application ("ANDA") before the patents for the brand-name drug have expired.[93] These shorter applications only need to contain evidence that the generic is bioequivalent and has the same characteristics as the brand-name drug; they can rely on the brand-name drug company's clinical trial data to meet the rest of the application requirements, including those related to the safety and efficacy of the drug.[94]

Second, in what is known as a Paragraph IV certification, a generic manufacturer can attempt to enter the market before the brand-name company's patent term(s) have expired. This is considered an artificial act of infringement and it generally triggers litigation over patent validity.[95] While the generic applicant has not done anything "wrong" in this case, the act of filing the application allows a brand-name company to sue and bring the dispute to a quick close. This also allows the generic applicant to face less risk in the process, since it has not actually infringed any patent and would not be liable for any damages if the patent were found valid. It is like being able to ask a court whether something would be illegal – that is, launching a generic in the face of existing patents – before actually doing so.

As a reward for facing the costs and risks of litigation, the first generic manufacturer to file a Paragraph IV certification and gain approval generally is entitled to 180 days (roughly six months) of market exclusivity alongside the brand-name drug.[96] In other words, during the six-month period, only the brand-name drug and the first generic filer are allowed to be on the market. While only six months long, this duopoly period can be extremely valuable, potentially adding hundreds of millions of dollars to the first generic's coffers before additional generics enter and drive the price down further.[97] This benefit is intended to give generic companies an incentive to challenge weak patents or patents that should not actually cover the drug at issue.

The Hatch–Waxman Act has overwhelmingly met Congress's goals of balancing adequate patent protection for original inventors with promoting the rapid introduction of generics once this patent protection has expired. Since 1984, more than 10,000 generics have entered the market,[98] and the percentage of prescriptions filled with generics rose from just 13 percent in 1980[99] to around 86 percent by 2013.[100]

[93] 21 U.S.C. § 355(j) (2012).
[94] 21 U.S.C. §§ 355(j)(2)(A)(i)–(v) (2012).
[95] 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012).
[96] 21 U.S.C. § 355(j)(5)(B)(iv) (2012). Exceptions and stipulations will be discussed in the Introduction.
[97] *See* Matthew Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 Hastings L.J. 171, 178 & 178 nn.55–56 (2008).
[98] *See* Schacht & Thomas, Cong. Res. Serv., Report R41114, *supra* note 90, at 5; *see also Medicare Prescription Drug, Improvement, and Modernization Act: Hearing on H.R. 1 Before S. Comm. on the Judiciary*, 108th Cong. (2003) (statement of Daniel E. Troy, Chief Counsel, U.S. Food & Drug Admin.), www.fda.gov/newsevents/testimony/ucm115033.htm.
[99] Cong. Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry 37 (1998).
[100] IMS Inst. for Healthcare Informatics, *supra* note 78, at 51.