

# SeyPharma

Keeping you on the right pathway



## Tips for Ensuring Your Competitors Do Not Steal the Valuable Fruits of Your Research and Development

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Every employer in the pharmaceutical industry is keenly aware of the need to ensure that a departing employee, a potential investor, or a business partner does not misappropriate the company's valuable trade secrets. If such valuable information falls into a competitor's hands, they may use it to gain a significant market advantage. Companies in the pharmaceutical industry face unique challenges because, while the fruits of their research and development are often protectable as trade secrets, companies are often required to communicate this valuable information to potential investors, partners, and governmental agencies, such as the U.S. Food and Drug Administration (FDA). Because pharmaceutical companies spend an extraordinary amount of money on research to develop new products, understanding how much of this valuable information is protectable as a trade secret, and how best to protect such information, is key to the company's success, regardless of whether its products are in early stage development or are well-established in the industry. This article is the first in a series about protecting trade secrets and enforcing non-competition agreements in the pharmaceutical industry.

### I. Trade Secrets Specific to the Pharmaceutical Industry

First we will address what kind of information you can protect and then we will explain how to protect it.

Companies cannot protect information contained in patent applications and patents as trade secrets, because they must disclose that information publicly to the U.S. Patent and Trademark Office (PTO) and ultimately to the public at large. However, there are many types of information at all stages of drug development, from the discovery phase through the commercial launch, that a company can protect as trade secrets. Indeed, the most sensitive information is often developed early in the process, before the company can even request a patent.

**Early Research & Development.** In the discovery or pre-clinical phase, a company generates a great deal of useful information that it can protect as trade secrets. Most of this information is intangible data, formulations, or processes, as opposed to tangible products. This includes, for instance, a "vision plan" (i.e., brainstorming of possible drug candidates, plans of attack, etc.), data regarding which candidates are viable and which pathway to follow, and early manufacturing techniques that the company has considered.

**Product Development.** During the development phase, a company generally produces more tangible products, processes, and data. For instance, during the clinical trials, a company can protect all of the following as trade secrets: lead candidate information, optimization data, bench trials, synthesis (organic or recombinant), formulations, safety and efficacy information, and clinical trial sites and data.

**Approval.** At the approval stage, a company can protect the following as trade secrets: FDA interactions, risk evaluation and management systems (REMS) data, current good manufacturing practices (cGMP), quality assurance and quality control (QA/QC), and ICH compliance. While the Company will have to share much of this information with the FDA to obtain approval, as discussed below, it can nevertheless maintain its trade secret status.

**Post-Approval.** Following the approval of a new drug, the most sensitive information is generally commercial in nature, such as sales data, marketing plans, customer lists, general marketing feedback, cost of goods sold (COGS), supply chain information and integrity, sales forecasts, adverse drug events, new indications, life cycle management, and new plans for related development.

## II. Protecting Trade Secrets

Information and data from the early stages of new drug research and development is arguably the most sensitive, because its misappropriation can lead to the most severe consequences. Specifically, a competitor could use misappropriated information to develop the same product and obtain patent protections before the original company even discovers that the information is missing. This is particularly problematic if the company utilizing the misappropriated information has greater resources and can develop the drug more quickly. Indeed, there are generally three motivations for misappropriating trade secret information during this early stage: (1) to directly compete by racing to develop the drug first; (2) to indirectly compete by creating another drug candidate in the same therapeutic class or by creating a combination therapy; and (3) to apply for patent protection under the new “race to file” system and thereby block out the original developer from doing so. Of course, information from the later stages is also highly important and must be protected, but that type of information—which is generally more commercial in nature—is less unique to the pharmaceutical industry, and there is not much commercial damage if the original company has patents in place.

We recommend the following processes to our pharmaceutical clients in order to ensure that you protect your valuable trade secrets: Implement and enforce strict post-employment restrictive covenants (i.e., non-compete and non-solicitation agreements) and non-disclosure or collaboration agreements with third parties (i.e., potential investors and partners) (stay tuned for part 2 of this series). In addition, you should create and disseminate internal and external policies and procedures (see part 3 of this series), including:

- Onboarding checklist and exit interview policies and procedures;
- Confidentiality policies and procedures (including annual training programs and disciplining or termination of employees who improperly disclose or use confidential information);
- Work from home policies and procedures;
- Internal notebooks that are marked confidential and kept in secure spaces, password protected computers, or clean rooms;
- USB usage policies and procedures;
- Social media and internet usage policies and procedures; and
- Cell phone usage policies.

Similarly, you should consider hiring an outside professional to conduct annual or semi-annual *trade secret audits* to determine how easy or difficult it is to exfiltrate sensitive information. You can even install mobile device management software that can protect sensitive information from being exfiltrated through mobile devices such as iPhones, and also permit the company to access and/or wipe company information if a mobile device is stolen or lost, or an employee leaves the company.

Finally, you may still maintain trade secret status for information that you provide to the FDA despite your limited disclosure for regulatory purposes. Federal regulations governing the FDA specifically exempt trade secret and confidential commercial or financial information from public disclosure by the FDA. Likewise, the federal Freedom of Information Act provides that a federal agency, such as the FDA, may withhold information if it constitutes or contains trade secrets, and certain patent, trademark, and copyright regulations permit companies to redact trade secrets from public filings, subject to certain limitations.

Of course, the best way to ensure that trade secrets are not disclosed, intentionally or otherwise, is to define clearly what information constitutes trade secrets and what your expectations are as to how your employees and investors/partners will treat such information. Moreover, you should only provide such information to those employees or potential investors/partners who need to know it, can be trusted, and are subject to strict post-employment restrictive covenants and/or non-disclosure agreements. The Company should also have a commitment to, and culture of, enforcing these agreements and company policies, and ensuring that anyone giving access to trade secrets understands the serious consequences of disclosure. This is not an easy task, but particularly in the pharmaceutical industry, where so much of a company's fortunes can be tied up in its ideas and development plans, it is imperative that the company take pains to do this correctly.

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