the "old" version is able to reach the market.[1] A second mechanism subverts FDA guidelines meant to ensure the safe use of potentially dangerous or potent drugs. These safety protocols are used in schemes that either (1) prevent potential generic manufacturers from accessing the drug samples necessary to test for bioequivalence or (2) block collaboration on shared risk strategies. Many of these tactics take advantage of a process available to the public to raise concerns about pharmaceuticals, known as "citizen petitions." These petitions can require extensive FDA review of the assertions made – and pharmaceutical companies know full well that the FDA is likely to take months (or longer) to review even entirely groundless claims.

In this chapter, we will focus on "early" Generation 3.0 strategies that mainly take advantage of generic substitution systems and the oddities of the pharmaceutical market to obstruct generic sales. Chapter 4 will detail strategies that subvert FDA regulatory measures to achieve delay.

The new era of obstructionist strategies can result in anywhere from a few months up to a couple years of delay, in contrast to the multiple years of delay that reverse payment agreements can create. (There have been, of course, some exceptions and edge cases, particularly when it comes to product hopping and other early strategies.) The tactics are unlikely to be successful beyond the months of delay garnered by filing an FDA petition or refusing to sell drug samples to a generic hopeful, and many of the attempts are likely to be rejected by the FDA. Nevertheless, even a rejected or dismissed attempt at obstruction can be worth hundreds of millions of dollars.

Recall the figures we described for showing that pay-for-delay strategies can be extremely valuable. If a branded drug has $1 billion in annual U.S. sales, an agreement with the generic to delay entry for three to four years is worth billions to the brand-name company – even when factoring in the cost of paying the generic to delay.[2] If the brand-name manufacturer is able to broker a delay of three years for a cost of $500 million, the branded manufacturer still walks away with $2.5 billion of additional revenue out of the deal.[3] With money like this on the table, even shorter forms of delay can be valuable if the costs and risks are low.

Consider the example of a citizen petition asking the FDA to delay approval for a generic. The cost of filing a citizen petition is trivial, perhaps just tens of thousands of dollars of legal fees, compared to the expected value of the benefits, even

[1] *See* Herbert Hovenkamp et al., IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law § 12.5 (1st ed. 2002) (discussing and naming the phenomenon "product hopping").

[2] Of the 100 top-selling drugs in the United States in 2013, the median drug had sales exceeding $1 billion. *U.S. Pharmaceutical Sales-2013*, Drugs.com, www.drugs.com/stats/top100/2013/sales (last updated Feb. 2014) (reporting sales data for Lovaza and Gilenya, the 50th and 51st best-selling drugs, respectively).

[3] This does assume that branded sales drop to immediately after generic introduction.