If the Orange Book lists one or more unexpired patents, the sponsor of the ANDA who seeks effective approval before the patent's expiration must either

- Challenge the listing of the patent (e.g., file a Paragraph IV certification that the patent is invalid or will not be infringed on by the manufacture, use, or sale of the drug product)
- File a statement that the application for use is not claimed in the listed patent

Exclusivity

The generic applicant must notify the patent holder of the submission of the ANDA. Because the patent holder can immediately sue the first generic sponsor company who submits an ANDA with a Paragraph IV statement, a 180-day period of market exclusivity is provided to that generic applicant. This special dispensation is considered as a reward to the generic manufacturer who took a risk in challenging the patent. If the patent holder files an infringement suit against the generic applicant within 45 days of the ANDA notification, an FDA approval to market the generic drug product is automatically postponed for 30 months, unless, before that time, the patent expires or is judged to be invalid or not infringed upon. This 30-month postponement gives the patent holder time to assert its patent rights in court before a generic competitor is permitted to enter the market. Only an application containing a Paragraph IV certification may be eligible for exclusivity, and to earn the period of exclusivity, the ANDA applicant must be sued by the patent holder and successfully defend the suit (see Chapter 15 for more details).

Under certain circumstances, the patent holder may obtain exclusivity for a branded drug product that essentially extends the time on the market without competition from the generic drug product. Exclusivity works similar to patents and is granted by the FDA if statutory provisions are met. Types of exclusivity are listed in Table 1.5.

TABLE 1.5
Types of Exclusivity

Exclusivity	Time for Exclusivity	Exclusivity Criteria
Orphan drug exclusivity (ODE)	7 years	Upon approval of designated orphan drug, the Office of Orphan Products issues letter when exclusivity granted—separate from other types of exclusivity
New chemical entity (NCE)	5 years	Upon first time approval of new chemical entity
"Other" exclusivity	3 years for a "significant change" if criteria are met	For certain "significant changes" approved on an NDA or supplement if new clinical studies essential for approval, conducted or sponsored by applicant, have been done "Changes" may include (but are not limited to) new ester/salt, new dosage form, new route, new indication, new strength, and new dosing schedule
Pediatric exclusivity (PED)	6 months added to existing patents or exclusivity	A period of 6 months' exclusivity is added to any existing exclusivity or patents on all applications held by the sponsor so that active moiety pediatric exclusivity does not stand alone