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"Generation 3.0"

New Tactics for Active Obstruction of Generics

A A NEW GENERATION OF PHARMACEUTICAL DELAY

As described in the prior chapters, pay-for-delay strategies appear to be on their last legs. *Actavis* and *Cipro* combined to deliver a knockout punch to rudimentary cash pay-for-delay deals. Similarly, although the trail of the large unexpected payment is harder to pin down in "Generation 2.0" deals – hidden behind multiple settlements, layers of superfluous deals, and valuable contract clauses – *King Drug* landed a major post-*Actavis* blow. When it comes to lengthy delay deals, pharmaceutical companies are on the ropes, and brand-name companies are less frequently looking to team up with their generic counterparts to extend the life of their monopoly. Instead, brand-name companies are now fighting back directly against generics with small jabs, and consumers are the unwitting recipient of the collateral damage.

The saying goes, "If you can't beat 'em, join 'em." Unsurprisingly, that is not the case for pharmaceutical companies, for which the guiding motto seems closer to, "If you can't join 'em by securing agreements to delay generic entry, *beat* 'em."

With their ability to enter into pay-for-delay deals severely diminished, brand-name drug companies are turning to new strategies no longer friendly to generics. Instead, they actively obstruct generics from entering the market. The point of obstruction can occur at different stages of generic development: before a generic application is submitted, during the generic application approval process, after a generic drug has been approved for marketing, or even once the generic has managed to enter the market.

As Chapters 4 and 5 will explain, the mechanisms of obstruction are varied and complex, but most involve strategic behavior in the generic substitution system or in the FDA regulatory process. One mechanism is known as "product hopping," whereby the brand-name drug company takes advantage of its market power to shift pharmacists, doctors, and consumers to "new" versions of drugs before a generic for