# Ten tips for managing life science patent portfolios

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*The importance of a robust IP strategy should not be overlooked, according to Greenberg Traurig's David J Dykeman, Chinh H Pham and Melissa Hunter-Ensor. They outline 10 key considerations for life science companies hoping to plant invaluable seeds for future growth, investment and revenue generation*

Patents are the currency of the life sciences industry and fundamental to the success of any company in the space. A well-planned IP strategy can bridge the gap from pre-clinical research to regulatory approval by creating value in a company's intangible assets and helping it attain market exclusivity for its proprietary products. Developing a strategic IP position surrounding a company's R&D is key to determining a product's commercial success.

IP strategy should be implemented concurrently with research, development and investment strategies, all of which must be aligned with a company's business goals. A company can leverage its intellectual property in many ways, including:

- raising capital;
- entering into strategic alliances;
- generating revenue through licensing;
- blocking competitors; and
- in connection with joint ventures, mergers, acquisitions and initial public offerings.

In addition, strong patent strategies may enable patent holders to avoid the high stakes and costs of attacking and defending patent infringement lawsuits.

The importance of a robust IP strategy should not be overlooked, so these 10 tips are critical for developing a strategic IP portfolio that will provide a strong foundation for future growth, investment, revenue generation and market leadership.

## One: find FTO in crowded patent areas

The term 'white space' refers to the open spaces surrounding a technology. If a technology area is crowded with patents, there is less room to develop new intellectual property. Alternatively, if the patent landscape is relatively clear, there is ample space to secure meaningful patent claims. Identifying and developing a strategy for patenting technologies within white space can be helpful for life science companies wishing to solidify a competitive edge in the marketplace.

By filing patent applications in white-space areas, companies can stake broad claims to potentially dominate a particular tech landscape. Analysing how crowded a particular area is with competing patents allows a company to forecast what technologies will be in common use 10 to 15 years in the future.

White space becomes problematic when a competitor develops a product that is so technologically close to a company's own product that it impedes the company's ability to control its commercial area, essentially blocking it from practising its own patents or expanding its product base.

To determine whether a product can be produced without infringing third-party patents, a company should undertake an FTO analysis, which would also help it to develop a strategy to maximise patent presence within that commercial area. In particular, such an FTO analysis can:

- identify opportunities to design around a competitor's technology to avoid patent infringement and help to identify new technologies for patenting;
- aid in the development of strategies for modifying a company's current patent portfolio to assure the broadest possible coverage for its products;
- allow a company to file patent applications covering improvements to a competitor's products and provide control over a competitor's product enhancement options; and

- allow a company to file patent applications covering potential commercial uses of a competitor's innovation to block the competitor, construct a fence around their core innovation and create leverage should cross-licensing be necessary.

## Two: determine claim type and scope

A strong patent portfolio includes claims of varying scope – broad claims that can cover potential infringers and narrow claims that may be more likely to survive a patent challenge in the patent office or the courts. For pharma and biologics companies, composition-of-matter claims, which cover drug products, drug intermediates and other materials, are often the most valuable. These are not limited to a single method of use or indication and provide a strong defence against competitors, as well as a solid foundation for future innovation.

As the 20-year lifespan of the initial composition-of-matter patent runs, companies may continue to file patent applications directed to dosage regimens, formulations, methods of treatment, methods of manufacturing and combination therapy claims. While composition claims cover the active ingredient, formulation claims are useful because they cover the commercial product to be taken to market and used in clinical trials. Patents directed to dosing regimens approved by regulatory authorities are also valuable. Such patents are not only helpful in protecting ongoing innovation, but also help to extend patent protection surrounding the company's core technologies into the future.

## Three: be proactive – Track One and the Patent Prosecution Highway

To build a patent portfolio faster, early-stage pharma and biotech companies should consider utilising the USPTO's fast-track patent examination programmes.

Due to the current backlog of pending patent applications at the USPTO, it can take up to three years for a life science patent application to obtain a final decision on patentability and be issued as a patent. In contrast, the USPTO's Track One prioritised examination programme strives to achieve a decision on grant within one year of filing and applications may be allowed in as little as six months. Other ways to accelerate USPTO examination include using the Patent Prosecution Highway – which is based on an issued foreign patent or a favourable search report – and the age-based programme, which speeds up examination for inventors aged 65 or older.

