

Life sciences AI/ML inventions, such as drug discovery platforms, medical diagnostic tools, and treatment prediction models, require detailed disclosure to meet the standards of patentability. This includes not only a description of what the ML does but also how it does it – the model architectures, training data, output, and other technical details. Some important questions for companies to consider when protecting their TechBio inventions involving ML are: (1) how much do we have to disclose in order to fulfill the patentability requirements; and (2) will disclosing that much detail in a patent application, which will eventually get published, give competitors too much information?

#### Striking a Balance: Legal and Practical Considerations

Under 35 U.S.C. §112, patent applicants must provide sufficient details (1) to establish that the applicant has possession of the entire scope of what is being claimed (written description) and (2) to enable someone skilled in the field to practice the invention without undue experimentation (enablement). However, the application of these requirements is nuanced, especially in ML technologies. AI/ML systems often rely on "black-box" models that are difficult to explain or practice, and without detailed disclosure - for example, how a ML model was trained, the curation and/or labeling of the data - the patent may fall short of legal requirements such as written description and enablement. In the life sciences, this is especially problematic, as ML models often deal with complex biological data, which adds another layer of complexity to the disclosure requirements.

The current state of disclosure in AI/ML life sciences or TechBio patents suggests that many patents are providing less information than required under 35 U.S.C. §112, thus posing a vulnerability of the patent to invalidation. A study analyzing AI/ML patents in the medical field revealed significant gaps in technical disclosure.<sup>2</sup> Many patents fail to specify crucial details, such as AI model architecture and training data, hindering reproducibility and practical application.

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Patent holders face a strategic decision: how much to disclose? While more thorough disclosures raise the bar for competitors and can strengthen a patent portfolio, they may also reveal valuable proprietary information. Conversely, minimal disclosures may result in weaker patents that are vulnerable to legal challenges and do not contribute to public knowledge.

From a business perspective, companies must balance the trade-off between patenting their innovations and protecting proprietary information as trade secrets. While patents provide public protection, they require detailed disclosure, whereas trade secrets keep crucial information private but offer no legal protection if independently discovered. Furthermore, in light of the high number of patent applications filed at the U.S. Patent and Trademark Office (USPTO) involving ML, companies should consider that patents and patent applications can be effective business tools for negotiations if a thirdparty sends a notice or offer letter of the thirdparty's patents. Trade secrets do not offer much of a bargaining chip against possible litigation threats from third-party patents. As such, patent applicants must carefully weigh the business benefits of public disclosure against the potential risks of losing competitive advantages through the revelation of proprietary ML technologies.

In addition, having more detail in the patent application is helpful to overcome any possible rejection under 35 U.S.C. § 101 for subject matter eligibility. For further information on the updated USPTO guidance on §101 eligibility for AI inventions, please see our article here.

## **Practice Tips**

The challenge of determining sufficient disclosure for life sciences ML patents remains crucial for balancing innovation protection and public benefit. By following best practices and focusing on practical, detailed information, patent applicants can strengthen their patent claims while promoting broader technological advancements. Here are key takeaways for successful life sciences AI/ML or TechBio patent filings:

- 1. AI/ML life sciences or TechBio patent applications must provide enough teachings, such as details of the AI model architecture, input features (such as training data), the method by which the model was used to generate the output, and the output itself to ensure others can practice the invention.
- 2. To increase the chances of overcoming possible § 101 rejections for subject matter eligibility and to transform abstract ideas into patent-eligible inventions, it is crucial to include additional steps that go beyond routine data processing and can be considered significant extra-solution activity. For example, synthesizing new data outputs, applying AI-generated results to subsequent processes, and integrating these into larger systems can demonstrate significant extra-solution activity.
- 3. Highlighting tangible advancements and realworld applications, especially in life sciences, is helpful for building a patentability story and rebutting any arguments from the USPTO for obviousness.

For tailored advice on specific situations, it is recommended to consult an experienced patent attorney who can navigate the complexities of life sciences AI/ML or TechBio patent disclosures.

## Notes

- 1. U.S. FDA. Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices (2023), https:// www.fda.gov/medical-devices/software-medicaldevice-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices.
- 2. Aboy et al., Nature Biotechnology, 42:839-845 (2024).

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