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Key issues for senior life sciences executives

Key issues in building life sciences patent portfolios

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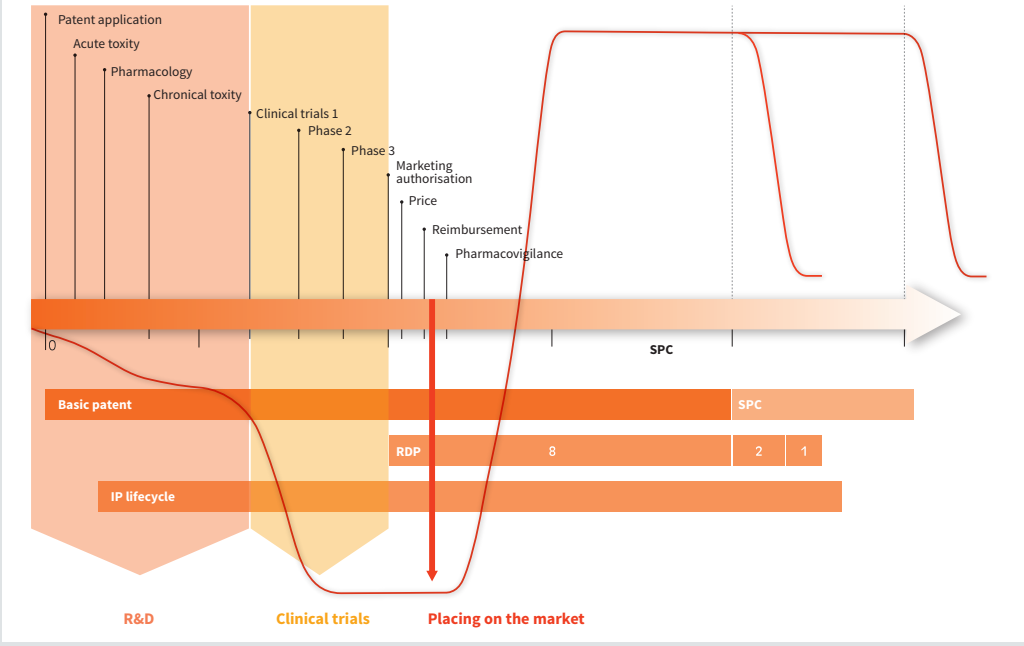
Key issues in building life sciences patent portfolios

By Emil Pot, NLO

The financial success of a life sciences company depends primarily on the scope, lifetime and strength of its patent portfolio. Successful life sciences companies by default have IP portfolios that are strong enough to withstand any challenge from competitors and have a lifespan that is long enough to capture the potential value of the products or technologies. The period during which a life sciences company can benefit from patent protection plays an important role in drug development, on account of the long period from first filing a drug patent application to grant of market authorisation (see Figure 1). Only from that point can a biopharmaceutical company generate returns on the significant sums that it has invested in developing the drug. The period during which the company sees no sales income from the drug – around 12 years – is justified only by the existence of adequate IP protection.

Figure 1. Return on investment versus patent protection/drug development



Source: F Landolt, vice president, intellectual property and legal, Ablynx NV

Spending so much time developing a drug or technology leaves a limited period in which to achieve a return on investment. Investments in drug development are substantial and can reach more than $1.7 billion (see Figure 2). However, such large-scale investment is not the only risk; the possible failure of the drug at the development phase is another daunting prospect. This means that the return on investment should be even larger to account for the risk of failure in the company's other drug development programmes.

Life sciences undertakings are generally divided between development companies and companies primarily involved in late-stage development, registration and marketing. The first group comprises start-ups that take a promising technology or product to the proof-of-concept stage, while the second group assumes the risk of further development and registration.

Most start-ups are backed by venture capital, which means that they have a limited lifespan. These companies ultimately succeed when a so-called 'exit' is reached – either an initial public offering or an acquisition by a larger biopharmaceutical partner. Exit always occurs long before the product under development reaches the market, because few investors are willing to finance costly Phase III clinical trials. For these companies, the intellectual property is essentially their only monetisable asset and represents the true value, regardless of the valuable clinical, regulatory and manufacturing data that can be shared. Intellectual property is at the core of the due diligence activities relating to these exits, which entails evaluating the scope, validity, geographical coverage and duration of the granted patents and the likelihood that any patent applications will be granted with the right scope of claims.

