# Duration of Drug Patents

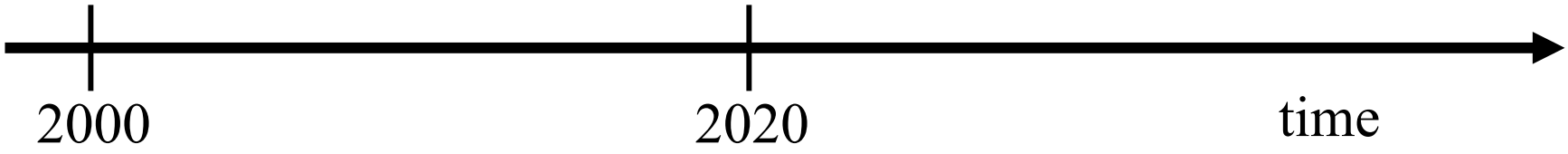
William Fisher

February 1, 2010

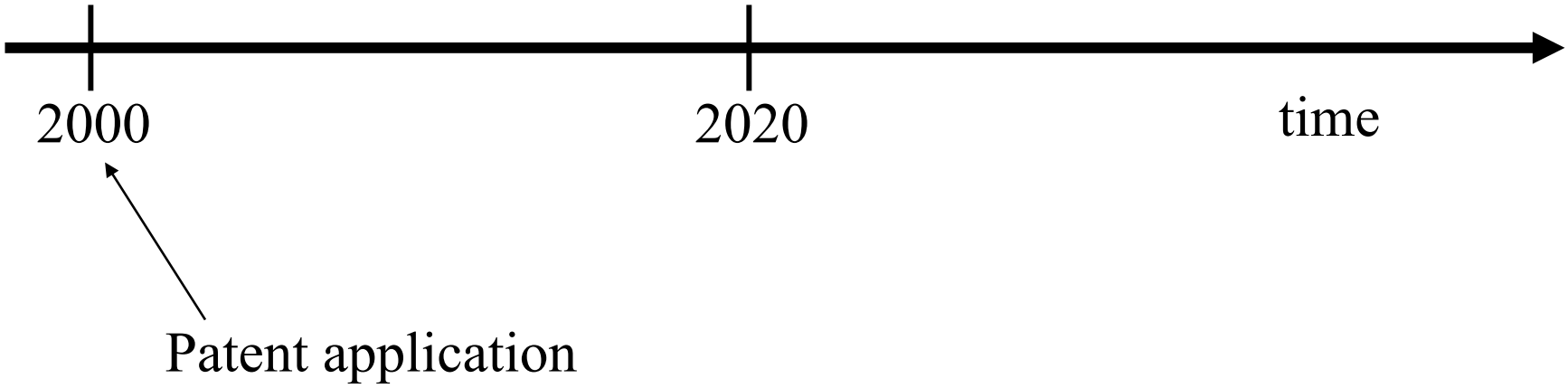
# Hatch-Waxman Act (1984)

- No liability for making, using, or selling "a patented invention" "solely for uses reasonably related to the development and submission of information" to FDA – §271(e)(1)
- Abbreviated New Drug Application procedure (ANDA) for seeking FDA approval for generic equivalent of FDA-approved drug -- or challenging validity of the patent on such a drug – §271(e)(2)
- Extension of patent term to offset FDA approval process –up to 5 years, but no further than 14 years from date of FDA approval – §156

