Duration of Drug Patents

William Fisher
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Treatment of Drugs

In the absence of Hatch-Waxman, the system would work as follows:

- **Patent application**
- **Patent Term**
- **Generic Drug Development**
  - FDA approval
- **Generic Drug Distribution**

Generic Manufacturers try to “jump the gun”
In the absence of Hatch-Waxman, the system would work as follows:

- **Patent application**: 2000
- **Patent Term**: 2020
- **Generic Drug Development**: 2000 to 2020
- **FDA approval**: 2020
- **Generic Drug Distribution**: 2020

*Roche*: this is infringement; No experimental-use defense
In the absence of Hatch-Waxman, the system would work as follows:

- 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
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2000

Patent application

2020

Patent Term

Extension -- 156

time
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- Generic Drug Development -- 271(e)(1)
- Patent Term
- Extension
- Patent application

Time

2000 2020
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- Generic Drug Development
- ANDA - 271(e)(2)
- Time
- Patent Term
- Extension
- Patent application
Treatment of Drugs

- Patent application
- Patent Term
- Generic Drug Development
- ANDA
- Generic Drug Distribution
- Extension

Time:
- 2000
- 2020
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
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- Patent application
- Patent Term
- ANDA
- Generic Drug Development
- Generic Drug Distribution
- Extension

Para 3 ANDA
Treatment of Drugs

- Generic Drug Development
- ANDA
- Generic Drug Distribution
- Patent Term
- Extension
- Patent application
- Para 4 ANDA

2000 - 2020

Time