

Reverse Payments in the US

Antitrust Aspects of Settlement of
Generic Drug Litigation from the
Perspective of a Pharma Patent Litigator

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Valley Drug v. Geneva

Normally, paying a competitor to stay off the market would be a per se antitrust violation

However, because Abbott owned a patent and because Geneva had admitted to infringement of that patent, this case is different

Valley Drug v. Geneva - policy

- The patent creates a legal monopoly.
- The exclusionary effect is not the payment of money, but the failure to produce a competing drug.
- Settlement is cheaper than litigation.
- *Per se* antitrust liability for reverse payments would chill such settlements, thereby increasing the cost of patent enforcement and decreasing the value of patent protection generally.

Valley Drug v. Geneva - analysis

- What is the scope of protection of the patent
- Do the agreements fall within the scope of protection of the patent?
- If so, there is no antitrust violation
- If not, analyze under the rule of reason

Quick-Look Analysis

Any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market is *prima facie* evidence of an unreasonable restraint of trade

which could be rebutted by showing that the payment

- (1) was for a purpose other than delayed entry or
- (2) offers some pro-competitive benefit.

Pending bills

- S.214
 - codifies quick-look analysis
 - procompetitive aspects must be proven under “clear and convincing standard
 - Allows up to \$7.5 M in litigation expenses
- S.504
 - Would divest settling ANDA from exclusivity;
 - Would allow exclusivity to subsequent filers if the first filer fails, or settles

“Anything of Value”

- Patent owner P sues alleged infringer D for patent infringement
- D agrees to withdraw from market if P forgives past damages
- Forgiveness of past damages is something of value
- Per se anticompetitive?