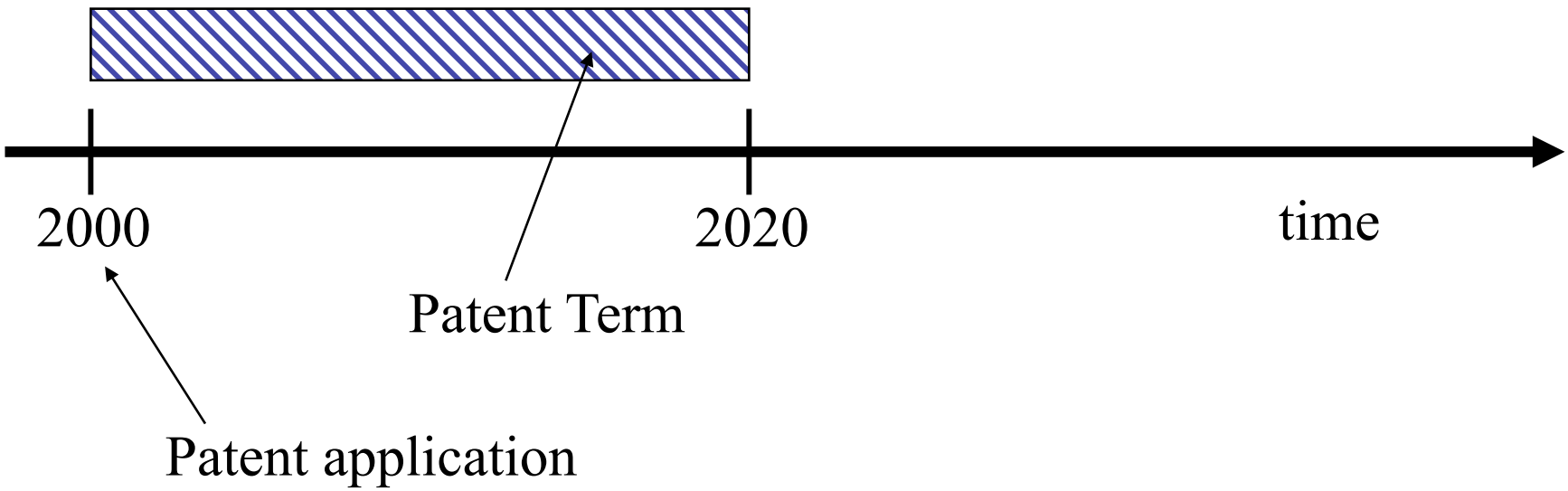
# Treatment of Drugs



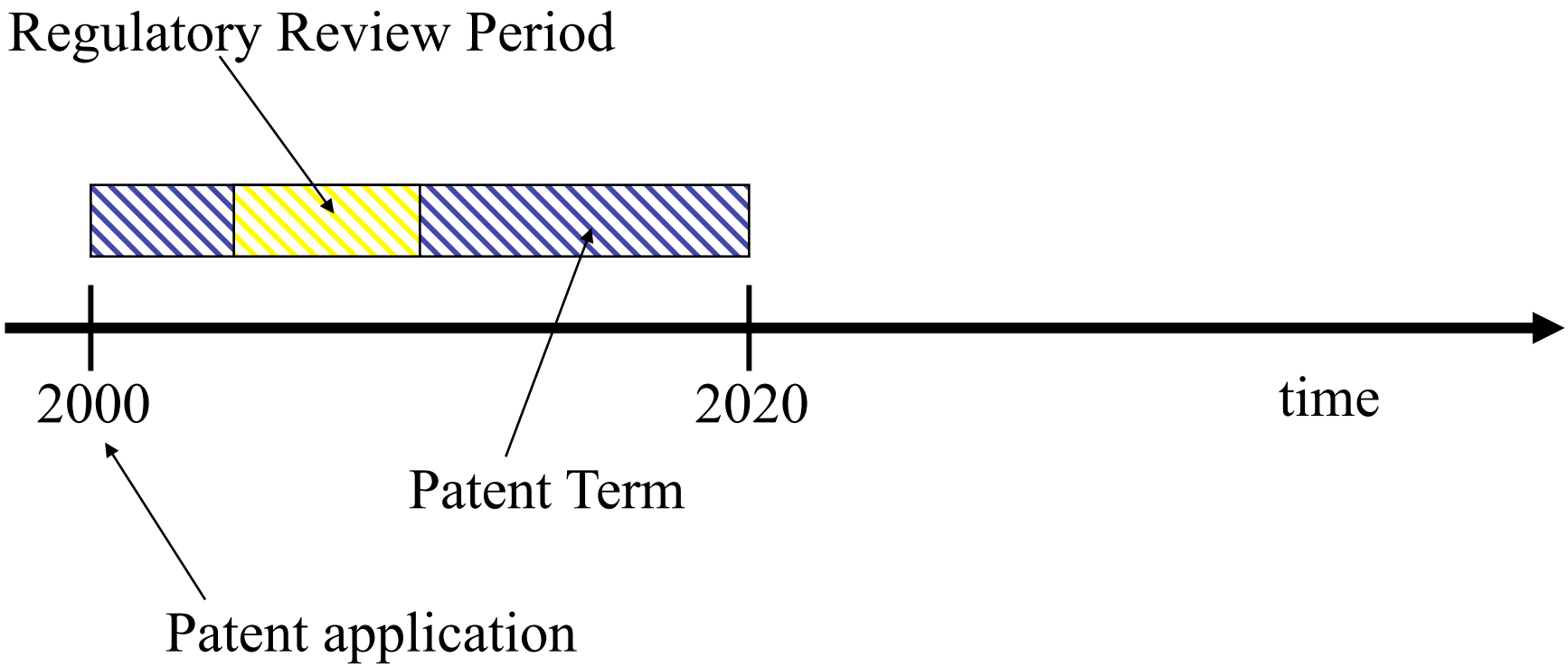
# Treatment of Drugs



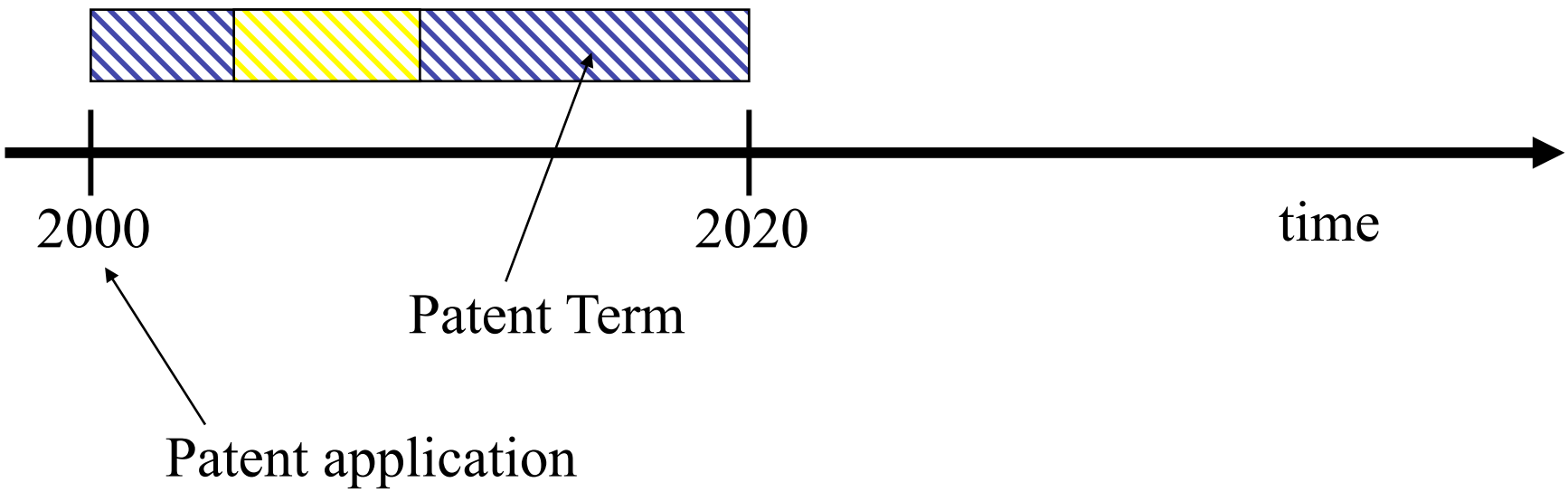
# Treatment of Drugs



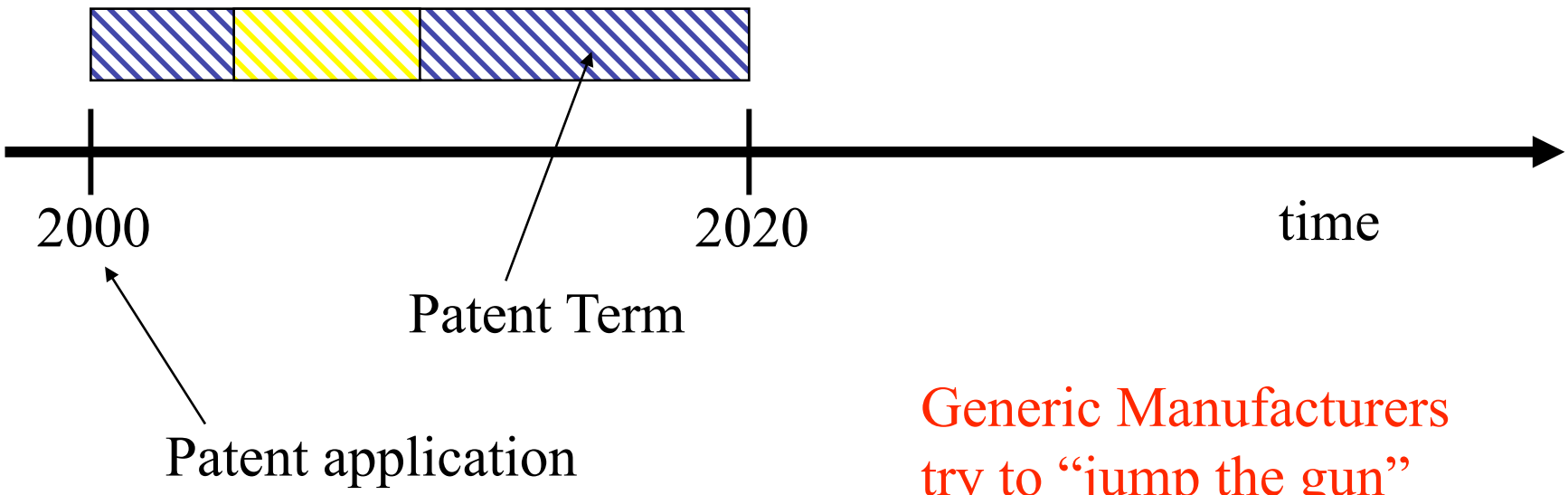
# Treatment of Drugs



# Treatment of Drugs

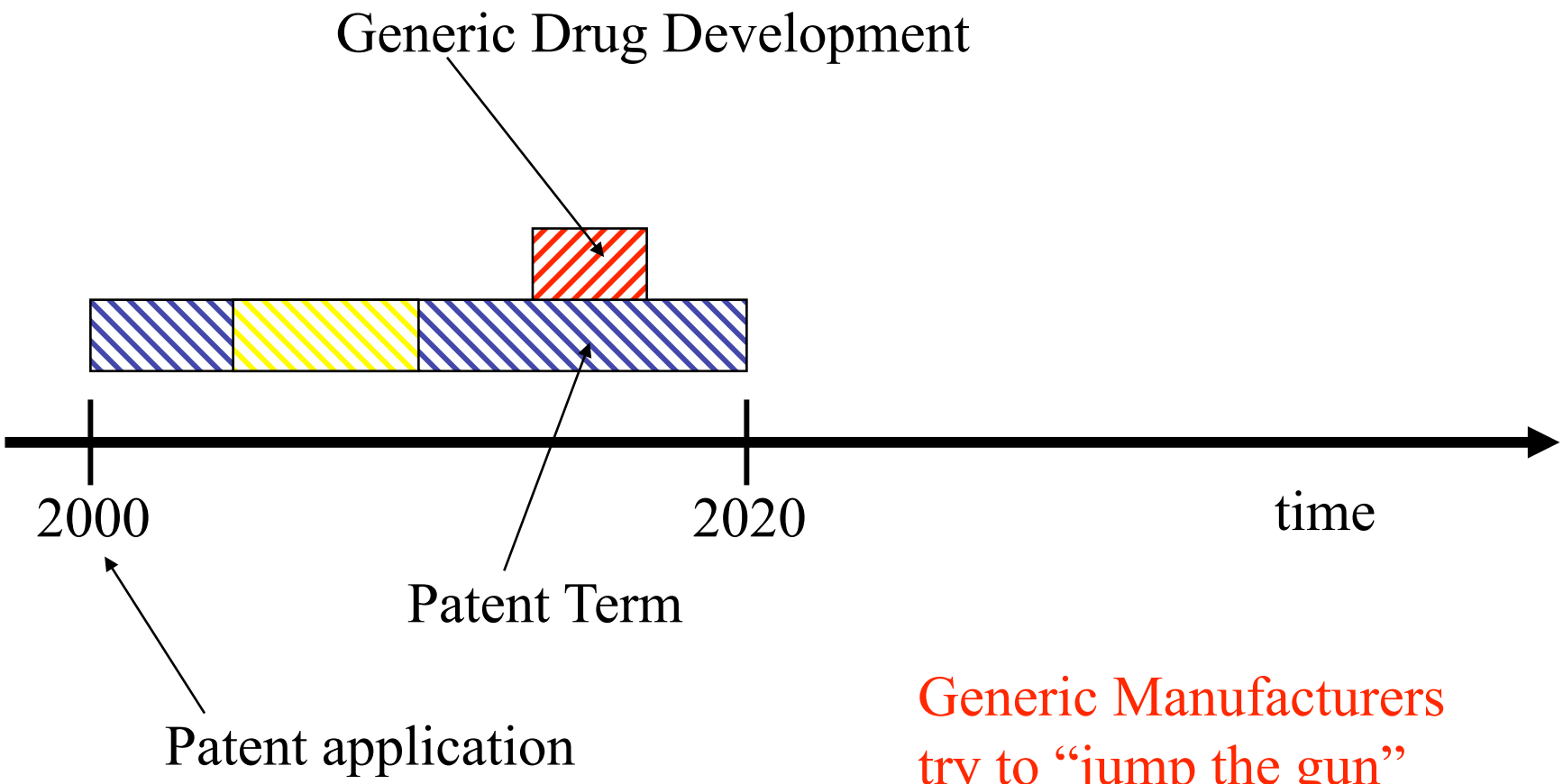


