

## LIFECYCLE MANAGEMENT: PATENT PROSECUTION STRATEGIES IN PHARMACEUTICAL AND BIOTECHNOLOGY CASES

The good news is you've developed your drug. The bad news is the compound patent expires in a year. The following discusses what you can do and how you can get new patents that will protect the commercial term of your product.

We have all seen the "follow on" patent filings claiming every possible salt, or every possible formulation, of a drug whose compound patent is expiring. And, we have all questioned their validity and enforceability. So, what is the best way to keep competitors at bay while ensuring enforceable protection for your product?

### KEEP THE FOLLOWING BASIC GUIDELINES IN MIND:

1. Have a regular review system of your product development pipeline so that patentable discoveries are documented and protected early; don't get lazy and entrust the entire cycle of your product to those early filings;
2. Dare to invent. When you're considering possible "follow-on" filings beyond the initial compound case, resist the urge to submit "scorched earth" filings listing every possible form of your compound. Collect data. Learn something new. Protect the discovery. Your protection may be more narrow, but it will be strong.
3. Look for "non-traditional" inventions. Protect manufacturing methods (or steps), characterization assays that might be part of batch release, biological markers that could end up on your label. Focus on technologies that operate in the commercial marketplace.
4. Watch your competitors. Know what they need. Issue patents on technologies that they want (whether related to your product or not) so that, if they issue a patent you want, you have something to offer in trade.

Below, we outline particular times in the drug discovery process when inventions tend to be made and offer tips for identifying valuable discoveries and timing the filings that protect them.

### WHEN SHOULD YOU LOOK FOR IP?

Every step in the drug discovery process has the potential to generate IP.

#### 1. Drug Screening

Should you file a patent application on your biological target or screen? Should you file on a broad genus of compounds if you think you might some day find a hit within it? Only if you have to. Particularly now that the Supreme Court has refined the obviousness standard in KSR, the risk of rendering your ultimate compound obvious will often outweigh the benefit of an early filing date.

## **2. Lead Selection and Medicinal Chemistry**

Now you have a smaller genus of compounds and some preliminary biological data on a few compounds. When do you file? You have entered the “careful what you wish for” part of the patent lifecycle. As tempting as it is to cleverly craft an application that justifies broad claims based on limited data, that very strategy risks walking you into an obviousness rejection over someone else’s published report with similarly limited data for a vaguely related compound. It is often therefore best at this stage to play a waiting game, and to hold off filing as long as possible while collecting data. It is also often desirable to define multiple alternative structural genera, as well as to consider protecting synthetic intermediates and/or methods of synthesis. Claim strategies that include both functional and structural elements can also be beneficial. Among other things, such claims can avoid inoperative embodiments and/or provide a straightforward test for infringement. It is also wise to remember that, if you do have a lead compound, you definitely want a “clean” claim to that compound. Don’t forget to claim your drug!

## **3. Compound Selection and Characterization**

It is during this stage of the drug development process that you typically find polymorphs, salt forms, prodrugs, metabolites, degradants (that may or may not have activity), combination therapies, etc. However, laundry list filings are rarely helpful and focused filings that commit to an invention (eg, of a particularly potent drug form) can be scary because they allow room for design-round. Yet they can also yield strong patents. And, if you’re right about the invention, they’re worth their weight (and then some) in gold. As we said, dare to invent.

## **4. Formulation and Manufacturing**

Drug formulation and manufacturing are too often overlooked as sources of new intellectual property. By this stage, many companies are resting on the laurels of their earlier filings. Yet, these stages are highly relevant commercially. Protection of key scale up steps, or commercially relevant formulations can have profound weight in the marketplace. Moreover, they often offer real possibilities for extended term beyond initial filings.

## **5. Clinical Trials**

Don’t forget to keep tabs on the results you get when your drug actually goes into humans. Many times, you will make highly relevant discoveries – defining effective doses, patient populations, and/or other aspects that may well end up on a product label. Anything that is on the product label should be in your patent portfolio, so make sure company policies include periodic review of clinical trial information and patent filings tied to finalization of product label language.

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