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Court Finds Access to Botox Trade Secrets and Similarity of Competitor Product Supported Inference of Trade Secrets Misappropriation

Minding Your Business on **February 26, 2024**

Proving access to and use of trade secrets are core elements in a trade secrets misappropriation case. Recent rulings in a trade secrets action filed by Allergan against its competitor Revance Therapeutics ("Revance") provide helpful guidance on what is sufficient to plead these elements. There, the court explained what facts are—and are not—sufficient to infer access to and use of trade secrets allegedly misappropriated. The court also explained how examining the similarity of design may help in this analysis. Finally, the court clarified that the ability to reverse engineer alone may not always preclude trade secret protection.

Plaintiff Allergan, a pharmaceutical company that manufactures and sells botulinum neurotoxin (BoNT) injectable products (under the trade name Botox) and dermal fillers (under the trade name Juvéderm), filed suit against its competitor Revance in May 2023. Allergan alleged that its development of confidential know-how concerning BoNT regulatory, technical, and manufacturing efforts have been critical to Botox's success. As such, it further alleged that it took significant precautions to ensure the confidentiality of its trade secrets, including implementing written policies and procedures governing its information technologies and limiting access to its trade secrets to certain employees.

As to its allegations against Revance, Allergan alleged that Revance misappropriated its trade secrets and repeatedly poached Allergan employees with access to those secrets, including certain high-level executives. In support of its misappropriation allegations, Allergan claimed that Revance's misappropriation scheme has allowed it to produce a biosimilar imitating Botox that would be "very challenging (if not impossible) to produce" without access to highly confidential information. That information, according to Allergan, includes its unique potency reference standard used to assess whether manufactured products fall within acceptable potency levels, as well as its regulatory best practices, manufacturing information, drug substance characterization analysis, critical reagents, validation techniques, and stability data.

In response, Revance promptly moved to dismiss, calling Allergan's complaint "an anticompetitive attempt by Allergen to preserve its place in the market for injectable botulinum toxin therapies." Revance asserted that to state a claim for trade secrets misappropriation requires more than simply alleging that Revance hired hired Allergan's former employees. Revance also argued that Allergan's complaint failed to describe with particularity the trade secrets that it allegedly misappropriated. In Revance's words, the "laundry list of purported trade secrets are so broad as to encompass every aspect of Allergan's business" and the "run-of-the-mill business information" described in the complaint was too vague to state a valid claim.

District Judge Eli Richardson disagreed, denying Revance's motion to dismiss. The court noted that one former Allergan employee had accessed and downloaded documents containing confidential information, and another prepared and shared a presentation containing Allergan trade secrets in connection with her Revance job interview. The court found those actions sufficient to plausibly allege that Revance acquired trade secrets. In its use analysis, the court acknowledged that Revance is currently seeking FDA approval for a potency testing method comparable to the method used by Allergan. The court also noted that, despite the fact that Revance's biosimilar has not yet been approved by the FDA or hit the market, the trade secrets described in the complaint are "precisely the type of information that an applicant would typically submit to the FDA about a particular biologic product to obtain biosimilar approval." As such, the court inferred use of the trade secrets based on access and similarity. Moreover, in finding that Allergan's claim for misappropriation could go forward, the court determined that Allergan's warning letter sent to and acknowledged by Revance sufficiently showed that Revance knew or should have known that its new employee had access to Allergan trade secrets and that the employee had a duty of secrecy to Allergan. However, the court found an offer of employment insufficient to show that the acquisition occurred by improper means where the complaint did not allege that Revance did not actually use the trade secrets. To this end, the court did not find it plausible to "infer from this fact alone that Defendant induced [the employee] to breach her duty to maintain secrecy."

Finally, the court rejected Revance's argument that because certain trade secrets could be reverse engineered, they were "readily ascertainable through proper means," such that they would not be afforded protection. The court noted that "[e]ven if a trade secret could potentially be discovered through reverse engineering but it would be expensive, difficult, time-consuming, impracticable, or for any other reason not a reasonably desirable option, then trade secret protection would still apply."

Key Takeaways

- In assessing whether a party used misappropriated trade secrets to manufacture its products, the relevant inquiry is whether the unique features of that party's products resemble the trade secrets to which it supposedly had access. Here, where the Botox biosimilar is not yet FDA approved, Allergan's allegations that the information was the type that would be required in order to develop and obtain FDA approval of a biosimilar were sufficient.

- Information may only qualify as a trade secret if it is not generally known or readily ascertainable through proper means. The fact that something can be reverse engineered may make it ascertainable, but not necessarily *readily* ascertainable.
- An offer of employment *alone* does not give rise to an inference that an individual was induced to breach her duty of secrecy. Such an inference would require additional facts, such as allegations that the benefits and perks of the employment offer were contingent in some way on disclosing trade secrets.

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