

separate drug made by the brand-name company as part of the deal – there has been a surprising amount of lower court judicial resistance to extending *Actavis* antitrust scrutiny to noncash deals. Recent decisions, however, have offered some guidance and consolidation in a confusing post-*Actavis* world.

We begin with the origins of “advanced” pay-for-delay strategies. The first Generation 2.0 settlement is generally understood to be a 1997 agreement to delay entry of K-Dur, a drug treating potassium deficiencies.¹ The drug was manufactured by Schering-Plough (now part of Merck), and, in 1995, Upsher-Smith became the first generic to file a Paragraph IV generic application for K-Dur. (If all of these pharmaceutical companies are going to consolidate, can they not at least consolidate their names as well?)

Hours before trial was set to begin in the ensuing patent infringement case, Schering and Upsher reached a settlement. Upsher agreed to delay entering the generic K-Dur market for approximately four years. What differed in this first Generation 2.0 agreement was what Schering, the brand-name drug company, added to the agreement as a noncash consideration. (In fact, Schering appeared quite fearful of signing on to a cash-only deal.)² Schering agreed to buy licenses to sell multiple Upsher medications – in particular, a cholesterol drug known as Niacor-SR, which Upsher had developed. Schering paid Upsher \$60 million and agreed to pay royalties on Niacor-SR, depending on its sales of the product.³ Before the settlement was even ratified, the two parties quickly abandoned their plans to make Niacor-SR, but suspiciously left the \$60 million “license” payment intact.⁴ (No refunds, it seems.)

In court, Schering and Upsher made an argument soon to be common in Generation 2.0 cases – that the \$60 million payment was only for the licensing deal and had nothing to do with the delay of generic K-Dur.⁵

Schering and Upsher were prescient in their settlement design: the *K-Dur* case presents the archetypical form of a classic Generation 2.0 settlement.⁶ As part of

¹ See *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 205–06 (3d Cir. 2012); C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 658 (2009).

² *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1059 (11th Cir. 2005).

³ See *In re K-Dur Antitrust Litig.*, 686 F.3d at 205–06.

⁴ *Ibid.* at 206. Also suspicious is the following: The generic demanded cash and early entry when the settlement was first being negotiated. But, concerned about pay-for-delay antitrust scrutiny even back in 1997, the brand-name company would not agree to these more basic terms. *Ibid.* at 205.

⁵ *Ibid.* at 206.

⁶ Recall that *Actavis* also had elements of a Generation 2.0 settlement (e.g. side deals, installment payments). We associate *Actavis* with Generation 1.0 in this chapter given that the *Actavis* argument has mostly been applied only to cash deals as of now.