

Patent strategies for biotechnology companies

Sandy Primrose & Richard Gillard

Taking an innovative idea in the field of biotechnology from the lab to the market place is a complex process. Sandy Primrose and Richard Gillard explain how to protect the invention from competitors.

There are three key financial issues for any new biotechnology company: value, funding and cash flow. Intellectual property rights (IPRs) such as patents, designs and trade marks have an impact on all three of these issues. For most early-stage biotechnology companies patents have the greatest importance. To understand why, it is important to remember that patents are exclusive rights to practise an invention which are granted by the state for a limited time (usually 20 years). Thus a patent does not provide any rights to put a product on the market or to use a process. Instead, patents are used to prevent competitors from putting a competing product or process on the market. Hence a company which has the technology to open up a particular market needs patents to prevent their competitors moving into that market, thereby improving market share and profit margins. As well as being a barrier to competition, patents can provide revenue through sale of the patent or through royalties from licensing agreements, usually with larger companies. Patents also provide opportunities for co-operation with other companies through cross-licensing agreements.

Patents and access to funding

Protection of proprietary technology and/or regular injections of cash through royalties are important for companies to obtain funding. Some initial funding may be available without patents, but it is rare for companies to get first-round funding without at least one patent application in their core area. Furthermore, few new companies can survive on first-round funding and to get second-round funding they need to have shown progress, including new patent filings and technology transfer, e.g. licensing of their patented technology. Moreover, patents significantly raise the value of a company and this is important when considering any fund-raising or sale, merger or acquisition of the company. Indeed, IPRs may be the only true assets of value owned by the company.

Obtaining patents

Innovative ideas in the field of biotechnology generally have no automatic protection (although copyright and unregistered design right may offer some limited protection against copying). Unless they have been protected through patent filings, competitors may freely and legally use the innovative ideas of others. Indeed, someone else may patent these ideas first since most countries, the US being a notable exception, have a so-called 'first to file' system. However, by protecting IPRs they acquire real value. Early-stage companies, particularly if founded by academics, are often unaware that they have made inventions that are patentable. For example, what may seem an obvious development to a highly qualified technical specialist, and hence

considered unpatentable, may not be obvious in the legal sense. Thus, companies regularly need to involve their patent attorneys in reviews of their technical progress.

When to file

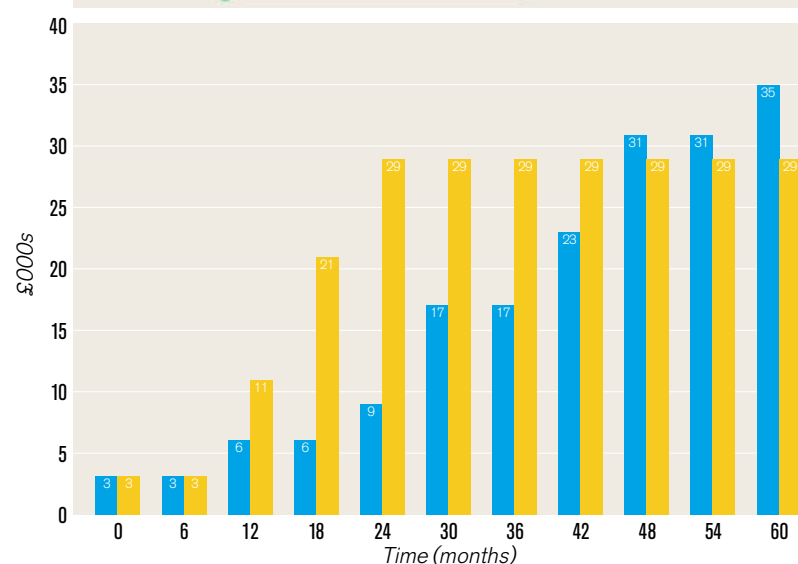
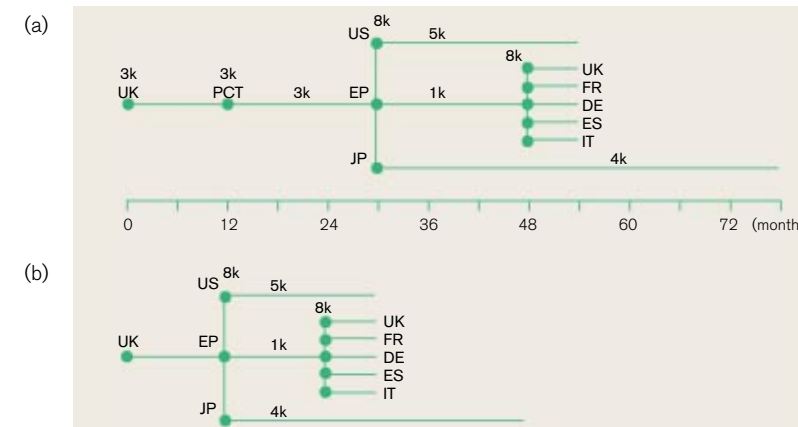
Having identified potentially patentable inventions, consideration needs to be given to whether a patent application should be filed and, if so, when. Usually the answers to these questions are 'yes' and 'as soon as possible'. However, it is worth mentioning that sometimes filing a patent application is not the best course of action, e.g. where the company only needs freedom of use or where it would be very difficult to detect infringement and a patent application may serve only to give away information to competitors which would be better kept as a trade secret. As a general rule a patent application should be filed if an invention is patentable and commercially relevant.

