

Is Your Patent an Asset or a Liability?

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Our marketplace understands the importance of patents, and their value to businesses cannot be overstated. Patents can provide many benefits for their owners or licensees, including preventing competitors from making, using, selling, and importing the owners' claimed products and methods, protecting and expanding one's presence in the market, and attracting investments from venture capitalists, potential corporate partners, and other investors.

Not all patents, however, are created equal. While some may provide its owners with ultimate benefits, others will simply collect dust and consume valuable resources. Generating valuable patents has become even more challenging in view of today's patent policies and regulations. Not only are patents being challenged through post-grant procedures enacted by the America Invents Act of 2011 (AIA), but they are also being challenged by more restrictive patent laws issued by the courts and the USPTO. Thus, patents are becoming more difficult to obtain and more susceptible to invalidation prior to their expiration.

So how can you tell if your patent is an asset or a liability? Below are five quick analyses that separate those patents that help a company reach its goals from those that strain a company's resources.

1. Patent claims should protect the commercialized product or method

The claims that ultimately issue in a patent should cover the commercialized product. This almost seems like an obvious point but many claims that issue do not cover the product that

a company intends to commercialize. This happens for a number of reasons including product changes that came about after the patent application was filed or amendments that were introduced to the claims during prosecution that were outside the product's scope. To be an asset, a patent's claims should, at a minimum, cover the commercialized product. If the patent does not cover the product, then it opens opportunities for competitors to copy or knock-off that product.

2. Patent claims should provide broad protection – but not too broad

In addition to covering the product, a patent's claims should also be broad enough to prevent competitors from making minor tweaks and designing around the protected subject matter. No matter how many patents or patent claims are issued, if a competitor can easily design around those claims, the patent is not a very valuable asset. If, however, the patent claims allow for some leeway, then a company can ward off competition by restricting the market from creating and selling not only its product, but also substantially similar products.

It should be noted that having claims that are too broad can also be problematic. We are seeing an increasing number of claims being invalidated because they cover more than the inventor is entitled to claim. One area where this is happening is with therapeutic antibodies. In the 2017 Amgen Inc. v. Sanofi decision ("Sanofi"), recently affirmed by the CAGC, the Federal Circuit held that claims directed to a class of antibodies that bind to a particular antigen and perform a particular function must be supported by data showing a sufficient number of representative antibodies across the claimed genus or establish a clear relationship between the function of the antibody and the genus of the antibody in their specification. Since Amgen's patent at issue did not show this written description support, the court invalidated them under 35 USC 112. Accordingly, for a patent to constitute an asset its claims should adequately balance the competing

interests of broadness and specificity.

3. Patent claims should be layered

Similar to drafting claims broadly, patent claims should be written in layers to afford additional protection. When written in layers, there are multiple variations of the claims. In other words, it is best to be the owner of a patent with 30 claims, each of varying scope, instead of a patent with only 5 very broad claims. A layered patent can ultimately withstand a challenge because if a claim of a patent is invalidated in a post-grant challenge, that patent can still be upheld if other more acceptable claims of differing scope are included.

To understand how this works in practice, let us look at antibody patent claims in the post-Sanofi world. For antibody claims to be upheld, each patent should claim the subject matter using several formats, each of which yields differences in scope so that even if some claims are invalidated in a post-grant challenge, other claims within the same patent could remain valid. For example, although functional claims directed solely to antigen binding are likely invalid after Sanofi, claiming by function should not be entirely ignored. Instead, such claims may be strengthened by adding backup claims, including a set of narrower claims that include parts of the antibody sequence or other features of the antibody, with a greater chance to withstand a challenge. Moreover, functional elements could be combined with structural elements in the same claim to create hybrid claims. Including one or two backup claim sets could, thus, increase the chance that the entire patent is not invalidated in a challenge. By taking advantage of the types of patent claims available for antibodies and other compounds—and by including backup claims in the form of layering—a company increases the likelihood that some of its claims will remain patentable when the patents are subject to invalidation.

4. Patent claims should be supported by the specification (and

data!)

As shown above in Point 2, the written description requirement of 35 USC 112 is becoming an increasingly popular mechanism for invalidating patent claims. Courts and patent Examiners alike are demanding more robust support of conception and reduction to practice, i.e. possession of the claimed invention. To avoid running afoul of Section 112, patent applications need to include enough information to satisfy the written description requirement.

To achieve this, the patent specification should, first and foremost, include as much information as possible about each component or feature of the claims. Often the patent application not only describes the features of the preferred embodiment but it also describes numerous variations of each feature and potential workarounds that competition could use to skirt any issued patents. In a CAR-T cell therapy application, for instance, not only is the preferred binder described, but other possible binders are described as well. While this type of drafting leads to much longer patent applications, it protects not only the invention but also modifications to it.

Second, any terms used in the claims, especially critical terms, should also be properly and fully defined in the specification, including as many variations as applicable. This information should not be overlooked because it can provide an important basis for claim interpretation and scope.

Finally, a patent specification should include enough data to support the claims. Experiments provide the support that shows that the invention does what it claims it does, i.e. that it is "enabled." For instance, an inventor cannot assert that a composition treats cancer without at least providing some experimental data to that effect. If no experiments have yet been conducted, hypothetical examples describing future experiments could be included. However, care must be taken to reflect the fact that these theoretical examples are prophetic

and were not actually conducted. Data should be supported by figures, graphs, charts, data tables, schematics, and/or sequence listings. The more complex your invention, and the more unpredictable the art, the more experimental examples will be needed to prove enablement under 35 USC 112.

By providing ample support for the claims, inventors can improve the likelihood that their patent applications will overcome the written description hurdle.

5. A patent should not try to cover everything under the sun
Finally, patents that are assets should not cover everything under the sun in regard to one invention. While it is necessary to include as much information as possible about the invention, it is also important to keep different inventions separate. I personally have seen too many instances where one patent application overly broadly covers many different possible inventions – infinite variations of a composition, methods of treatment, method of making the invention, diagnostics, and much more.

The problem with including all this information in one application is twofold. First, it prevents the patent owner from maximizing the overall patent-protected term of the product. With AbbVie's blockbuster drug, Humira®'s, for example, AbbVie managed to extend Humira®'s patent-protected life by 16 years past the initial expiration of the primary patents in 2018 simply by temporally staggering its patent applications. This strategy requires that additional features of an invention be covered in a second family of follow-on patent applications and included in as much detail as possible in the second family of patent applications. This ensures that any claims reciting these new features will distinguish the "second" invention from the first invention and restart the 20-year clock on the overall patent term.

The second problem created by including too much information in one patent application is that that patent application

could potentially create prior art problems against subsequent patent applications. This is because all that disclosure about additional embodiments, even embodiments that were not fully figured out yet, if included in the first family of applications, will have to be overcome during the prosecution of any subsequent patent applications. In other words, some information about the invention, such as embodiments not yet fully worked out or not yet “ready for prime time,” should be reserved from, and not included in, the first family of patent applications.

Therefore, when it comes to drafting a patent specification, it is important to be mindful of the types of claims you seek in the application, rather than include embodiments that could and should be covered in subsequent filings. Giving yourself some room to file subsequent applications that covers new features can provide an inventor with additional years of exclusivity by expanding the ultimate patent-protected time on the market beyond the normal 20 years.

Patents that are assets to a company are therefore those that provide its owners with value in the marketplace. Not only do they protect the commercialized product against competitors for an extended period of time, but they also can withstand challenges to its validity.

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