

# Patent Problems

Haydn Evans at CPA Global discusses the issues surrounding patent expiry and suggests steps that companies can take to protect their intellectual property for as long as possible

If there was ever a question about the importance of intellectual property (IP) and patent protection to the pharmaceutical industry, it is about to be answered. The world's top drug makers are shuffling towards the edge of a patent cliff that may cost the industry £70 billion in annual sales by 2016, as key product patents expire and cheap generic versions of their blockbuster medicines hit the market.

The industry will no doubt survive the fall, but patents are likely to become even more important to corporations, as they reformulate their strategies and become more competitive and acquisitive. Those companies that spend the time and money up front on patent strategy and awareness are likely to emerge the strongest.

## HIGH PROFILE EXPIRIES

Even before the global economic recession hit, the pharmaceutical industry was beginning to steady itself for an uncertain future. Perhaps the most conspicuous of these high profile expiries will be the core patents protecting the bestselling drug of all time: Pfizer's cholesterol-lowering medicine, Lipitor™. In November 2011, these patents will expire, and industry experts predict that, within the first year, generic competition will cost Pfizer approximately 80 per cent of the £8 billion it receives annually from global sales of the drug. This would put the current combined value of the two or three core patent families protecting it at approximately £6.5 billion a year – the equivalent to approximately 20 per cent of Pfizer's total sales for 2008.

Other drug companies are also feeling the heat of impending patent expiries. Eli Lilly has announced recently that it is to shed 5,500 jobs, due, in no small part, to the fact that between 2010 and 2013 more than half of Lilly's current revenue will become exposed to generic competition and essential patents on four of its five top-selling drugs will expire.

While it has always been the case that drug patents run out around 20 years after they have been filed, this round of patent expiries is causing particular concern to those pharmaceutical companies who do not have drugs in the advanced stages of development, which will generate the sales needed to replace this lost revenue. The rich vein of 'blockbuster' drugs that are about to lose patent protection was created during a period of highly successful innovation in the 1990s. Since then, higher regulatory hurdles, increased competition and less effective innovation have all contributed to the relatively anaemic R&D pipelines we see today.

## REDUCING THE IMPACT OF PATENT EXPIRY

Having done what they can to cut costs, pharmaceutical companies are looking at other solutions to recoup predicted

revenue losses and rebuild their faltering drug pipelines. The big firms are keen to consolidate, in an attempt to head off gathering problems; Pfizer has recently announced a deal to buy rival Wyeth for £50 billion, while Merck is going through the process of acquiring Schering-Plough in a bid to boost its pipeline. Merck's asthma medicine, Singulair™, which accounts for a sixth of its revenues, loses patent protection in the next few years and it is hoped that the Schering-Plough acquisition will help to reduce the impact of the loss by doubling the number of drugs that Merck has in the later stages of development.

In order to generate additional revenues, cash-rich pharmaceutical firms are also focusing their attention on adjacent market opportunities, and the biotech sector has been under especially close scrutiny for some time. In March this year, Roche completed the acquisition of the biotech bellwether, Genentech, for £34 billion. Other pharmaceutical companies are also concentrating on becoming favoured co-development partners for biotech companies, even embracing young startups and reversing the long-standing trend of investing only in later-stage candidates with lower risk products. In the future, it is likely that pharmaceutical firms will spread their nets even wider, potentially looking further afield at the likes of medical device companies or even the generic manufacturers that compete against them.

