

“Generation 2.0”

Complicating Pay-for-Delay

A ALREADY STEPS AHEAD OF ACTAVIS

Although *Actavis* dealt a blow to traditional pay-for-delay settlements, it was years too late. By the time the decision was handed down, drug manufacturers had long moved on to other forms of settlement. With heightened scrutiny applied to pure cash pay-for-delay agreements even before the *Actavis* ruling, drug companies quickly began to combine delay provisions with noncash provisions. These noncash deals are meant to obscure the fact that the generic firm is still receiving large considerations, valued at tens or hundreds of millions of dollars, in return for delayed entry. In these “Generation 2.0” games, the reverse payment is still very much alive – just not so clearly denoted by dollar signs.

Before moving forward, we want to reiterate that our framework of “generations” does not imply that *Actavis* completely foreclosed Generation 1.0 settlements and replaced them with Generation 2.0 controversies – *Actavis* was decided in 2013, and, as we will discuss shortly, the first Generation 2.0 settlements occurred as early as 1997. In addition, cash payment agreements continued well into the 2000s and beyond. Instead, “generations” should be thought of as marking the evolution of delay strategies and grouping them in helpful organizations. Evolution does not mean previous strategies do not exist; the branches of a multigenerational family exist simultaneously although its members are of different ages, and all generations still have their place and unique strengths within the family.

This chapter will explore the structure of standard Generation 2.0 agreements, along with examples that demonstrate the evolving complexity of such settlements. Further, we introduce some of the consequences of increasing complexity: as some generic-hampering strategies have become the norm, pharmaceutical companies will now promise to refrain from certain actions in exchange for a delay, provisions we have dubbed “boy scout clauses.” The chapter also turns to a discussion of how these agreements have been interpreted by courts. Although the *Actavis* agreement itself was in part a “later generation” settlement – *Actavis* agreed to promote a