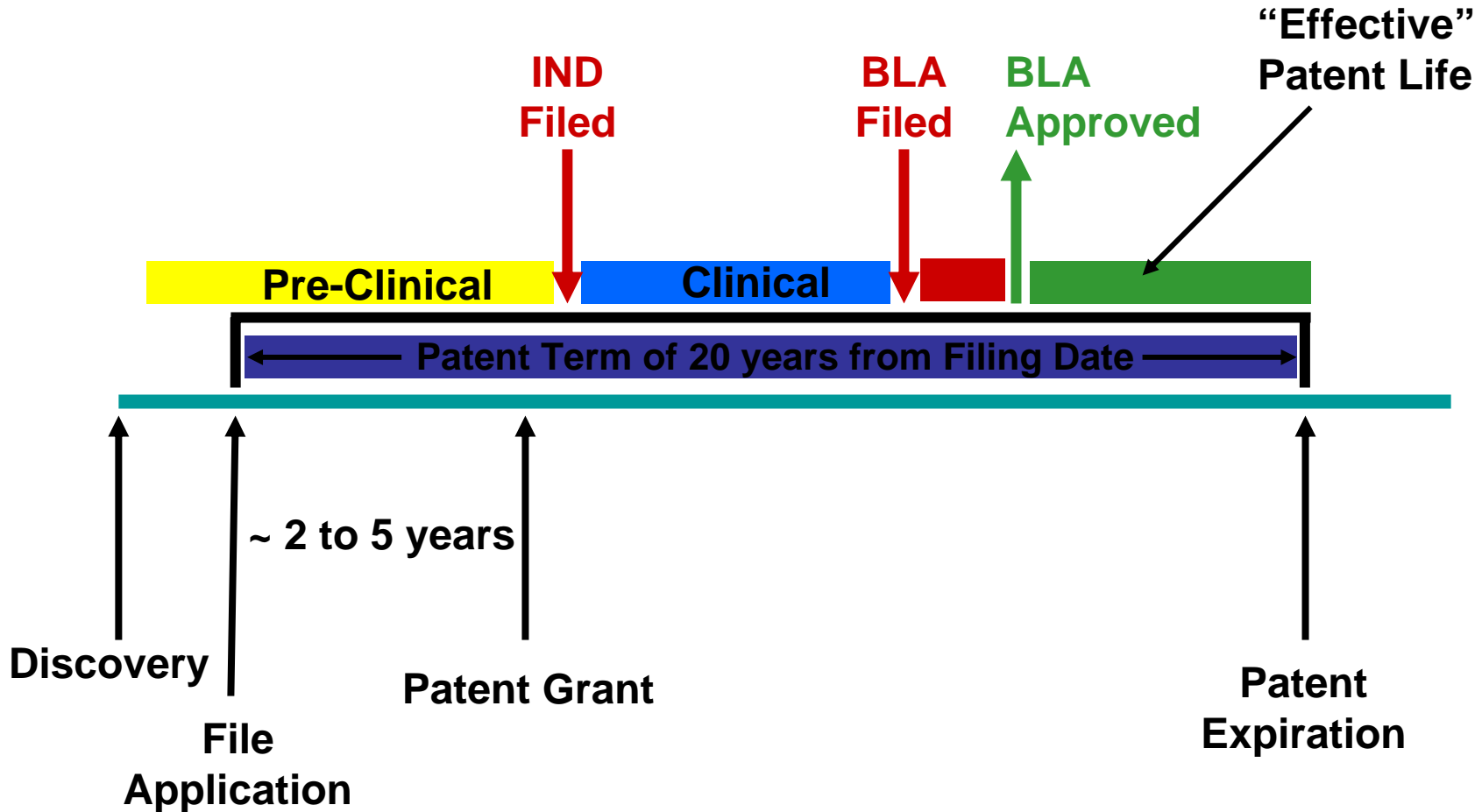