# Treatment of Drugs



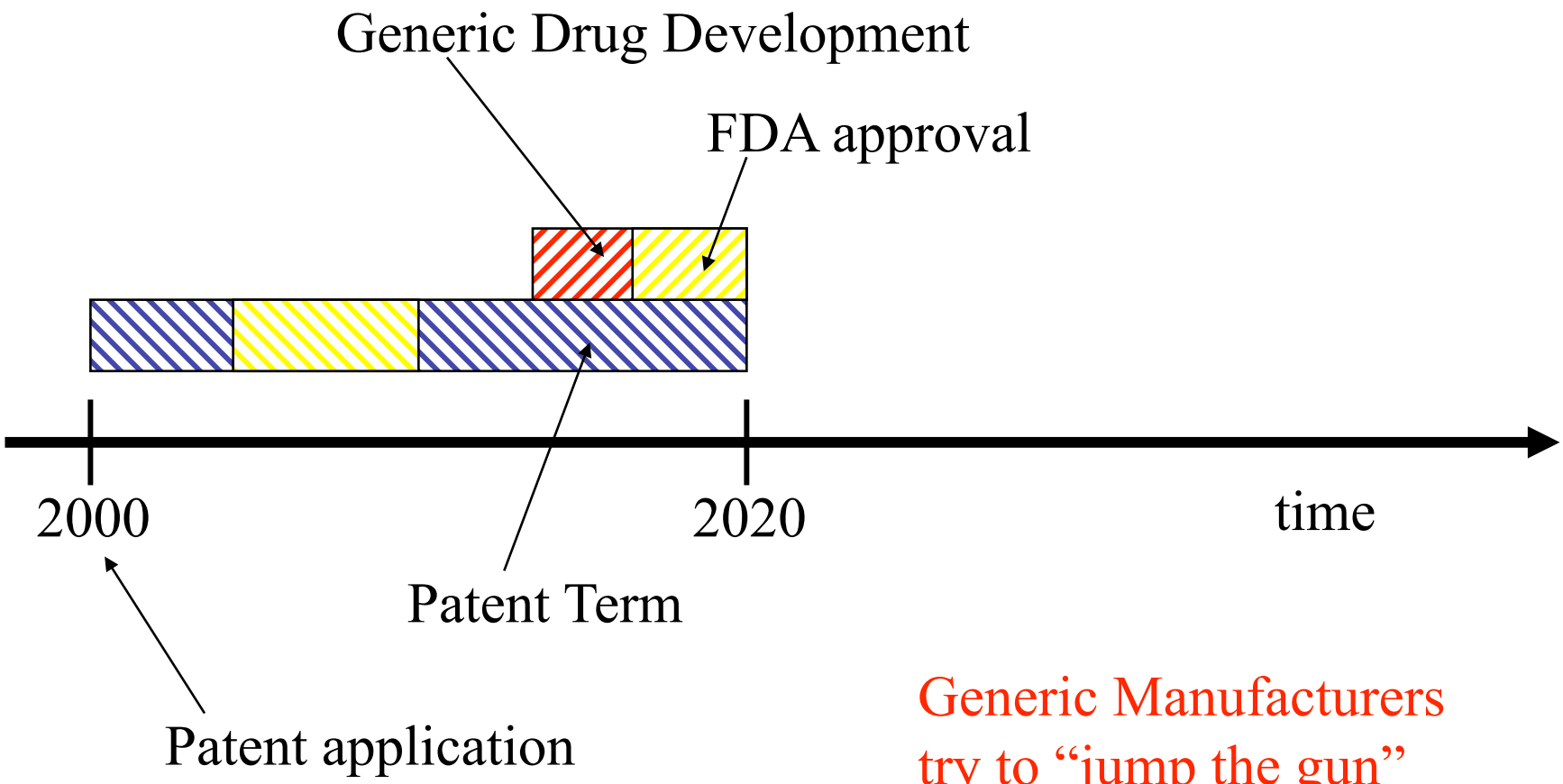

Generic Manufacturers try to "jump the gun"

# Treatment of Drugs



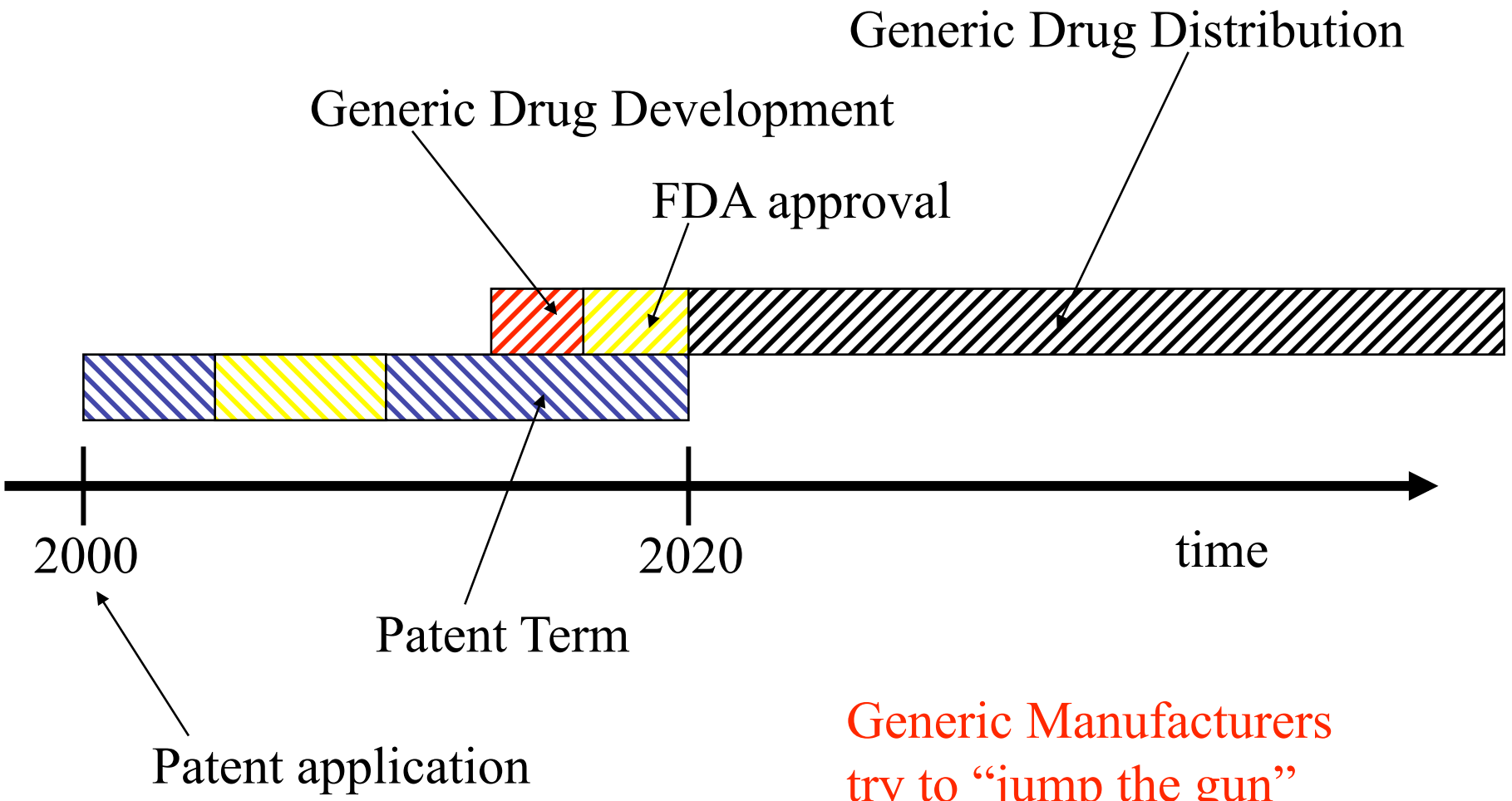

Generic Manufacturers try to "jump the gun"

# Treatment of Drugs



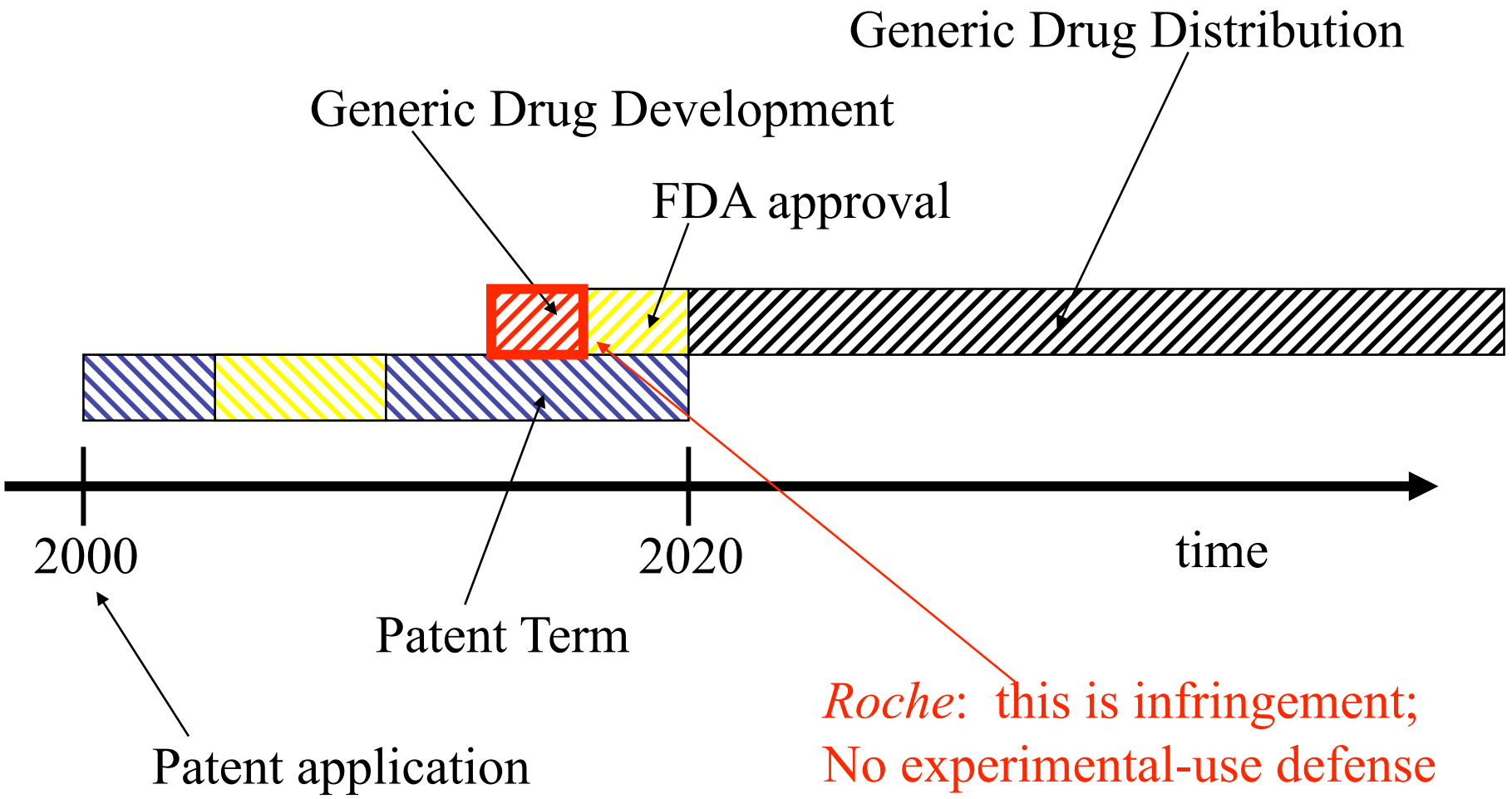

Generic Manufacturers try to "jump the gun"

