

David Opderbeck

Rational Competition Policy and Reverse Settlement Payments in Hatch-Waxman Patent Litigation

Abstract

This paper argues that recent efforts by courts, regulatory agencies and commentators to address the problem of "reverse payment" settlements in Hatch-Waxman paragraph IV patent infringement litigation have overlooked the importance of specifying particular pharmaceutical product markets. As a result, existing proposals either threaten to over-deter or under-deter potentially beneficial settlements, or fail to supply meaningful guidance about which agreements should be permissible. This paper offers a new, empirically-based approach that is consistent with how courts and regulatory agencies currently assess analogous agreements between competitors, including exclusive intellectual property licenses and mergers. This approach results in a quantifiable "Settlement Index," which can be used to establish antitrust safety zones, zones of per se illegality, and ranges in which a full-blown rule of reason analysis should be applied.