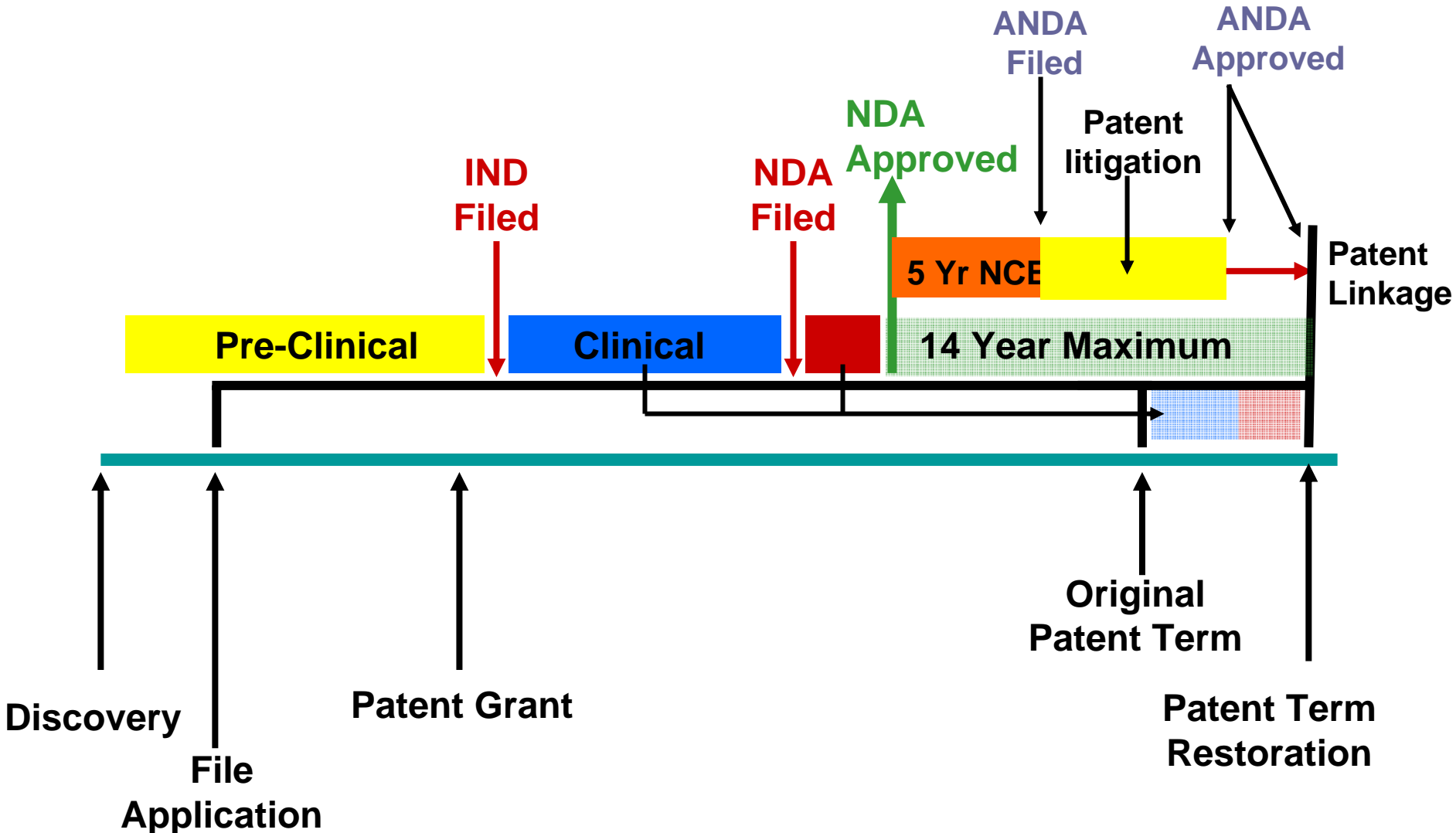