# Treatment of Drugs

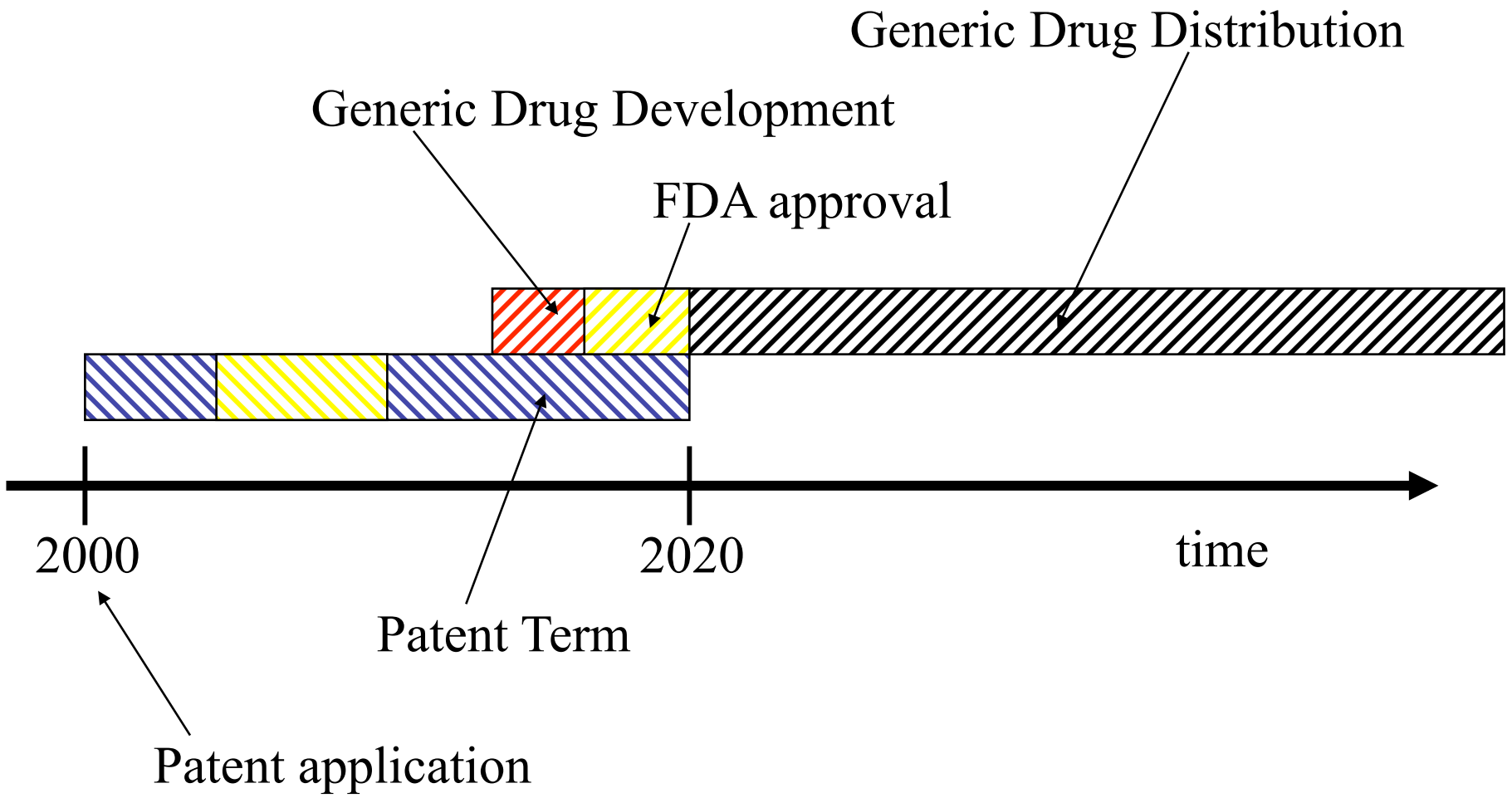



Generic Manufacturers try to "jump the gun"

