

A GUIDE TO DEALMAKING

Protecting biotech IP to support deal value

Inadequate or unsuitable intellectual property (IP) protection could allow competitors to more easily launch a competing product, jeopardizing the opportunity for meaningful return on investment and consequently potential dealmaking. This feature discusses key factors for biotechnology companies to consider in creating IP strategies to support value.

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Thousands of deals are signed each year in the pharmaceutical and biotechnology sectors. Most of them are driven by an innovative and promising therapeutic product or diagnostic, which will be protected by patents—a form of intellectual property (IP). Effective patent protection is crucial to the potential of achieving a return on the investment in a product in the biopharma industry, given the lengthy timelines for product development and the high development costs. Consequently, rigorous assessment of a potential partner's IP position is a standard part of a deal. This article provides advice to companies on steps needed to establish a strong IP position, including a checklist.

More than numbers

A vast number of patent applications are filed each year relating to pharmaceuticals and biotechnology, and there are an ever-growing number of granted patents. To give an indication of the magnitude, Fig. 1a and Fig. 2a show the trends in new patent application filings and patents being granted relating to therapeutics for disorders of metabolism and the nervous system, as well as anti-infectives and antineoplastic agents. These are among the

most active therapeutic areas, but there will be thousands more pieces of IP relating to other areas. Patents protecting underlying scientific developments, methods and procedures also have a role to play. For example, Fig. 1b and Fig. 2b show trends in new patent application filings and granted patents relating to new technologies in microbiology and genetic engineering. Again, there are thousands of pieces of IP.

From a dealmaking perspective, however, it is not merely the numbers of patent filings and granted patents that a potential partner has that matter—it is essential that their patent portfolio is robust and fit for purpose. This means that a company hoping to do a deal must ensure their IP portfolio and the strategy governing it are ready for due diligence by potential partners. So, what does this entail?

Correct capture of IP

Researchers at innovative biotechnology companies reveal new information and make new discoveries regularly and rapidly. Many of these developments are steps forward on the path toward a new therapeutic product or diagnostic. It is worth noting, however, that

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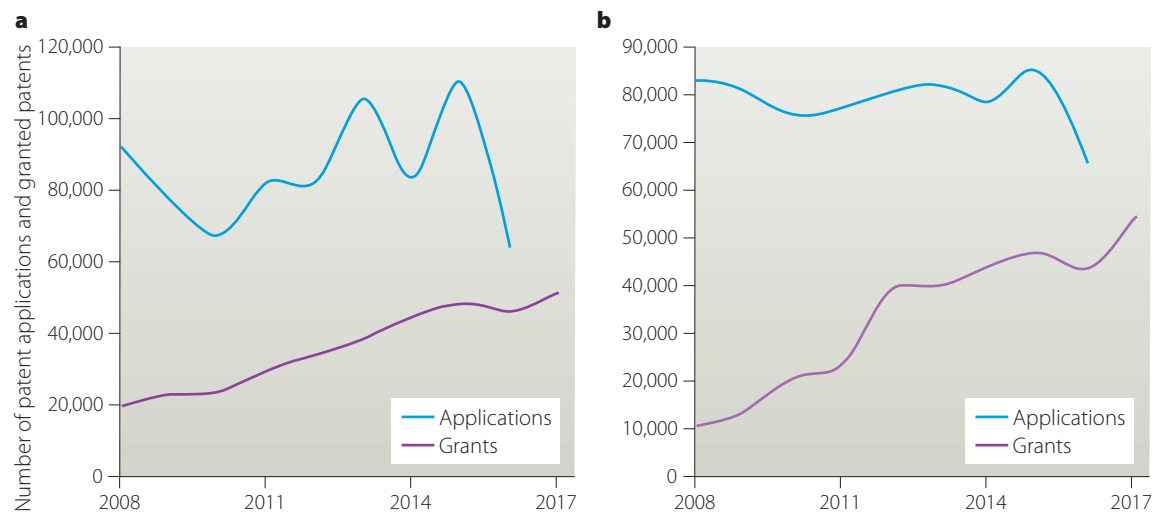


Fig. 1 | Worldwide patent filings and numbers of granted patents from April 2008 onwards. a, Patents related to therapeutics for disorders of metabolism and the central nervous system, as well as anti-infectives and antineoplastic agents. **b,** Patents related to technologies in microbiology and genetic engineering. Source: PatBase.

