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Cleary's Pharma Bites

Trade Secrets:

The Super Supplement for Pharmaceutical IP

Cleary Gottlieb Pharmaceutical, Biotech and Healthcare Group

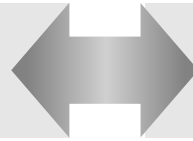
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Trade Secrets Can Supplement Patent Protection for Pharma IP

Innovations in the Pharma Industry

Patents



Trade Secrets

Pharmaceutical companies typically seek patent protection for new drugs and medical devices where possible, and for good reason:

- Can provide exclusivity for 20-year term of patent;
- Even when challenged by generics, Orange Book patents can provide up to 30 months of exclusivity while litigation is pending.

Trade secrets can provide a powerful supplement, especially for innovations that do not lend themselves to patents or would not qualify for Orange Book status.

A company developing a new pharmaceutical product can choose to patent some innovations and keep others as trade secrets to maximize the benefits of both.

Benefits of Patent Protection

20 years exclusivity

from the patent application date

Orange Book treatment

for certain types of patents.

- ✓ Patents for drug substance (active ingredient), drug product (formulation and composition) or method of use can be listed in Hatch-Waxman Act's "Orange Book."
- ✓ Orange Book treatment gives the patent's owner an automatic 30 months of exclusivity if challenged by a generic manufacturer through Paragraph IV litigation while the suit is pending.
- ✓ Successful infringement claim can result in court ordering that FDA's approval of the infringing competitor's product be delayed until expiration of the patent.
- ✓ On the other hand, Hatch-Waxman Act creates incentives to the first generic manufacturer to challenge an Orange Book patent, including 180-day exclusivity if challenge is successful.

Benefits of Trade Secret Protection

- ✓ Trade secrets do not expire, as long as kept secret
- ✓ Qualifying for protection is easier than obtaining a patent
- ✓ Although claims require proof that defendant improperly obtained trade secrets, the standard for establishing use is flexible
- ✓ Can provide effective remedies
- ✓ Can provide a basis for International Trade Commission (ITC) actions to bar importation of accused products

Trade Secrets Do Not Expire

Unlike patents, which expire after 20 years from application date, **trade secrets continue to be enforceable as long as they remain secret**. Trade secret protection therefore is a good fit for innovations that can be kept secret.

The manufacturing processes for a pharmaceutical product is a good candidate, because it is developed and operated in the company's confines.

— Plus, manufacturing processes are not eligible for Orange Book treatment.

By contrast, patent protection would be a better choice for a drug substance or drug product, given that such products are sold publicly and may be reverse engineered.

To establish and maintain protection, a trade secret's owner must engage in efforts that are reasonable under the circumstances to maintain its secrecy.

— Should be careful not to disclose in patent applications or articles concerning related innovations.

Qualifying for Trade Secret Protection Is Easier Than Obtaining a Patent

Obtaining a patent requires an innovation that is novel and non-obvious when compared to existing technology in the field. Also must qualify as eligible subject matter. The patent office will scrutinize applications to ensure they satisfy all statutory requirements.

Trade secrets, by contrast, need only have economic value from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from their disclosure or use.

Trade secret protection covers all forms of information.

— This includes formulae, manufacturing processes or techniques, business strategies, business management information, compilations (e.g. customer lists), programs, devices and methods.

Combinations of steps and elements that are themselves publicly known can qualify for trade secret protection.

Trade secret protection therefore applies not only to crown jewels, such as the formula for Coke, but also to more practical and incremental types of know-how, such as techniques for improving efficiency of production or purity of products.

Trade Secret Law Is Flexible As To Establishing Liability

Trade secret claims address misappropriation by improper means, such as breach of contract, violation of a confidential relationship, theft, bribery or misrepresentation.

- ▶ Thus, a claim requires a reasonable basis for alleging that the defendant has improperly obtained one's trade secrets.
 - For instance, a competitor may hire an employee with knowledge of the trade secrets and then subsequently develop a similar product.
- ▶ Once improper access has been established, the standard for establishing use of trade secrets is flexible.
 - Establishing improper use does not require that the competitor's process be an exact match. One need only show that the competitor benefitted from using the trade secrets in developing its own process, even if it makes modifications or improvements of its own.
 - By contrast, patent infringement requires showing that the competitor's product or process matches each element of the patent claims, which may enable it to escape infringement by making modifications.

Trade Secret Claims Can Provide Effective Remedies

Successful trade secret claims can produce powerful remedies: **injunctions and damages** (lost profits, disgorgement of profits, reasonable royalty).

Injunctions are typically tailored to offset the head start that a defendant achieved through its use of the trade secrets.

As with patent cases, attorney's fees can be recovered based on a showing of willful misappropriation.

The Manufacturing Process for Pharmaceuticals Is A Good Candidate for Trade Secret Protection

Several considerations point to trade secrets as a better option than patents for protecting a manufacturing process.