Patents have always been important to the pharmaceutical industry. With the average cost of developing a new medicine estimated at more than \$800 million, strong patent protection provides the

opportunity to recoup investments in new products. It takes an average of 10 to 15 years to develop a new medicine from compound discovery through to FDA approval, so significant portions of the 20-year patent term for a new drug are lost before a product ever generates any sales. In fact, the average effective patent life for medicines is only 11 and a half years. This causes the strength of patent protection and the requirement for exclusivity to become vital considerations for drug companies investing in new technologies or products.

market opportunities over the next few years, so it is essential that firms are conscious of the competitive patent landscape and conduct adequate due diligence to understand the patent holdings of any potential targets. It is thought that these factors are likely to lead to an increased focus on innovation and patent protection, not just in company legal departments, but also across R&D departments, at board level and perhaps, more crucially, among shareholders and investors.

commissioned to ensure full awareness of any prior art (previous publications) that may prohibit or reduce an invention's chances of obtaining strong patent protection. Throughout the life of a research or development project, additional searches should be conducted to determine whether the company will end up with a successful product and if it will have the right to use that product without infringing any third-party patent rights. New patent publications are published weekly, so it is important to regularly update these searches in order to be confident that each project is truly continuing on a fruitful track.

**Table 1: Some of the most valuable patents in the world**

Patent(s)	Drug	Probable expiry	Annual US revenue at risk*
US5273995 RE40667	Lipitor	June 2011	\$5.8 billion
US5877192 US6875872	Nexium	November 2014	\$4.8 billion
US4847265	Plavix	November 2011	\$3.8 billion
US4879288	Seroquel	March 2012	\$2.9 billion
US5565473	Singulair	August 2012	\$2.9 billion
US5508042	Oxycontin	April 2013	\$2.5 billion
US4687777	Actos	January 2011	\$2.4 billion
RE34712	Lexapro	March 2012	\$2.4 billion
US5006528	Abilify	April 2015	\$2.4 billion
US5023269	Cymbalta	June 2013	\$2.2 billion

\*Approximately 80 per cent of this annual revenue is at risk in the first year after expiry  
Source: CPA Global

There is no doubt that there will be further industry fall-out as the impending patent cliff reaches a crescendo of expiries in the next few years. Yet the pharmaceutical firms that are planning ahead for this issue are facing increased attack from generics manufacturers, who seek every opportunity to invalidate patents as a means to speed up their access to a 'blockbuster' product.

It is expected that the pharmaceutical industry will become even more acquisitive and interested in adjacent

recruit highly trained staff, appoint quality service providers, bring in state-of-the-art tools and implement water-tight processes to manage these valuable assets.

### PROTECTING YOUR INTELLECTUAL PROPERTY

Throughout the patent lifecycle, there are steps that can be taken to protect intellectual property; patents should be managed from cradle to grave, from filing to expiry. It is essential that the right decisions are made at the time of patent filing in order to reduce the chances of complications further down the line, when patents are at the end of their life and hopefully achieving their highest values. Admittedly, it will not be known with any certainty at this early stage which filings may go on to protect billions of pounds of revenue, but having the right processes in place for all filings will act as an insurance policy against possible future mishaps.

Even before a first filing, steps should be taken to understand the patent landscape in the technical domain of interest. For each new filing, patent searches should be

With patents protecting, or potentially protecting, billions of pounds of revenue, it is somewhat surprising that, to date, they have often not received as much attention or resources as they perhaps deserve. Companies' intellectual property departments need to ensure that they

It is also a requirement that patents are periodically renewed at each of the global patent offices for which protection is sought. Companies with a portfolio of more than a handful of patents can find it very difficult to manage this internally, and the risks of missing a renewal payment can be as severe as complete loss of patent protection. If a large portfolio has been amassed, the cost of renewing each patent will be significant and it will be necessary to review the portfolio on a regular basis to ensure that each one of the patents is in some way linked to the company's business strategy. On occasion, patents that are not core to business activities can still be of value if they can be outlicensed to generate additional revenue.

With the management of patent assets under increased scrutiny, many pharmaceutical firms choose to appoint an IP management partner who works with the company's IP department to ensure that its patent portfolio is kept in good health and aligned with the company's wider business strategy. Patents play a crucial role in driving a company's direction.

### CONCLUSION

Patents are some of the most valuable assets that a pharmaceutical company holds and must be given the time and attention they deserve. With the industry facing an impending round of blockbuster patent expiries, it is likely that they will become even more valuable. Meticulous patent management and process rigour will therefore become a prerequisite for those working in the pharmaceutical field.

#### About the author



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