

Key issues in building a strong life sciences patent portfolio

Senior executives in the life sciences industries need a keen understanding of how to build and maintain a strong portfolio in order to enforce and defend their IP rights. Well-managed IP rights will also be an enabler of collaboration and further innovation

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The life sciences have become a major source of innovation and a global driver of economic growth. This is especially true as classic small molecule organic chemistry will probably be unable to recover from the ever-decreasing numbers of new molecular entities and drug candidates. The spectre of the “patent cliff” also looms large over many pharmaceutical innovations and blockbuster drugs which will come off-patent in the next few years, when generic products will surge onto the market. Pharmaceutical innovators must weather the storm by investing in new research areas, engaging in smart patent lifecycle management and cultivating a broad patent portfolio in order to secure the long-term success of their business development strategy.

As some of the key enabling technologies of the 21st century, the life sciences can unlock remedies for hitherto incurable diseases. However, as with classic pharma, innovation in the life sciences is characterised by skyrocketing R&D costs and high regulatory burdens; strong patent protection is thus crucial. Moreover, solid IP protection is the cornerstone for the business model of many small life sciences start-ups, which often build on a single

invention as their major intangible asset.

A review of the strategic nuts and bolts of previous life sciences success stories reveals that key inventions are protected not by a single master patent, but rather by a whole host of patents that are clustered around the core invention, thus offering the broadest possible protection of the commercialised product. This broad protection, in the form of a patent portfolio, has proved to be a fundamental determinant of success for blockbuster drugs.

Therefore, building a strong life sciences patent portfolio is vital from an economic perspective. This article highlights the key issues in building a strong portfolio, with a particular emphasis on practical aspects and cost effectiveness.

Patent portfolio as strategic business value

Building a strong patent portfolio is the best way for a company to increase its strategic business value. It not only serves as a powerful barrier to market entry for competitors, but may also promote freedom to operate by discouraging further patenting in the respective technological field.

Moreover, a strong patent portfolio increases negotiating power, both with potential investors (eg, in view of capital inflow) and with competitors (eg, in view of potential cross-licensing opportunities).

Patents are the engine that drives venture capital investment and initial public offer funding, as well as mergers and acquisitions in the life sciences industries. Venture capitalists, Big Pharma and the stock market all need to be convinced that a start-up has enough IP protection to gain an edge over its competitors. The business potential of a given life sciences company will be evaluated on whether its patent portfolio has promising offensive and



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defensive strategies in place to safeguard long-term exclusivity or market share.

Portfolio breadth

To ensure sufficient breadth of the patent portfolio, it is key to think from a competitor's perspective and to understand that not all patents are equal. For instance, some patents may seem to be a perfect mirror image of the company's commercialised product and may therefore appear to offer optimal protection for the product. However, such patents may in fact offer ample possibilities for competitors to design around and thereby sidestep patent protection. Such strategies should be anticipated at the outset of drafting the patent application. The ease with which a competitor might design around the patented solution should also be re-evaluated periodically as prosecution of the application progresses.

Studies on patenting and litigation patterns have shown that the quantity of patents alone has a protective effect. Companies with about 500 patents in their portfolio are four times less likely to be involved in patent litigation (see Li and Yu (2007), *BioPharm International*).

A more offensive portfolio strategy is to envisage products that competitors might develop in the future and file patents on those. This may even be advisable if the company itself is not planning to develop such products. Also during prosecution, there may be opportunities to amend the pending claims to cover a competitor's product. Even for companies that eschew aggressive IP enforcement strategies, holding a patent that covers a competitor's product is often the best insurance against being sued by that competitor.

Focus on quality, not quantity

At the time of their inception, most life sciences start-ups hold fewer than five initial patents and their business plan usually centres on these core patents. They will then build up a patent portfolio by filing patents on R&D results, in-licensing intellectual property from other companies and universities, and acquiring entire IP portfolios. In the medium-sized enterprise and Big Pharma context, a distinct number of basic patents usually protect the products in the pipeline and form the cornerstone of the business unit's patent portfolio.

