

# Life Science Industries, Trade Secrets, And The ITC

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Trade secrets are among a life science company's most valuable assets, allowing it to obtain and maintain a competitive edge on the open market. As such, trade secrets are the cornerstone of a life science company's success and profitability. The development of these trade secrets, and of the technology behind them, requires a company to expend vast resources, including its time and money. The tradeoff,

however, can be very lucrative. Competitors, therefore, may be tempted to avoid making those large investments and instead profit from trade secrets obtained illicitly. Life science companies possessing valuable trade secrets must therefore be mindful of the serious threat of trade secret misappropriation, proactively guard against it, and effectively respond in the event trade secrets are stolen.

Trade secret misappropriation can occur in a number of ways but is most commonly a result of one of the following: (1) external theft by outsiders to the company who should not have access to any trade secrets; (2) internal theft when current employees leave with sensitive information that they have or had access to by virtue of their employment but should no longer have or use; (3) breach of confidentiality agreements with third parties; and (4) employee poaching, when employees with knowledge of the inner-workings of the company are hired by a competing venture to improperly exploit that knowledge.

If a company falls victim to trade secret misappropriation, there are several ways it can seek a remedy, including negotiation, civil litigation, and, under some circumstances, criminal prosecution. In this article, we explore cases of trade secret misappropriation brought before the International Trade Commission (“ITC”). Specifically, we will highlight examples of how alleged trade secret misappropriation occurred and discuss what can be done to prevent similar instances from happening. Lastly, we consider the benefits of utilizing the ITC as a venue in cases of misappropriated trade secrets.

## External Theft

Granting access to sensitive information or materials (or to where they are stored), sharing information with non-authorized persons or third parties, or falling victim to cyber security attacks could all lead to the theft of confidential trade secrets. For example, in *Certain Botulinum Toxin Products and Processes for Manufacturing or Relating to the Same*, Inv. No. 337-TA-1313, the alleged trade secret misappropriation occurred when an employee of Medytox, a prominent Botox company, granted an unauthorized third party access to a restricted area. Medytox’s CEO Dr. Hyun Ho Jung allowed Professor Yeon Soo Seo to visit his research lab without a prior appointment or proper authorization. During this visit, Medytox claims that Seo allegedly obtained a sample of a proprietary strain of *C. botulinum*. The stolen strain of bacteria then turned up in botulinum neurotoxin drug products marketed and sold by Hugel, Inc.

External theft can also occur virtually. Like any other company operating in today's digital world, life science companies are vulnerable to cyberattacks, including phishing schemes, system hacking, and malware to name a few. These attacks can result in the theft of many types of information, including a company's trade secrets.

Preventative actions can be taken to ensure that trade secrets are not lost to external theft. Companies focused on innovation, such as life science companies, may be more inclined to share confidential information with others in the spirit of collaboration. For example, companies may find that their scientists, often trained in academia, may be accustomed to an environment of open discussion and shared findings. Companies may also be looking to expand its team of researchers or other personnel and offer to provide a behind-the-scenes look at its projects or technology as a recruiting tool. Whatever the scenario may be, protective measures to mitigate the risk that unauthorized personnel have access to and ultimately obtain confidential information are essential. First and foremost, companies should consider placing restrictions on who can access confidential business information and trade secrets, such as using passwords, limiting access to sensitive information to essential personnel, and restricting remote access to vital confidential information. For example, a life sciences company with trade secrets concerning chemical formulas or pharmaceutical development may want to consider whether marketing and business personnel require access to these trade secrets or whether such access should be limited.

Other protective measures may include preapproving any visitors who may have access to secure areas, keeping detailed activity and sign-in logs, and ensuring that visitors are accompanied by an employee at all times. It may also be beneficial to have all outside visitors sign a non-disclosure agreement so as to provide notice as to the confidentiality duties required in relation to the visit. This is especially helpful when inviting others to meet with researchers in lab spaces.

To protect against cyberattacks, life science companies should implement the same measures as any other company with sensitive information housed digitally. This includes having secure networks with robust cybersecurity measures, such as firewalls, antimalware programs, and strong password protection, and provide employees with regular cybersecurity trainings.

Certain aspects of employees working remotely, which has become much more prevalent in a post-Covid world, can also make companies more vulnerable to external

theft of trade secrets. Companies should guard against employees connecting to unsecure Wi-Fi networks, using personal e-mail to exchange confidential business information, leaving computers or phones unattended in public, or storing sensitive information on personal devices.