# Patent vs. Product Development Timeline

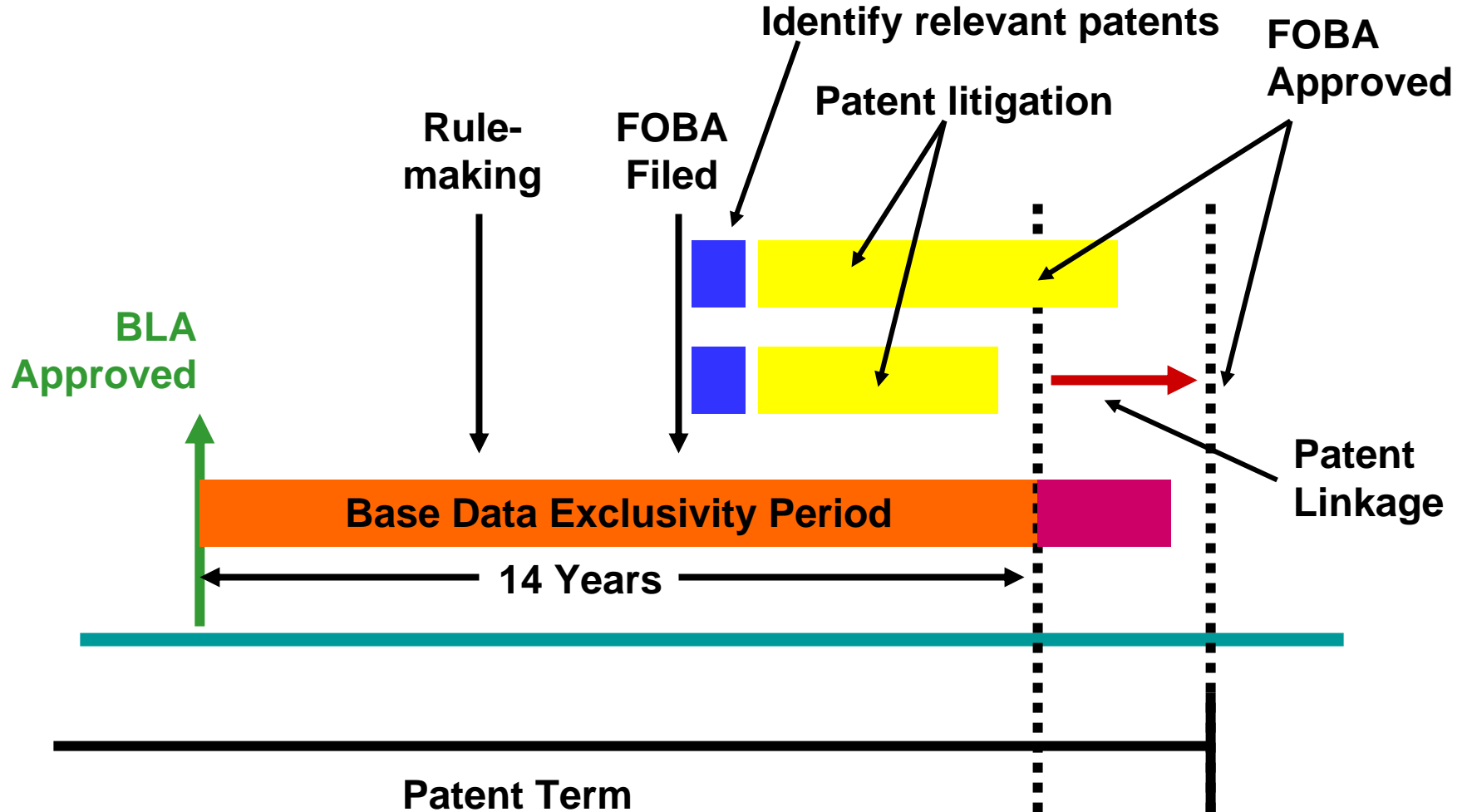


# Hatch Waxman System

## Data Exclusivity and Patent Term Restoration



# An Alternative System



# BLA vs. NDA Patent Issues

- **Dominating patents differ**
  - ANDA products likely to be dominated only by patents covering compound, composition, method of treatment
  - BLA/FOB products likely to be dominated by:
    - All of the types of patents for NDAs
    - “Manufacturing” patents (e.g., host cell, expression systems, nucleic acids, process of making)

# BLA vs. NDA Patent Issues

- **Who owns the patents?**
  - Active ingredient (protein), formulation, method of use likely to be owned or licensed to (controlled by) BLA holder (like NDAs)
  - Many “manufacturing” patents will be owned by entities other than BLA holder (e.g., universities, small biotech companies)
    - Expression systems and components, host cell types, purification procedures, stabilization techniques, etc
    - Generally are non-exclusively licensed to BLA holder, but controlled by non-BLA holder

# BLA vs. NDA Patent Issues

- **Patent listing not feasible mechanism for identifying patents relevant to FOB**
  - ANDA must have identical active ingredient as NDA so patents infringed by NDA product will be infringed by ANDA product
  - FOB product will not be identical to and will not be made in the same way as BLA product – patents “infringed” by BLA product may not be relevant to FOB product
  - Identification of relevant patents requires knowledge of FOB product, formulation and method of manufacture – only the FOB applicant will possess!