

Protecting Trade Secrets in Life Sciences and Pharma

TROY GROETKEN
McANDREWS IP

CCBJ: To start off, please tell us what a trade secret is and how it differs from a patent or trademark.

According to the US Patent and Trademark Office (USPTO) a trademark is “a word, phrase, symbol or design that identifies your goods and services.” Identifying specific products or services as coming from a specific source distinguishes them from the product or services of other companies. If you see big golden arches, you know that’s a product from McDonald’s. Similarly, the unique contoured shape of a Coca-Cola bottle also indicates brand identity and qualifies as “trade dress,” which refers to the various elements used to package a product or service.

Patents or more specifically “utility patents”—the most common type—are issued by the USPTO for the “invention of a new and useful process, machine, manufacture or composition of matter, or a new and useful improvement thereof,” to protect the interests of the inventor by excluding others from making or selling the patented product during its patent term. For a patent to be issued, you have to meet the three requirements of patentability—novelty, non-obviousness and utility—and two sub-requirements, which are true requirements under 35 US Code §112—enablement and best mode. There’s also a written description requirement so after the patent expires, the patent can be used to teach the public how to implement the invention.

Just as trademarks can have a certain lifespan if you don’t file your Section 8 and 15 Declarations demonstrating your continued, appropriate use of your trademark in commerce, patent protection lasts for 20 years after the filing date of the patent application.

A trade secret differs from both of the above. It has three components: (i) information whose (ii) economic value derives from not being generally known by others and

(iii) reasonable efforts have been taken to protect the trade secret. In other words, you’re required to do all you reasonably can to conceal the information from which you derive independent economic value from the public. Trade secrets can include a vast amount of information and know-how: from early-stage inventions and manufacturing processes that cannot be protected through patents to lists of suppliers and clients.

What’s nice about a trade secret is there’s no expiration. If you can maintain the secrecy around that information, including taking reasonable steps to prevent unauthorized use or disclosure of such information by employees and business partners, then it can go on and on and on for an infinite period of time.

People tend to like trade secrets, but the difficulty is two-fold. First, you’ve got to maintain the secrecy, which is not always easy to do. Secondly, what if somebody reverse engineers? Reverse engineering is when somebody didn’t get the trade secret, directly or indirectly, by inappropriate means, but came up with their own technology which encompasses the trade secret. That is completely legal to do.

There’s always a risk of somebody taking a look at your technology—say you put a product out on the market—breaking it down and then figuring out the trade secret by reverse engineering, or if they’ve come up with something completely on their own (independent development) that is like the trade secret. Neither is illegal as long as they haven’t acquired the trade secret by inappropriate means.

How important are trade secrets in driving a company’s value? Why is protection of trade secrets such a critical challenge for companies in the life sciences and small-molecule pharma space?

When a trade secret becomes public, it can be used by somebody else legally. As a result, the value of the trade secret obviously goes down. Plus, you don’t have the means



to protect it that is available to patents, trademarks and copyrights. We recommend to our clients that they look at multiple ways to protect technology that may be difficult to patent, such as, say, a design patent that can't satisfy the requirement that it be primarily ornamental. In such a case, a trade secret program may be best suited.

Take the recent decision by the Supreme Court regarding life science cellular products in the case of *Amgen Inc. v. Sanofi*. Amgen lost because it did not provide sufficient information in its patent specification to enable its claims. What it said was, "We're going to claim that our technology is what attaches, how it attaches, functionally attaches to a certain segment of DNA called epitope. What they did there was define the claims by how something functions. The Supreme Court came back and said, "You can have functional claiming, but the requirement to disclose information about that is quite high. You have to give quite a bit of information so that someone of ordinary skill in the art when they read that patent can make and use the invention without undue

experimentation." Amgen lost lots and lots of money relating to that technology because they didn't have a different way to claim it, at least in those patterns.

In the life sciences/cellular space, a major issue is how to describe technology that is so new. You want to describe it with structure—the structure of the cell, the DNA, the mRNA, the antibody—it's properties, characteristics and so forth, but what if the technology just isn't there yet? That is especially true with respect to mRNA and CRISPR outcomes. Describing that technology is very difficult. Since we can't really describe it in a way that is likely to meet patentability requirements, the better solution may be to keep it as a trade secret.

In other words, sometimes a trade secret is better if the technology is particularly unique in the way that we derive, process or even utilize it. In the diagnostic space, it's very difficult to get a method patent through under 35 US Code §101 for patent eligibility. As a result, a number of

companies have decided that, based upon their technology, algorithms, reagents and so forth, it's better to just have a trade secret program and license it out in certain modalities, where the licensee gets certain things but other things remain trade secrets. We have contracts and monitoring programs in place to do that with third parties.

There can be another cost to a trade secret: having to do all the manufacturing, commercialization, etc., on your own because you believe the more people who know about the trade secret, the more difficult it would be to keep it secret. However there are certain situations where you can have a trade secret and work with third parties under certain confidentiality agreements, joint development agreements, collaboration agreements and the like to maintain your trade secret protection.