Track One is more expensive than regular examination and accelerates costs that would normally be spread over a few years. However, the additional expense is often worth it because the programme allows a company to quickly obtain a patent to cover a key technology or product – such coverage can be crucial in demonstrating an IP strategy's strength to potential investors. An issued patent can also be helpful in creating a barrier to entry for potential competitors. Additional patent applications with claims of different scope can be filed via regular examination to build multiple layers of patent protection around the company's core technology.

## Four: develop an international strategy

To further strengthen a patent portfolio and expand a company's global presence, life science companies should also file international patent applications. While expensive, strategic filings in key countries are critical to a product's global commercial success.

The Patent Cooperation Treaty (PCT) provides a mechanism to initially file one international application that provides protection in 157 contracting states, including the United States and most foreign countries that are key life science markets. A PCT patent application can delay filing costs in specific countries for at least 18 months.

To optimise international patent protection, life science companies should consider filing patent applications in countries with large markets for the product, as well as those where competitors' manufacturing facilities may be located. Key locations for pharma and biotech companies include Australia, Brazil, Canada, China, Europe, India, Japan, South Korea and the United States. Because many of those jurisdictions have prohibitions against patenting methods of treatment or diagnostics, it is vital to consider how best to protect innovations through creative claim drafting before filing individual applications. A patent in these countries will protect the company against potential infringers who may wish to make, use or sell the company's invention around the world.

## Five: strengthen your portfolio by licensing patents

Licensing can be a vital strategy for pharma or biotech companies to strengthen or enhance their IP portfolios. For drugs, the fundamental discovery and initial research often occur at universities or research institutions, and it is crucial for life science companies to gain access to the earliest patents and data through licences. In-licensing can provide companies with access to technology they need to develop promising therapeutic candidates and compete in the marketplace, while avoiding potential infringement lawsuits.

When in-licensing a patent portfolio, a few things should be kept in mind. Licensees should try to control patent prosecution of the in-licensed portfolio. Allowing the licensor's patent counsel to prosecute the portfolio may be fine, but the ability to develop and capture the nuance of expanding patent coverage to enhance a commercial product may be compromised. Also, ensure that the in-licence allows you to own any improvement or modification to the underlying licensed technology made by your employees or contractors. By doing so, you can control the innovation process and avoid having to negotiate another licence for technology that is developed later.

Cross-licensing with competitors is another way to enhance a patent portfolio. A cross-licence may provide companies with FTO in a crowded technology area without the exchange of licence fees. Cross-licensing opportunities arise when companies have overlapping patents, and practicing one patent may mean infringing the other company's patent. Companies can pool the relevant patents and divide the rights among themselves by field so that each party takes exclusive or non-exclusive rights to a particular field covered by the combined patents. Such cross-licences can lower licensing fees, encourage earlier and lower litigation settlements and promote innovation by preventing competitors from blocking another's products.

## Six: resolve ownership issues

Ownership disputes may arise in academic settings when collaborators from a variety of universities and research institutions conduct research over several years, and the patents they file fail to account for all individuals that contributed to the invention's conception. Inventorship is a legal determination that cannot be settled by contract. Nevertheless, companies entering into collaborations with universities or other companies should establish, from the outset, what ownership rights each party will have and what rights each party will retain upon the collaboration's termination. Establishing rights at the beginning of the relationship will minimise the chances of disputes later on.

When entering into joint ventures, participating companies have several options for addressing ownership of jointly developed products. First, a company may want to consider assigning the patented invention. The patent may be assigned entirely to the other party or jointly to each party. As co-owners, each party has the right to sell or transfer rights to the patented invention without the other party's consent. A company may also want to consider granting the other party a licence, which may either be exclusive or non-exclusive. Under an exclusive licence, the licensee may have the exclusive right to use or sub-license the patented invention. Under a non-exclusive licence, on the other hand, the licensee may be permitted to practise the invention within the scope of the agreement while the licensor retains title and all other rights to the invention, including licensing the patents to other third parties. Addressing ownership of jointly developed patents before product development minimises potentially costly disputes arising after the product has been released on the market.

