

Further, generic manufacturers have the incentive and ability to enter the market immediately after (or even before) the original patent terms expire. Change did not happen overnight; nor was Hatch–Waxman the kind of legislation that engendered enormous public controversy and debate – and yet it ended up making one of the greatest changes to the health care system in modern U.S. history.

A second miracle has occurred alongside the dramatic rise of generics – for the most part, the benefits of Hatch–Waxman have held up despite its complexity and the persistent attempts at undercutting its aims. In fact, it is the complexity of Hatch–Waxman that has unfortunately created a veritable playground of opportunities that pharmaceutical companies have used to hold off generic competition. And it is these strategies that are the focus of this book.

Our goal for this book is twofold: first, to shine light on the complex strategies as they have unfolded over time, and, second, to suggest ways to cabin those behaviors and create incentives for companies to follow the path that is optimal for society. Quite simply, pharmaceutical companies should be directing their creative energies toward research and development, not toward inventing new legal challenges and regulatory obstructions.

To be clear, when pharmaceutical companies preserve their hard-earned patent exclusivity by legally knocking down generic challenges, such behavior is consistent with societal goals and important for the patent system. Rights are worth little if the rights holder cannot enforce them, and that is as true for patents as for any form of legal right. In contrast, when firms attempt to extend their monopolies unlawfully, such behavior undercuts the goals of the patent system, and the cost to society can be troubling. Patients and the general public lose, giving up billions of dollars in savings while ready-to-market generics languish on the sidelines. The energy spent on manipulation of the legal system diverts time and resources away from innovation activities.

[The Introduction](#) explains the Hatch–Waxman Act pathway to generic entry in more detail, discussing the economic incentives behind its structure and detailing amendments designed to improve the functioning of the act. The workings of Hatch–Waxman are quite complicated, even when compared to other legislation and regulatory regimes, and we will explain its principles and pathways in an easy-to-understand way that also highlights the reasoning behind each step in the process. From the beginning, Hatch–Waxman has faced issues with unintentional consequences, loopholes, and subversion. We also discuss early gaps in the act and later amendments designed to patch these holes.

[Chapter 1](#) explains the origins of generic delay tactics, called “Generation 1.0” – the first of three “generations” the book uses to categorize the tactics that have evolved over time. The organizational system of generations that we use here is not meant to suggest that these each of these periods has taken place sequentially and