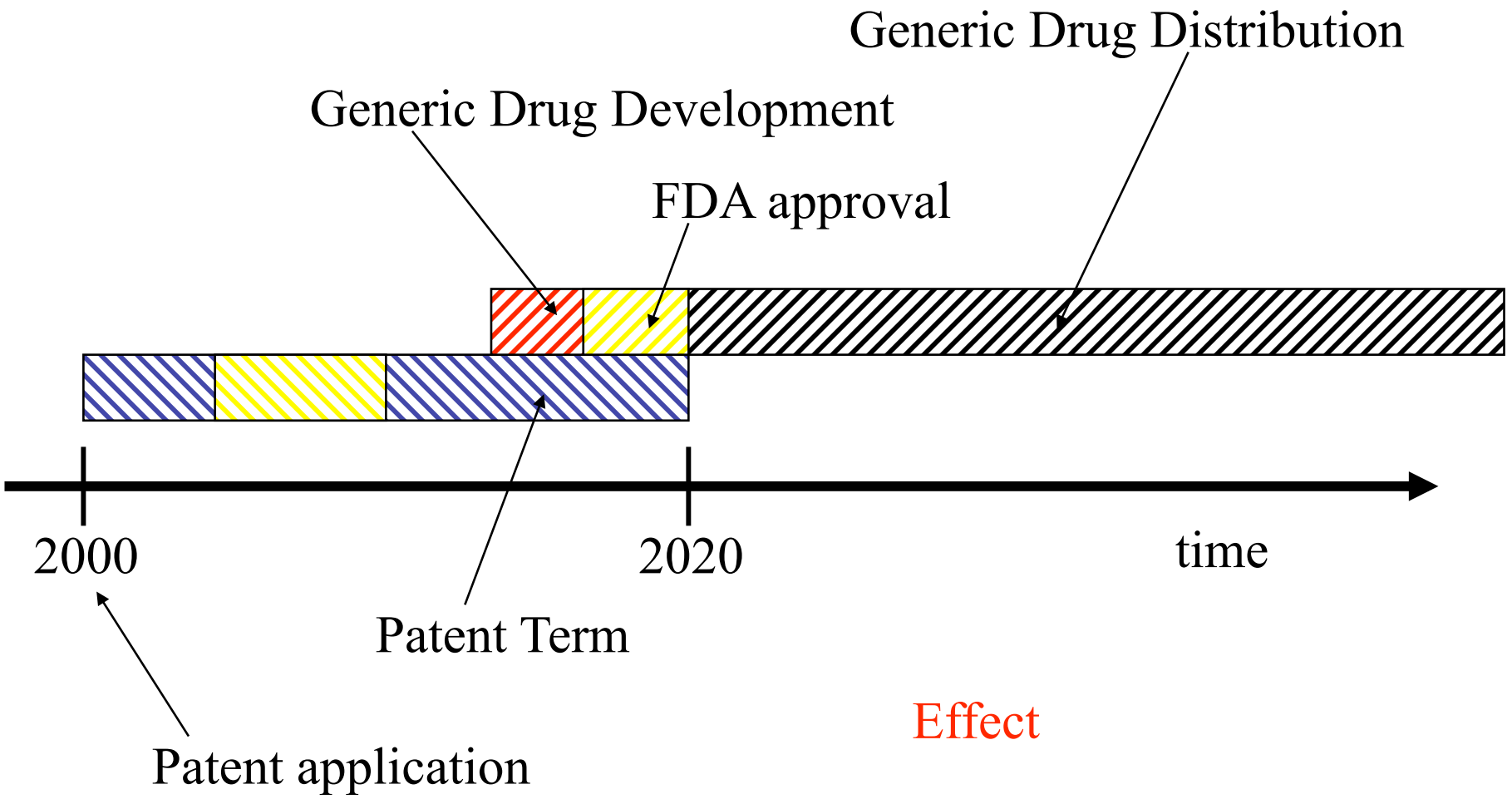
# Treatment of Drugs



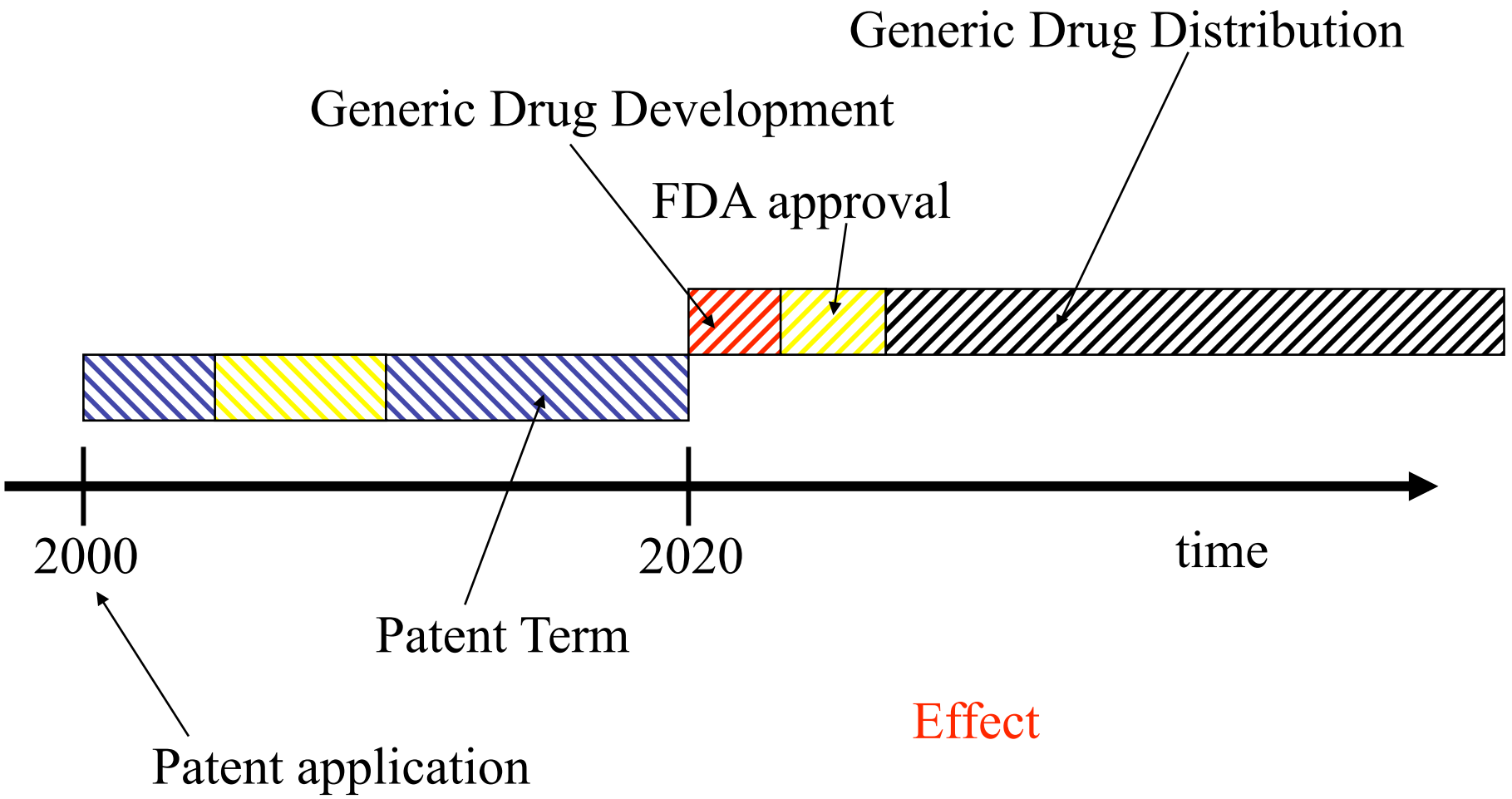
# Treatment of Drugs



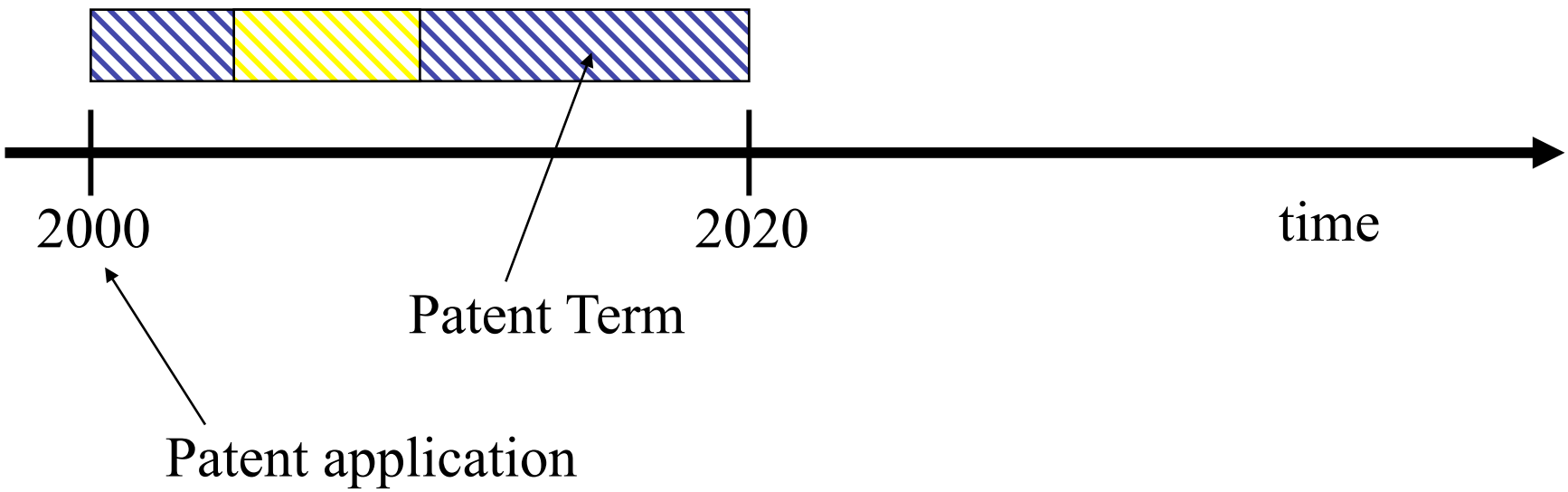
# Treatment of Drugs



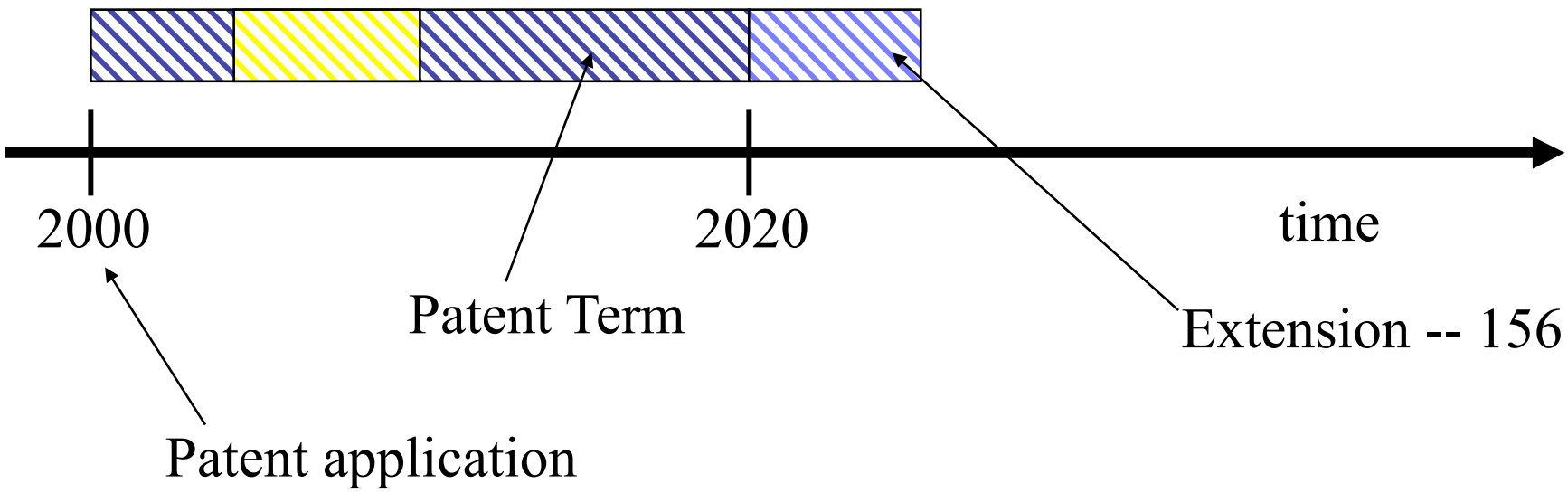
# Treatment of Drugs



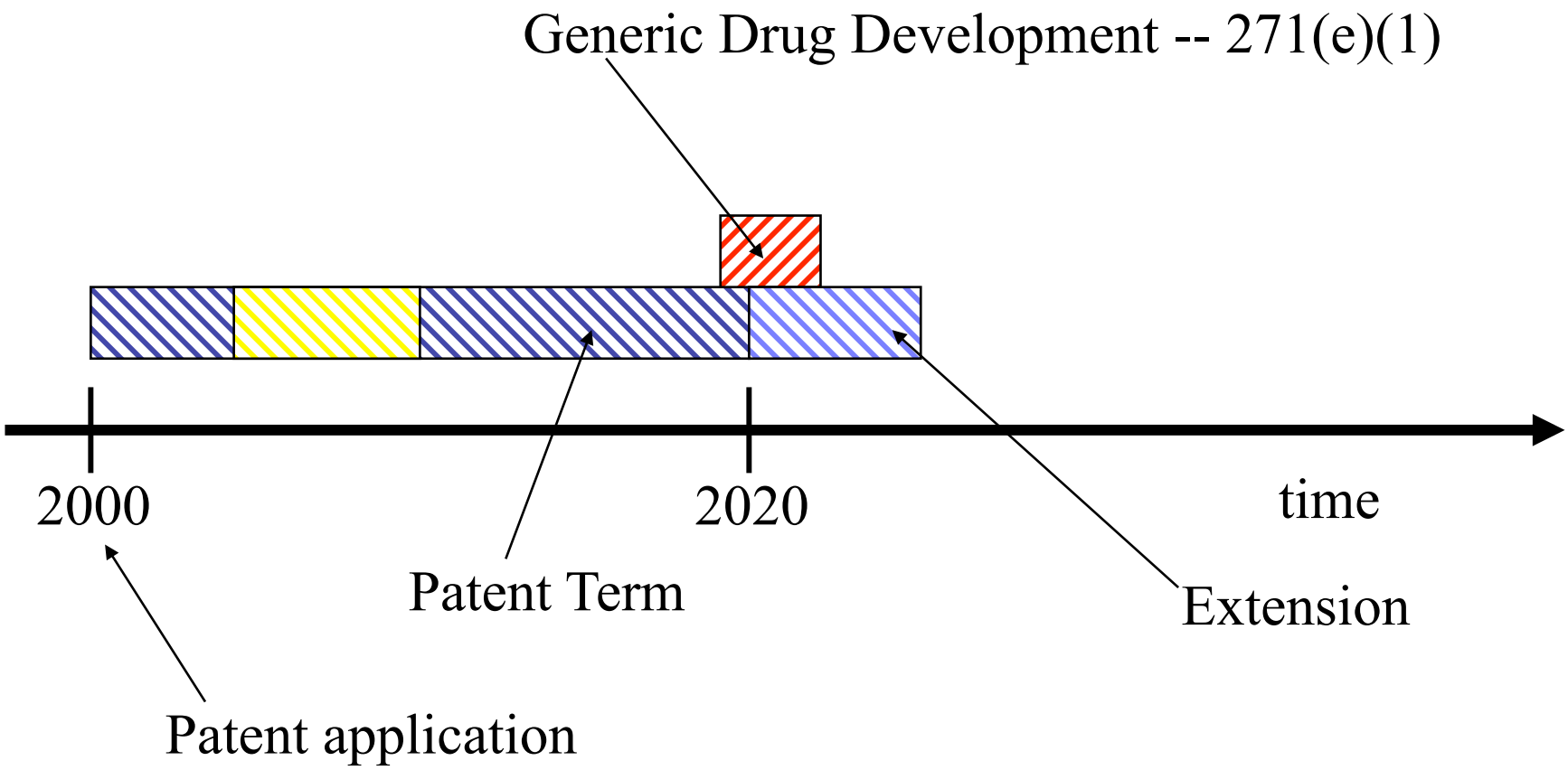
# Treatment of Drugs



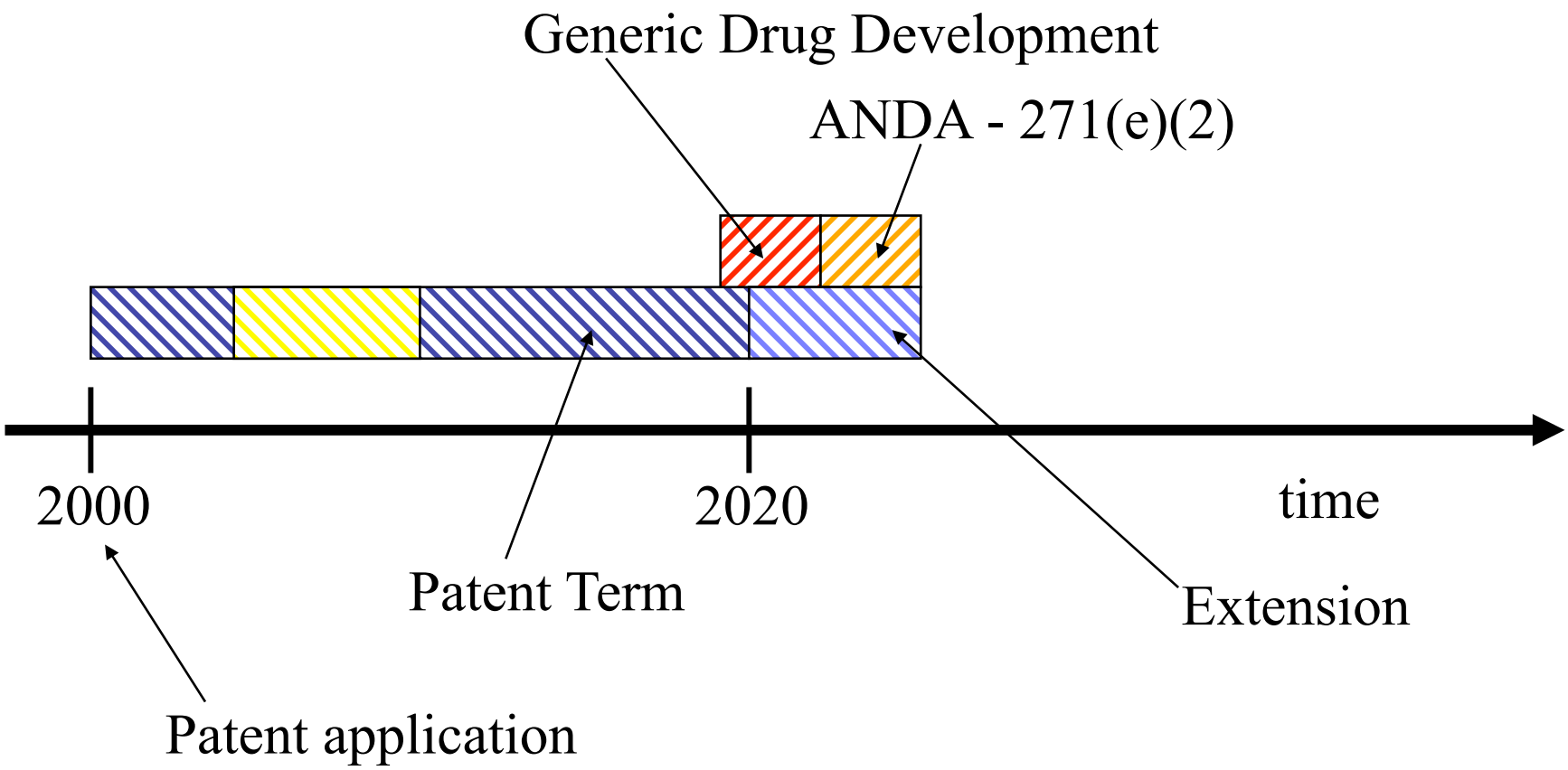
