

other – but not with society’s interests. In particular, a generic may find it more lucrative to enter into a pay-for-delay settlement than actually pursuing a lawsuit to its conclusion – in fact, a generic application might even be filed with the intent (or hope) of eventually managing to secure a settlement from the brand-name drug maker. Once again, the economics of competition come into play when describing this phenomenon.

The value of a pay-for-delay settlement is best understood by realizing that both the brand-name company and the first generic can obtain substantial benefits through a settlement delaying entry.⁵ When the first-filing generic enters the market, it is entitled to six months of marketing exclusivity alongside the branded drug. This period is valuable – valuable enough that it also leaves both parties open to bargaining. Unfortunately, in creating an incentive for early entry, Congress and the FDA also created a bargaining chip that can be essentially sold away to brand-name drug companies.⁶

A generic could easily prefer an agreement to delay entry over the risks of losing in court, knowing that the agreement will still *guarantee* six months of duopoly that may not otherwise be available. The generic has locked in its right to the exclusivity period by filing first, and this period generally is not forfeited absent a court judgment finding the patents valid. The six-month exclusivity benefit for first generic filers was designed so that generic filers would have an incentive to challenge the validity or the application of patents. Instead, the generic and the patent holder settle, and the generic still walks away with the benefit. In other words, the six-month exclusivity was designed for the benefit of society but operates here for the benefit of the companies alone. Instead of getting generic drugs to market as quickly as possible, society gets delays.

The incentive for the generic company to agree to delay is even stronger when the brand-name company throws in some form of payment. The generic filer still gains the benefits of the six-month duopoly period, but it receives an additional payment as well – a payment that results from inflated drug prices. Specifically, during the period in which the generic has agreed to stay off the market, the price of the drug stays at its height; the brand-name company shares some of its profit from those high prices with the generic company. Both are perfectly happy. It is consumers who lose out.

The scenario is the bizarre consequence of the 180-day exclusivity bargaining chip. Without the exclusivity incentive, a Paragraph IV challenge would have one of two endings: losing the challenge or winning the challenge and being able to

⁵ Hemphill, *Paying for Delay*, *supra* note 1, at 127–28.

⁶ See *ibid.* at 134–39, which offers a wonderful, clear explanation of the incentives at work for the branded and the generic.