Optimizing The Patent Portfolio in a Pharmaceutical Industrial Set-Up

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Abstract: *In the context of an innovator pharmaceutical company, successful patent portfolio management is rooted in managing the patents along their life cycles mainly with the objectives of attracting investors and delaying the generic entry into the market. An optimised patent portfolio is a powerful tool which enables market power, technology development and innovation while reducing risks. The key to patent portfolio management is timing and strategic decision making.*

Definition and Advantages of An Optimised Patent Portfolio:

A patent portfolio is a collection of patents or patent applications of a single entity, such as an individual or a corporation. It may be related to a specific product or technology. Successful patent portfolio management is rooted in managing the patents along their life cycles mainly with the objectives of attracting investors and delaying the generic entry into the market.

Portfolio management can be generally classified into two areas: portfolio evaluation and portfolio optimization.

- Portfolio evaluation is the measurement of the state of a portfolio against specified metrics, such as value and risk.
- Portfolio optimization comprises the optimal selection of strategies available to the firm to fulfil the given objectives.

True value of patents derives from the collective value of the portfolio as a whole and not individual patents. Any risk would be spread across many patents and decreases dependency on individual patents. An optimised patent portfolio is a powerful tool which enables market power, technology development and innovation while reducing risks. The key to patent portfolio management is timing and strategic decision making.

Strategies for an Optimised Patent Portfolio:

An innovator pharmaceutical company would adopt one or more of the following strategies as aligned with its business strategy.

Scale

- Scale is the effective total filing in a given subject matter.
- It enables market and category leadership.
- It is a defensive weapon against litigation and offensive weapon creating an entry barrier for competitors.
- It drives profitability.

Diversification

- Diversification refers to obtaining patents in different areas.
- It minimizes long-term risks.
- It provides benefits of risk, asset and business diversification.
- Categories chosen for diversification should align with the long-term business strategy.

Balance

- Balance refers to the need for periodic and systematic review of the portfolio depending on company's needs, market and life-span of the patent.
- It helps to determine as to which patents to discard, and which to maintain and pursue.
- Patents may be discarded if it amounts to a waste of resources to renew. Patents may be renewed, if it covers the product in early or middle stage of its life-cycle.
- Balance can be maintained by filing continuation and continuation-in-parts application, a practice typical to the US.

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Patent Lifecycle Management Model

Management of patent portfolio by management off the lifecycle of the patents involved is with the following objectives:

- To not only cover the product but also an area around product to catch any competitor modifications.
- To file further applications for modifications and improvements.
- For products, to file applications covering related process technology.

Every innovator pharmaceutical company would go through the following phases for lifecycle management of the patents:

- Explore;
- Generate;
- Protect;
- Optimize; and
- Decline.

