Thus, the first filer theoretically can create an absolute bottleneck by never starting the clock on its six months. In its early 2002 report on pay-for-delay, the FTC referred to this as "park[ing]" the exclusivity period.[15] Parking the exclusivity period was less of a problem before a set of Federal Circuit cases in 1998. Until that time, the FDA had ruled that a generic applicant making a Paragraph IV certification had to win its patent infringement suit in court, in order to receive the six-month exclusivity period – the "successful defense" requirement. A settlement would not be enough. Two Federal Circuit cases in 1998 ruled that this was not the case, leaving the door open to settlements in which the generic could still enjoy its exclusivity without winning a challenge.[16] This created the so-called bottleneck.[17]

As part of the 2003 Medicare Modernization Act, Congress made changes to Hatch-Waxman that can cause a generic first filer to lose its six months of exclusivity, a change that was meant to close the first-filer bottleneck.[18] This "forfeiture" provision sets out a number of scenarios that can take away the exclusivity period. Notably, exclusivity can supposedly be forfeited in certain circumstances. This should occur if commercial marketing does not take place (1) within 75 days of the drug receiving final approval, or (2) within 75 days of the generic manufacturer either winning a case or entering into a settlement finding the brand-name patents to be invalid or not infringed.[19] The generic company also may forfeit its exclusivity period if it does not secure tentative approval from the FDA within 30 months of submitting its application.[20] Provisions such as these were meant to close the pay-for-delay roadblock

[15] *See Generic Drug Entry Prior to Patent Expiration* Fed. Trade Comm'n 63 (2002), www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf.

[16] Hemphill, *Aggregate Approach to Antitrust*, *supra* note 1, at 658 n. 117 (citing *Granutec, Inc. v. Shalala*, 46 U.S.P.Q.2d (BNA) 1398, 1401 (4th Cir. 1998); *Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 130 (D.D.C. 1997), aff'd, 140 F.3d 1060 (D.C. Cir. 1998) ("The language of the statute … is plain and unambiguous. It does not include a 'successful defense' requirement, and indeed it does not even require the institution of patent litigation.")); *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 and Drug Administration), *available at* www.fda.gov/NewsEvents/Testimony/ucm115033.htm.

[17] In a recent paper, Matthew Avery and Mary Nguyen discuss the possibility that later generic filers could attempt to enter the market by going on the offensive and seeking a declaratory judgment that the original drug patents are invalid – an alternative route to filing a Paragraph IV generic certification and waiting for a lawsuit from the brand-name drug maker. However, according to the authors, the Federal Circuit has blocked most of these attempts, saying that later filers do not present a legitimate Article III "case or controversy" in their attempts to seek a preliminary injunction. *See* Avery and Nguyen, *Roadblock for Generic Drugs*, *supra* note 1. Brand-name companies can also engage in strategies to stagger lawsuits and sue different generics on different patents so one noninfringement judgment does not open the entire market to all competitors. *See* Robin Feldman, Rethinking Patent Law 164–66 (2012).

[18] 21 U.S.C. § 355(j)(5)(D).

[19] 21 U.S.C. § 355(j)(5)(D)(i)(I).

[20] 21 U.S.C. § 355(j)(5)(D)(i)(IV).