



# **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

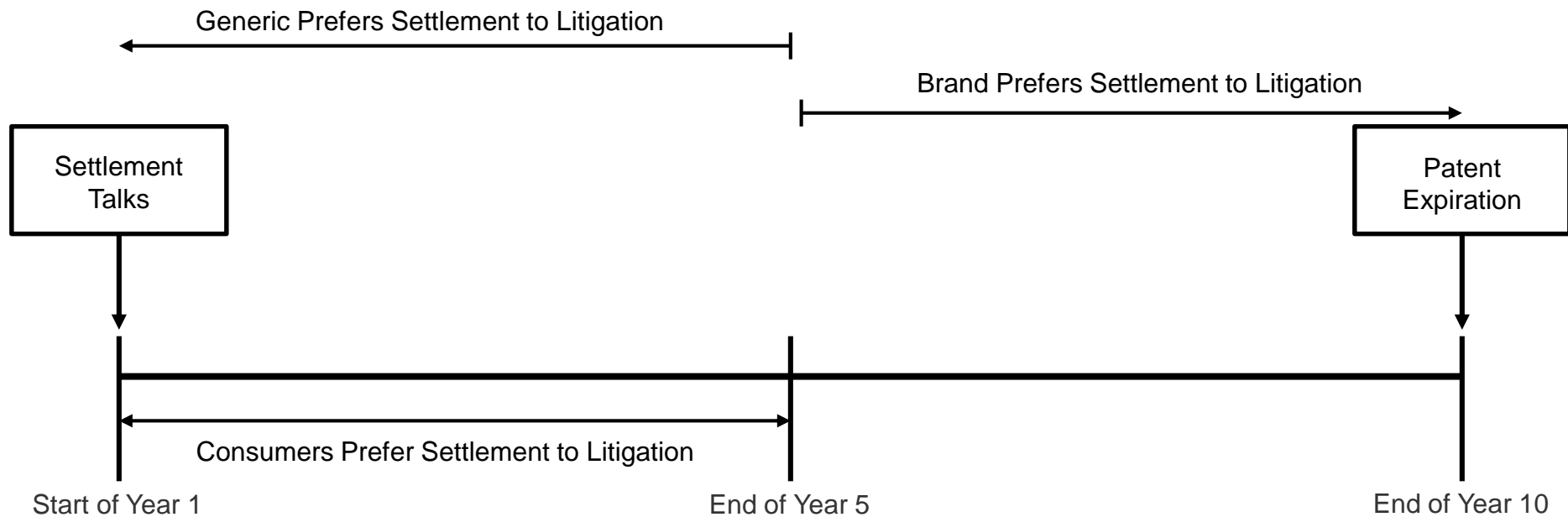
- Tension in all high tech industries between benefits of static/short-term competition (e.g., price) and dynamic/long-term competition (e.g., innovation)
- Particularly true in pharmaceuticals where patents (and patent challenges) can be important tools in determining incentives to innovate
- Primary 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

