# IP Strategies for the Launch of Pharmaceutical Products

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Launching pharmaceutical products in the market is a complex and expensive process permeating different departments of a pharmaceutical company, as well as government agencies that regulate the sector and eventually partnering companies. Besides the complexity in keeping all stakeholders updated with the information flow, which is often sensitive and requires caution to maintain its confidentiality, the time constraint is a recurring obstacle from development to launch of new pharmaceutical products.

In this regard, intellectual property, especially patent protection, is a tool of major importance to guarantee exclusivity to explore pharmaceutical technologies and protect them from unauthorized use. Further, patent protection can leverage economic return from the expenses in R&D of new drugs and consequently their market positioning in territories where drug prices are regulated. In Brazil, for example, having a patent that protects the active ingredient of the new drug allow a better allocation on the pricing categories. Not surprisingly, the pharmaceutical business is classified as a patent-intensive industry, with usage from the development cycle throughout the launch and commercialization.

It is worth noting that the pharmaceutical research does not always result in a viable drug candidate, despite the substantial costs and prolonged periods spent throughout the process. In fact, the initial pool with as many as thousands of candidates is significantly reduced as the research advances from the pre-clinical stage, through Phase I, Phase II and Phase III clinical trials, eventually with a Phase IV post commercialization trial (considering a viable candidate is identified).

Surely, the scope of patent work may vary during this lengthy timeframe. For example, it can be triggered as early as during the molecule design process, where multiple substances (small molecules or biologics, depending on the research target) with potential therapeutic effect are conceived. Alternatively, it can start after the lead compounds identification and optimization, a stage where candidates with acceptable therapeutical activity are sighted and improved to achieve better secondary properties. On either case, a patentability assessment is recommended to identify the chances to protect said molecules. With the green flag of this analysis, the next step is filing one or more related patent applications. The definition on exactly when to file the application, however, can be particularly intricate.

If a patent application is filed too early during the development process, there is a risk of not having test results for molecules eventually found to have higher chances of success later in the process, impairing the invention's sufficiency of disclosure. Conversely, if a patent application is filed later during the development cycle, with a well-defined set of candidates having a good success probability, the patentability requirements of novelty and inventive

step may be at risk, considering that third parties may, in the meantime, publish articles, disclose test results, or even file patent applications directed to molecules that are similar or identical to those under development.

Disclosure by in-house personnel should not be disregarded as a potential risk to patenting as well, although some territories, including Brazil, do exempt the prior art disclosure as a bar to patentability whenever it occurs in a determined period of time before the actual filing of the patent application (Grace Period) and is performed by the inventor or by third parties based on information obtained from the inventor. In any case, it is highly advisable to first file the one or more patent applications and only afterwards publishing the structures of the new molecules and test results in the form of articles, congress presentations, or any type of public disclosure.

Ideally, the company is structured in such a way that its internal stakeholders, including Research & Development, Intellectual Property, Regulatory, Legal, Business, and Marketing, are aware of the importance of patenting inventions and their related responsibilities during the process, which are often cross-departmental.

Other important patent tools to pharmaceutical companies include landscape search, patentability and scope analysis, as well as freedom to operate analysis (FTO). Landscaping is performed on patent and article databases to provide insights on relevant technologies, such as current treatments of specific diseases or evolution of molecular structures within a determined drug class. A patentability and scope analysis sets the limitations of a patent case (issued or pending) and the effective/expected range of protection. Finally, an FTO is suitable to anticipate and mitigate eventual infringement of third parties' patent rights, which may lead to litigation, and is critical for example when launching new formulations of known active ingredients which may still be protected by one or more valid patents.

Further, assessing the patent portfolio of a partnering company during negotiations to incorporate its technology in the form of an in-licensing agreement is extremely relevant when setting up the business plan. In this regard, metrics such as patent valuation, protection timeframe and scope must be weighted to ensure the licensee will be vested to explore the technology in its full potential.

The outcome of each of these patent services provide technical support to the decision-making process during the research and development of new pharmaceutical products by mapping the challenges and risks while maximizing opportunities. As a result, innovative pharmaceutical companies can better define a strategic market positioning when launching new drugs.

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