PATENT PRIMER

Maximizing exclusivity for drug products

Hayley French

Major patents on blockbuster drugs continue to expire. Each drug requires huge investment and many years of R&D before marketing. How can return-on-investment be maximised?

Drug companies must obtain regulatory approval before a drug is marketed, and ideally they would like to reduce this time in order to leverage maximum sales before the generic companies enter the market. A patent grants 20 years protection to the holder; however, the period taken to achieve regulatory approval for a drug remains lengthy. As a consequence, patent holders might not be able to secure a sufficient return on their development costs. There is a fear within the drug industry that lengthy delays in new drug approvals from overly cautious regulatory authorities will occur in the wake of several high-profile safety withdrawals last year, such as the pain medication rofecoxib (Vioxx; Merck).

To 'compensate' the patent owner for lost patent protection caused by the length of time taken to obtain regulatory approval from the relevant authorities, many countries have developed regimes that allow them to effectively extend the term of protection afforded by a patent to a particular product.

European position

European patent holders can extend protection by applying for Supplementary Protection Certificates (SPCs). An SPC is a separate right from the patent that takes effect on expiry of the patent. It confers the same rights on its holder as are conferred by the patent. However, this is only in respect of a specific active ingredient in a product for which its regulatory approval by way of a marketing authorisation has been granted. The patent holder must select a suitable 'basic patent' (the patent holder has a choice if there are several potential patents) for the product and make an application in each EU country that issues a patent and for which the SPC is desired. The SPC application must be filed within six months of the grant of the first marketing authorisation in each country. If the basic patent has not been granted until after the marketing authorisation is given owing to a lengthy delay in the granting of a patent, then the SPC application must be filed within six months of the grant of patent. In either case, the period for application cannot be extended. The term of the SPC cannot exceed the lesser of five years from patent expiry or fifteen years from the first European marketing authorisation.

A patent holder cannot have more than one SPC per product, but two different patent holders can have an SPC for the same product as long as the respective applications are filed before the first SPC is granted (see box). In addition, in contrast to the US system, more than one SPC can be granted on the 'basic patent' as long as the products have a different active ingredient and a separate marketing authorisation.

The protection conferred by the SPC extends not only to the particular use of the product that was the subject of the marketing authorisation, but also for any other use of the product authorised before the expiry of the basic patent, even if such authorisations have been secured by third parties.

US position

US patent holders can apply for Patent Term Extension ('PTE') under the Hatch–Waxman Act[1]. In contrast to the European system, a PTE extends the particular claims under a patent rather than creating a separate right on expiry of the patent.

The patent holder must file for a PTE within sixty days of receiving marketing approval from the US Food and Drug Administration (FDA). In addition, the patent holder must have participated in the regulatory review process and this must be properly documented. A PTE, like a SPC, cannot exceed five years.

The Hatch–Waxman Act only extends the term of the patent claims that are directly covered by the FDA's approval for the product (see box). A PTE is patent-specific and hence limits the number of patents eligible for a PTE to one PTE per product and one PTE per patent. Therefore, if a patent contains claims relevant to more than one product, a PTE is only available for one of those products.

Conclusion

Drug companies need to coordinate their patent drafting, filing and prosecution with their regulatory activity and need to appreciate the differences between the US and European regimes within their patent strategy. Extension of effective patent terms are important to the innovative pharmaceutical industry because they provide five years marketing exclusivity after expiry of the patent at a time when sales are usually at their highest. For many high-selling drugs, SPCs and PTEs have had a major role in securing high sales after patent expiry. One high-profile example is fluoxetine (Prozac; Eli Lilly). Almost 80% of Prozac's sales over the last ten years of 'effective patent' protection in Europe were achieved in the five years covered by the SPC.

Drug companies involved in licensing patent rights need to consider PTEs and SPCs and both need to be factored into the licence in terms of selecting a 'basic patent' (for an SPC), royalty payments, prosecution and maintenance.

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1. The Drug Price Competition and Patent Term Restoration Act 1984 (known as the "Hatch–Waxman Act").

RECENT CASES IN THE US AND EUROPE

Pfizer Inc vs Dr Reddy's Laboratories Ltd., 359 F.3d 1361 (Fed. Cir. 2004).
The Federal Circuit reversed a judgement of the United States District Court relating to PTEs and active ingredients. The District Court held that the defendant did not infringe Pfizer's patent relating to the product amlodipine (Norvasc) because the PTE was limited only to the amlodipine besylate salt. The Federal Circuit reversed this decision by finding that the PTE granted to Pfizer in respect of the active ingredient of its amlodipine product applied to all of its salts and esters. This decision makes it difficult for generic drug manufacturers to avoid infringement claims by creating a 'loophole' in the Hatch–Waxman Act.

Biogen Inc vs SmithKline Beecham Biologicals SA [1997] RPC 833.
SmithKline Beecham had licences for a recombinant vaccine Engerix-B to protect against Hepatitis B from Biogen and Institut Pasteur under two separate patents. Biogen sought an order compelling SmithKline Beecham to provide a copy of the Belgian marketing authorisation to enable it to obtain an SPC in Belgium (having already provided a copy to Institut Pasteur). The European Court of Justice (ECJ) held that Biogen could secure an SPC. In addition, the ECJ held that multiple SPCs could be granted to holders of different basic patents for the same product.