

PATENT PROTECTION IN THE BIOTECHNOLOGY INDUSTRY – A UNIQUE APPROACH TO OBTAINING FAST PATENT RIGHTS

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ABSTRACT

Strong intellectual property protection is as essential in the biotechnology field as in any other cutting-edge field. Biotechnology patents can serve to promote the advancement of new medicines, diagnostic equipment and agricultural products. Biotechnology patents not only reward inventors for their inventions through market exclusivity, they can stimulate research and the flow of scientific and technological knowledge on a global basis. Biotechnology patents further encourage companies to invest in developing new drugs, therapies and equipment. This development often takes many years and is a very expensive and risky process. Without patent protection, competitors could copy the developed drugs, for example, and sell these drugs at a substantially lower price because they have not expended the resources necessary to develop the drugs. In this situation, the competitor could capture the market with its lower priced drug and the innovating company would be required to lower its price to compete and, as a result, may never recoup its substantial development costs. Thus, it becomes critical to obtain patent protection and to do so as expeditiously as possible. This article addresses a unique approach to obtaining fast patent protection to help companies capture or maintain market share and exclusivity and prevent would-be copiers from undercutting the substantial investment expended by these companies.

INTRODUCTION

A reoccurring complaint in the biotechnology and nanotechnology industries is the millions of dollars (sometime hundreds of millions of dollars) spent to develop, for example, new drug therapies, diagnostic equipment or medical treatments only to see these developments copied by others who have not incurred such a substantial investment. While diligent in pursuing patent protection to fend off these would-be copiers, these companies remain frustrated at the length of time it takes to obtain patent protection for their newly developed drugs or equipment. On average, these companies are not receiving patents on their inventions for at least two to three years after the application has been filed, sometimes longer. What is most aggravating is that despite diligently pursuing patent protection, the new developments lose their market exclusivity after they are quickly copied, resulting in a loss of market share and potential revenue for these companies. What is equally frustrating is the fact that some of these developments have a relatively short useful life given the rapid advancement of knowledge and technology in certain fields – a useful life often shorter than the time it takes to obtain one or more patents on the new developments. And to make matters worse, these companies will have no recourse for a considerable amount of time against the copiers that hit the market with their products several months later. By the time the patents have granted, not only has the developed technology potentially run its course, competitors have taken a portion of the company's market share with the infringing products, resulting in a loss of revenue that may never be recouped.

The problem described above is not exclusive to the biotechnology and nanotechnology industries. Indeed, thousands of companies across the nation seek to enhance their competitive positions by creating or further developing new markets through new product development,

obtaining exclusivity and maintaining profit margins by seeking to obtain patent protection as expeditiously as possible. Because, as everyone in today's world knows, the faster an organization can obtain patent protection, the faster it can maintain its competitive edge.

TRADITIONAL PATENT PROTECTION: A SLOW PROCESS

Traditionally, fast patent protection was not readily obtainable. In fact, obtaining patent rights has historically been a very slow process. Prior to recent changes in the U.S. patent laws, an applicant for patent would not expect to obtain patent rights for several years after filing a patent application. For example, "small molecule" pharmaceutical inventions would often take two or more years to issue as a patent, while "large molecule" inventions would take even longer. Given the speed of innovation in the pharmaceutical industry, a lot can happen during that period of time: developments evolve, manufacturing processes or techniques improve, market demands shift, competitors move into the marketplace, and so on. Consequently, the primary benefit of the patent – exclusivity to create or maintain marketplace position – becomes less of a benefit as the critical time when patent rights are needed has passed.

PATENT LAW CHANGES DESIGNED TO PROVIDE EARLY PATENT RIGHTS

More recently, the U.S. patent laws have been amended in an effort to harmonize the U.S. laws with foreign patent laws. As part of these changes, an applicant for patent can now obtain patent rights beginning on the date the application is published – as opposed to the date the application becomes a patent. Once published, an applicant can notify a potential infringer of the published application and, when the application becomes a patent, can then collect damages in the form of a royalty from the date the potential infringer was notified.