With respect to life sciences in particular, how do trade secrets contribute to company's value?

The value of a trade secret is that if you can protect it, you're the only one that's deriving economic value from it. Your competitors don't have access to that information. They can't go read your patent and then decide "we want to license that." Yes they're paying, but they're also making money off of those products if they're selling or sublicensing them.

A lot of banks know that if you have a product you can protect and can illustrate that you're doing so through a trade secret program, that you have a significant economic competitive advantage over others.

A trade secret program starts with identifying your business's trade secrets, and then putting in place a strong program to protect them. We help companies install such a program at whatever level is appropriate for them, and advise them on how to maintain it. We find that if you have a good trade secret program for information that can be properly defined as such, and you take steps to keep it secret by limiting access to

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those that really need to know within your executive teams, research, manufacturing, teams and supply chain partners—controlling who gets what, when and how—then you can derive economic value from it for an infinite period of time.

Then the ultimate goal is: Can you improve that technology and keep that improvement secret as well? In doing so, in essence, you're leap-frogging your value from trade secret one to trade secret improvement two to trade secret improvement three, etc., and you don't have an expiration like you do with a patent, where you have to publicly disclose it. All you have to worry about is maintaining and monitoring your trade secret and keeping it secret. You will also want to watch the industry to see: 1) is it going away from you? and 2) that others aren't reverse engineering. To reiterate, if you can maintain your trade secret, there is true value in utilizing this means to protect your innovations.

The banks respect that so if you can do it properly, you can see additional investment that you can put towards your commercialization efforts, manufacturing efforts, R&D efforts and so forth. A lot of trade secret programs are feeder programs into other programs that are additional sources of income, usually with utility patents, design patents, trademarks, R&D value, et cetera. Trade secrets can be a good springboard to other things.

How can companies go about establishing an effective trade secret protection program?

I would highly recommend that they interact with an intellectual property attorney who has significant trade secret experience because they may have to do a trade

secret audit to identify protectable trade secrets and whether they are still secret. If they're not—if they're too easy to reverse engineer, becoming public or already public—protecting them is going to be difficult.

But, if there is technology that can be set up as a trade secret and the audit supports that, we advise companies on how to set up a trade secret program, how to make sure all their teams understand the program, how to implement the program, and how to maintain the program. From the executive team all the way down to anyone who might have even a slim chance of interacting with trade secrets (i.e. R&D teams, commercial teams, marketing teams), the program should be set up so that it can truly adjust as necessary based upon which team is interacting with the trade secret.

We also advise companies on how to maintain their trade secrets when somebody comes onto their property, how to handle information being provided for review, how to manage technical discussions to make sure that trade secrets do not become part of it, how to handle confidentiality situations, not just with NDAs, but other measures to ensure that if you ever have to bring a claim of "misappropriation," you can prove careful management of the secrecy, including with respect to related or interrelated information.

Because trade secrets are tricky and you want to make sure you define them correctly and then protect them correctly, engaging a seasoned intellectual property attorney is highly recommended. Many missteps can happen that could cause you to lose your trade secret if you're not thinking about several dynamics.

Can you expand on how a pharma or life sciences company can protect its trade secrets?

First of all, define what you think may be a trade secret. Is it a certain type of cellular or small molecule technology that is difficult to define? To reverse engineer? To understand?

Is the technology very cutting edge and maybe so new that, because of the difficulty in describing, installing, applying or manufacturing it, other protections where you have to disclose and you have to give enough information, e.g., utility or design patents, are not available? If so, then trade secrets would be something that life science programs, small molecule pharma programs and other pharma and diagnostics programs, would find most suitable.

Just look at the case law. It's currently very difficult in the United States to get patent protection on diagnostics. In light of the significant headwinds that you would have to face, it may be better to find other ways to protect that technology. Sometimes it may not be the whole device that needs protection, but some subcomponent that's critical to the device or system that could be protected as a trade secret. There are opportunities in the diagnostic space worthy of consideration. Reagents are one example, as are certain types of algorithmic outcomes, that may not be suitable for patenting.

The same thing is true in the life sciences space. Cellular material is so cutting edge that it's often very difficult to describe with all its nuances. Trade secrets are one way to protect your technology as you continue development. They can provide value to drive commercialization or investment strategies until you form enough information such that you can consider other types of intellectual property protections. ■



Troy Groetken is a Shareholder, Board Member, and Executive Committee member with McAndrews. He has approximately 25 years of legal experience in the intellectual property field and more than 25 years of technical experience in the pharmaceutical, biotechnological, and chemical fields. He is recognized in the IAM Patent 1000: The World's Leading Patent Professionals and has been listed as one of the Best Lawyers in America since 2012. Reach him at tgroetken@mcandrews-ip.com.