



Latest developments in trade secrets strategy and enforcement

Trade secret litigation soars in the life sciences industry

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The life sciences industry is experiencing a surge in trade secret litigation. While 2016's Defend Trade Secrets Act (DTSA) undeniably contributed to this rise, the full story is more nuanced and implicates trends in the life sciences industry more generally. Multiple factors have contributed to the recent increase in trade secret cases across the US.

First, trade secret enforcement is inversely proportional to patent enforcement. Recent developments in patent law, in particular the limitations on the patentability of inventions taking advantage of “laws of nature”, “natural phenomena”, or “abstract ideas”, have increased the importance of using trade secrets in both the pharmaceutical and biotech industries. Life sciences patents have been curtailed in other areas as well, as recently highlighted by the Supreme Court's decision in *Amgen v Sanofi*, which involved functional claiming of antibodies.

Second, the relative volume of confidential data and other information that may be protectable by life sciences companies—whether arising from R&D efforts or in the clinic—has increased dramatically, due to the industry's reliance on larger and larger amounts of data as well as the ability to put such “big data” to better use.

Third, there is increased employee mobility in the life sciences sector, and increased overlap in companies, small and large, working in the same “hot” spaces in the life sciences—such as vaccines, gene therapy, immuno-oncology, or the science of pain (just to name a few). This article discusses some of these industry trends and how they intersect with life sciences trade secret litigation since the passage of the DTSA.

The DTSA adds a federal civil cause of action for trade secrets

Traditionally, litigators relied on the Uniform Trade Secrets Act (UTSA) and parallel state laws as a guiding framework for trade secret proceedings. The DTSA, enacted on 11 May 2016, changed the landscape by establishing a federal civil cause of action for trade secret misappropriation, thus giving plaintiffs easier access to federal district courts.

The DTSA's definition of trade secrets is broad, resulting in a greater range of information falling within trade secret protection. The DTSA additionally offers the potential seizure of property, injunctive relief, double damages, and a whistleblower safe harbor. As a result, the DTSA introduced a new era in trade secret litigation: it added a tool for companies to protect and enforce

their intellectual property rights, and it largely guaranteed access to an additional forum for such actions (federal court, in addition to state court).

The weakening of patent claims and patent enforcement

Although the DTSA undoubtedly contributed to the rise of trade secret claims in the life sciences, it cannot be credited with all of the increase. Interestingly, multiple court decisions over the past decade have weakened patent claims in the life sciences, likely leading to a rise in trade secret cases.

Many patent claims have been trimmed for eligibility reasons because they are “directed to” natural phenomena, laws of nature, or abstract ideas. This growing body of case law, stemming from the Supreme Court’s *Mayo/Myriad/Alice* trilogy, raises concerns about the future value of life sciences patents—not just those that involve a software or computer component, but also those directed to important discoveries in disease detection, prediction, and analysis. For example, innovations in the diagnostics industry often rely on identifying small molecules, nucleic acids, proteins, or other biomarkers, and then correlating their presence, absence, or amounts to certain disease states.

Patent protection for diagnostic inventions has taken a serious blow since the *Mayo* case, where the Supreme Court held that the process involved in the patent for testing proper dosage levels of drug treatments was an unpatentable law of nature.

Consequently, many life sciences companies now choose to retain their R&D data and diagnostic information as trade secrets. These companies believe it is safer to keep such information undisclosed as a trade secret rather than disclose it in a patent application, only to risk that patent later being declared ineligible or unenforceable.

In addition to the patent eligibility problems that life sciences patents now face, the recent Supreme Court case *Amgen v Sanofi* highlights the challenges in meeting the enablement requirement under 35 U.S.C. § 112(a) for patents with “functional” claims.

In *Amgen*, the Supreme Court found that Amgen’s patents failed to provide enough information to enable others to make and use the entire class of antibodies covered by the patent claims. The *Amgen* decision, while not necessarily revolutionary, solidifies the law in this area and will make it more difficult for life sciences companies to obtain broad patents with functional claims, such as those previously obtained for antibodies.