The quality of these initial cornerstone patent filings is crucial. Sufficient time, expertise and effort must be invested in planning, drafting and prosecuting these initial patent filings, even if this may be

expensive. Guidance should be sought from an experienced patent counsel if the company does not yet itself have this sort of business and IP intelligence. Any short-term monetary gains that are made from cuts and compromises in laying the cornerstone of a patent portfolio will be offset by the long-term ramifications. A key issue in building a strong life sciences patent portfolio is thus to focus on quality over quantity, especially in regard to the initial cornerstone patent filings on which the portfolio will build and evolve.

Active portfolio development and management

Building a strong patent portfolio is an active management task that should involve resources that are already available in the company. An experienced patent counsel should identify promising inventions that are worth pursuing in a patent application.

Due to budget constraints, it will often be impossible to patent all of the company's ideas and discoveries. It is thus important to establish a framework for informed decision making on which inventions to pursue in patent applications. In this regard, marketing experts who can judge the importance and commercial potential of a given invention should team up with technical experts who know the current state of the art and can give an initial estimate of patentability in view of the novelty and inventive step requirements.

A crucial question to answer periodically is whether a patent application is underway for every product in the pipeline. Also, the patent counsel should consult with technical and marketing experts within the company on ways in which a competitor could skirt the current patent portfolio or curtail future freedom to operate by patenting improvements, additions or alternatives to the patented solution.

A mandatory exercise for every successful IP manager is to review and mine the patent portfolio and pending applications periodically to ensure that they align with the company's current needs. A regular inventory of the patent portfolio should be made and reviewed between patent counsel and the company's management executives. The resulting bird's-eye view affords a unique opportunity to adjust and mine the company's long-range IP portfolio strategy, and to identify and plug gaps in protection with new patent filings or divisions of pending applications (where possible).

Validity and enforceability

Expanding on the maxim of "quality over

quantity”, it is important to appreciate that although a patent may have been granted by a national patent authority, this does not yet constitute proof of the patent’s validity or enforceability. Many patents are challenged in post-grant opposition and nullity proceedings.

In general, predictions as to the validity and enforceability of life sciences patents are often still shrouded in uncertainty. The biologics IP environment is higher risk than the traditional pharma small-molecule IP environment, in that biologics patents are often less clear-cut and more difficult to interpret in terms of protective scope, validity and enforceability.

To secure the validity and enforceability of patents, one key safeguard – which may appear trivial and is often overlooked – is not to generate prior art that could be used against the patent. Especially in the life sciences, where impact factor and publication output are key metrics of scientific reputation and success, prior disclosure by the patentee is a major problem. Some scientists may be unaware that in most jurisdictions, prior use and oral disclosure – for example, at a scientific meeting – can constitute novelty-destroying prior art for their own inventions. Therefore, it is important to educate and train employees periodically in order to foster IP awareness and compliance with secrecy requirements.

Another important issue is the timing of patent filings. On average, it takes three to six years to obtain a patent for a typical life sciences invention. Putting a new drug on the market takes roughly 10 to 12 years from the initial discovery. With a patent lifespan of 20 years, companies may thus be inclined to file patents later in the development of the drug, in order to secure longer patent protection for the time that the drug is actually commercialised. However, this option is not recommended. There are other ways to extend the life of a patent (as explained further below). Patents should be filed early in order to secure market share and discourage any existing competition. The later the patent is filed, the greater the probability that there will be prior art published that can stand against the validity of the patent.

Market analysis and monitoring of competitors’ intellectual property

To achieve the goals of strategic planning, cost effectiveness and targeted portfolio development, a company must align its patent portfolio to the specific market situation and patent landscape of the

technical field in which it competes. Periodic analysis of the technological field and market for new competitor patent filings is vital. In addition, the prosecution status of important competitor applications should be monitored so as not to miss the issuance of patents or the respective opposition deadlines.

In many cases, it makes sense to allocate a separate budget for freedom-to-operate opinions and IP monitoring, in order to identify “white spots” in the patent landscape that may serve as impetus to develop and expand the company’s patent portfolio in these areas. Patent mapping is a powerful tool for business development; it is futile to try to expand one’s portfolio in areas that are already dominated by competitors’ intellectual property.

With biologics, the manufacturing process of the molecule and the formulation for administration are much more technology driven than for classic small-molecule pharma. Also, the manufacturing process of biologics and their specific formulation are more closely regulated than those for small molecules. It is thus more important in the life sciences to secure freedom to operate in all three areas – manufacturing, formulation and delivery – at an early stage in drug development.

