

Catherine Sandoval
Santa Clara University School of Law

Antitrust Immunity or Liability in Pharmaceutical Reverse Payment Settlement Cases; The Intersection of Civil Procedure, Patent Presumptions, and Antitrust Doctrine

This Article will analyze the intersection of civil procedure, patent presumptions, and antitrust doctrine in pharmaceutical reverse payment settlement (RPS) cases. It will develop the argument in my previous article, “Pharmaceutical Reverse Payment Settlements: Presumptions, Procedural Burdens, and Covenants Not to Sue Generic Drug Manufacturers,” 26 SANTA CLARA COMPUTER AND HIGH-TECH LAW JOURNAL 141 (2009-2010), that recent RPS court decisions have conflated procedural presumptions about patent burdens of proof with antitrust immunity, erroneously applying the relevant tests. Courts have inappropriately extended the presumption of patent validity to find antitrust immunity in cases involving patent infringement where there is no presumption of infringement. The patent holder bears the burden of proof to make a prima facie case of infringement so antitrust immunity cannot be found under the patent’s penumbra if the generic drug has not been shown to infringe the patent. This Article will examine these issues in the context of the Second Circuit case concerning the reverse payment settlement by the maker of Ciprofloxacin, a drug used to treat anthrax and other bacterial diseases, and the Second Circuit’s invitation for a petition for a rehearing en banc.

It will also analyze pending Congressional bills that would ban or restrict reverse payment settlements in infringement cases, recommending changes to curb abusive uses of covenants not sue intended to deprive generic drug companies of jurisdiction to obtain a legal judgment about challenges to the patent’s validity or determinations about non-infringement of the generic drug. It explores the circumstances under which litigation defending covenants not to sue as removing case or controversy jurisdiction may be an abuse of process that creates antitrust liability.