

Throughout all this strenuous negotiation, the biggest loser is destined to be the public, which continues to suffer higher prices during the period of delay. The FTC has estimated that reverse payment settlements cost consumers \$3.5 billion each year.⁹

For example, suppose a branded drug is able to preserve four years of exclusivity through this type of settlement, a not at all unreasonable assumption.¹⁰ Perhaps the brand pays the generic applicant \$500 million for this delay. At \$1 billion in annual sales,¹¹ the brand-name company retains \$3.5 billion – that is, \$1 billion each year minus the \$500 million payment. The generic earns \$500 million. Assuming a 20 percent price discount when duopoly competition takes place, and an equal sales volume before and after competition, that means consumers would lose \$200 million a year in potential cost savings – 20 percent of \$1 billion. Over the course of four years, consumers would forfeit \$800 million in savings, an estimate likely to be conservative considering that further price drops would occur in subsequent years after generic entry, if additional generics enter as well.

B PAY-FOR-DELAY AS A BOTTLENECK TO ENTRY

As discussed, pay-for-delay settlements are attractive because they offer substantial gains to both parties. They are also lucrative because the Hatch-Waxman incentive scheme can be used to reach a settlement *without* leaving the door open to other competition.¹² It is reasonable to ask, in a situation where a generic has agreed to delay entry, why another generic filer would not try to swoop in and enter the market. The answer is simple. Only the first generic filer making a Paragraph IV certification on a drug is eligible for the six months of exclusivity. Even if the certification is withdrawn or the generic filer loses its infringement case, the six months of exclusivity are not available to any subsequent filer.¹³ Later generics with a Paragraph IV certification (arguing that a patent is invalid or improperly applied) cannot be approved until the six months of first generic exclusivity have elapsed.¹⁴

⁹ *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* FED. TRADE COMM’N 2 (2010), www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff.

¹⁰ Hemphill studied 21 drugs with settlements including monetary payments (some included other stipulations, which will be discussed in Chapter 2). The average preexpiration delay for these drugs, weighted by sales, was 4.1 years. Hemphill, *Aggregate Approach to Antitrust*, *supra* note 1, at 649–50 & 649 tbl. 2.

¹¹ In the 21 settlements studied by Hemphill, the average annual U.S. sales adjusted for inflation was \$1.3 billion for each drug. Hemphill, *Aggregate Approach to Antitrust*, *supra* note 1, at 648.

¹² Hemphill, *Paying for Delay*, *supra* note 1, at 129–34.

¹³ 21 U.S.C. § 355(j)(5)(D)(iii)(II).

¹⁴ 21 U.S.C. § 355(j)(5)(B)(iv)(II)(aa).