# Treatment of Drugs



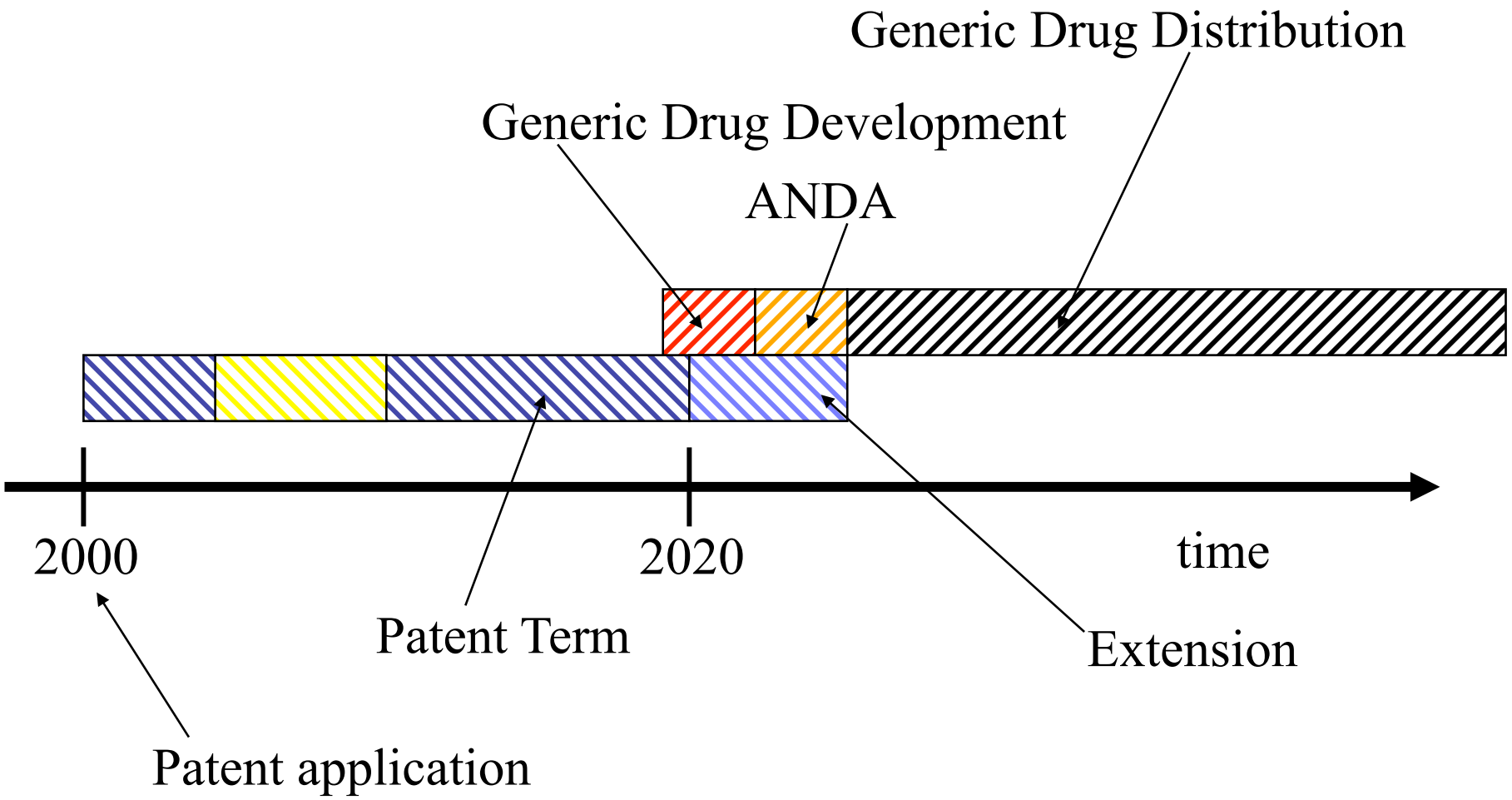
# Treatment of Drugs



# Treatment of Drugs



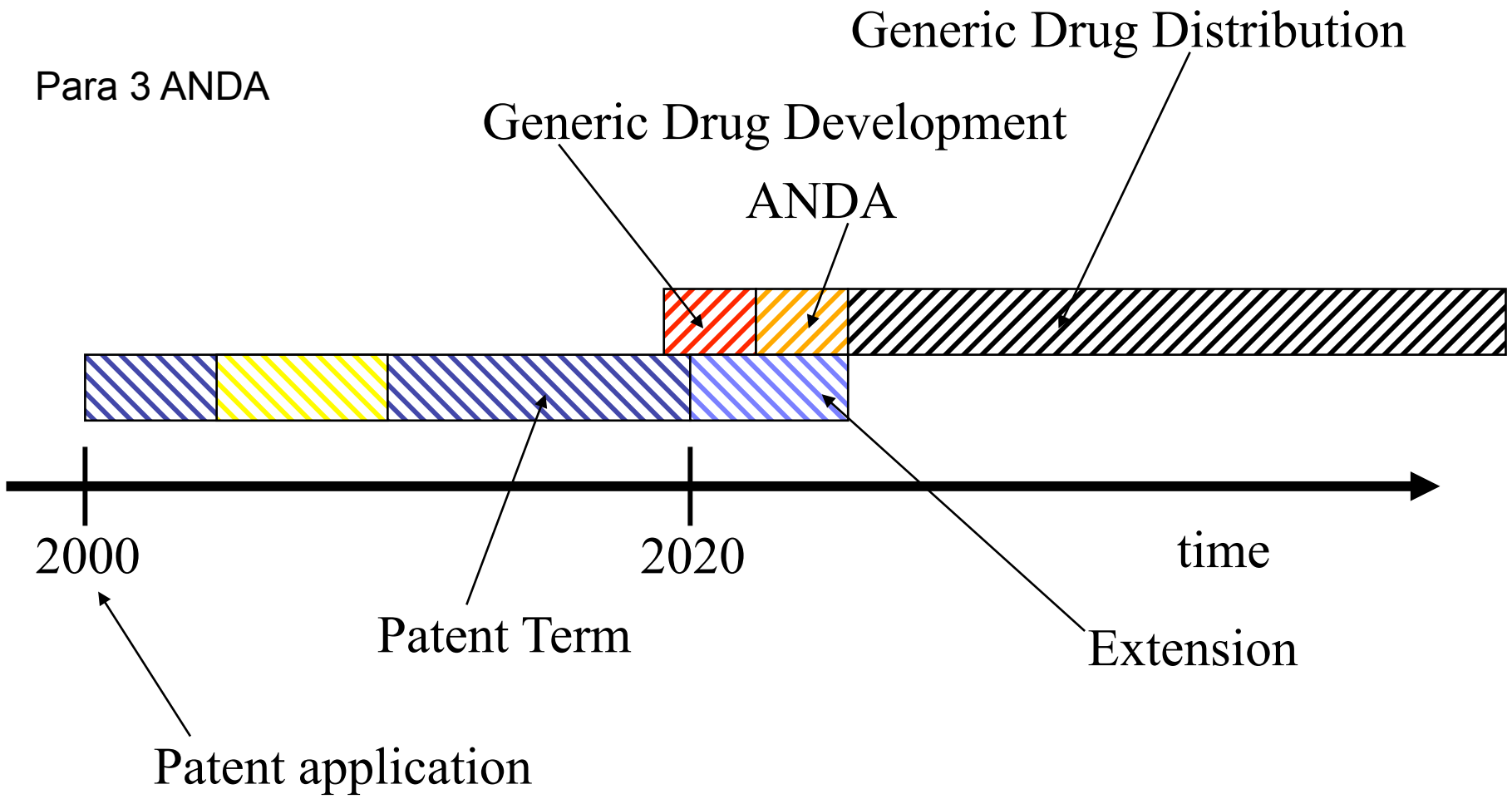
# Treatment of Drugs



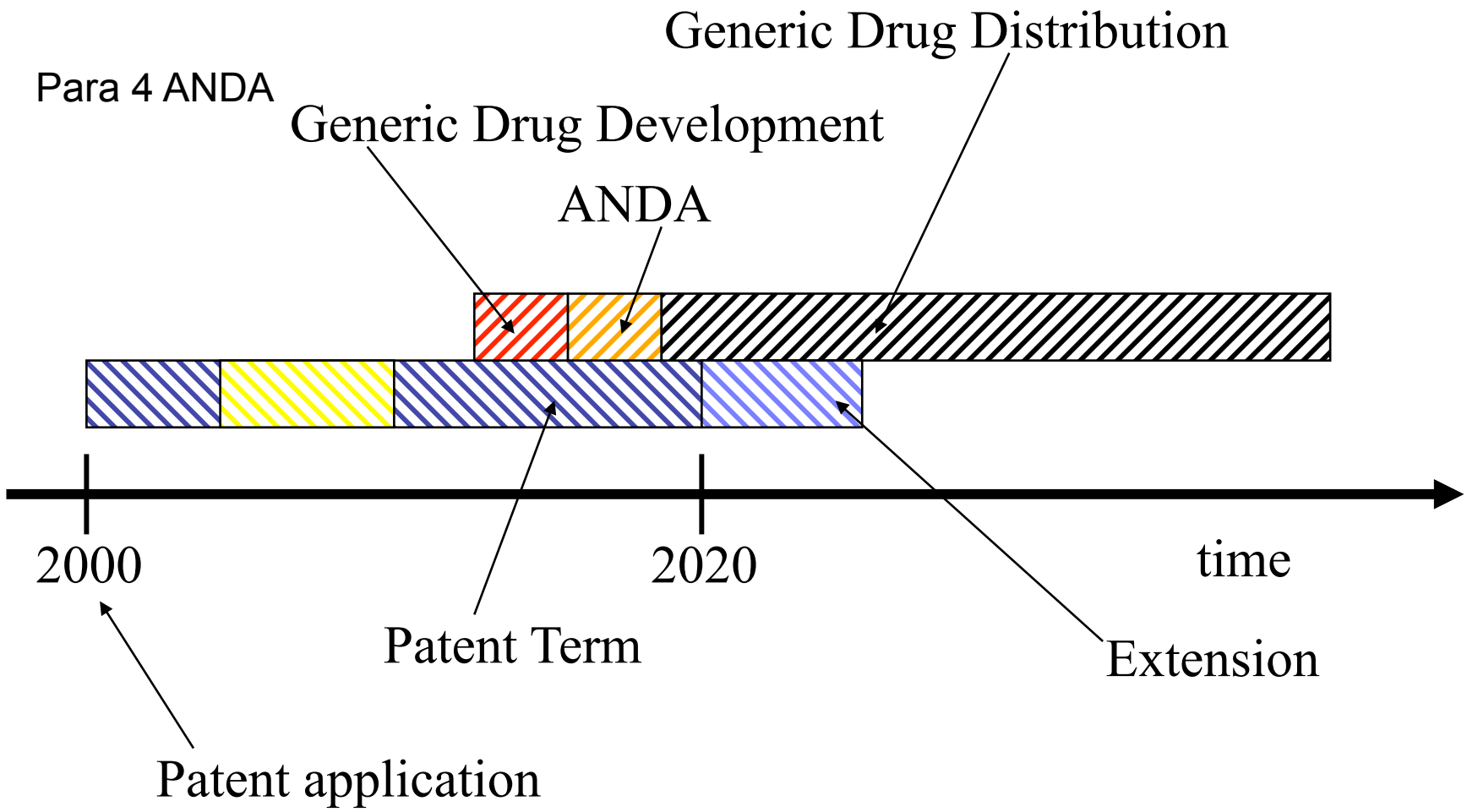
# ANDA applicant must show:

A. Bioequivalence
B. No patent impediment to commercial distribution of the generic version
