Introduction

The Winding Road to Generic Entry

The Hatch-Waxman Act is a deeply complex piece of legislation, codified in four different sections of the United States Code.[1] While it creates a streamlined pathway for generic manufacturers to seek approval of their drug, it does so in a way that testifies to the difficulty of satisfying all stakeholders in the pharmaceutical market. The goal of protecting innovative activity, balanced with the desire to make low-cost drugs available to patients, has produced a labyrinthine series of statutes. Complexity breeds opportunity, however, and Hatch-Waxman's legacy is littered with evidence of manipulation.[2]

This chapter focuses on the core components of FDA drug approval most often implicated in generic delay, in the clearest terms possible, omitting discussions of exceptions and complex subsections where appropriate. Later chapters will introduce other sections of the act to help make sense of these intricate games of generic delay. These include descriptions of amendments meant to tighten the functioning of Hatch-Waxman (while frequently creating their own difficulties). Hatch-Waxman's establishment of a new generic drug landscape also means that an entire lexicon of jargon has developed to discuss the field, and this chapter will define the main terms and acronyms before continuing further.

Hatch-Waxman's core contribution was allowing prospective generic manufacturers to submit an Abbreviated New Drug Application, almost exclusively referred to as an "ANDA," to seek approval of a drug equivalent to one already approved by the FDA.[3] To prevent weighing the material down in endless jargon, we will refer to ANDAs as "generic drug applications" whenever possible. A generic drug application must be for a medication that is bioequivalent to the

[1] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98–417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 21 U.S.C. and 35 U.S.C.).

[2] Robin Feldman, Rethinking Patent Law 160 (2012) ("As so often is the case, complexity breeds opportunity, and clever lawyers have been exploiting the details of the act since its inception.").

[3] 21 U.S.C. § 355(j) (2012).