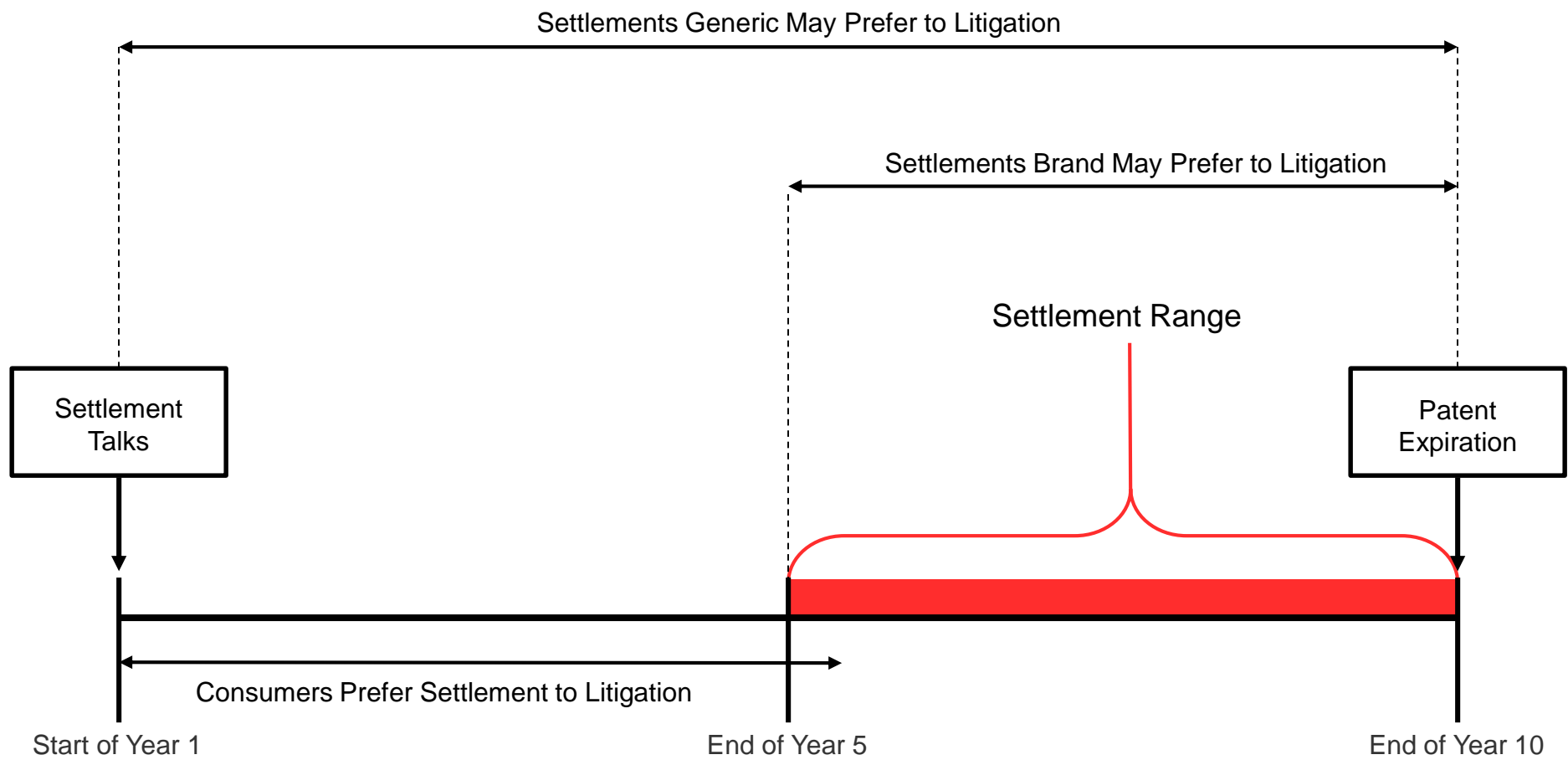
- To better understand potential effects, useful to look more closely at specific settlements (with and without reverse payments)
  - Example 1: Alternate settlement agreement possible
  - Example 2: Alternate settlement agreement not possible
    - Risk aversion, asymmetries in information/beliefs/discount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

# Example 1a: Settlement with Generic Entry Date Only

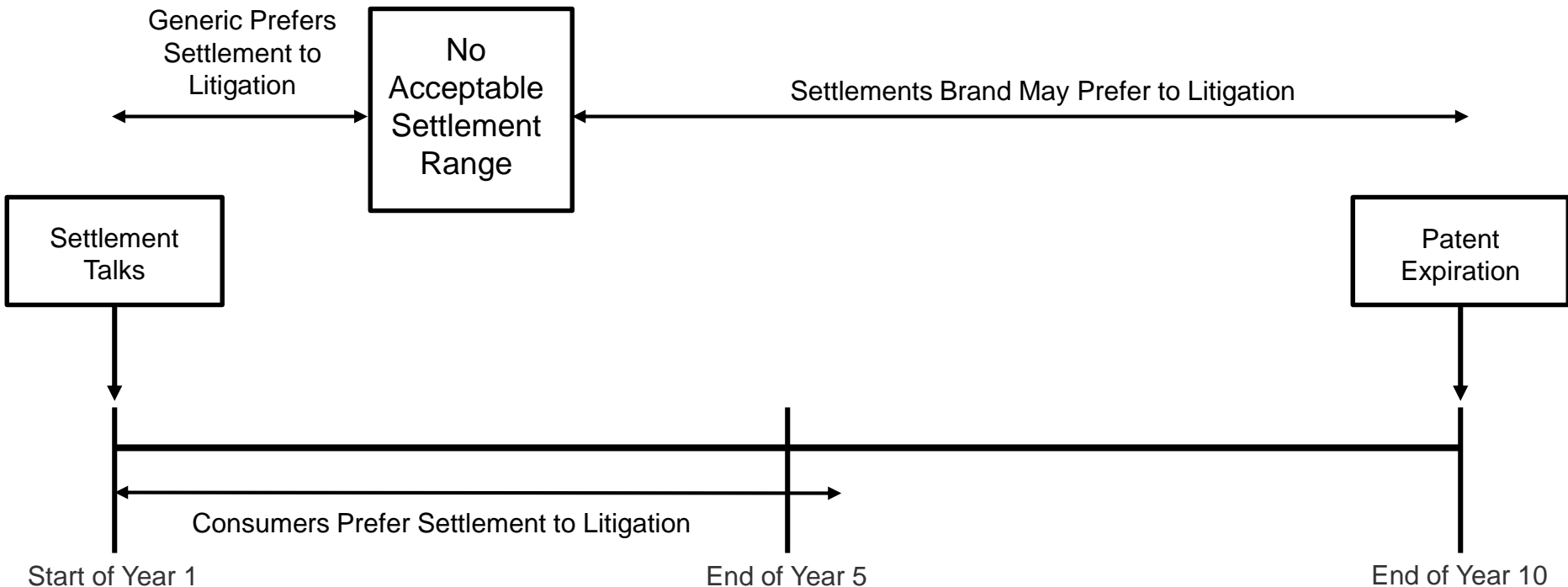


*Note:* Settlement at end of year 5 is only settlement that makes both brand and generic at least as well off as litigation.

