however, unless a court enters a final order declaring the patents at issue invalid, unenforceable, or not infringed.[25]

Although Hatch-Waxman generally is discussed in the framework of generic drugs, the act also was designed to add new protections for brand-name drug companies. Given the U.S. Patent and Trademark Office's patent approval process and the FDA's own approval process for the drug, which generally overlaps with a portion of the patent term, the effective life of a drug patent is often substantially shorter than the 20-year patent term.[26] Thus, Hatch–Waxman allows pharmaceutical companies to receive an extension of the patent term, in an effort to partially restore the time lost to the approval processes.[27] This "restoration" is the origin of the Hatch–Waxman Act's full name, the Drug Price Competition and Patent Term *Restoration* Act.

The Hatch-Waxman Act also provides some new drugs with methods of keeping others out of the market in addition to patents. These are known as nonpatent exclusivities. For example, drugs with an active ingredient never before approved by the FDA are eligible for either four or five years of what is known as a "marketing exclusivity."[28] This is not an extension of the patent term – it only means that the FDA is not allowed to accept generic applications that use the original drug maker's data for at least four years after initial FDA approval. Although a generic applicant theoretically could engage in the lengthy and expensive process of conducting its own clinical trials, the cost would be prohibitive. An original drug maker receives a 20-year patent to help recoup such costs, while the most a generic applicant could get would be six months of a duopoly.

This nonpatent exclusivity in Hatch-Waxman gives the brand-name drug maker breathing space before a generic company can start the ball rolling. The brand-name drug maker is guaranteed at least four years without direct competition, even if the patents are invalid.[29] Other exclusivities are available, for example, for new clinical

[25] *See ibid*. If the first Paragraph IV generic filer loses its case, it forfeits the 180-day exclusivity period, and the Paragraph IV certification is usually changed to a Paragraph III certification agreeing not to enter until the expiration of all FDA and patent exclusivity. *See Small Business Assistance: 180-Day Generic Drug Exclusivity*, U.S. Food & Drug Admin., www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069964.htm (last updated February 11, 2016).

[26] *See* Schacht & Thomas, Cong. Res. Serv., Report R41114, *supra* note 6, at 3.

[27] *See* 35 U.S.C. § 156(g)(6)(A) (2012); 35 U.S.C. § 156(c) (2012). *See generally* 35 U.S.C. § 156 (describing the full patent term extension process). Although the patent can be extended by a maximum of five years, the maximum term remaining after approval cannot exceed fourteen years. *See id*. § 156(c)(3).

[28] The benefit is called a New Chemical Entity ("NCE") exclusivity. *See* 21 U.S.C. § 355(c)(3)(E)(ii) (2012); 21 U.S.C. § 355(j)(5)(F)(ii) (2012). The longer five-year right is reduced to four years, if a generic applicant files a Paragraph IV certification, declaring that the patent is invalid or would not be infringed by a generic version. *See* 21 C.F.R. § 314.108(b)(3).

[29] For an extensive discussion of the 13 forms of nonpatent exclusivities that exist for pharmaceuticals, *see* Robin Feldman, *Regulatory Property: The New IP*, 40 Columbia J.L. & Arts 53 (2016).