## Internal Theft

Arising even more frequently than external theft is internal theft, which occurs when company employees misappropriate trade secrets from their employer. For example, in another case involving Medytox, the company claimed an employee stole a sample of a proprietary *C. botulinum* bacteria strain along with confidential documents detailing the company's top secret Botox manufacturing process and thereafter allegedly delivered these trade secrets to competitor Daewoong Pharmaceuticals Co. in exchange for a job. *Certain Botulinum Toxin Products, Processes for Manufacturing or Relating to Same and Certain Products Containing Same*, Inv. No. 337-TA-1145.

Preventing internal theft may seem like a difficult task, especially because it involves protecting against individuals who may rightfully have access to confidential business information or the trade secrets themselves. A critical first step any company can take is to foster a corporate culture that emphasizes the importance of the duty of confidentiality. This may include having employees sign non-disclosure agreements and agreements detailing the ownership of intellectual property, providing frequent trainings as to the company's policies on protecting trade secrets, and educating new and current employees as to what the company considers trade secrets and how employees are expected to handle confidential information throughout and after their employment.

Measures put in place to prevent external theft can also be helpful in preventing internal theft, such as keeping detailed logs of employees who have access to secure areas or information and securing confidential information either physically or virtually with passwords. It may also be beneficial to limit the number of employees who have access to trade secrets which in turn limits the number of potential exit points. A life science company with trade secrets concerning testing procedures and protocols, for example, may only want those involved in such procedures to have access to this information as opposed to other departments in the company, such as the marketing or sales departments. Conversely, if a life science company has trade secrets concerning customized client lists, it may be beneficial to limit researchers' access to this information, for example, if it is not needed in their work.

This is not an exhaustive list of actions that may be taken, however. Companies should consider the nature of their trade secrets and how they are stored to determine the best way to protect the information. For example, where a trade secret could be leaked through a physical sample, such as in the Medytox case, life science companies may want to implement exit procedures to ensure departing employees do not leave with any samples. And where trade secrets are data, exit procedures should ensure departing employees return all work devices and lab notebooks, and confirm the return or destruction of all company information on personal devices and at home.

Guarding against internal theft requires some level of trust with your employees. Nevertheless, mitigating the risk in the event a bad actor indeed lies within your company is paramount, and having strong internal protections is a key building block to trade secret protection.

## **Breach Of Confidentiality Agreements**

Companies must also be wary of trade secret misappropriation resulting from a breach of confidentiality agreements with business partners, suppliers, or other collaborators. Even with the use of confidentiality clauses and non-disclosure agreements, a company's trade secrets may be at risk simply from the exchange of confidential information with collaborating third parties. For example, in the event business relationships may sour, third parties may attempt to circumvent the technical wording on the confidentiality or non-disclosure agreement and use the confidential information it learned for its own advantage.

For example, in *Certain Selective Thyroid Hormone Receptor-Beta Agonists, Processes for Manufacturing or Relating to Same, and Products Containing Same*, Inv. No. 337-TA-1352, the complainant alleged that a foreign competitor took information revealed under a non-disclosure agreement relating to the development and commercialization of thyroid hormone receptor drug under the guise of expanding distribution abroad. Instead, the competitor allegedly later used that confidential information to promote competing interests in developing their own drug. Similarly, in *Certain Modified Vaccinia Ankara and Vaccines and Pharmaceutical Compositions Based Thereon*, Inv. No. 337-TA-550, competitors allegedly stole trade secrets relating to the production and commercialization of a safer medication despite signing a non-disclosure agreement. The competitors then used the confidential information it learned to develop a competing product.

As discussed above, confidentiality and non-disclosure agreements are an important first step in protecting a company's trade secrets, but more must be done. Before entering into any potential collaboration, life science companies should research their potential collaborator, including any prior disputes or legal actions in which it may be involved, and inquire about the procedures it has in place to protect confidential information. Life science companies should also limit discussions with potential collaborators to high-level and publicly available information until the parties enter into proper confidentiality and collaboration agreements.

Once the parties agree to work together, any confidentiality or non-disclosure agreement should be specifically tailored to the collaboration project and provide unambiguous notice to the receiving party as to the expectations of how, if at all, that information may be used or further disseminated. Setting clear expectations may help avoid misappropriation of trade secrets shared during the collaboration. Even more so, if enforcement of an agreement is necessary, well-tailored confidentiality clauses can provide the basis for a breach of contract claim in federal or state court as an alternative or additional claim aside from trade secret misappropriation.

## Employee Poaching

With the increased mobility of employees' careers today, the risk of trade secret misappropriation is at its highest when departing employees who have either worked with, or even developed, a company's trade secrets leaves and becomes employed by a competitor. In some instances, employees will go to a competitor for innocuous reasons, but in other instances, competitors may seek out and poach specific employees specifically to benefit from their confidential knowledge. For example, this was allegedly the case in *Certain Adalimumab, Processes for Manufacturing or Relating to Same, and Products Containing Same*, Inv. No. 337-TA-1296. There, a competitor hired employees involved with Humira's top-secret manufacturing process, allegedly for the purpose of establishing a manufacturing facility in accordance with the poached employees' knowledge of Humira's production and commercialization strategies.