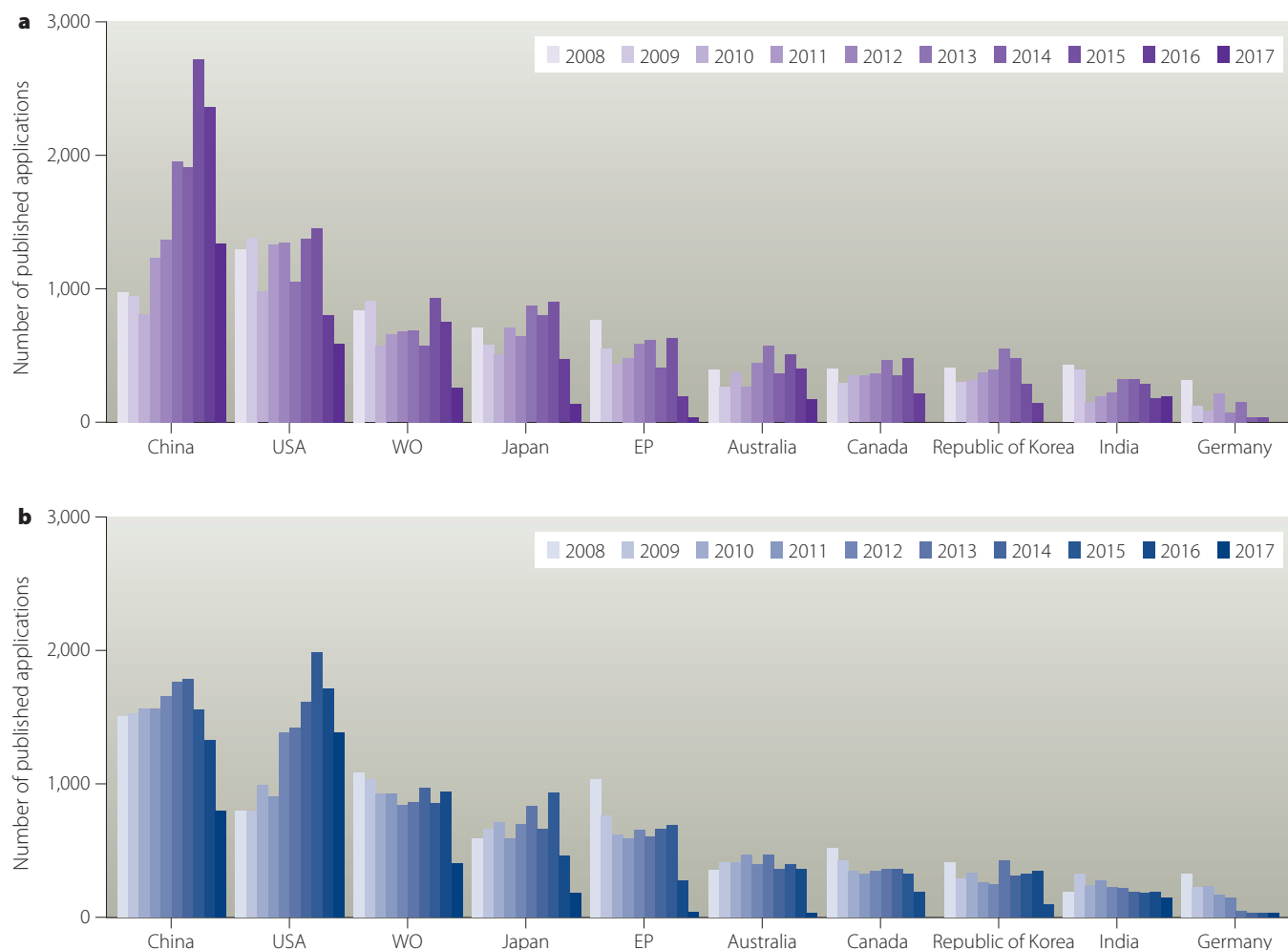


Fig. 2 | Patent application filing numbers in the top jurisdictions from April 2008 onwards. a, Filings related to therapeutics for disorders of metabolism and the central nervous system, as well as anti-infectives and antineoplastic agents. **b,** Filings related to new technologies in microbiology and genetic engineering. EP, European patent application; WO, international patent application. Source: PatBase.

some of those steps forward will be separately patentable developments and may have wider applicability than the main focus of the research from which they originated. An effective IP strategy should include a process to identify and then protect valuable newly generated IP and so prevent IP leakage that could undermine the value in a company.

For commercial success, a key part of the patenting process in the highly active and competitive pharmaceutical and biotechnology sectors is to file a first patent application before competitors and thereby get an earlier priority date. So, a first patent application for a new therapeutic product is normally filed years before clinical trials are completed. However, there is an opposing pressure. Patent rules mean that it is essential for the patent specification to include enough description and evidence to show that the new healthcare product can be made and that it will function as claimed. On the one hand, waiting too long before filing a first patent application could mean that a competitor files a new application before you and takes the lead and/or excludes other companies from a particular technology space. On the other hand, filing too soon could mean that there is not enough evidence to support the argument that a new healthcare product actually works as claimed, potentially undermining the case for granting the patent. Careful review of innovation as it occurs is needed to balance these conflicting pressures.

Align to the business plan

Each new therapeutic product or diagnostic in development will have one or more target markets, and part of the analysis behind a deal will assess the size and location of the target markets for the products being developed, their likely sale prices and the duration of patent protection available in them. Careful linking of the business plan to the execution of the patent-filing program is needed to maximize the potential to realize value in the target markets. Some examples of the considerations involved are set out here.

