

Thus, even with the settlement, the delay may have been worth up to \$2.3 billion for Glaxo – a tidy sum.

The value of petitioning or other obstructionist strategies is even higher when you consider the possibility that the petition might actually be accepted, forcing the generic to retool its application or withdraw from the market. For example, Michael Carrier and Daryl Wander found that the FDA granted about 20 percent of the citizen petitions filed by brands against generics between 2008 and 2010 – a small but significant number.¹²

This chapter continues with a discussion of some of the earliest market-based Generation 3.0 delay strategies that make up the toolbox for a branded pharmaceutical manufacturer, starting with perhaps the most well-known: product hopping and evergreening.

B PRODUCT HOPPING AND THE PURPLE PILL

Commentators have written for some time on the phenomenon known as “evergreening,” in which a company tries to refresh its market monopoly by making slight modifications to a drug’s delivery mechanism, dosage, or other characteristics to make the drug eligible for additional exclusivity or patents.¹³ One of the most dramatic forms of obstruction uses refreshed or “evergreened” patents as part of a strategy called “product hopping.” With product hopping, drug companies attempt to shift the entire market for their brand-name drug to a new or improved version of the medication.

The following steps make up a product hop. First, the brand-name drug company makes a small change to its existing drug – just as its patents or regulatory exclusivities are about to expire – and introduces the new formulation as an entirely new drug. This new form generally is protected by new patents or exclusivities corresponding to the minor changes, and these new rights block generic competition from quickly moving to the new market. The strategy forces a market shift away from the old drug – just as it is approaching its patent cliff.

The brand-name drug company brings about the market shift in a number of ways. Notably, the company usually undertakes a significant promotion and advertising

¹² Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 *CARDOZO L. REV.* 249, 276 (2012), <http://cardozolawreview.com/content/34-1/Carrier.34.1.pdf>.

¹³ See generally ROBIN FELDMAN, *RETHINKING PATENT LAW* 170–77 (2012); Michael A. Carrier, A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping, 62 *FLA. L. REV.* 1009 (2010); Jessie Cheng, Note, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 *COLUM. L. REV.* 1471 (2008); Vikram Iyengar, *Should Pharmaceutical Product Hopping Be Subject to Antitrust Scrutiny?* 97 *J. PAT. & TRADEMARK OFF. SOC'Y* 663 (2015); Steve D. Shadowen, Keith B. Leffler, & Joseph T. Lukens, *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 *RUTGERS L.J.* 1 (2009).