Maximising the Return from IP Assets

With impending patent cliffs and increasing challenges in achieving new product approvals, protecting and generating maximum value from intellectual property is more important than ever.

Intellectual property (IP) (1) is recognised as a driver of economic growth and a foundation underpinning innovation-based industry. Apart from supporting commerce in these industry sectors, new business models are springing up around IP assets themselves. A recent UK government report stated that: “International trade in intellectual property is increasingly important worldwide. Global patents and creative industry licences alone are estimated to be worth as much as £600 billion or five per cent of world trade” (2).

Of the various different types of IP rights, patents are of prime importance when it comes to research and development of new therapeutics. Different aspects of pharmaceutical and biotech products can benefit from patent protection – provided of course they meet the criteria of being novel and inventive. New chemical or biological entities can be patentable, providing broad protection for the compounds in question irrespective of their end use or how they are produced. Analogues, derivatives or new physical forms of a compound may be patentable, as may be the case for pharmaceutical compositions containing the active ingredient. Methods of treatment or use of a particular therapeutic agent can be claimed in one form or another, as well as processes for manufacturing the active or compositions containing it (although there can be some drawbacks to process patents, as discussed below).

While confidential information or trade secrets do not constitute intellectual property rights in the legal sense, from a commercial perspective the know-how that is often built up in the development and exploitation of a particular invention can be extremely valuable. Trade secrets can complement patents, and indeed it is sometimes the case that technical know-how can give rise to a commercial edge over the competition, even after patent protection has expired. For example, manufacturing know-how around optimum processing parameters may be reflected in a reduced cost of goods. Or to look at this another way, a lack of technical capability in a critical area may represent a practical barrier to entry for competitors. So even if a technical advance is not patentable, there may well be value in ensuring that it is kept confidential and therefore not made available for the benefit of competitors.

A Commercial Tool

It is important to appreciate that patents are essentially commercial tools. Generally speaking, the practical issues involved in getting the best from your IP fall into two broad categories: first, managing the creation and protection of your IP rights; and second, exploiting the commercial advantages that IPRs can afford. Each of these areas of activity requires a well-defined and executed strategy and, as you would expect, the two must be properly coordinated for maximum effect. Otherwise you’re likely to end up with an inability to capture IP as it is generated, with a subsequent loss of commercial opportunities/value, or an inefficient use of resources through failure to properly exploit IP assets that take time and money to develop. Obtaining, maintaining and enforcing patents is time-consuming and costly, and so unless these tools are used to generate or support revenue they may become nothing more than a drain on resources. Therefore it is important that the IP strategy being pursued is dictated by the needs of the business, rather than vice versa.

There are some basic questions that any company, irrespective of its size, needs to address when implementing an IP strategy. Who is responsible for IP within your organisation? Is there a dedicated IP budget and, if so what is it and is it realistic in terms of planned IP activities? Do you have appropriate procedures in place to manage your IP? Next it is important to understand what is involved in operational terms – that is, how new IP is generated or acquired, what IPRs are at your disposal and how these are currently used by the business. The commercial value of these assets can only be properly determined by understanding the business initiatives that they
support. This is why the linkage between IP and commercial strategies is so vital.

Market Exclusivity

In terms of sales of pharmaceutical and biotech products any (legal) means of maintaining market exclusivity that may be available should be considered. So, for example, regulatory exclusivity (data or market exclusivity), patents and technical barriers to entry (embodied in trade secrets or confidential know-how) can provide multiple layers of protection in the market place. There may be important links between different elements; for example, the granting of marketing authorisation can trigger regulatory exclusivity periods, but may also present an opportunity for patent term extension through the Supplementary Protection Certificate process in the EU, or Hatch-Waxman provisions in the US. Again this requires coordination of action – in this case, between regulatory and IP functions.

For a fully integrated pharma company capable of bringing a new compound all the way from discovery through to the market, the most straightforward way to obtain value from the associated patents is to use the exclusionary rights they provide to generate (temporary) market exclusivity, with a view of course to recouping the substantial investment involved and consequently returning a profit. For those not in a position to commercialise an opportunity alone, there are numerous partnering and collaboration models that can be used to combine expertise and IP so that each contributor gets a share of any forthcoming revenues. Licensing of patent rights to a partner, or partners, that can help bring the product to market is a well-worn path for many pharma and biotech companies that are trying to capitalise on the valuable IP they have generated. The ultimate option available to a patentee is the ability to sue competitors for patent infringement when they encroach on the patent holder’s rights. While patent litigation is both expensive and unpredictable, when successful it can secure significant sums in damages and, where injunctive relief is granted, reinforce the position of the patentee’s product in the market.