Compared with classic small-molecule organic chemistry, patent search and monitoring for life sciences patents is much more burdensome. While small molecules and their respective IP protection can be found relatively easily through structure-based searches of established and well-maintained chemical patent databases, this is more challenging in the life sciences, where one can often rely only on full-text searches, which are highly dependent on the specific terminology and keywords used.

Patent lifecycle management

The value of a company’s life sciences patent portfolio depends on the duration for which it can keep competitors at bay. It is insufficient to file just a single patent application for the initial product that makes it to market. The old maxim of “one molecule, one patent” is outmoded. Although this principle may ensure market exclusivity for the first decade, competitors and generics will surge onto the market once the patent term has expired. However, often no return on investment has yet been achieved at this point, because of the immense upfront R&D expenses required.

The European legislature has recognised this problem and established supplementary protection certificates (SPCs) for new



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medicinal products that can extend patent protection for up to five years. SPCs are a powerful tool and allow companies to amortise investments during the years of research before marketing authorisation is obtained. At the end of the patent term – when, in the case of blockbuster drugs, billion-dollar revenues are at stake – each day of additional patent term extension counts. However, with only a few applications filed in Europe every year, SPCs are still considered a specialty in patent law. Because of the tremendous economic importance of SPCs, the advice of a patent counsel who is experienced in SPC matters is indispensable.

Another important patent lifecycle management strategy is to diversify patent protection around the commercialised product and obtain protection at an early stage for potential follow-up products. From a freedom-to-operate perspective, it is imperative to patent improvements actively and not to rest on one's laurels; competitors may improve on patented technology and obtain patents on improvements or special applications of the patented technology. Although equipped with the basic milestone patent on the technology, the originator company would then be dependent on licensing deals to sell improved versions of its initial product. Therefore, patent lifecycle strategies are of paramount importance to secure long-term freedom to operate.

Examples of effective patent lifecycle management include filing patents for alternative production methods, derivatives, add-ons and applications of the product. From the first discovery of a class of molecule active against a given drug target ("genus" patents) and the identification of hits ("species" patents) and the lead compound to inventions made on formulation of the compound for clinical trials and the final upscaled manufacture of the active pharmaceutical ingredient for marketing of the drug, the lifecycle of a pharmaceutical offers ample opportunities to file patents on technical advances made during its development. In addition, patents on crystal forms, enantiomers and pro-drugs of the active pharmaceutical ingredient are possible, as are patents on specific treatment regimens and combination therapy. In view of the vast possibilities that patent lifecycle management affords, it is important to establish a framework for informed decision making at each stage in the patent lifecycle.

As a note of caution, when implementing patent lifecycle strategies, companies should be aware of the criticisms set out in the European Commission's 2008

pharma sector inquiry. Especially when they enjoy a dominant market position, companies must be aware that certain patent lifecycle strategies may be challengeable under antitrust law.

IP monetisation

The electronics and telecommunications industry serves as a telling example of how intellectual property has become a crucial business asset. Patent licensing has become an industry in itself. The big players – including Apple, Google and Samsung – are stocking up their IP arsenals, despite the cost. What some commentators boldly termed a "patent war" has sparked a global gold rush to acquire entire patent portfolios, even if this entails mergers and acquisitions of entire companies. Although patent pooling, licensing and litigation in the life sciences have not yet reached the same levels of intensity as are currently seen in the electronics and telecommunications industries, monetising intellectual property is a smart approach to leverage the full potential of a company's patent portfolio.

If possible, it is advisable to actively license non-core intellectual property for profitable returns on investment. Although patents on core technology serve to defend market share, there may be patents in the portfolio that protect technology which is of no direct commercial interest to the company, but is highly attractive for other companies to acquire or license. An experienced patent counsel should review the portfolio together with technical and marketing experts from within the company, to ensure that informed decisions are made about which patents to purchase, license or sell in order to foster and support the company's strategic goals.

Outlook

Cultivating and managing a strong patent portfolio is a skill that is well worth acquiring and perfecting. For this, it is imperative that patent counsel, R&D intelligence, innovation management and marketing executives join forces to build a strong life sciences patent portfolio that adds sustained value to the company. ■

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