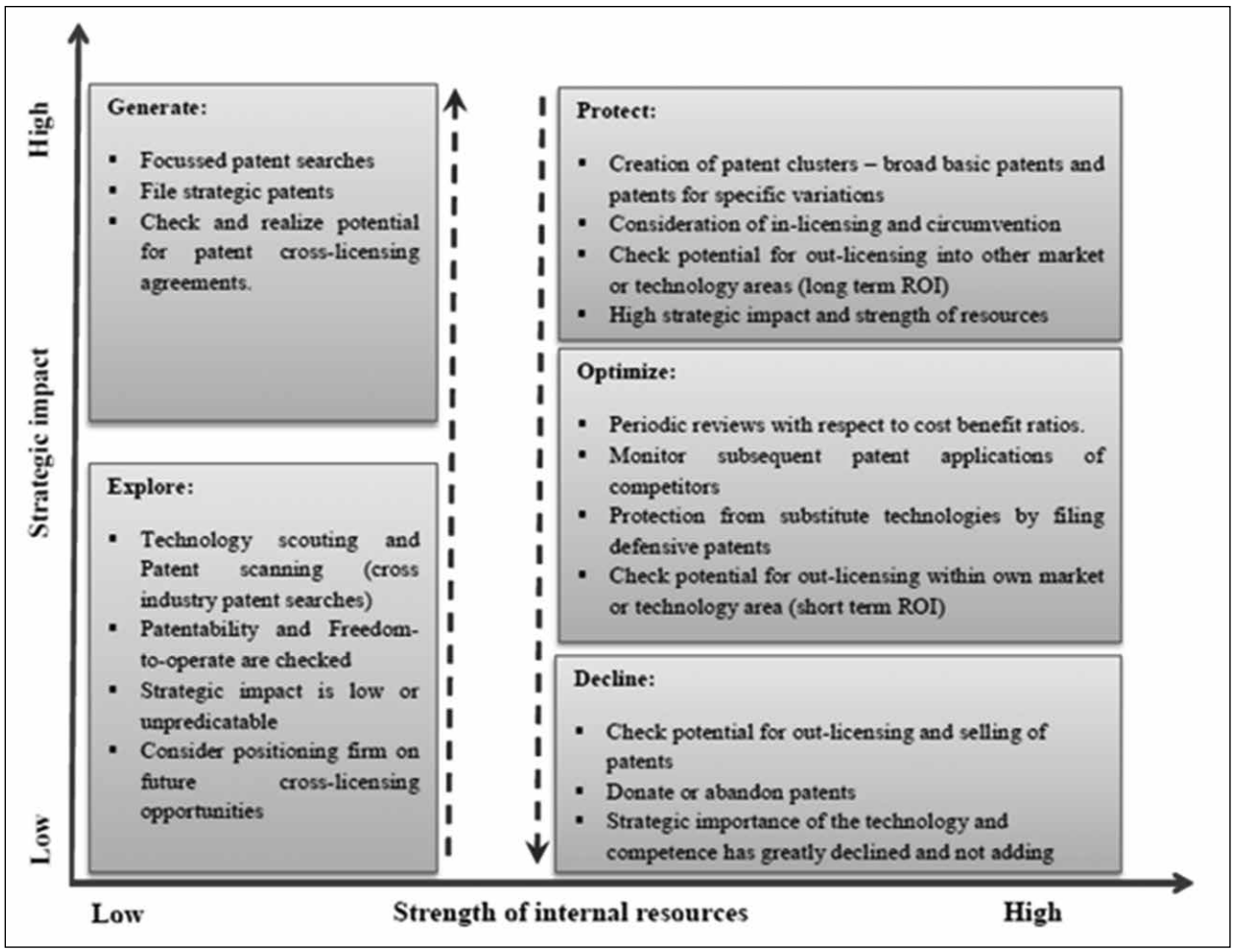
The different phases are schematically described in relation to the strategic impact created vis-à-vis the strength of internal resources used.

Criteria for pruning patents – Layered approach

Each patent of the portfolio needs to be analysed based on multiple parameters:

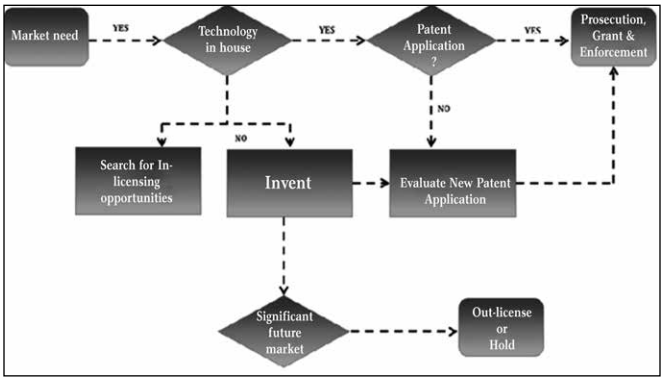
- life of patent (renewals due);
- nature of patent (how core is it to the business);
- strength of patent and future potential of each patent (technology density, activity, monetary potential of the patent; and
- relevance of technology which can be determined by the number of forward citations.

Based on the review, a decision can be made on whether or not to renew a patent.

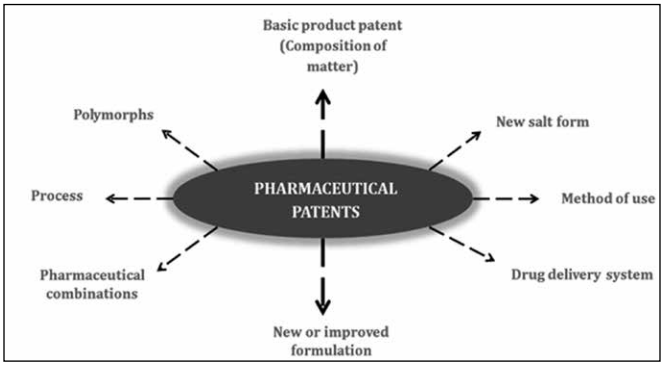


Patent Portfolio Strategic Planning:

The flow sheet diagram provided below indicates the flow of activity stemming from a market need to determining whether the technology is present in-house to whether there is a need for inventing or in-licensing and further filing of patent applications leading to prosecution, grant and enforcement. On the other hand, in absence of an immediate significant market, the technology may be out-licensed or held.



