Eight Reasons Why "No-Authorized-Generic" Promises Constitute Payment

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Drug patent settlements present some of the most nuanced issues in patent and antitrust law today. Does a brand-name drug company's payment to a generic firm cause delayed entry? Does a brand’s forgiveness of a generic’s potential damages constitute payment? How should courts evaluate parties’ simultaneous settlement of multiple cases?

To this universe of complex questions, courts have added one that is embarrassingly easy: Is there a payment when a brand promises not to introduce its own generic (known as an “authorized generic” or “AG”), which could be worth millions of dollars to the generic? Under any reasonable interpretation of economics, the Supreme Court’s 2013 decision in FTC v. Actavis, or common sense, such a promise constitutes payment.

In two recent cases, however, courts held that brands’ no-AG promises did not count as payment. The New Jersey district court in In re Lamictal Direct Purchaser Antitrust Litigation found that “nothing in Actavis” indicated that “a no-AG agreement is a ‘payment.’” And in In re Loestrin 24 FE Antitrust Litigation, the Rhode Island district court found that Actavis “fixates on the one form of consideration that was at issue in that case: cash.”

This article first provides background on drug patent settlements and authorized generics. It then examines the Lamictal and Loestrin cases. Finally, it offers eight reasons why a no-AG promise constitutes payment. First, such a conclusion is consistent with the language of Actavis. Second, it accords with the facts of Actavis. Third, a no-AG pledge typically provides significant value to generics. Fourth, generics receive more through such promises than they would by winning patent litigation. Fifth, brands act against their self-interest in making no-AG promises, which reveals generics’ gain from the pledges. Sixth, treating no-AG promises as payment emphasizes substance over form. Seventh, such pledges can be more coercive than cash payments. And eighth, the clauses present a classic example of market division.