   1) The drug at issue has not been patented
   2) The patent on the drug has expired
   3) Identify the date on which the patent will expire
   4) The patent on the drug is invalid or will not be infringed by the generic

# Treatment of Drugs



# Treatment of Drugs



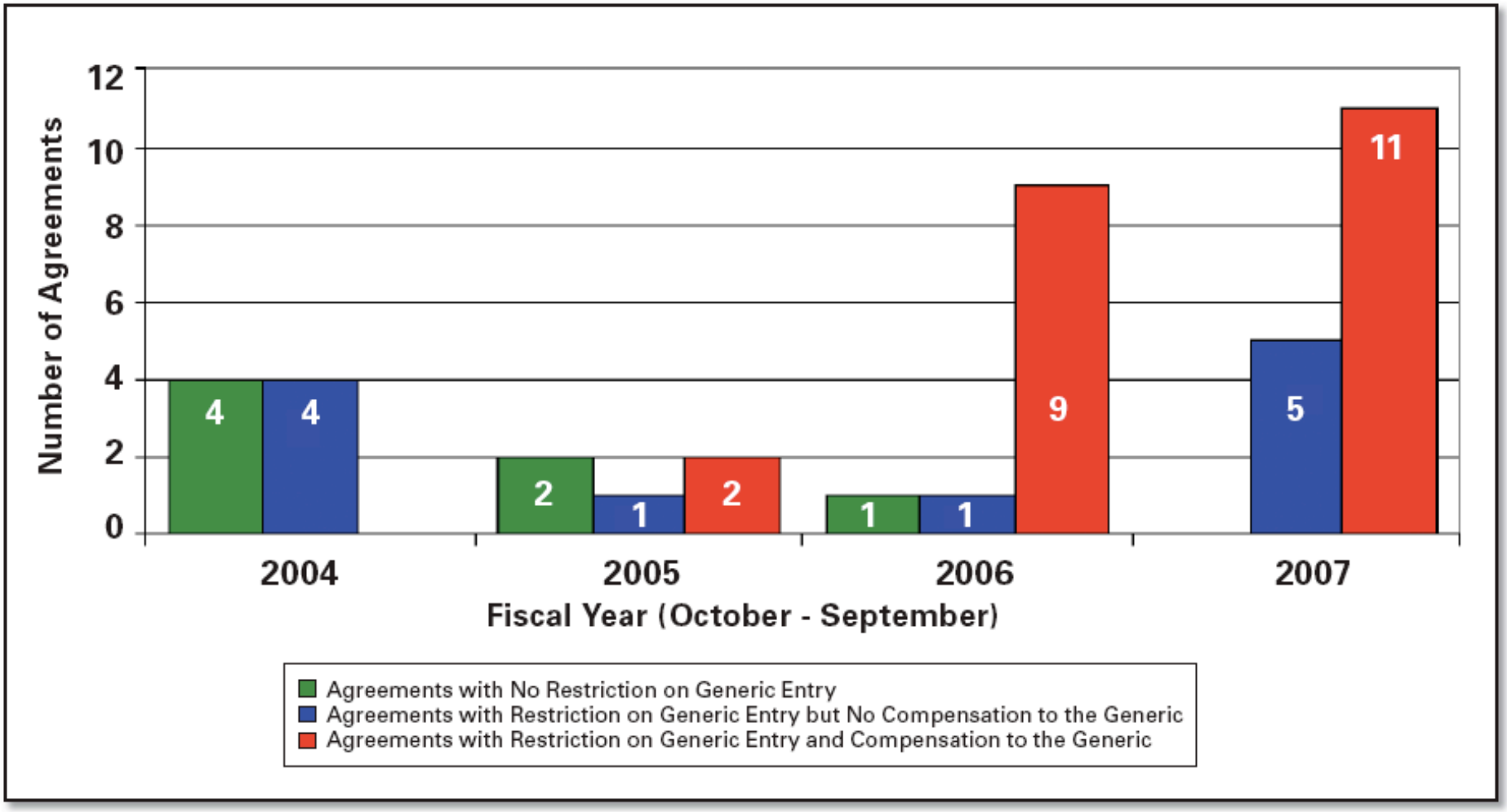
# Treatment of a Paragraph 4 Certification

