# BioSpectrum BioSpectrum

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## INSIGHTS Industry leaders



## REGULATORY



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## **Patents: Pillars of** biotech companies

IN THE past few decades, globalization phenomenon has received considerable attention and has fashioned both the discourse and the behaviour of academics, policymakers and managers. One symptom of a globalizing world is the surfacing of entrepreneurial start-ups that have an international outlook from inception.

However, before early-stage entrepreneurs can go to market, they must literally prove to themselves with their innovations, which may involve developing a research technology further, perhaps to a working prototype, and/or studying the markets to see if the business concept will create an economic impact.

While start-up firms create a substantial economic impact on most economies, the failure rate of startup firms seems to remain high over time. There is an ever growing influence of intellectual capital management on business performance, which generally includes the human capital of the entrepreneur, organizational capital, and relational capital are important intangible assets, which seem to be related positively to venture performance.

### PATENTS: YES OR NO?

A patent is one of the ways by which technological innovations are protected. The most ironical fact about a patent is that although it gives monopoly for a number of years, but in order to gain the monopoly, the invention has to be disclosed. Hence, it's not a secret anymore, and the competitor knows how it works. Therefore, it becomes necessary to enforce rights of a patent, by taking legal actions,



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either to make others who are violating patent rights from stop infringing or to make them pay for the privilege of using the patent. If a patent is not enforced, its value is questionable. In simpler terms, if violators are not taken to court, they will continue to infringe.

In contrast, some patents have a

short life, as the market windows for many technologies can be very slim. Many patents are filed which don't have the potential to generate revenues for the inventors.

It is well known that organizations spend thousands of dollars for filing patents each year. It is interesting to know how they gain an edge over their competitors by filing a large number of patents. The example of Tag patent justifies this to a certain extent. Tag polymerase is a thermostable enzyme employed in polymerase chain reaction (PCR) for amplification of a specific genetic sequence. The rights to both the enzyme and the PCR were owned by Cetus Corporation, and in 1991, they sold their rights to Roche for \$300 million. The life sciences industry is full of various such instances.

#### BIOTECH START-UPS & PATENT RISKS

The risks involved in a biotech start-up are quite enormous and hence they undergo greater scrutiny than most other industry startups. At this point, it is very critical to specifically point out what exactly a biotech company has that is valuable compared to other companies. Essentially, they have nothing else but an application for a patent that promises monopoly profits in the far future and some individuals that may or may not be able to carry it to that point. Thus, when viewed from this perspective, the application for the patent and the individuals that are driving the ship are of utmost importance. In essence, the patent application promises potential monopoly profits in the future. Thus, the patent itself needs to be sound.

## IMPORTANCE OF PATENTS FOR STARTUPS

Securing funding from either venture capitalists or large pharmaceutical companies is by no means trivial and straightforward. Biotech startups have to tell their potential investors a very attractive and appealing story in order to draw their interests. The most important factor in this story is what proprietary information (mainly patents) the companies have in order to gain an edge or a niche over their competitors. Hence, the role patents play in obtaining funding and launching biotech startups is nothing less than instrumental. It is fair to say that patents are the cornerstones of biotech startups and they can make or break a young, fledgling company.

Companies usually file for patents during the very early stage of development. There are both pros and cons for doing this. One of the advantages is that companies can secure their market share and

The only way to receive high profits for a business is through monopoly profits, and patents secure these monopoly profits

capitalization as well as discourage any competition in the early stage. However, they will also lose a couple of years of the patent life of their drugs. Despite drawbacks from filing patents early, all companies file for their patents in the initial development stage to protect them from their competitors. Patents are an instrumental part of the biotech startups' portfolio that is presented to the venture capitalists. These startups need to convince VCs that their ideas, based on patents, give them an edge over all of their competitors.

In addition, patents for biotech startups serve two other functions. First, patents help companies secure an initial clientele base by presenting the uniqueness of their products, and secondly, patents serve as a competitive barrier of entry into the same field. As mentioned earlier, small biotech startups usually focus on specific drugs for specific diseases. Since the markets for these diseases are fairly small, it is imperative for them to have a dominant position in their respective fields.

To understand the role of patents in biotech companies, various aspects of a biotech company's life cycle are to be considered and it should be examined that where and how patents are crucial in its success. During early stages of a company, patents are important for receiving funding as they provide the future promise of monopoly profits in a very volatile and risky industry. As the company develops, it generally creates a portfolio of patents around their initial concept. The patents that are developed and acquired in the early stages of the company are crucial to the company's continued success. In order to maintain a patent's legitimacy, a company must police other companies to make sure that the patent is not being infringed upon. In addition to actively policing others, a company may have to defend its own patents from claims of invalidity. Therefore, once the company's primary technology becomes more successful or starts generating revenues, they can use that capital to pursue other technologies. Moreover, for protection of a company's IP, they may need to sometimes litigate against other companies that are infringing on their patents and often need to defend their own patents also.

Patents are the pillars for biotech companies and are essential for their survival. Without the promise of the monopoly profits in the future, biotech companies cannot protect themselves later in their life cycle. Thus, they must pursue and protect their IP in a timely manner and with great care.