

Building strong fences to protect your biotech product

In some ways, it seems simple – you have an idea for a new drug and so you want to patent it. But what will your patent protect? This may depend on your goals.

- Are you seeking a defensive position to protect the compounds you will market?
- Do you want patent coverage to cordon off space around your compounds to keep competitors at bay?
- Do you want to protect methods of using the compounds? And what about methods of making the compounds?

The answer may be "yes" to all of these. But the scope of protection will also depend on what the patent laws allow.

What can you protect?

Patent claims can cover the active ingredients of a drug and its formulation as well as combinations of products. You can also choose to cover methods of making the compounds, including the processes of synthesis and purification. In some cases, however, there may be advantages to not patenting manufacturing processes. In the US and many other countries, patent applications generally publish about 18 months after filing. Thus, the described methods become public. In contrast, a company can choose to keep the methods a trade secret and not file a patent application. Each strategy has its pros and cons, and the balance will vary with your particular circumstances.

How much "territory" can you protect?

The scope of what your patent can protect generally depends on a few basic principles:

1. *What is publicly known:* To be valid, a patent claim can't cover what is already publicly known through published materials as well as products already on sale (referred to as "prior art"). Thus, a first assessment generally includes an analysis of what prior art exists and how your products or methods are distinguished from what is already known.
2. *What you are able to describe in the patent:* You may wish to fence off a large territory around your actual products to keep competitors at bay. For example, you may want to patent variants of your chemical structure or amino acid alterations to a protein or antibody structure. The breadth of what the patent claims can cover may depend on the description you provide about the variants and how to make them. The level and scope of detail required for the application may depend on the type of chemical and biological compounds at issue.

Claims that cover a very large number of compounds can also make an easier target for an invalidation challenge down the road. For example, a challenger need only find a single compound that falls within the scope of a broad claim and pre-dates the patent to successfully invalidate your patent. Therefore, it is generally helpful to have a tiered strategy, with some claims stated broadly, others reduced in scope to cover smaller classes of compounds, and yet others limited to single compounds of key interest to the company.

The ups and downs of methods claims

Methods claims come in many flavors, but two common types are *methods of making the compound* and *methods of using the compound*. The former can be difficult to enforce, primarily because a competitor's manufacturing method is not usually

publicly known or readily ascertainable. Thus, it takes some guesswork to decide whether a competitor may be using your methods. Another aspect to keep in mind with regard to methods of making drugs: for small molecule drugs, patents claiming methods of making the drug don't follow the Hatch-Waxman pathway for litigation and thus don't provide the 30-month stay against a generic manufacturer that patents with product claims can provide.

Methods of using compounds can include, for example, methods of administering a drug to patients. These claims may involve steps carried out by more than one person. For example, some claims could involve the manufacturer providing the formulated drug, then the doctor administering the drug (eg, through an injection or intravenous administration), then the patient carrying out additional steps (such as taking a second drug or supplement orally). Recent changes in the law have made it more difficult to prove patent infringement in these circumstances.

Some Food for Thought

Here are some considerations you may wish to keep in mind as your product development evolves and you advance your patent portfolio strategy.

Do your patents protect your products from being copied or imitated?

- Variety of patent claim types (products, methods, combinations)
- Tiered strategy for breadth and strength

Assess your patent portfolio on a regular basis – are changes needed?

- What is the competitive landscape around your product and its uses?
- Have changes in patent law affected the validity and/or enforceability of your patent claims?

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