

## PATENTS

New drugs, like most other new products, are developed under patent protection. The patent protects the investment in the drug's development by giving the company the sole right to sell the drug while the patent is in effect. Patents are granted by the U.S. Patent and Trademark Office anytime in the "life" of the drug. A patent expires 20 years from the date of filing. When patents or other periods of exclusivity expire, manufacturers can apply to the FDA to sell generic versions.

The Orange Book provides patent and exclusivity information in an Addendum. This Addendum identifies drugs that qualify under the Drug Price Competition and Patent Term Restoration Act (1984 Amendments) for periods of exclusivity, during which ANDAs and applications described in Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) for those drug products may, in some instances, not be submitted or made effective, and provides patent information concerning the listed drug products. Those drugs that have qualified for Orphan Drug Exclusivity pursuant to Section 527 of the Act and those drugs that have qualified for Pediatric Exclusivity pursuant to Section 505A are also included in this Addendum.

Exclusivity prevents the submission or effective approval of ANDAs or applications described in Section 505(b)(2) of the Act.

Patents that are listed in the Orange Book include

- Patents that claim the active ingredients or ingredients
- Drug product patents that include formulation/composition patents
- Use patents for a particular approved indication or method of using the product

The Bolar amendment to the Drug Price Competition and Patent Term Restoration Act allows a pharmaceutical manufacturer (sponsor) to seek approval from the FDA to market a generic drug product before the expiration of a patent relating to the brand name drug product upon which the generic is based. As part of the ANDA, the sponsor must consider the pertinent patents and provide the results to the FDA. The Act requires patent information to be filed with all newly submitted Section 505 drug applications and that no NDA may be approved after September 24, 1984, without the submission of pertinent patent information to the FDA. The ANDA sponsor must provide a "certification" that, in the opinion of the sponsor and to the best of the sponsor's knowledge with respect to each patent that claims the listed drug, some or all of the following certification may be submitted:

Paragraph I: That such patent information has not been filed

Paragraph II: That such patent has expired

Paragraph III: Of the date on which such patent will expire

Paragraph IV: That such patent is invalid or will not be infringed on by the manufacture, use, or sale of the new drug for which the application is submitted

A certification under Paragraph I or II permits the ANDA to be approved immediately, if it is otherwise eligible. A certification under Paragraph III indicates that the ANDA may be approved on the patent expiration date.