

# Patent Law Issues When Artificial Intelligence (AI) Interfaces with the Life Sciences

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PRACTICES Biotechnology, Patents, Life Sciences, AI and Deep Learning

Artificial intelligence (AI) is playing an increasingly prominent role in life science-related inventions. While securing meaningful patent protection is critical for the owners of these technologies, there are a number of nuanced issues found in U.S. patent law that need to be considered in order to successfully prepare and prosecute these AI-life science inventions.

- 1. Patent Subject Matter Eligibility.** Incorporating AI with more traditional life science inventive concepts results in some complexity in terms of what is and what is not considered to be patentable subject matter. Recently, the United States Patent and Trademark Office (USPTO) issued a *Guidance Update on Patent Subject Matter Eligibility, Including on Artificial Intelligence (Ref)* (“*Guidance*”); the *Guidance* provides an up-to-date summary of how patent subject matter eligibility relating to AI should be examined by Patent Examiners. The first step of the USPTO’s subject matter eligibility analysis addresses whether the claimed invention falls into at least one of the four categories recited in 35 U.S.C. 101, namely a process, machine, manufacture, or composition of matter. The second step of the USPTO’s subject matter eligibility analysis applies the Supreme Court’s two-part framework from the *Alice/Mayo* decisions to identify claims that are directed to a judicial exception and then evaluate if additional elements of the claim render the claim patent eligible. Applicants are well advised to seek professional counsel early in the patent process so that the subject matter of the invention is put in the best light for being patent eligible; once formal patent applications are filed, it can be too late to correct these issues.
- 2. Inventorship.** Another important issue that has been raised based on the role that AI is playing in the life sciences invention process is how to address inventorship. Both the USPTO and the United States Court of Appeals for the Federal Circuit have ruled that inventors listed on a patent application must be natural persons. While the law here is reasonably settled, the factual circumstances surrounding many AI-life science inventions become challenging if a situation arises where a natural person has not played a significant role in the inventive process. Again, applicants are advised to communicate with their patent counsel so that delineating inventorship does not become an issue later on during prosecution, subsequent commercialization, or in litigation.
- 3. Data.** Another area in which AI has played a significant role in the life sciences space is the rapid generation of scientific data. An upside to this robust data generation is that it increases the possibility that the applicant will be able to secure broad genus claims that cover multiple species of related biological variants; these types of patents are generally viewed as being more valuable given that they can effectively prevent design-around options from would-be competitors. However, it is important to note that data generation for the sake of data generation is usually insufficient to warrant broader patent coverage at a patent office. Rather, an applicant needs to ensure that the generated data correlates with a particular biological or chemical function. The generation of significant AI-derived data is really only useful if it is properly tied—through chemical or biological analyses—to the underlying invention.