Duration of Drug Patents

William Fisher

February 1, 2010

- 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

Patent application
Treatment of Drugs

Patent Term

2000

2020

Patent application
Treatment of Drugs

- Patent application
- Patent Term
- Regulatory Review Period

Time line from 2000 to 2020.
Treatment of Drugs

- Patent application
- Patent Term

2000 - 2020
Treatment of Drugs

Generic Manufacturers try to “jump the gun”
Treatment of Drugs

- Generic Drug Development
- Patent Term
- Patent application
- Generic Manufacturers try to "jump the gun"
Treatment of Drugs

- Patent application
- Generic Drug Development
- FDA approval
- Patent Term
- 2000
- 2020
- time

Generic Manufacturers try to “jump the gun”
Treatment of Drugs

- Generic Drug Development
- FDA approval
- Generic Drug Distribution
- Patent application
- Patent Term
- 2000
- 2020
- time

Generic Manufacturers try to “jump the gun”
Treatment of Drugs

- Generic Drug Development
- FDA approval
- Generic Drug Distribution

2000 - Patent application
2020 - Patent Term
2020 - time

Roche: this is infringement;
No experimental-use defense
Treatment of Drugs

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

Time:
- 2000
- 2020

February 1, 2010
Treatment of Drugs

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

2000 - 2020

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Treatment of Drugs

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

2000 to 2020 timeline
Treatment of Drugs
Treatment of Drugs

Patent application

Patent Term

2000

2020

Extension -- 156

time
Treatment of Drugs

Generic Drug Development -- 271(e)(1)

Patent application

Patent Term

2000

2020

Extension

time
Treatment of Drugs

- Patent application
- Patent Term
- Generic Drug Development
- ANDA - 271(e)(2)
- Extension

2000 - 2020

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Treatment of Drugs

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

Para 3 ANDA

Generic Drug Development

ANDA

Generic Drug Distribution

Extension

Patent application

Patent Term

2000

2020

time
Treatment of Drugs

Generic Drug Development

Para 4 ANDA

ANDA

Generic Drug Distribution

Patent Term

Extension

Patent application

2000

2020

time

2010
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

- **2004**: 4 Agreements (Green: No Restriction on Generic Entry)
- **2005**: 1 Agreement (Blue: Restriction on Generic Entry but No Compensation)
- **2006**: 2 Agreements, 1 Agreement (Green: No Restriction on Generic Entry)
- **2007**: 5 Agreements (Blue: Restriction on Generic Entry but No Compensation), 11 Agreements (Red: Restriction on Generic Entry and Compensation)


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FTC Policy

• Continue to file complaints
  – Cephalon (DDC, transferred to ED Pa.)
  – Androgel (Solvay) (2009) (CD Cal.)

• Seek statutory change
Treatment of Drugs

- Generic Drug Development
- ANDA
- Generic Drug Distribution
- Patent Term
- Extension
- Patent application
- 2000
- 2020
- Time
Treatment of Drugs

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

2000 - 2020

Time
Treatment of Drugs

Generic Drug Distribution

Generic Drug Development

ANDA

Patent Term

2000

2020

Extension

Invalidity ruling

Patent application

time

February 1, 2010

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