Professional Perspective

Biotechnology & Trade Secret Protection

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In the biotechnology industry, the high cost of technology innovation and bringing products to market necessitates broadening the impact of research investments. Collaboration to develop the next nascent technology presents ownership risks to the developed intellectual property, particularly when a partnership sours or employees perceive better opportunities elsewhere.

In such a situation, these new technologies and their embodied intellectual property, particularly trade secrets, could be quickly lost along with the expected market advantage. The remaining option in many cases is litigation, which is an imperfect solution to correcting the lost market opportunity. But proactive measures can either deter intellectual property theft or improve odds in litigation. This article identifies three lessons learned from recent disputes to help companies improve their intellectual property protection.

Identify Trade Secrets with Specificity

Pleading rules require that a party assert facts sufficient to put a defendant on notice of the basis for the claim. In a trade secret case, an early and avoidable misstep is not sufficiently identifying asserted trade secrets, which may lead to delays in obtaining discovery, or denial of a preliminary injunction. In preparation for filing suit, a plaintiff should identify their trade secrets with more granularly than by simply identifying broad categories of information.

Trade secrets should be pled "with sufficient particularity" so as to allow an accused defendant to "ascertain at least the boundaries within which the secret lies." *Five Star Gourmet Foods, Inc. v. Fresh Express, Inc.*, No. 19-cv-05611, 2020 BL 34861 (N.D. Cal. Jan. 31, 2020). Even absent pleading requirements, some jurisdictions include mandatory identification disclosures of asserted trade secrets before any discovery may commence. Thus, in preparing for the lawsuit, it is prudent to spend time contextualizing the asserted trade secrets to avoid unnecessary delay.

Of course, disclosure for purposes of providing notice to a defendant regarding the asserted trade secrets presents the tension of accidentally disclosing the trade secret in a public filing that initiates the lawsuit. While a defendant may push for greater and greater specificity, and place the trade secret in greater risk, a common, and what should be acceptable, middle ground is defining specific categories of information that provides some detail of the content but is not the actual information.

The identification of types of information that may be a trade secret, found in trade secrets statutes, can act as a guide. Identifying categories of information at a level of specificity equivalent to the statutory identification is likely not enough, and should be coupled with more specific company/industry/technology-specific information.

Absent the requisite particularity, a case may be dismissed in its entirely. For example, the court dismissed a case brought by Human Longevity, Inc. (HLI) against its founder's new company, the J. Craig Venter Institute, after HLI could neither plead the existence of a trade secret nor misappropriation. *Human Longevity, Inc. v. J. Craig Venter Institute, Inc.*, No. 18-cv-1656, 2018 BL 471162 (S.D. Cal. Dec. 18, 2018). HLI attempted to claim trade secret status over "bi-weekly business development updates, leadership updates, executive summaries, and weekly reports" related to its "Health Nucleus," which is a platform integrating genomics, advanced imaging and machine learning to provide clients with an assessment of potential health risks. HLI's expansive allegations lacked particularity. Moreover, the court reasoned, dismissal of the complaint was warranted because no facts were alleged that would have been adequate to infer improper acquisition or disclosure by Dr. Venter.

In a more recent case involving genetically modified seed, Syngenta Seed's trade secret claims survived a motion to dismiss because its Second Amended Complaint described "at least some trade secrets with enough particularity for the pleading stage." *Syngenta Seeds, LLC v. Warner, et al.*, No. 20-cv-1428, 2021 BL 61423, at *12 (D. Minn. Feb. 22, 2021). This included "data generated from pan-genomic analytics" and genotyping data, as well as data about corn and soy breeding programs and results for a corn drought program.

Even if a case proceeds beyond the pleading stage, a plaintiff may find the scope of its case narrowed if it cannot sufficiently describe its trade secrets. In a discovery dispute in a case between former joint venture partners, a district court ordered

Quintara Biosciences to provide a summary description for each trade secret, as well as an explanation for how it derived economic value by virtue of not being generally known, as well as a description of the ways in which it had been the subject of reasonable efforts to maintain its secrecy. *See Quintara Biosciences, Inc. v. Ruifeng Biztech Inc.*, No. 20-cv-04808, 2021 BL 91524 (N.D. Cal. March 13, 2021).

The plaintiff provided adequate disclosures for its customer profile database, explaining that it included purchase and payment histories, as well as customer feedback, and that it was used to tailor its communication with customers and to guide internal business planning. It also explained that its vendor database included its purchasing plans and business arrangements with third-party service providers essential to its operations, and was used to tailor purchasing decisions and guide negotiations with vendors for future purchases. Though Quintara Biosciences' descriptions were "minimal," they were adequate for the purpose of allowing discovery to proceed.

By contrast, Quintara described nine additional trade secrets primarily by identifying categories of information, such as "laboratory protocols and recipes, informatics and marketing plans" for its Turbo DNA Sequencing Service, with the product goal of completing sequencing reactions within short time periods. The court narrowed the scope of Quintara's trade secrets, as pled, reasoning that "[p]resumably all providers of DNA sequencing services seek to do it faster," and plaintiff cannot "preempt the entire field just by claiming [] trade secret" status.

When a trade secret "consists of incremental variations on, or advances in the state of the art in a highly specialized technical field, a more exacting level of particularity may be required to distinguish the alleged trade secrets from matters already known to persons skilled in that field." Similarly, Quintara failed to identify its house-customized computer code—for plasmid map viewing, editing and alignment—with particularity. Although the computer code might be valuable, Quintara offered no description to distinguish its computer code from its competitors' code for doing precisely the same things.

