The Effect of Actavis on the Current Incentive Environment

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Effect on Reverse Payment Settlements

- Still too early to determine to what extent *Actavis* will strengthen judicial enforcement
  - Reverse payment settlements were frequently and vigorously challenged before *Actavis*
  - Considerable uncertainty as to how courts will implement *Actavis*’s rule of reason standard
- *Actavis*’s impact will be substantial relative to other potential frameworks under consideration (e.g., scope-of-the patent)
Static vs. Dynamic Effects

- Tension in all high tech industries between benefits of static/short-term competition (e.g., price) and dynamic/long-term competition (e.g., innovation)

- Particularly true in pharmaceuticals where patents (and patent challenges) can be important tools in determining incentives to innovate

- Primary focus of Actavis (and FTC) is short-term competition
  - Harder question is not whether Actavis will decrease effective patent term and innovation incentives – it likely will. Rather, how large is the effect and does it move us closer or further away from “optimal” patent life that appropriately balances static and dynamic
Specific Examples of Reverse Payment Settlements

- To better understand potential effects, useful to look more closely at specific settlements (with and without reverse payments)
  - Example 1: Alternate settlement agreement possible
  - Example 2: Alternate settlement agreement not possible
    - Risk aversion, asymmetries in information/beliefs/discount rates
Example 1a: Settlement with Generic Entry Date Only

Settlement at end of year 5 is only settlement that makes both brand and generic at least as well off as litigation.

Note: Settlement at end of year 5 is only settlement that makes both brand and generic at least as well off as litigation.
Example 1b: Settlement with Generic Entry Date and Reverse Payment

Settlements Generic May Prefer to Litigation

Settlements Brand May Prefer to Litigation

Settlement Range

Consumers Prefer Settlement to Litigation
Example 2a:
Settlement with Generic Entry Date Only
Cash-Strapped Generic

Settlement with Generic Entry Date Only
Cash-Strapped Generic

- Start of Year 1
- End of Year 5
- End of Year 10

- Consumers Prefer Settlement to Litigation
- Settlement Talks
- Generic Prefers Settlement to Litigation
- No Acceptable Settlement Range
- Settlements Brand May Prefer to Litigation
- Patent Expiration
Example 2b: Settlement with Generic Entry Date and Reverse Payment Cash-Strapped Generic

Settlements Generic May Prefer to Litigation

Settlements Brand May Prefer to Litigation

Procompetitive Settlements Possible only with Cash Payments to Generic

Settlement Range

Consumers Prefer Settlement to Litigation

Start of Year 1

End of Year 5

End of Year 10

Settlement Talks

Patent Expiration
Effects of Actavis on Innovation

- Where (earlier entry) settlement is possible without reverse payment, reduced effective patent life
- Where settlement is **not** possible without a reverse payment, increased cost and risk of litigation for both brand and generic.
  - Reduced incentives for brand firms to innovate (esp., e.g., small manufacturers that rely heavily on a single product)
  - Reduced incentives for generic firms to challenge patents