

A guide for life sciences entrepreneurs

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Small companies face the same long product cycles and upfront costs as the big players but have different IP challenges, explains Chad Shear of Fish & Richardson.

The strength of a company's IP is a central factor in determining its value, and perhaps nowhere is this more evident than in the life sciences industry. Because of the huge upfront expenditures required to develop products in the pharmaceutical, biotechnology, and other life sciences industries, a strong IP portfolio can be the difference between success and failure.

Life sciences entrepreneurs often face different IP challenges from those in other industries due to long product life cycles and expensive research and development (R&D), among other concerns.

Long product life cycles

The product life cycle for life sciences companies, particularly pharmaceutical companies, differs significantly from that in other sectors, and that difference affects both patent protection and investment strategies.

To illustrate, product life cycles in the tech sector tend to be short due to the short shelf life of most tech products, so patent protection on those innovations tends to be less important than it is in the life sciences sector.

Pharmaceutical products, on the other hand, have lengthy product life cycles, often requiring ten or more years of R&D before they launch, with shelf lives that can last decades. And even when a product enters the market, it generally takes about three years for the company to become profitable. A product that fails within its first three years can spell disaster.

Hefty upfront expenditures

Upfront R&D expenditures for pharmaceutical companies can be enormous, in some cases reaching up to \$2 billion years before the product hits the shelves and the company sees even a dollar in return. The high upfront cost to develop a pharmaceutical product and the gap in time before its market entry raises the stakes for entrepreneurs and investors.

"It is thus essential for a company's patents to be strong enough to withstand litigation challenges." - Chad Shear, Fish & Richardson

This makes patent protection perhaps more important than it is in other sectors. To recoup their R&D costs, pharmaceutical companies need to be able to establish market dominance for a certain period, which they can do through a combination of patent protection and US Food and Drug Administration regulatory exclusivity.

Absent this period of exclusivity, innovator pharmaceutical companies likely would never turn a profit, and investors would be unwilling to take the risk. It is thus essential for a company's patents to be strong enough to withstand litigation challenges during this time to maintain their market position.

Extensive due diligence

Many established life sciences companies return 25 to 30% of their topline revenue into R&D—a higher percentage than in most other sectors. For early-stage life sciences companies that do not have the cash on hand to fully fund their R&D, that is not an option.

A common alternative strategy for smaller companies is to partner with an established company or sell the company outright. But the value to a partner or an acquirer depends upon the market opportunity for the company's product and the strength of its IP protection.

Achieving successful partnerships or acquisitions requires early-stage companies to demonstrate to their partners or acquirers that their IP portfolios will allow them to achieve their business objectives, which requires extensive due diligence investigations. Defects in a company's IP portfolio—such as limited freedom to operate or a high risk of a future infringement suit—can sink a company's long-term prospects.

A sourcebook for the life sciences entrepreneur

Not all law firms can handle every stage of the life sciences product cycle, from R&D to building a patent portfolio, obtaining regulatory approvals and defending and enforcing assets against infringers. Fish & Richardson's "[Life Sciences Entrepreneur Sourcebook](#)" was designed to aggregate some of the wisdom we have acquired over our years of practice in this space into a single, easy-to-read format. Our insights draw from our experience obtaining patent protection on life sciences innovations, conducting due diligence and designing deals for partnership and acquisition, and asserting and defending our clients' patents in litigation.

Rather than writing a treatise on life sciences IP, we wrote the Sourcebook to alert life sciences entrepreneurs to the IP issues they should be on the lookout for and where to go for help should they arise.

Download "[Life Sciences Entrepreneur Sourcebook](#)" [here](#)

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