- The filing of such an ANDA is an act of infringement (if wrong)
- Patentee has 45 days to file suit
- ANDA is then suspended until the earliest of:
  - District court declares the patent invalid or not infringed
  - Date on which the patent expires, if the district court finds the patent valid and infringed
  - 30 months from notice of the certification
- First challenger gets 180-day exclusivity period, starting on the date on which challenger first commercially markets the generic
  - 2003 amendments to this procedure

# Treatment of Reverse-Payment Settlements

- FTC consistently opposes
- Courts of Appeals:
  - Cardizem (CA6 2003): per se AT violation
  - Schering-Plough (CA11 2005): RoR: no violation
  - Tamoxifen (CA2 2006): RoR: no violation
  - Cipro (CAFC 2008): RoR: no violation
- Supreme Court: consistently denies cert.

## Figure IV
## Breakdown of Final Settlements with First-Filers by Restriction and Compensation



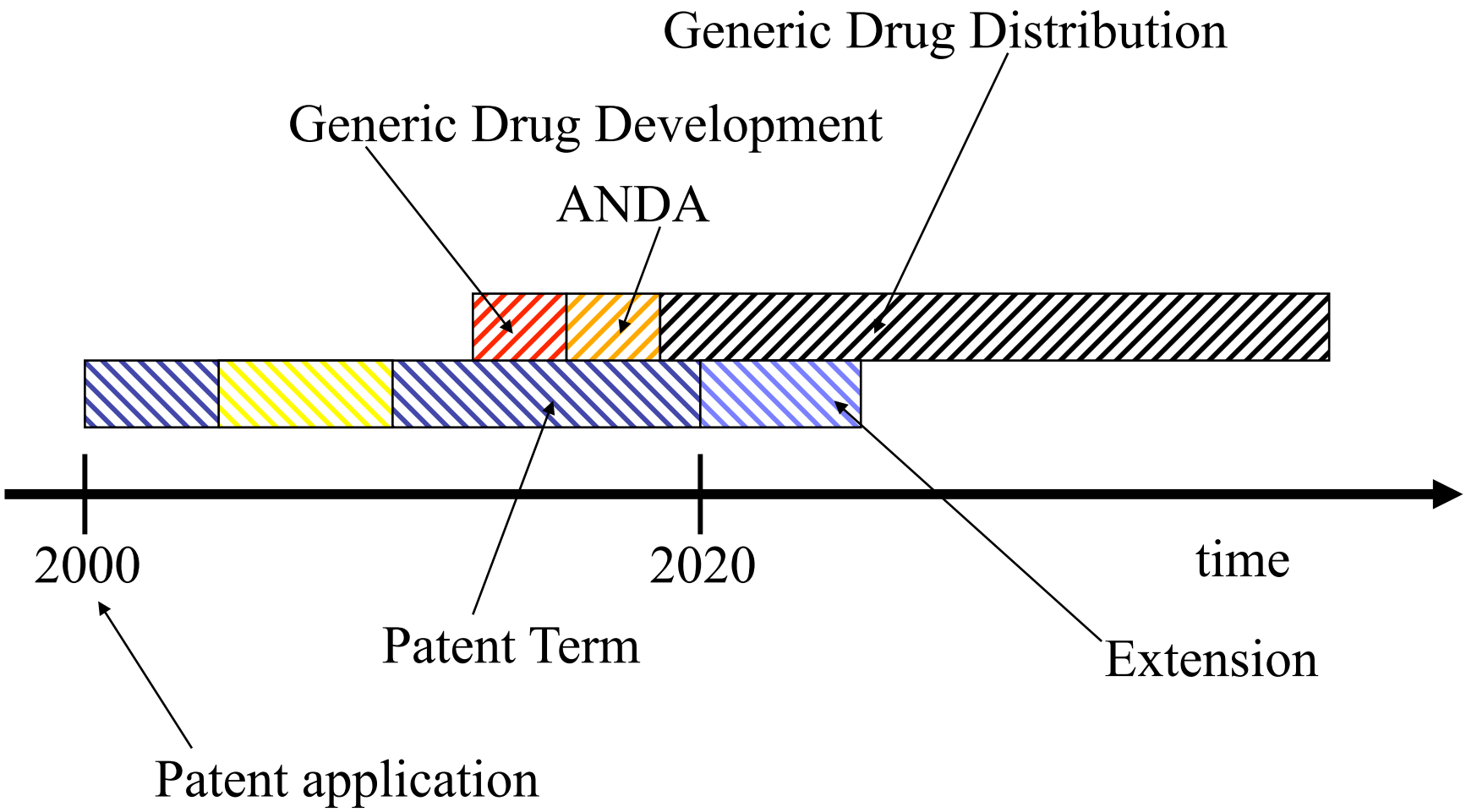

Source: Bromberg & Sunstein, http://www.bromsun.com/media/PaymentsV6DEC.pdf



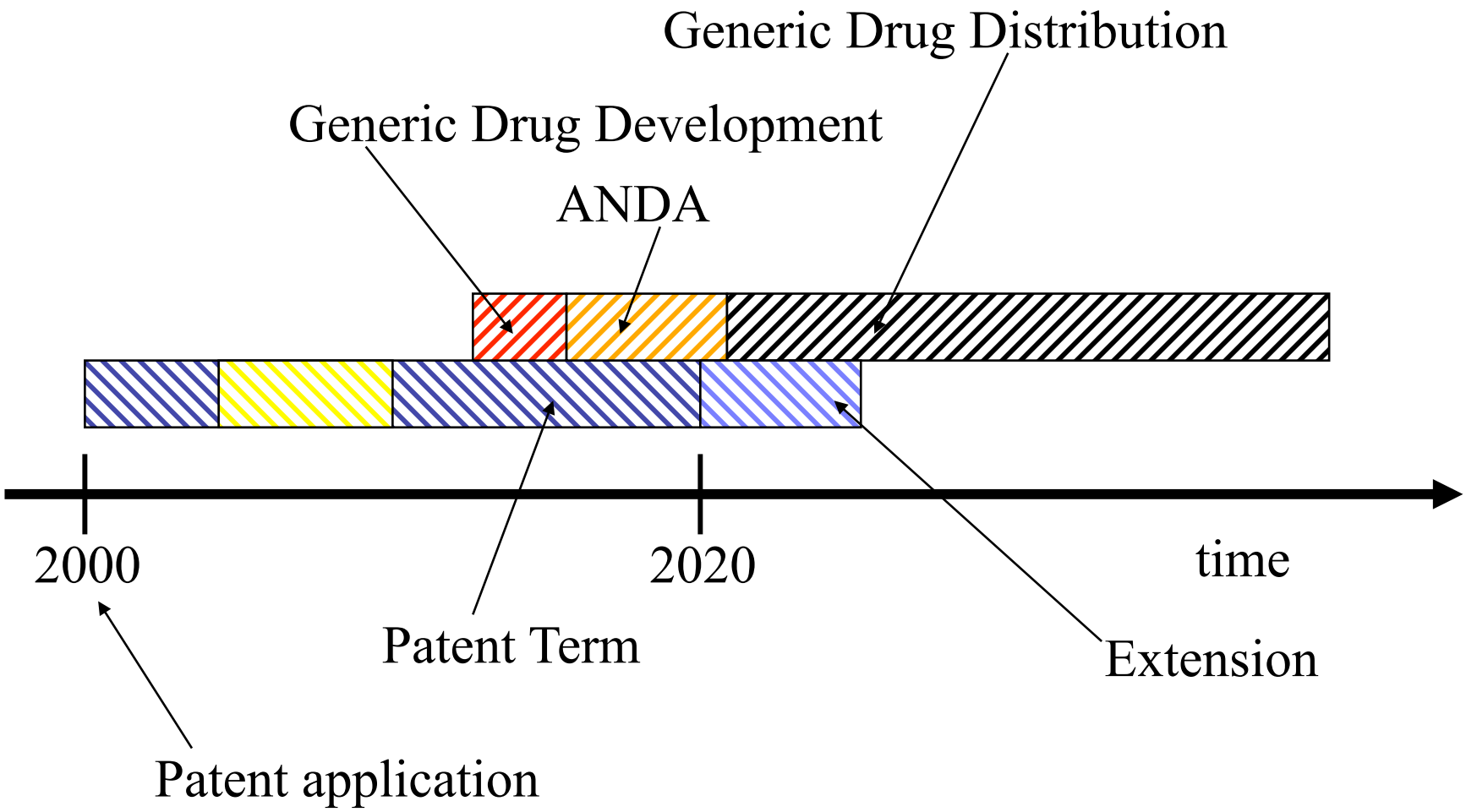
# FTC Policy

- Continue to file complaints
  - Cephalon (DDC, transferred to ED Pa.)
  - Androgel (Solvay) (2009) (CD Cal.)
- Seek statutory change

# Treatment of Drugs



# Treatment of Drugs



# Treatment of Drugs