loophole by punishing the generic for not seeing a case through and earning marketing approval by winning its patent challenges. The modified statute even allows exclusivity to be forfeited if the FTC or U.S. attorney general determines a settlement to be an antitrust violation and wins its case in court.[21]

Parties, however, have found a way to work around the new provisions in drafting pay-for-delay settlements. Academics and practitioners have discussed how the drafting of the provision leaves a glaring loophole that seems to permit many pay-for-delay settlements to continue to hold up other generic applications from approval.[22] Specifically, forfeiture from a "failure-to-market" event occurs only when the *later of* two conditions is satisfied: (1) 75 days have passed since the first generic application is approved or 30 months have passed since the generic application was submitted and (2) 75 days have passed since a final court determination that the patents in question are invalid or not infringed.[23]

In this case, "final court determination" includes court-signed settlement orders entering a final judgment that the patent is invalid or not infringed, a definition you, too, can find if you make your way to 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(BB) in the United States Code. But if an event in (2) never occurs – if a final judgment of invalidity or infringement is not entered – the "*later of*" provision never applies and forfeiture does not occur.[24] Thus, generics and brand-name companies can craft their settlements so as not to assign a determination of blame or reach a judgment on patent validity.[25] Thus, one leg of the provision never occurs and the generic can settle without forfeiting anything.

In fact, five years after the 2003 amendment, monetary pay-for-delay settlements had instead increased, rising along with the popularity of Paragraph IV challenges.[26] The new provision did little to stem the tide.

[21] 21 U.S.C. § 355(j)(5)(D)(i)(V).

[22] Matthew Avery, *Continuing Abuse of Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 Hastings L.J. 171, 191–93 (2008), www.mavery.com/academic/Avery_Continuing_Abuse_Hatch-Waxman.pdf; *see also* Avery and Nguyen, *Roadblock for Generic Drugs*, *supra* note 1, at 10; *see also* Letter from Gary J. Buehler, Dir., Off. of Generic Drugs, Ctr. for Drug Evaluation and Research, FDA, to Marc A. Goshko, Exec. Dir., Teva North America, Teva Pharms. Medicines, regarding Docket No. 2007N-0389/ANDA 77–165, at 5 n. 6 (Jan. 17, 2008) (acknowledging the possibility of further exclusivity "parking"), *available at* www.fda.gov/ohrms/DOCKETS/dockets/07n0389/07n-0389-let0003.pdf; *see also* Hemphill, *Aggregate Approach to Antitrust*, *supra* note 1, at 660–61.

[23] 21 U.S.C. § 355(j)(5)(D)(i)(I). The second requirement also allows forfeiture when 75 days have passed since the patent holder delisted a patent from the Orange Book.

[24] Avery and Nguyen, *Roadblock for Generic Drugs*, *supra* note 1, at 11.

[25] *See ibid.* at 11. In this case, the same pathway of declaratory judgment discussed in note 17 could be used for recourse if a second filer makes a Paragraph IV certification and no lawsuit is filed in response, but it is just as unlikely to be successful as it was in the pre-2003 amendment period.

[26] Hemphill, *Aggregate Approach to Antitrust*, *supra* note 1, at 649 tbl.2, 660.