Finally, in asserting method claims, life sciences companies often face issues with respect to induced infringement or divided infringement. In cases of divided infringement, multiple parties perform different steps of a patented method. This makes it challenging to hold any single entity liable for the entire infringement. For example, diagnostic tests often involve multiple actors—laboratories, health care providers, and even patients themselves—who may contribute to different stages of the testing or treatment process. Proving that a single entity “directs or controls” another’s action or participation in the infringement—which is a requirement in a multiple-actor case if one does not wish to sue each actor separately—can be very difficult.

In sum, all of these developments place a thumb on the scale in favour of trade secret protection, rather than patent protection, for certain kinds of life sciences innovations.

Enhanced reliance on confidential data

Confidential information created during R&D programs and clinical studies offers life sciences companies a significant edge against their competitors. As companies generate, store, and mine more of this kind of data, trade secrets become a more popular choice for IP protection against competitors.

Whether coming from R&D activities or the clinic, the volume of sensitive data and other information that many life sciences companies now possess is staggering. And, the amount of potentially useful data that companies are generating has increased as more companies seriously incorporate artificial intelligence and machine learning into their research programs and analytical methods. If a company develops a nifty algorithm for finding molecules that bind previously “undruggable” targets, is that better protected with trade secrets or with patents? Similarly, if a company uses machine learning to predict a particular disease outcome based on genetic or phenotypic data, is that better protected with trade secrets or with patents? Trade secrets are often—though not always—the better fit for these data-driven innovations.

Moreover, biopharmaceutical companies are increasingly outsourcing their R&D, leaving them vulnerable to trade secret theft (or accusations of the same against them).

Sensitive information is shared with external suppliers during such outsourcing efforts, and the risk of an information leak is high. In *Eli Lilly v Emisphere Technologies*, for example, the parties established several licensing and collaboration agreements for new chemical carrier compounds used to treat osteoporosis.

The parties exchanged confidential information before the arrangement ultimately failed. Eli Lilly then allegedly organised a new, secret team engaged in related research. Emisphere sued Eli Lilly for breach of contract, but incorporated many trade secret misappropriation elements into its complaint. The case ultimately settled for a seven-figure sum. While *Eli Lilly* is a pre-DTSA case, it depicts a fact pattern that is quite common in life sciences collaborations, especially as less and less R&D is performed by large companies in-house. This case also highlights the frequent overlap between breach of contract actions for patent ownership, trade secrets, and inventorship actions.

Employee turnover and overlapping competition

The life sciences industry is experiencing greater employee mobility and company overlap as more businesses operate in the same "hot" areas of science, and as non-compete protections continue to erode.

Contracts, particularly in the form of nondisclosure agreements (NDAs), can strengthen and expand the scope of a trade secret claim. Breach-of-contract claims frequently accompany DTSA misappropriation claims and can substantially impact the outcomes of those cases. Companies often define their confidential information very broadly in NDAs, thereby increasing protection of their information vis-à-vis collaboration partners and employees.

New York recently followed California's lead by enacting laws largely eliminating employee non-competition clauses except under very narrow circumstances. Other large states may follow as well. This will allow employees more freedom to work for competitors immediately after leaving a job. While the California and New York laws are intended to promote employee mobility and prevent unnecessary restrictions on career opportunities, when coupled with the existence of strong NDAs and other confidentiality clauses, these laws will inevitably lead to a rise in trade secret litigation.

Moreover, technological advancements such as cloud computing, social media, remote work, and company-issued technology have made trade secret misappropriation easier, eliminating the need for physical presence in a particular office or room to access confidential information.

The concept of locking a file in a filing cabinet, or locking a bacterial strain in a refrigerator, is largely a thing of the past—because there is a high likelihood that the contents of the document or the genetic information from the strain exist somewhere electronically. Where a former employee has been closely involved with a propriety project, he or she may not even need to physically "take" material containing trade secret information, as that knowledge may be ingrained in the former employee's memory by way of long experience with the project.

Balancing strategies

Compared to the "tech" sector, the life sciences industry has been known for a greater reliance on patent protection and a greater resistance to change. With the passage of the DTSA in 2016, as well as the above-described changes in patent law and the life sciences industry itself, these two truths may no longer hold.

Trade secrets and the DTSA are not a cure-all, to be sure, and patents in the life sciences industry will continue to have value.

Nevertheless, the landscape for IP protection in the life sciences has become more complex. Thus, the importance of understanding a life sciences company's trade secret protectable (and enforceable) assets will only be heightened in the coming years.

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