These cases instruct that the trade secret assertions that succeed are the ones in which a plaintiff invests in sufficient diligence to be able to describe the trade secrets at each stage of litigation, and to adequately support those claims with documentary evidence. Absent early preparation, there is a greater risk that an assertion is delayed by early motion practice asserting insufficient disclosure.

Public Knowledge & Trade Secret Status

In general, trade secret protection does not extend to information that is known to the public. Still, simply because certain information is in the public domain does not mean any use of that information is not protectable. Combination of publicly available information in a nonpublic way may be afforded protection. For example, in a dispute between CardiaQ and Neovasc, former collaborators over transcatheter mitral heart valves, a jury awarded $70 million in damages to CardiaQ for Neovasc's trade secret misappropriation. *CardiAQ Valve Technologies, Inc. v. Neovasc Inc.*, 780 F. App'x. 654 (Fed. Cir. 2017).. Neovasc argued unsuccessfully that two of the trade secrets were not entitled to trade secret status because they included publicly available knowledge.

First, Neovasc argued a trade secret related to a valve prosthesis design was simply a combination of known elements. But a combination of known components may be protectable so long as the "unified process, design, and operation" is unique. Here, Neovasc's own expert admitted that the full combination of features did not exist anywhere in the prior art. Second, Neovasc argued that a trade secret related to the mandrel used to construct the valve had been disclosed in a patent application.

However, the application did not provide as much information as was available to Neovasc—which had access to a physical mandrel and CAD design information. Neovasc therefore had access to information that was nowhere in the patent filing, including precise dimensions, manufacturing details, and materials.

As reinforced in *Pioneer Hi-Bred Int'l. v. Holden Found. Seeds, Inc.*, 35 F.3d 1226, 1229 (8th Cir. 1994), whether a trade secret is publicly accessible is highly fact dependent. Defendant Holden Foundation Seeds challenged whether the plaintiff Pioneer had taken reasonable precautions to protect the genetic sequence of hybrid corn, the alleged trade secret. The trial court determined Pioneer had taken reasonable precautions, despite public distribution and use of the genetically modified seed.

Fields in which the seed was grown were deliberately unlabeled, and bags of seeds were identified only by code. Pioneer additionally co-mingled the protected seeds with other seed varieties to make it more difficult to identify and obtain the

seed containing the relevant genetic sequence. Additionally, Pioneer's seeds "did not exist outside [of its own] fields and its contractors' fields," and its contractors were under a non-disclosure obligation.

The *Pioneer Hi-Bred International* case also reinforces the value of securing agreements to limit the potential dissemination of trade secrets for embodying products that could be reverse engineered. While in general reverse engineering of a product is a legitimate way to obtain information about that product, and potentially embodied trade secrets, the product itself must be obtained through proper means. Again, the issue is fact dependent.

For example, in *Atricure, Inc. v. Meng*, No. 20-3264, 842 F. App'x 974 (6th Cir. 2021), Atricure sued its former distributor for misappropriation of trade secrets on cardiac ablation technology, which included an ablation/sensing unit (ASU) as well as a switch box and single use clamps and pens. The distributor had designed an adaptor that would work with Atricure's ASU, but allow it to be coupled to the distributor's own products instead.

The parties, however, had signed a distribution agreement that included a non-compete clause. The district court granted Atricure's motion for a preliminary injunction, finding that the distributor's production and distribution of its adaptor amounted to misappropriation of Atricure's proprietary source code in its ASU. Although the distributor's own adaptor used completely different software, the distributor nonetheless profited from the adaptor's interaction with Atricure's ASU software. Absent any contractual obligation, such a design might have fallen into the category of non-protectable reverse engineering.

Circumstantial Evidence

A plaintiff may prevail even if it lacks direct evidence of trade secret misappropriation. Many courts have recognized that it is exceeding difficult to find "direct evidence of industrial espionage[.]" *Pioneer Hi-Bred Int'l.*, 35 F.3d at 1239. This challenge presents opportunities for creative establishment of various lines of proof to build a story based on circumstantial evidence that may convince a trier of fact that the conclusion is consistent with a determination of misappropriation. This is where a litigation team with diverse perspectives and experiences can be an asset to develop explanations for why the circumstantial evidence implies misappropriation, as well as to explain away alternative theories of the meaning of the available circumstantial evidence.

For example, again in *Pioneer Hi-Bred*, Pioneer lacked evidence addressing how Defendant Holden obtained the hybrid seeds alleged to contain the trade secret genomic sequence. Pioneer successfully proved misappropriation through historical activity of Holden, including that Holden had a long history of "doing anything he could" to obtain Pioneer's corn seed, and Pioneer had a full record showing how it developed its seed corn.

Similarly, in an ITC enforcement action brought by two Korean companies against their U.S. licensee for Botox treatments, the Korean companies lacked evidence that their former employee, hired by the licensee, facilitated the misappropriation. Instead, the Korean companies relied on expert testimony and genomic sequence comparisons demonstrating that their relatedness of certain identical nucleotide polymorphisms at the same nucleotide positions in a DNA sequence was effectively impossible.

Conclusion

The right assets and the right talent make all the difference in the biotech industry. That may mean collaborating with other companies, or outsourcing certain aspects of product development. It may also mean that a handful of employees will develop deep technical expertise, essentially possessing the keys to the kingdom. Any of these scenarios present the risk of trade secret misappropriation, which explains why many of an estimated 1,500 trade secret cases each year involve a bioscience company.

In high-pressure, high-stakes litigation, every company wants to maximize its chances of success. By carefully and proactively shaping a case to avoid common litigation pitfalls, companies can improve their intellectual property protection.