Under the current U.S. patent laws, the U.S. Patent Office is required to publish all filed applications within 18 months. Typically, the application will not publish earlier than 18

months. In today's world, this might not be fast enough as 18 months is often a sufficient amount of time for a competitor to make its way into the marketplace with a competing product thus reducing the value of the patent rights. In an effort to speed up the publication process, an applicant for patent can make a request for an early publication of the application. Under this scenario, the timeframe for publication can be reduced to about four to six months. Depending on the product or process protected by the patent application, four to six months may still be enough time for a competitor to gain at least a foothold in the marketplace, potentially costing the company its competitive advantage and a loss of millions of dollars in sales taken by the competitor. This is where a patent attorney savvy in the U.S. and foreign patent laws comes in.

FAST PATENT RIGHTS: SEEK HELP OUTSIDE THE U.S.

A unique approach to obtaining very fast patent rights in the U.S. involves, ironically, looking outside the U.S. By taking advantage of the benefits of the Patent Cooperation Treaty (PCT), a company can obtain patent rights as quickly as 30 days and substantially hinder, if not stifle, a competitor's entrance into the marketplace. Generally speaking, the Patent Cooperation Treaty is a treaty amongst member countries, including the U.S., to provide a way for obtaining patent protection in the member countries in a streamlined, cost-effective manner. Patent applications published under this treaty through any international receiving office (including the office in Geneva, Switzerland) benefit from U.S. laws regarding publication. Many receiving offices are more efficient at publication of applications than others and the fastest is in Geneva, Switzerland. Companies knowledgeable of this difference can use it to their competitive advantage. By following the seemingly odd route of filing an international patent application in Geneva, an applicant or company can get the application published and therefore obtain U.S. patent rights in as quickly as 30 days. Many biotechnology and nanotechnology companies

operate on a global basis and therefore file right away to preserve patent rights in many foreign countries, such as Europe and Japan, for example. These companies often file an international PCT patent application to preserve their foreign patent rights. By seeking early publication of the PCT application using the techniques described below, patent rights in the U.S. can be quickly obtained.

After filing in Geneva, Switzerland, there are some tricks of the trade to obtaining a fast publication and consequently fast patent rights. Know-how and attention to details are essential, but so is monitoring the progression of the application and diligently following up with the right people. By understanding the protocol of the receiving office in Geneva as well as the roles of the Geneva office officials, the typical publication timeframe for international receiving offices (which is the standard 18 months) can be shaved to as little as 30 days. By way of insight, it is vital to understand what part of the Geneva receiving office protocol can slow the application. For example, by filing a Petition to Make Special with the application, which is often done in the U.S. Patent Office as well as foreign patent offices to speed up the application process, this common strategy can actually delay publication of the application, unless the Petition is filed after publication. It is also important to appreciate the Geneva receiving office's affection for electronic communications which can tremendously speed up the publication process by permitting the applicant to instantly provide additional information, if requested.

In one instance, a client of ours, a consumer display company, became aware that a competitor had copied its newly developed displays and was preparing a large shipment of the knock-off goods in six to eight weeks. This scenario creates a challenge that many biotechnology and nanotechnology companies regularly face: how to take a new product to market while ensuring it is protected from copycats. In this situation, we filed a patent application for the

displays in Geneva, Switzerland, and secured publication of the application in 28 days. We then notified the competitor of the application's publication. Under the new U.S. patent law, this put them on the hook for damages for the entirety of their imminent shipment.

Intellectual property attorneys are always challenged to find new ways to solve old problems and companies today are demanding more creative thought in addressing patent issues. The next time you need fast patent protection in the U.S. to preserve market share and the substantial investments involved in development, consider the atypical approach of seeking help outside of the U.S.

SUMMARY

- Strong patent protection is critical to obtaining exclusivity and market share for newly developed medicines, diagnostic equipment and agricultural products.
- Patents stimulate the flow of scientific and technological knowledge.
- Patents encourage companies and investors to invest in discovering new genes, drug therapies and diagnostic equipment.
- Obtaining early patent rights gives companies a competitive edge and puts competitors on notice of the patent rights and hinders them from copying new developments.
- For very fast patent rights in the U.S., consider seeking help abroad and consult with a patent attorney skilled in the nuances of PCT practice.