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Litigating Trade Secrets in Biotech, Life Sciences, and AI: The High-Stakes Battle Over Clinical Trial Innovations

Proskauer on Trade Secrets on **July 15, 2024**

In the rapidly evolving biotech and life sciences sectors, the importance of trade secrets has grown significantly. Companies are investing heavily in research and development to create cutting-edge treatment therapies. Protecting proprietary methodologies and innovations is crucial for maintaining competitive advantage and fostering innovation. Moreover, the rise of artificial intelligence ("AI") in these fields has amplified the value of trade secrets. AI algorithms and machine learning models, which can streamline drug discovery and enhance clinical trial efficiency, represent significant intellectual property that companies need to safeguard. Given the high stakes and the critical nature of these proprietary technologies, it is not uncommon for trade secret and intellectual property disputes to arise, as companies fiercely protect their valuable innovations and competitive positions. We recently saw this when a pharmaceutical company partnered with an artificial intelligence company to ease the clinical trial process. But instead of producing new technologies, the companies are embroiled in litigation about trade secrets.

Eisai Inc. is a U.S.-based affiliate of Japan-based Eisai Co., Ltd ("Eisai"). The company's primary focus is developing new drugs, therapies, and treatments for cancer and neurological diseases like Alzheimer's Disease. Eisai's business requires it to conduct and analyze clinical trials. But such trials can be difficult to enroll, which often leads to significant delays and high failure rates. To deal with the difficulty of conducting these clinical trials, Eisai invested in Unlearn.AI, Inc. ("Unlearn") in 2020. Unlearn claimed to have created the first machine learning platform that makes Digital Twins: statistically indistinguishable digital versions of the patient population. Unlearn further claimed its Digital Twins technology could make clinical trials more efficient, leaving Eisai eager to evaluate the technology.

By January 2021, both parties had entered into a Mutual Confidentiality Agreement and an Evaluation Agreement. Under the Evaluation Agreement, Eisai would provide its patient data to Unlearn and evaluate Unlearn's Digital Twins technology. However, after conducting its evaluation, Eisai found the technology unimpressive. Unlearn later attempted to enter into another agreement with Eisai regarding a combination of Digital Twins and a new statistical analysis known as prognostic covariate adjustment (PROVOCA™). But given Eisai's prior disappointment, Eisai declined to enter into a new agreement.

In March 2022, an Eisai scientist with expertise in statistical modeling, algorithms based on machine learning, and artificial intelligence gave a presentation which included a discussion of a prognostic covariate analysis supposedly developed by Eisai. Unlearn learned about the presentation and claimed the information to be "essentially identical" to its proprietary PROVOCA™ methodology. Unlearn likewise claimed that through that presentation, Eisai improperly disclosed Unlearn's trade secret information in violation of the Mutual Confidentiality Agreement and Evaluation Agreement. According to Unlearn, PROVOCA™ constitutes a trade secret because it is scientific and technical information that increases the power and efficiency of clinical trials.

Eisai then filed a complaint in the Northern District of California seeking declaratory judgment: a clarification from the court that it did not disclose trade secrets. More specifically, Eisai seeks a determination that it did not violate the Defend Trade Secrets Act ("DTSA"), a federal law which prohibits the disclosure of a trade secret without express or implied consent, or the California Uniform Trade Secrets Act ("CUTSA"), a similar state law. Eisai also seeks a declaratory judgment that it did not breach its Mutual Confidentiality Agreement and Evaluation Agreement with Unlearn.

In light of the critical importance of trade secrets in the biotech, life sciences and AI sectors, it is imperative for companies to work with experienced trade secrets counsel who possess scientific backgrounds and a deep understanding of these industries. Counsel with multidisciplinary expertise in life sciences, biotech and AI can help create and maintain robust trade secret portfolios, ensuring that valuable intellectual property is adequately protected. Additionally, their specialized knowledge is essential in defending against trade secret claims. Ensuring proper trade secret and legal strategies and protections are in place not only mitigates the risk of costly litigation, but also supports the continued advancement of groundbreaking therapies and technologies.

Summer Associate, Edwin Chikukwa, assisted with writing this post.

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