## Seven: manage confidential information to avoid unintentional loss of IP rights

One of the most important ways to protect intellectual property is to avoid inadvertent or unplanned public disclosure. If the invention is released into the public domain before a patent application has been filed – whether by publication, presentation, posting on a website, blogging or discussion with potential customers or suppliers – then loss of the right to obtain a patent can occur. Additionally, such disclosure can reduce or eliminate competitive advantage.

In the United States only, an inventor has up to one year from the first public disclosure to file a patent application. In all other countries, absolute novelty means that patent applications must be filed before any public disclosure. Thus, it is strongly advised that an inventor first take precautions to protect all intellectual property or risk losing patent rights.

Some basic documents that should be in place to protect IP ownership and confidentiality include:

- invention assignment agreements – these should state that all ownership rights are automatically assigned to the company. Present-tense language like "hereby assign(s)" should be included to help avoid any ownership discrepancies;
- non-disclosure agreements (NDAs) – these may be used to maintain confidentiality and protect rights if disclosure to third parties is necessary for business reasons and should be utilised when entrepreneurs present their inventions or business plans to potential investors, vendors or advisors in an effort to secure financing or commercialise a product. Never divulge sensitive information until an NDA is signed; and
- employee handbooks – these are great for laying out expectations of employment, particularly the expectation that the company's intellectual property is not to be shared, disseminated, misappropriated or stolen under any circumstances.

## Eight: extend patent life

Over 60 countries around the world provide an extension option for medicinal product patents. In the United States, this is known as a patent-term extension and can extend patent life due to Food and Drug Administration (FDA) regulatory delays. In Europe, a comparable extension is the SPC, which can extend the term of a medicinal patent by up to five years, with the

possibility of a further six-month extension term in some circumstances. SPCs can be obtained in the United Kingdom, all EU member states and Switzerland, Norway and Iceland, among others.

The term of US patents can also be extended by a patent-term adjustment (PTA), which accounts for USPTO delays during patent application prosecution. To the extent possible, a patent applicant should avoid taking time extensions to maximise any PTA.

## Nine: ensure availability of domain names and trademarks

To make the best use of time, effort and marketing dollars when branding the product, ensure that the chosen domain name is available and consider a trademark. Domain names and trademarks are two separate entities, so it is critical to consider both. Without a domain name, having a trademark that users cannot easily associate with a product can be detrimental.

It is also crucial to ensure that trademark protection is available in major market countries before spending resources on a branding campaign. It would be unfortunate and, more importantly, costly to discover late in the process that a competitor owns a similar trademark for a competing product. Savvy companies perform worldwide trademark searches before settling on a product name.

## Ten: do not forget about trade secrets

Used in conjunction with – or as an alternative to – patents, trade secret protection can provide another option for protecting pharma and biotech companies' intellectual property. This involves taking measures to keep ideas secret, which can also avoid the effort and expense associated with filing patent applications. Trade secrets can provide protection for as long as the underlying technology is kept secret, but any public disclosure means that protection is lost.

Examples of trade secrets for life science companies include:

- methods of manufacture;
- screening methods; or
- any other aspects of a product that are not ascertainable through reverse engineering, independent discovery or observation of the product.

With the availability of both patent and trade secret protection, how does a company decide which strategy to pursue?

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| **Is technology susceptible to reverse engineering or independent discovery?** | If yes, pursue patent protection. | If no, keep technology as a trade secret. |
| **Is it easy to detect infringement and to enforce patented technology?** | If easy, pursue patent protection. | If not, keep technology as a trade secret. |
| **Is it difficult to maintain confidentiality of the technology?** | If difficult, pursue patent protection. | If not, keep technology as a trade secret. |
| **What is life expectancy of commercial value of the technology?** | If short, pursue patent protection. | If long, keep technology as a trade secret. |

Many life science companies pursue dual strategies of patenting breakthrough discoveries and incremental improvements, while maintaining trade secrets for other innovations.

## The way ahead

Obtaining issued patents in the pharma and biotech space can be challenging but valuable. Strategic planning in conjunction with your patent attorney at the early R&D stage can help maximise the chances of being awarded commercially meaningful patents. By implementing a strong patent strategy, life science innovators can streamline patent application preparation and examination, which can lead to more robust patent protection.

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