Deriving Value from IP Assets

As well as these established models, there are also some less frequently encountered models through which revenues or other advantages can be derived from IP rights.

Selling royalty streams provided for under an IP licence for late stage or marketed products can present a way of ‘monetising’ future royalties. The rationale is that the IP holder generates cash and reduces the risk associated with the unknown – and somewhat unpredictable – value of what the future royalty payments eventually turn out to be; the buyer, on the other hand, assumes the risk on the basis of a discounted value of the royalty stream in the expectation that the actual royalty (now due to them rather than the IP holder) will generate a profit for them. One such deal was the 2005 sale of emtricitabine royalties by Emory University (Atlanta, GA) to Gilead Sciences, Inc (Foster City, CA) and Royalty Pharma (New York, NY) for $525 million (3).

Critical to both sides agreeing on a deal that is sufficiently attractive to each party, is the level of discount rate to be applied. The two primary considerations in arriving at an appropriate discount rate are the forecasts for future sales and duration of market exclusivity. The potential market size, pricing and reimbursement, competing products and options for line extensions and additional indications are amongst the factors that will impact the forecast sales projections. The IP position, along with regulatory exclusivity, will be key to the likely duration of market exclusivity. The number, type and strength (or vulnerability) of patents protecting the product will all need to be assessed. Basic compound patents tend to withstand invalidity challenges better that secondary patents, such as formulation patents (4). Process patents can present challenges in terms of enforcement. Where the manufacturing process used cannot be determined from an analysis of the end product – as will often be the case for pharmaceuticals – it may be difficult to prove infringement. Discharging the burden of proof can be particularly problematic when there are multiple processes available. That said, the rules of evidence, and legal procedures for the gathering it, vary from country to country, and some jurisdictions provide mechanisms for accessing manufacturing process information, such as the sasie contrafaçon in France and elsewhere.

Like any asset, patents and other forms of IP can be used as collateral for borrowing purposes. In addition there are other financial instruments that can be constructed around suitable IP assets. Following on from the pioneering 1997 ‘Bowie bond’, secured on future royalties of David Bowie’s recordings, more IP-backed securities have appeared, including some patent-backed securities in the pharmaceutical sector (5). As with future royalty buy-outs, accurately determining the value and risk profile of a patent, or portfolio of patents, is a primary challenge with patent-backed securities. Although IP-backed securities were never as popular as those backed by other types of assets, the ongoing turmoil in the financial markets may make this type of instrument even less common in the future (6).
New ways to derive value from IP continue to be explored. Various tax efficient structures can be used to maximise revenue, but these vary from country to country and – other than noting their existence – further discussion is really beyond the scope of this article. What would appear to be the first pharma licensing arrangement involving a patent pool – a mechanism widely used in some other fields such as telecoms, for example – was announced just recently (7). Another interesting and innovative way of leveraging IPR is the use of IP assets to support pension plans (8).

Extracting value from obsolete IP assets is a perennial problem. Rather than simply abandoning these non-core assets, it may be possible to obtain some residual value by licensing or selling at a significantly discounted rate. An alternative may be to donate patents to an academic institution or other not-for-profit organisation; apart from the potential public relations value, such a move can have associated tax benefits in some countries. A further option – albeit more prevalent in the information technology and communications sectors than the life science industries – may be to offer patents for sale in one of the growing number of IP auctions and exchanges (9).

Closing Remarks

Many pharmaceutical companies are reassessing their approach to R&D in an effort to streamline operations and boost pipelines. At the same time, new businesses continue to emerge, based on imaginative ways of extracting value from IP. On a fundamental level, strong IP is based on good science, so these two evolving vistas are intimately linked. With impending patent cliffs and increasing challenges in achieving new product approvals, protecting and generating maximum value from IP assets is more important than ever.

References

1. The term ‘intellectual property’ refers to a bundle of separate exclusionary rights which enable the owner to prevent others from doing certain things, such as making or selling a patented invention; branding products with a similar trademark which is likely to cause confusion in the market place; or copying a work which subject to copyright.


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