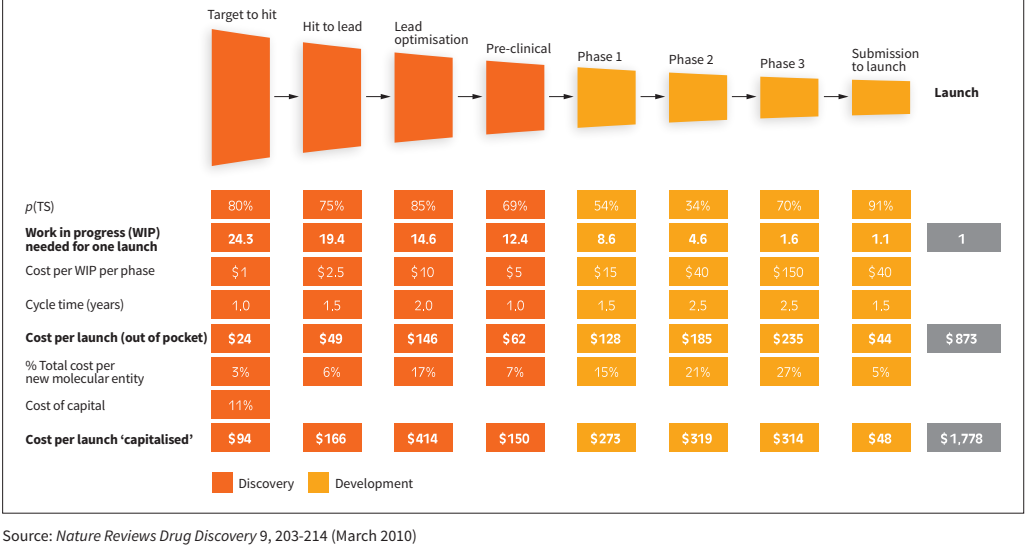
Companies that market drugs and are involved in late-stage development (ie, Phase III and marketing) are mainly concerned about the duration of the patent, lifecycle management and patent term extensions. Every day without IP rights protection can incur a loss worth millions of dollars, in light of generics taking over an ever-increasing share of the market (see Figure 3).

Aligning IP strategy with R&D and business development strategy

Start-ups tend to think strategically about their patent portfolio only after a few years have passed. In the beginning, they are focused on the proof of concept of the technology, raising money and hiring key employees. While some intellectual property may be filed initially, this is often done without a clear sense of direction, resulting in broad applications with little written support for the whole scope. Companies should therefore be aware that the description and claims of the first application will determine the boundaries of any successful future applications.

Start-ups often do not know from the outset the

Figure 2. Drug development costs



Source: *Nature Reviews Drug Discovery* 9, 203-214 (March 2010)

molecule that they will ultimately seek to bring to clinical development or what the primary disease indication will be. As such, a frequent outcome of R&D activities is that a molecule is developed which is not covered by the granted claims or which lies within the range of obviousness from the published patent applications filed by the company. This will limit the scope and duration of the IP rights to the drugs, which can in turn endanger their development. For a first patent filing, broad claims and reach-through claims should be avoided, as they will create prior art for future patent filings which may contain the final drug to be put on the market. Companies should not be afraid to retract a priority document before publishing if doing so means that they will be able to secure the final drug (and since a first application can be filed only once).

In order to avoid issues arising from inadequate IP protection – in terms of both scope and patent life – a proper IP strategy should be designed and implemented. For a life sciences company, having a sound IP strategy is as important as having a sound R&D and business development strategy. Together, these three elements constitute the foundations on which the company's success will be based. All decision making in respect of these three strategic elements should be closely aligned, with each element influencing the others throughout the company's lifespan.

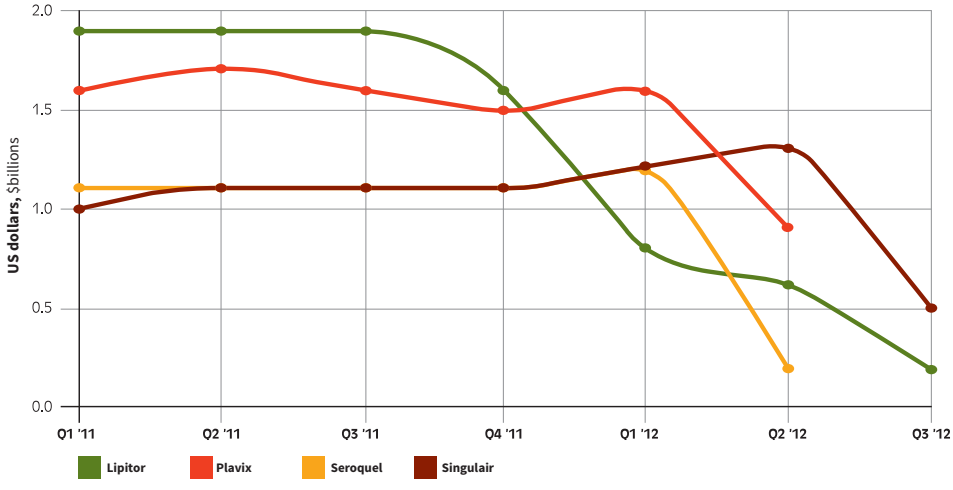
In this regard, the continuous involvement of an experienced IP executive is recommended. He or she should be involved in decision making at management and executive level during the R&D and business development processes. Although responsibility for aligning the IP strategy with the R&D and business development strategies is shared between the IP executive, the management and board executives, it is ultimately the responsibility of the IP executive to ensure that a meaningful IP strategy is designed and implemented which results in a clear roadmap showing when and what to file. The intellectual property should be continuously monitored in view of possible future changes in R&D and business focus. R&D activities see fresh failures and successes on a daily basis, while new business opportunities can arise at any time. All of this should be considered when deciding what to do with the existing intellectual property or whether to file for new IP rights. By involving the IP executive in this decision making, the company can ensure that it possesses an up-to-date and practical patent portfolio.

