

separately. Some “Generation 1.0”-style settlements still survive; early “Generation 3.0” tactics have plagued generics for more than a decade – the overlap between generations can be substantial. Instead, the system serves as a helpful way of organizing sets of related tactics, and the use of “generations” implies that each era of tactics has evolved from or developed in response to strategies from previous generations.

Throughout the book, we detail examples of companies engaging in various aspects of the three generations of behaviors. The companies we describe, however, are not the only ones employing these tactics. Some companies have had the misfortune of landing in the spotlight, and some have been a tad more aggressive, but these behaviors are rampant throughout the industry.

In Generation 1.0, delay generally takes the form of “pay-for-delay,” or “reverse payment,” settlements, in which a potential generic manufacturer is simply paid by the pioneer drug maker, often hundreds of millions of dollars, to refrain from entering the market until a stipulated date. “Reverse payment” refers to the odd nature of the arrangement – instead of a defendant paying a plaintiff to settle a suit, brand drug companies pay off the generic to end a patent infringement lawsuit. The reasoning behind the counterintuitive direction of these settlements reflects the economics of pharmaceutical markets and unintentional incentives created by the Hatch–Waxman generic pathway. These settlements were commonplace for many years, but the Supreme Court’s 2013 ruling in *FTC v. Actavis* opened the door to intense antitrust scrutiny of such agreements.

Chapter 2 describes the rise of a new generation of pay-for-delay tactics – “Generation 2.0.” Beginning long before *Actavis*, these strategies generally involve the transfer of benefits from the branded firm to a generic manufacturer, but not through a simple cash settlement. Generation 2.0 agreements include patterns of multiple side deals, where two companies settle a number of Hatch–Waxman disputes at once, resulting in a net benefit for the generic firm but without any large, conspicuous payment. Other instruments include overvalued agreements wherein the generic delays entry, but it is paid handsomely to promote, manufacture, or otherwise assist the brand-name company with the sale of its drug. Finally, Generation 2.0 includes “boy scout clauses” – agreements to behave honorably that actually mask anticompetitive collusion. As described in Chapter 2, these side deals are now themselves facing antitrust scrutiny in the courts.

Chapters 3 and 4 provide a comprehensive look at emerging “Generation 3.0” strategies. Until now, these tactics have been deployed largely under the radar. Generation 3.0 tactics no longer focus on delay agreements with generic competitors, but rather on using administrative processes and drug modifications to obstruct generics from getting to market.

Many of these strategies have little justification beyond obstruction of generics, and some recent fact patterns are falling further outside the boundaries of common