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Essential Patent Protection Areas for Pharma Startups

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This entry, Part III in our multi-part series, focuses on why biotechnology startups should (or should not) patent their unique processes and proprietary manufacturing techniques to secure competitive advantages, safeguard business growth, and differentiate themselves in the market.

The Strategic Importance of Process IP

The biotechnology startup industry is fiercely competitive, making a startup's ability to develop and implement unique processes and manufacturing techniques a decisive factor in its success. Proprietary methods often confer significant cost efficiencies, provide quality improvements, or enable production of differentiated products that can command a premium in the market or drive innovation. As such, securing robust intellectual property (IP) protection around these innovations is not merely a legal formality, it is a strategic business necessity that protects the businesses core and supports long-term growth.

What Are Process Patents?

Process patents, also referred to as “method” patents, cover specific ways of making, using, or performing a sequence of operations. In the biotechnology context, this might include a novel purification step for a therapeutic protein, a unique fermentation protocol, the synthesis of a lead small molecule compound, or a new therapeutic use of a known compound. Manufacturing patents typically narrowly focus on safeguarding the proprietary techniques used to produce the marketable technology at scale. By patenting these processes, startups can prevent competitors from using the same methods, regardless of whether the end product is the same, thereby maintaining a competitive edge in terms of cost, quality, or speed to market.

The “Secret Sauce”

Proprietary manufacturing techniques, often a startup's secret sauce, allow the biotech company to produce higher quality products (e.g., enantiomerically pure, superior safety, consistent), achieve better yields, or reduce costs compared to competitors. Such techniques are often hard earned, but unfortunately without adequate protection, are vulnerable to being copied or reverse-engineered by larger, better-sourced companies. By securing patents on these key processes, startups gain exclusive rights to exclude others and to license their innovations, which can enhance their negotiating power with investors, partners, and potential acquirers. Additionally, such IP protection signals to competitors, or the market in general, that the company's products are not only innovative, but also difficult to replicate.

How is Our Sauce made?

Ask yourself:

1. Which of our processes or manufacturing techniques provide us with a clear cost, quality, or market differentiation advantage, and have we identified them as candidates for patent protection?
2. Have we documented such processes and techniques with sufficient technical detail and experimental data?
3. Do we have a plan for updating our IP portfolio as our processes and manufacturing techniques evolve?

Key Legal Concepts: Enablement and Trade Secrets

When seeking process or manufacturing patent claims, a startup's legal team must pay close attention to the requirements of enablement and written description. Enablement means that the patent application must teach someone skilled in the art how to carry out the process without "undue experimentation." This threshold is overcome by including detailed protocols, data, and examples.

An alternative means of protecting innovative information that gives a company a competitive edge, if such information cannot be reverse engineered and can be kept out of the public domain, is through trade secrets. Trade secret protection refers to the legal safeguarding of confidential business information, such as formulations, practices, processes, designs, instruments, or compilations of information, which provide a company with a competitive advantage. Importantly, such information is not of the type which is amenable to reverse engineering and not known or readily ascertainable by others. Trade secret protection does not require formal registration and lasts as long as the information remains secret so long as reasonable measures are taken to maintain its confidentiality. Prominent examples include the Coca-Cola formula and KFC's Original

recipe of 11 herbs and spices. Choosing between patent protection and trade secret protection is a nuanced decision that should be guided by IP counsel.

Integrating Process and Manufacturing IP into Business Strategy

As innovative processes and manufacturing techniques often arise in advance of marketable products, a proactive approach to IP which covers them should be integrated into the broader business strategy from the outset. This means early identification of potentially patentable methods, clear and consistent documentation of research or development activities, and careful coordination between the scientific and legal teams. Such coordination ensures patentable innovations can be protected, while also ensuring there is no inadvertent infringement of a third-party's patent. Such practices not only ensure a successful startup launch, but also the ability to implement a forward-thinking approach of regularly updating the IP portfolio as the company scales and refines its processes so that it may maintain a strong defensive position.

Patent Enforcement

Startups often face unique challenges in enforcing patents that are directed to processes rather than products, particularly when the patented process, is not readily visible in the marketable product. Fortunately, U.S. law provides robust enforcement mechanisms which allow for discovery of manufacturing records and compelling disclosure of process details during litigation. Additionally, courts recognize circumstantial evidence and expert testimony as valid means to establish process patent infringement, ensuring that patentees are not left without recourse merely because the infringement is not apparent from the product's physical characteristics.

Patent laws can vary significantly from country to country, and not all jurisdictions offer the same level of protection or enforcement tools for process patents as the United States. For example, as discussed U.S. courts allow broad discovery to obtain evidence of process patent infringement, while many European jurisdictions limit discovery and often require the patent owner to present more direct proof of the alleged infringing activity, making enforcement of process patents more challenging in those regions. As a result, a thoughtful international filing and enforcement strategy is essential for startups seeking to protect and capitalize on their process innovations in a global marketplace.

Kilpatrick's Support for Biotech Process Innovation

At Kilpatrick, our Intellectual Property teams are dedicated to counseling biotechnology startups through the complexities of process and manufacturing patent protection. We work closely with founders and technical teams to identify, secure, and leverage IP assets that form the backbone of operational and commercial advantage. Whether you are looking to patent a breakthrough technique, protect critical know-how, or navigate the balance between patents and trade secrets, our attorneys offer practical, and strategic advice tailored to the fast-paced needs of innovative biotech companies. In addition, we collaborate with trusted attorneys in key international markets to ensure your process innovations are protected and enforced wherever your business grows. For more information on building a resilient process IP portfolio, or to connect with our experts for personalized guidance, please visit our website or contact our team directly.