

generally deemed to begin when the first commercial marketing of the drug takes place.²¹ Generic entry normally occurs after one of the following events: all relevant patents and exclusivities expire; the generic drug maker wins a challenge invalidating all relevant patents or finding that infringement did not occur; or the generic company reaches a settlement with the branded drug maker allowing entry. This six-month exclusivity period can easily be worth hundreds of millions of dollars to a generic, representing a substantial majority of the potential profits to be gained from generic entry.²²

The entire Paragraph IV process is intended to give generic companies an incentive to do battle with powerful pharmaceutical companies. (This metaphor may have had stronger relevance at the start of the modern era of generics. With the tremendous consolidation in recent years, many generic companies are now subsidiaries or units of much larger pharmaceutical conglomerates. The battle is now more likely to be *Part of Goliath vs. Part of Goliath*, with fewer actual Davids on the scene.)

The Paragraph IV first-filer exclusivity is thus an enormous incentive for a generic applicant to file as soon as possible and secure the six months of exclusivity. In addition, if the generic succeeds in overturning the patent, the generic also gains market entry long before the patent would have expired. The artificial nature of the patent infringement action provides other benefits as well. It allows the generic to trigger litigation without actually entering the market and potentially accruing substantial damages. Despite its many benefits, however, this complicated and lucrative pathway has made Hatch-Waxman susceptible to abuse, due in large part to the economic incentives created by the exclusivity period.²³

Going back to the filing process – if the patent holder chooses to initiate litigation, a 30-month stay is placed on generic approval. The goal is to allow the infringement litigation to work its way through the courts while the FDA continues reviewing the generic application.²⁴ The generic application cannot be approved for 30 months,

²¹ See 21 U.S.C. §§ 355(j)(5)(B)(iv)(I)–(II) (2012). However, this does not entirely prevent the presence of other competition. Brand-name companies can launch their own generic version of the drug at a lower price-tier (or permit another company to do so), creating instant competition for the generic. These generics are often called “authorized generics” and are discussed later in [Chapter 2](#).

²² See Matthew Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, at 178, 178 nn.55–56 (2008).

²³ When there are multiple first-filing ANDA applicants (all submitting on the same day, usually the first day that ANDAs will be accepted), all applicants are eligible for exclusivity. See generally U.S. Food & Drug Admin., GUIDANCE FOR INDUSTRY 180-DAY EXCLUSIVITY WHEN MULTIPLE ANDAs ARE SUBMITTED ON THE SAME DAY (2003), www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm072851.pdf.

²⁴ See 21 U.S.C. § 355(j)(5)(B)(iii) (2012).