To avoid loss of trade secrets through employee poaching, as discussed previously, life science companies should take proactive measures to ensure a company-wide culture that emphasizes the importance of confidentiality and gives employees clear guidelines on what is considered a trade secret and how to properly handle confidential information both while currently employed and after. For example, life

science companies should conduct exit interviews that include a review of all applicable non-disclosure agreements and procedures on how to return any confidential information the employee may have had in his or her possession. This also includes ensuring that former employees are no longer able to access a company's network after leaving. This issue arose in *Certain Activity Tracking Devices, Systems, and Components Thereof*, Inv. No. 337-TA-963, where former employees of a fitness tracking company allegedly continued to access files relating to the underlying technology.

Companies should also consider separation policies and procedures to minimize the risk that departing employees will share critical trade secret information with competitors. For example, separation agreements should set forth clear expectations for maintaining confidentiality and include incentives and/or penalties that may lessen the likelihood of trade secret misappropriation. Life science companies may also want to consider entering into noncompete agreements for certain key employees as an additional preventive measure, if allowed in their jurisdiction. However, use of noncompete clauses may be coming to an end in the US, in light of the Federal Trade Commission's proposed rule banning employers from imposing noncompete clauses on workers, making other preventive measures more critical.

While non-disclosure, separation, and noncompete agreements will control the behavior of most former employees, it is important for life science companies to take a "trust-but-verify" approach and continually audit whether its trade secrets have remained secured particularly where departing employees worked with especially valuable or profitable trade secrets.

## **Seeking Remedy At The ITC**

In each specific example discussed above, the injured parties were able to seek remedies at the ITC. While the ITC is more commonly known as a venue for patent infringement cases, it has a broad range of authority to hear actions arising from a variety of unfair trade practices, including trade secret misappropriation. In recent years, life science companies have used the ITC as a forum for trade secret misappropriation more frequently. Should your company fall victim to trade secret theft, seeking a remedy at the ITC may be a viable and even preferred option.

Below is a non-exhaustive list of benefits to litigating before the ITC, specifically for trade secret misappropriation:

- **Clarity of Standard.** Bringing a trade secret misappropriation claim at the ITC may provide a more predictable framework for determining the relevant standards and likelihood of success. Unlike state or federal district courts, which may apply the trade secret misappropriation laws of a particular state, the ITC uses federal law. State trade secret laws can be quite similar but may have fine nuances in who can bring an action, what qualifies as a trade secret, when trade secrets must be identified in litigation, what actions constitute misappropriation, and what type of remedies are available.
- **Exclusion Orders.** Though the ITC does not provide monetary damages, it is easier to obtain injunctive relief at the ITC than in the district courts, because exclusion and cease and desist orders are the only remedies available at the ITC. This is beneficial if your main objective is to halt adverse activity as soon and as completely as possible.
- **No Statute of Limitations.** Remedies at the ITC are prospective in nature. As such, there is no statute of limitations precluding complainants from bringing trade secret misappropriation claims as opposed to in district courts, where the statute of limitations precludes a party from bringing trade secret actions after two to five years. If the statute of limitations possibly have or have expired in your case, the ITC may provide a suitable forum to still seek a remedy.
- **Broad Jurisdiction.** The ITC's jurisdiction extends beyond the borders of the United States, allowing complainants to seek remedy for harm caused by any products imported into the country that were developed through unfair trade practices, regardless as to whether the unfair activity occurred entirely abroad. The ITC's expansive extraterritorial reach therefore can be helpful in situations where traditional service is impossible or impracticable because the respondent remains outside of the United States when a complaint is filed.
- **Speed of Adjudication.** Trade secret misappropriation claims may take years to resolve in district court. The ITC provides rapid adjudication. Complainants can expect a disposition on the merits within 15 to 18 months. Compared to district court actions, investigations at the ITC can provide more immediate relief.
- **Preclusive Effects.** Although the ITC is limited to providing injunctive relief, the decisions rendered at the ITC relating to trade secret misappropriation and other non-patent issues generally have preclusive effect on future disputes in

the district courts. Favorable determinations at the ITC can support further favorable decisions for monetary damages in parallel litigation at the district courts.

The ITC is a viable, effective, and efficient forum to adjudicate trade secret misappropriation claims. Even with the best measures in place, trade secret theft remains a possibility for any company. In the event your life science company's trade secrets have been stolen, it is worth considering filing a complaint with the ITC. Troutman Pepper has a robust intellectual property practice that specializes in ITC litigation and can assist in counseling and ultimately pursuing your claims.

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