Maintaining secrecy:

The manufacturing process for a drug substance or drug product is ordinarily developed and operated in the confines of the company. It therefore can be kept secret and is not exposed to the same risk of reverse engineering as the resulting drug, which is sold on the market and available to competitors for reverse engineering.

Protection for practical and incremental improvements:

Trade secret protection does not require satisfying the stringent requirements for obtaining a patent. It can extend to practical and incremental improvements, even if they involve elements that are known in the field, as long as the process as a whole is not generally known or readily accessible to others in the field.

Ineligible for Orange Book treatment:

In contrast to patents for a drug substance, drug product or method of application, patents on a manufacturing process are not eligible for Orange Book treatment. Because this potential benefit of patent protection is not available, trade secret protection may be a better strategy.

Flexible standards for establishing use of trade secrets:

If a trade secret owner can establish that a competitor improperly obtained a trade secret – such as by hiring an employee with knowledge of the trade secret and then exploiting that knowledge – liability can be established by showing that the competitor used the trade secret in its development process. Making modifications or improvements of its own will not shield it from liability.

Trade Secret Claims Are Good Candidates for ITC Actions

Actions in the International Trade Commission (ITC) – referred to as Section 337 Investigations – can be effective for companies that participate in the U.S. market and seek relief against a competitor’s importation of products.

ITC cases move fast – with a goal of reaching a hearing within 9 to 12 months and producing a decision within 15 to 16 months.

If successful, ITC claims will result in an exclusion order prohibiting the importation of the competitor’s products and a cease and desist order barring the sale of products that have already been imported.

While the ITC is an effective forum for many patent cases, Orange Book patents are typically not seen as good candidates

- Because Orange Book patents enjoy exclusivity for up to 30 months while an infringement proceeding against a competitor is pending, the speed of an ITC proceeding – which might produce an unsuccessful outcome in far less than 30 months – may be seen as a disadvantage for the patent owner.

Trade secret claims can provide a good basis for ITC actions

- The ITC has jurisdiction over trade secret claims.
- An ITC action may proceed even if the trade secrets have been misappropriated and used outside the U.S., if the products that are developed or made with the trade secrets are imported into the U.S.
- While claimants in the ITC must establish a “domestic industry” that will be harmed by the respondents’ unfair competition, this may be satisfied based on a product that does not practice the trade secrets or by products of a licensee of the trade secret owner.

A pharmaceutical company could bring a trade secret case in the ITC, while also pursuing an action in court for infringement of an Orange Book patent.

Two Key Times to Consider Trade Secret Protection

When innovations are developed

- The development of a new pharmaceutical product typically involves extensive research and development with accompanying innovations.
- For each innovation, the viability and benefits of patent protection versus trade secret protection should be assessed.
- When innovations will be protected as trade secrets, care should be used to ensure that they are not disclosed in patents or publications and are the subject of reasonable efforts to maintain secrecy.

When another company has developed a competing product

- When a company has developed a competing pharmaceutical product, the creator of the original product should consider, in addition to potential patent claims, whether there is a basis for trade secret claims.
- This includes investigating possible means by which the competitor could have improperly obtained the trade secrets, such as by hiring an employee with knowledge of the trade secrets or obtaining access under a confidentiality agreement or joint venture agreement that was subsequently breached.
- When there is a basis for a trade secret claim, it may be pursued in addition to or instead of a patent infringement suit.

Cleary Gottlieb’s recent representation of Medytox in the ITC demonstrates the effectiveness of trade secret claims

Cleary Gottlieb

— recently represented a pharmaceutical company, Medytox Inc., in successfully pursuing a trade secret claim in the ITC.

Medytox

— was the first Korean company to develop and obtain regulatory approval for a botulinum toxin (BTX) product, akin to BOTOX®.

Another Korean company, Daewoong Pharmaceuticals, later developed a competing BTX product.

Medytox learned of facts suggesting that Daewoong misappropriated Medytox’s manufacturing trade secrets and *C. botulinum* strain.

When Daewoong and its U.S. distribution partner, Evolus Inc., gained FDA approval and introduced their BTX product in the U.S., Medytox launched an ITC case.

Allergan (now AbbVie), the maker of BOTOX®, joined Medytox as co-complainant, based on being the U.S. licensee of Medytox trade secrets. BOTOX® satisfied the “domestic industry” requirement for a Section 337 claim.

With the benefit of robust discovery in the ITC proceeding (which was not available in a parallel suit Medytox had filed in Korea), Medytox was able to establish that Daewoong had in fact misappropriated its manufacturing process and also had improperly obtained its *C. botulinum* strain.

This led to the ITC’s issuance of an exclusion order and cease and desist order banning the importation and sale of the Daewoong/Evolus products. That success in turn led to a favorable settlement with Evolus.

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Nowell D. Bamberger's practice focuses on complex civil litigation and government investigations, with a particular focus on cross-border matters.

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