

balance, giving pharmaceutical companies the opportunity to recoup investment without blocking the incentive for others to innovate further in the future.

That balance means all good things must come to an end – maybe. When a drug’s patents or exclusivities expire or are found invalid, in theory, anyone who can obtain FDA approval becomes eligible to sell the medication, and thus generic competition begins. The expectation is that the brand-name pharma company, having likely enjoyed more than a decade of unimpeded sales, heads back to the lab bench, ready to discover new treatments with improved therapeutic benefits for patients. R&D activity, however, is expensive and difficult – mergers, acquisitions, and obstruction are cheaper and simpler. As a result, it has become far too easy to spend time and resources exhausting legal and regulatory options, pushing the patent cliff as far away as possible.

The temptation to avoid the impact of the patent cliff can be overpowering when even a few months of additional monopoly profits can be worth hundreds of millions of dollars or more.⁴⁶ For example, Gilead’s previously mentioned hepatitis C drug, Sovaldi, earned \$7.9 billion in sales in 2014, making it the top-earning drug in the United States. Three additional months of sales at that rate would be worth \$1.98 billion. Similarly, Pfizer’s Nexium took in \$5.9 billion in revenue in the same year – three additional months would be worth \$1.48 billion.

These enormous and precariously fleeting revenue streams encourage companies to expend tremendous energy blocking generic entry by any means possible, with companies using ever more clever and complicated strategies. As a result, many pharmaceutical firms may no longer compete solely on the basis of innovation, but rather on their ability to manipulate policy mechanisms and pathways to extend monopoly and duopoly terms. The lure of the easy way out means that many companies fail to follow the advice of their colleague Mr. Shkreli and instead prolong the generic mourning period.

Of course, this behavior undermines the goals of intellectual property and can provide less than optimal innovation and pricing effects. As an example, let us return to Mr. Shkreli and his actions at Turing. While Daraprim was already off-patent at the time Turing purchased distribution rights for the drug, Shkreli’s company used a modified version of an emerging generic delay strategy to keep all competition off the market, allowing the eye-popping price increase to occur.

Develop a Drug? New Estimate Makes Questionable Assumptions, N.Y. TIMES (Nov. 18, 2014), www.nytimes.com/2014/11/19/upshot/calculating-the-real-costs-of-developing-a-new-drug.html (describing the conflict in determining how much it costs to develop a drug).

⁴⁶ Lacie Glover, *Here Are the Top-Selling Drugs in the US*, TIME (June 26, 2015), http://time.com/money/3928166/top-selling-drugs-sovaldi-abilify-humira/?xid=soc_socialflow_twitter_money. Fifty-five drugs earned more than \$1 billion in revenue in 2013. *U.S. Pharmaceutical Sales – 2013*, DRUGS, www.drugs.com/stats/top100/2013/sales (last updated Feb. 2014).