studies that lead to new indications or formulations of an existing drug (three years) or for drugs with indications to treat certain rare diseases (seven years, as established under the Orphan Drug Act).[30] In all, there are at least 13 forms of nonpatent exclusivities available under various statutory regimes.[31]

Important changes have been made to Hatch-Waxman and its related mechanisms since its enactment, mostly notably through the Medicare Modernization Act in 2003 and the Food and Drug Administration Amendments Act of 2007.[32] Many of the changes were aimed at curbing abuses and plugging loopholes in Hatch-Waxman, and they will be discussed in the chapters ahead.

In short, Hatch-Waxman set the stage for a new era in medicines: generic competitors were able to develop and test their products, as well as apply for FDA approval, before expiration of the brand-name drug company's patent. In addition, the Hatch-Waxman Act created incentives for generics to challenge weak patent claims. The goal, essentially, was to speed generic versions of drugs to market as quickly as possible, introducing competition and dramatically lowering prices for consumers.

[30] *See* 21 U.S.C. § 355(c)(3)(E)(iii) (2012), 21 U.S.C. §§ 355(j)(5)(F)(iii)–(iv) (2012) (explaining new clinical study exclusivity); 21 U.S.C. §§ 360bb–360cc (2012) (explaining Orphan Drug Act definitions and exclusivities).

[31] *See generally* Feldman, *supra* note 29.

[32] *See* Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108–173, 117 Stat. 2066 (2003); Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110–85, 121 Stat. 823 (2007) (codified as amended in scattered sections of 21 U.S.C.).