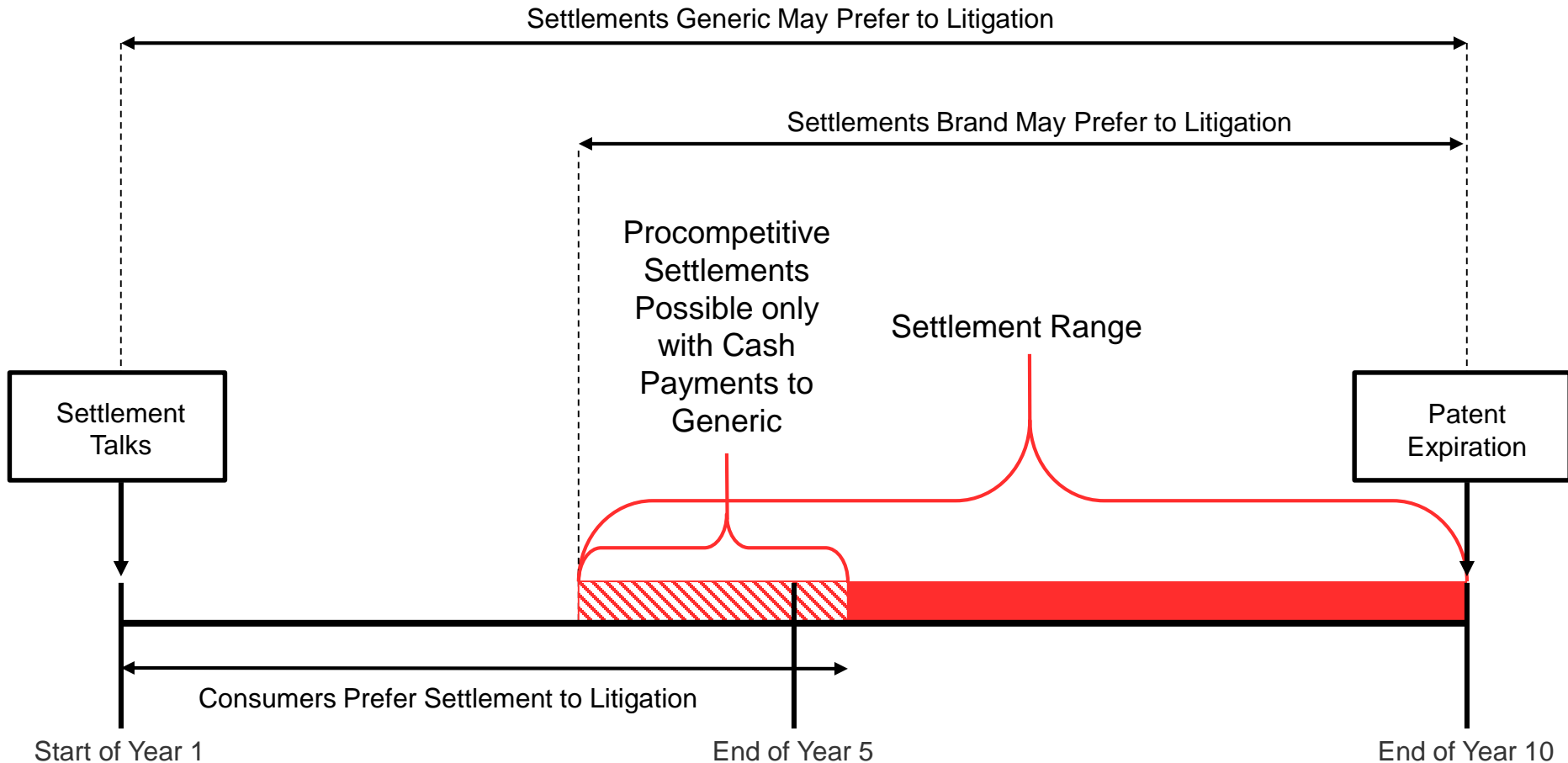
# Example 1b: Settlement with Generic Entry Date and Reverse Payment



# Example 2a: Settlement with Generic Entry Date Only Cash-Strapped Generic



# Example 2b: Settlement with Generic Entry Date and Reverse Payment Cash-Strapped Generic







# 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