

(2) would not be infringed by the generic drug application.¹⁶ The goal is to resolve questions of weak or misapplied patents so that the generic can enter as soon as possible.

A Paragraph IV certification is treated as an “artificial” act of patent infringement – as if the generic company had already started selling the drug. Thus, the brand-name drug company is permitted to initiate litigation, which it must do within 45 days of receiving notification from the generic filer. If the brand-name drug company does not litigate, the FDA is free to approve the generic’s application once the Agency verifies the safety and efficacy of the generic drug.¹⁷

Why would a generic applicant purposely choose to invite costly and potentially damaging litigation? First, there are weak patent claims – a topic that has inspired numerous writings about the state of the modern-day patent system. Generic companies have enjoyed considerable success challenging weak drug patents. One early study reported by the Federal Trade Commission in 2002 found that generic applicants won their “Paragraph IV challenge” 73 percent of the time.¹⁸ Another study from 2010 found that generics won fewer than 50 percent of their Paragraph IV challenges between 2000 and 2009; however, if settlements and cases eventually dropped by the brand-name company are included in the calculation, the win rate in this study rises to 76 percent for the 2000–2009 period as well.¹⁹

Second, baked into Hatch-Waxman is a significant incentive for the first generic to submit an application with a Paragraph IV certification to at least one of the listed patents for the drug. As long as the applicant does not lose its patent infringement case, the first generic filer generally is entitled to 180 days of marketing exclusivity alongside the brand-name drug.²⁰ In other words, for about six months, only the brand-name drug company and the first generic can sell the drug; no other generic company can enter the market.

This essentially creates a duopoly consisting of the brand-name drug and the first generic for 180 days. The FDA is not permitted to approve any other applications with a Paragraph IV certification until the 180-day period elapses; the period is

¹⁶ 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012).

¹⁷ See 21 U.S.C. § 355(j)(5)(B)(iii) (2012).

¹⁸ See *Generic Drug Entry Prior to Patent Expiration* FED. TRADE COMM’N 16 (2002), www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrug_study_o.pdf.

¹⁹ *In re K-Dur Antitrust Litigation*, 686 F.3d 197, 215 n. 11 (3rd Cir. 2012), citing RBC Capital Mkts., *Pharmaceuticals: Analyzing Litigation Success Rates* 4 (2010), available at www.amlawdaily.typepad.com/pharmareport.pdf.

²⁰ See 21 U.S.C. § 355(j)(5)(B)(iv) (2012). After 2003 amendments to Hatch-Waxman, it is possible to forfeit the 180-day exclusivity period without losing a patent infringement case. Further, it is also possible that the brand-name drug company chooses not to bring litigation during the 45-day period. In this case, the first filer still retains its rights to 180 days of exclusivity.