



# Patent Term Extensions

Patent term extensions (PTE) extend the term of a patent covering a pharmaceutical product that undergoes regulatory review in order to obtain marketing authorization. There are two principal types of PTE: patent term restoration and pediatric exclusivity.

## Patent Term Restoration

In the United States, patent term restoration is granted under the 1984 Drug Price Competition and Patent Restoration Act, also known as the Hatch-Waxman Act ("The Act"). The Act restores a portion of the patent term that is lost while the patent holder is awaiting FDA review of the safety and efficacy of the product. The restoration period is based on the time the product is in clinical testing and regulatory review. The restoration period cannot exceed five years, and the total patent term including the restoration period cannot exceed 14 years following agency approval.

In addition to partially restoring lost patent life, the Hatch-Waxman Act and other global policies dramatically reduced the regulatory requirements for manufacturers of generic copies after patents expire. Following patent expiration, generics manufacturers, that do not incur the risks and costs of development and marketing of the drugs they produce, compete to sell products at considerably reduced prices.

Similar patent term restoration periods are available in other jurisdictions, such as in Australia, Korea and Japan. In European Economic Area countries (and Switzerland), patent rights for drug products are extended by way of a Supplementary Protection Certificate ("SPC"). SPCs are rights separate from patents and were introduced to compensate for the long time needed to obtain regulatory approval of drug products. An SPC comes into force only after the corresponding patent expires and relates to a specific product. It has a maximum lifetime of five years, and the total combined duration of market exclusivity of a patent and SPC (before any possible pediatric extension) cannot exceed 15 years.

Merck believes that it is essential to balance incentives for innovation with cost containment. The partial restoration of lost patent life and the acceleration of generic entry

that have been fostered by patent term restoration policies work toward that balance, advancing the health of people everywhere and leading to cost savings over time.

## **Pediatric Exclusivity**

Pediatric patients obviously have different medical needs than do adults. Among other things, differences in physical size and metabolism can result in medicines having different effects or requiring different dosing in children than in the adult patients for which they were primarily developed.

To encourage innovator pharmaceutical companies to conduct additional research on safety and effectiveness for pediatric patients, the United States has enacted separate provisions for granting a six-month extension of patent term known as "pediatric exclusivity."

Pediatric exclusivity in the U.S. adds to any existing exclusivity period and applies to all approved uses for the covered product.

Other countries and regions also provide opportunities for pediatric exclusivity. For example, in European Union member countries, the duration of an SPC can be extended to five and a half years when data from approved pediatric clinical trials have been submitted to the regulatory authorities.

## **Merck's position on PTE**

Intellectual property protection is essential to incentivize investments in the research and development of new medicines that address unmet medical needs. Due to the unusual circumstances and extensive time investments related to pharmaceutical discovery, development and regulatory review, Merck believes it is necessary and appropriate to take steps to maintain effective marketing exclusivity through PTE, whether to compensate for patent periods lost in development and regulatory review, or to reward the development of knowledge gained through pediatric testing to provide the most appropriate care for children.

Merck considers PTE to be an essential intellectual property right that appropriately balances the increased benefit to the public resulting from an extensive clinical program and regulatory review process with the needs of innovator companies to both recover the financial investment made during the development of innovative products and incentivize further drug discovery efforts that will benefit society as a whole.