First, the IP strategy must obtain, or at least keep options open for obtaining, patent protection in the target markets. Patents are territorial rights. This means that a patent provides protection and exclusivity for a specific geographical area, which is often just one country. Therefore, an important question is where to seek patent protection. Issues including the geographical prevalence of a particular disease, the willingness of healthcare systems to pay for the product being developed and where potential generic competitors have manufacturing plants will come into play. Consequently, there could be country selection differences between different patent-filing programs for different types of healthcare products.

Linked to patents being territorial rights, there are variations in the approach to patentable subject matter between different jurisdictions. This is an issue that hits the pharmaceutical and biotechnology sectors particularly hard. Patent law has evolved in some countries so

that some types of subject matter are not considered as 'inventions' or are specifically excluded from being awarded patent protection. For example, this means that something that is patentable in Europe may not be patent-eligible subject matter in the United States and vice versa. Key examples include methods of medical treatment, diagnostic methods, innovations that can be viewed as products of nature or laws of nature. An effective IP strategy takes this into account from the outset of any new patent-filing program.

Second, there are ways to demonstrate that patents are likely to be granted and to show their expected scope of protection even at an early-stage of the life cycle of a patent family. Deals made when a research and development (R&D) program is at an early stage might rely on a patent-filing program that is similarly at an early stage. Providing reassurance that patents are likely to be granted can be crucial for potential partners. Several patent offices, including the European Patent Office (EPO) and the United States Patent and Trademark Office (USPTO) offer accelerated prosecution programs. However, there can be cost implications. The UK Intellectual Property Office (UKIPO) can offer a low-cost, rapid and high-quality service. If the patent portfolio is at an even earlier stage, obtaining a positive opinion on an international patent application can be useful.

Third, regular patent scope reviews can be a valuable exercise to ensure that the most preferred compounds or other commercially important aspects fall squarely within the scope of patent protection being sought. Often a patent application is drafted and first filed early in an R&D project, and it may be several years later that the drug candidate is identified from multiple promising compounds and then optimized, or it may take years for a diagnostic test to be validated. Furthermore, pre-grant interaction with patent offices can take a few years. Good communication between those managing the IP and the R&D team should prevent unhelpful divergence and help keep the patent protection aligned with product development.

Fourth, the use of follow-on patent filings is one way to enhance a patent portfolio. Good IP governance and communication with the R&D team should also be encouraged to help spot when a development program has produced a refinement or incremental step that is itself a patentable invention. This could create a new layer of patent protection to strengthen a patent portfolio and potentially extend the overall duration of patent coverage for the product, as such patent filings occur later in time.

Fifth, patent term extensions—also referred to as supplementary protection certificates in Europe—extend the effective duration of exclusivity. These mechanisms are provided to compensate for the lost portion of IP protection and exclusivity due to the need to complete clinical trials before marketing approval. An IP strategy should include an awareness of how such extensions might be achieved later and take appropriate steps during patent prosecution to make obtaining such term extensions easier.

Sixth, patent audits are also part of effective IP management because there is value in identifying elements of a patent portfolio that no longer provide what is needed. Although the cost of maintaining a patent portfolio is minor in comparison with performing clinical trials, there is still a cost associated with maintaining and defending patents. Knowing the purpose for having each piece of IP shows that the IP is actively managed and no unnecessary costs

Box 1 | IP checklist

The following provides a checklist of the factors discussed in the article, which collectively support a strong and effective IP position.

- Prevent intellectual property (IP) leakage
- Find the 'right' time to file each new patent application
- Obtain appropriate geographical coverage
- Jurisdiction specific patenting
- Have a strong indication that patents will grant as required
- Regularly review patent claim scope
- Actively manage the IP portfolio
- Capture the IP in product refinements
- Create a layered patent portfolio
- Obtain patent term extensions or supplementary protection certificates
- Analyze competitor IP
- Assess freedom to operate

are incurred. IP that is no longer core might be divested to provide a source of income or allowed to lapse to prevent any further unrecovered expenditure.

Finally, having a granted patent does not provide a legal right to go ahead and commercialize the patented invention ignoring other IP rights. An effective IP strategy must therefore include appropriate steps to gain competitor intelligence and to analyze and provide reassurance around freedom to operate. The IP landscape for many diseases is likely to be crowded with competitors around the world, working on healthcare products that may have similarities to those being developed by your company. Patents held by such competitors can also have an impact on your commercialization plans.

In certain technical fields, it may be clear who the competitors are. Analysis of competitor IP that focuses on certain companies or specific inventors can be useful. A more complete freedom to operate analysis is usually essential prior to commercialization, involving extensive searches of patent databases to identify any potentially relevant third-party IP. Should conflicting IP be identified, it needs to be carefully analyzed to determine whether it creates a barrier to commercialization and, if so, what can be done about it. Licensing arrangements might be an option. Alternatively, most patent systems provide a number of mechanisms to 'attack' third-party IP and these can be useful in ensuring a clear path to commercialization.

Conclusion

As the discussion above highlights, it is only with a strong understanding of the interplay of the factors discussed here that an insightful IP strategy can be devised and a robust patent portfolio that is fit for purpose can be built and maintained. A checklist of the key considerations discussed here is provided in **Box 1**. These do not represent an exhaustive list, however, and do not replace specific legal advice and bespoke IP strategy development.

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