Types of Pharmaceutical Patents and Scope of Protection:



An innovator pharmaceutical company applies for and obtains multiple patents relating to the product active pharmaceutical ingredient, polymorphs, particle size, salts, solvates, formulation, drug delivery systems and method of use. The strongest patents are the drug substance patents as well as the method of use patents. Manufacturing process patents may also be filed but they are comparatively weak patents because of narrow scope and hence the claim scope can usually be circumvented.

Patent Portfolios in an Innovator Pharmaceutical Set-Up:

An innovator pharmaceutical company usually begins with an effective competitive intelligence analysis of the product involving technology scouting vis-à-vis its own capabilities and the market scenario in relation to the said technologies. Unmet medical needs are monitored, the area of innovation or disease area is selected and molecules with corresponding active drug moieties are designed. A variety of molecules are synthesised and the structure-activity relationship is established. At the outset, a patent application may be filed broadly covering a huge range of compounds. Gradually after a clinical candidate is identified, specific selection patent applications may be filed subsequently. The portfolio is built up with follow-on patent applications such as salts, crystalline forms, formulations, drug delivery systems and method of use, which is considered as effective evergreening strategy to extend the product life cycle.

In the USA, after receiving drug approval, the granted patents are listed in the Orange Book (OB) by the holder of the New Drug Application (NDA) holder. It is in the interest of the NDA holder to have longest patent term remaining after drug approval which provides a market exclusivity by keeping generics off the market. The NDA holder then decisively and strategically lists the patents in the OB as and when granted in an attempt to create roadblocks for the generics.

The interest of the generic is to have a market entry as soon as possible; hence in USA the Hatch Waxman Act makes a provision for the generic of filing an Abbreviated New Drug Application (ANDA) application accompanied by Paragraph I to Paragraph IV certifications against the listed patent(s) in the OB, even during the life of the patents. In particular, the generic gains highly in terms monetary benefits by obtaining market exclusivity if the generic can successfully withstand the Paragraph IV challenge. However, in the case of a Paragraph IV certification, the generic would be required to invalidate the listed patent or create a product non-infringing with the claim scope of the listed patent(s), which would be extremely difficult in case of a drug substance patent or a method of use patent. Further, for a generic company it is an extremely costly affair to invalidate a patent in the court of law. The patent portfolio of the innovator, particularly the listing of patents in the OB for a specific product is strategically planned with the objective of delaying generic entry.

Case Study-Imatinib Mesylate

The basic product patent for imatinib mesylate as an anti-cancer agent expired in 2013. However Novartis succeeded in extending the patent term for the marketed form in US, the beta crystalline

form of imatinib mesylate by acquiring another patent grant, which expires in 2019. It is worth noting that this patent application was rejected in the Indian context for need to show therapeutic efficacy and not mere improvement in physical characteristics such as solubility or bioavailability.

Case study-Dapagliflozin

The basic product patent for dapagliflozin as an anti-diabetic agent expired in 2013. However AstraZeneca successfully identified the active form as the crystalline propylene glycol solvate for which a patent was obtained in US expiring in 2029, delaying the generic entry by successfully innovating and optimising the patent portfolio.

Case Study-Prilosec

Astra obtained a patent for Prilosec (omeprazole) as a proton pump inhibitor, expiring in 1989 while its formulation patent expired in 2007. It was a blockbuster drug from 1996-2000 with the highest sales of 6.9 billion USD in 2000 in US. In an attempt to extend the patent term, Astra collaborated with Zeneca and AstraZeneca then launched Nexium (S-omeprazole) in 2001. The patent term in US for Nexium extends till 2018 while that for its formulation extends till 2020. Not only by optimising the patent portfolio but also through trademark and trade dress followed by active litigation with generics and reverse settlements did AstraZeneca succeed in keeping generics off the market and retained their exclusivity. It is worth noting that S-omeprazole was expected to have double the efficacy of Prilosec since the R-form of omeprazole was found to be rapidly metabolized by CYP 450 enzyme. The S-form of omeprazole would naturally constitute half of the racemic omeprazole and may not strictly qualify for a patent grant. However AstraZeneca could continue to maintain its position as a category leader in the market till date.

In general, invention is not a singular event and neither is innovation. Success in the market place with innovation is a journey involving appropriate decision making and effective strategizing, while building on the optimum patent portfolio. Intellectual property protected is value created.

In this century, the future will be determined by the ability to convert knowledge into wealth and creativity into social good!