IV certification in a generic application. Under the terms of the settlement, the generic receives a cash payment and agrees to delay its entry into the market for a specified period. For example, "Brand" Company might have four years left on its patents on Drug X, but "Generic" Company is challenging the patents. To maintain its lock on the market for as long as possible, Brand might pay Generic $150 million to delay generic entry of Drug X for three years, by dropping the suit and agreeing on a specific date when Generic can enter.

These settlements are sometimes referred to as "reverse payment" schemes, a reference to the fact that payment is transferred from the suing brand-name drug company to the defending generic competitor. This runs counter to the standard expectation that a defendant would pay a plaintiff to settle a suit. The practice first came to light when Paragraph IV challenges significantly increased in the decades following Hatch-Waxman's enactment. Few drugs were subject to a Paragraph IV challenge immediately after the passage of Hatch-Waxman, but 55 percent of drugs approved between 2000 and 2002 were challenged.[2] By 2006, the median time from FDA approval of a brand-name drug to the first Paragraph IV challenge by a generic company had dropped to a flat four years for all categories of drugs.[3] That four-year figure is particularly significant because the FDA cannot accept a generic application with a Paragraph IV certification until four years after the brand-name drug was initially approved, for brand-name drugs with new active ingredients.[4] Thus, when drugs with new ingredients, which are likely to be popular or novel, are approved, generic challengers are filing with the FDA as soon as they are allowed under the law.

Put another way, more drug patents and drugs are challenged than ever before, and generic drug manufacturers are gathering resources to make challenges more quickly than they ever did previously. Today's new blockbuster drug generally can expect to be subject to a so-called preexpiration challenge. In response, drug manufacturers have developed responses to keep generics off the market.

The insidious element of pay-for-delay settlements is that the incentives of both the brand-name drug company and the generic company are aligned with each

[2] *See* C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?* 8 J. Empirical Legal Stud. 613, 624, 624 fig. 4 (2011); *see also* Hemphill, *Aggregate Approach to Antitrust*, *supra* note 1, at 657–58 (noting increased intensity of antitrust enforcement and development of new strategies starting around 1997).

[3] *See* Henry Grabowski *et al.*, *Pharmaceutical Patent Challenges and Their Implications for Innovation and Generic Competition* fig. 3 (Am. Econ. Ass'n, Working Paper, 2015), www.aeaweb.org/aea/2015conference/program/retrieve.php?pdfid=1203.

[4] 21 U.S.C. § 355(j)(5)(F)(ii) (2012). As noted in the Introduction, a generic applicant theoretically could submit an application replicating all of the brand-name company's clinical trials, but the cost of such work without the possibility of recoupment through a patent term makes that route extremely unlikely.