Deciding the right time to file a patent application requires careful consideration. Late filing allows the company to carry out more R&D and should permit a broader and stronger patent. However, the company risks prior publication of relevant prior art anticipating their patent. Early filing minimizes the risk of anticipation, but ultimately there is often some sacrifice in terms of scope of protection and strength of the patent. Thus early filing versus late filing must be weighed up on a case by case basis. In a competitive field early filing will be essential. In a new field, where the company is establishing disruptive technology, later filing may be more appropriate. For safety, it is often sensible to file early and then abandon and re-file if appropriate. This strategy allows applicants to regenerate their priority date if they are not yet in a position to file further (e.g. foreign) applications. The advantages of this approach are that it is cheap and allows for flexibility. The disadvantage is that the applicant risks prior publication of relevant prior art anticipating their patent.

In considering when to file, it should also be borne in mind that the patent term of 20 years runs from the filing date so the timing of the filing affects the patent term. This will be less relevant in fast moving technologies, but is an important consideration where the full patent term is important, e.g. pharmaceuticals. Also, publication of the application occurs at 18 months from the priority date and so early filing leads to early publication. Publication of the application can be a useful source of information for competitors. The corollary is that publication is also a useful source of information on your competitors.

Anticipating the costs of patent filings

Once a decision to file a patent application is made, the costs are predictable with what may seem to many a surprising degree of precision. Such information is of particular use to finance directors or those in a similar position. Before setting out the likely costs, however, it is



Review of patent portfolios

In maintaining value and for monitoring cash flow, it is important that companies regularly review their patent portfolio. Decisions as to the relevance of patents in the portfolio should be made at key points where expenditure will be highest, e.g. at the PCT filing stage, national/regional-phase entry and validation of a European patent.

Considerations regarding the portfolio will also

necessary to provide some background to the different patent filing strategies.

For a patent to be valid, the invention must be new. By filing a patent application, the company establishes a priority date. Provided the company can keep their priority date, nothing disclosed after that date can prejudice the validity of the patent (there is an exception for earlier filed patent applications published after the priority date). The priority date is also valid in most countries in the world, provided foreign patent applications are filed within 12 months of the priority date.

Foreign patent applications may be filed directly with the different countries within the 12 month period mentioned above. For example, three separate applications may be filed in Europe, the US and Japan. Alternatively, a single international (PCT) application may be filed which must eventually be split into separate applications in, say, Europe, the US and Japan. These two filing strategies are shown schematically in Fig. 1 and cumulative costs are shown in the bar chart in Fig. 2.

The appropriate patent filing strategy will depend on commercial strategy and cash flow. A balance must be struck between cost and potential reward. Early grant of patents is good for obtaining funding and licensing. Deferring costs may assist cash flow. In addition, deferring weak patent applications will make decisions difficult for competitors who will not be sure whether or not a patent will eventually be granted.

It should be pointed out that there are some patent costs which are less predictable, such as litigation costs, oppositions and opinions given by attorneys. A view can be taken, however, on the possible risks of litigation, oppositions, etc., depending on the area of the market in which the company is operating. As a rough guide, only about 7% of granted European patents are opposed and of these, about one-third of the decisions go to appeal.

depend on the company's position in the business cycle. At an early stage granted patents and applications having positive examination reports will be important. Once funds have been raised, managing cash flow, for example by deferring costs, must be considered. By the time the company is looking for a stock market flotation it should have as many granted patents and pending patent applications as possible to increase the potential value of the company.

Conclusion

In conclusion, companies involved in the biotechnology sector should appreciate that patents are vital for increasing the value of the company by keeping competitors out of the market and by providing revenue through royalties from licensing agreements. Patents are a key factor in obtaining funding from investors. The costs for procuring patents and the timing of such costs are predictable with a high degree of precision allowing control over cash flow. Filing strategies may also be tailored to the needs of each company. A proper patent strategy requires professional advice.

● *Dr Sandy Primrose is Senior Partner at Business & Technology Management, 21 Amersham Road, High Wycombe, Bucks HP13 6QS, UK. Tel. 01494 474226; email sandy@btm-uk.com*

● *Dr Richard Gillard, is a Chartered Patent Attorney and European Patent Attorney at Elkington and Fife, Beacon House, 113 Kingsway, London WC2B 6PN, UK. Tel. 020 7405 3505; email r.gillard@elkfife.co.uk*

TOP LEFT: Fig. 1. Exemplification of two filing strategies. (a) Single international (PCT) application; (b) direct filing with different countries. EP, European patent; JP, Japan; FR, France; DE, Germany; ES, Spain; IT, Italy.

LEFT: Fig. 2. Cumulative costs for filing strategies 'a' (■) and 'b' (■) shown in Fig. 1.

Resources

The UK Patent Office produces a number of useful booklets on different aspects of intellectual property and details can be found at www.patent.gov.uk

A full list of UK patent attorneys can be found at www.cipa.org.uk

Readers wishing to access issued patents can download these from either the US Patent and Trademark Office website (<http://patft.uspto.gov>) or the European Patent Office website (<http://gb.espacenet.com>).