Life sciences companies that have an IP strategy and IP roadmap will be able to capture all of the value generated in the R&D process and fully monetise this value in future business deals (eg, licensing, trade sales and acquisitions).

Patent landscaping

Patent landscaping is a popular procedure

Figure 3. Effect of patent expiration of blockbuster drugs



Source: BaseCase (2013)

offered by many service companies. However, most of these companies provide poor results with little practical insight. This is unfortunate, since patent landscaping – when performed correctly – can be immensely helpful in creating IP positions that will strengthen the company's competitive advantage and increase its market value. Patent landscaping makes sense only when there is input from the IP, R&D and business development executives and keywords are chosen carefully (eg, by excluding false positives and including false negatives). In particular, competitors' intellectual property should be mapped and each aspect of R&D and the product under development should be identified, as well as the target market. R&D and business development staff should work together with IP staff on the final results of the patent landscaping to identify and fill IP gaps, which will facilitate a strong, mature portfolio.

Risk of invalidation and multi-layered patent approach

The risk of invalidation of crucial patents covering clinical drug candidates is always present. Losing IP rights protection for a drug will likely inhibit its development, as the inability to prevent competitors from taking advantage of future successes in the drug development process poses too great a risk. Moreover, invalidation will have serious adverse effects on the value of the drug and the company itself. The risk of invalidation should therefore be accounted for in the company's IP strategy and IP roadmap. Identifying the nature of the risk and having as many applications running for as long as possible are ways of mitigating the risk, as is taking a multi-layered patent approach that will provide a more reliable defence against competitors seeking to obtain freedom to operate.

Layers of patents covering the drug or technology and the different aspects thereof not only reduce the risk of invalidation, but also extend the lifespan of the patent portfolio. Again, as part of the close coordination between IP, R&D and business development departments, all aspects of the development of the drug or technology and the manner in which it will be placed on the market should be identified and covered by IP rights. Not only should the product itself be covered, but also related manufacturing methods, packaging, quality control mechanisms, measurements, algorithms, software, formulations, administration and dosing.

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Emil Pot has wide-ranging experience in commercialising innovative ideas, from drafting and negotiating licence and R&D agreements to preparing business plans and advising start-ups and innovative companies on their IP strategy. As a co-founder of ActoGeniX NV, he has been actively involved in business development and corporate legal and was responsible for building an effective IP portfolio, until the company was successfully sold to US company Intrexon Corporation in 2015. Mr Pot is a regular speaker at seminars and conferences. He also works as a patent expert for the World Intellectual Property Organisation.

"Losing IP rights protection for a drug will likely inhibit its development, as the inability to prevent competitors from taking advantage of future successes in the drug development process poses too great a risk"

In addition to patent protection, the branding and design of the technology or product should be considered and protected by trademarks or design rights. These efforts will result in a strong layer of different IP rights that will allow the company or its licensee to enforce its rights effectively against infringers and maximise value over an extended period.

Geographical validations

Not every patent should be filed in 25 or more countries, as not every patent has the same value or is as easy to police in every jurisdiction. Addressing market size is a potential way of determining the requisite geographical coverage. Holding a patent in the United States, Europe and Japan covers 80% of the worldwide market in pharmaceutical sales; extending patent protection to China, Canada, India and Australia adds a further 10%, while including Brazil, Korea, Russia and Mexico accounts for a further 3% – bringing total coverage to around 93% of the global market. For a patent that claims the composition of matter of a drug, designating all of these countries is practically mandatory, especially for potential blockbuster drugs. However, if the patent relates to different components of the drug or technology (eg, manufacturing aspects, quality control, mechanisms of action or excipients in the formulations), it may be sufficient to file only in the United States, Europe and Japan.

External versus internal counsel

Whether a life sciences start-up should have an IP professional in-house or simply rely on external counsel is a matter of debate. Although using an IP firm normally affords the advantage of broad prosecution experience, the most important factor is whether the external or internal IP professional responsible for the portfolio is sufficiently experienced and works closely with key R&D and business development staff. All too often, the IP counsel – whether internal or external – is unaware of the R&D activities underway or envisaged and does not understand the implications of failures or successes within the R&D department, or the opportunities that arise on the business development front. *iam*

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