

# Biotech Mergers: FTC Review Process and Guidance

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*January 2007*

# Overview

- Background on FTC
- FTC Merger Review
- Theories of Anticompetitive Harm
- Case Studies
- Guidance

# Demystifying the FTC



# Background on the FTC

- Small, but effective agency
- Why on earth do we have two antitrust agencies?
- FTC has “jurisdiction” over biotech/  
pharmaceuticals industry

# FTC Merger Review

- Clayton Act standard
  - “may be substantially to lessen competition”
- Resources
  - Merger Guidelines
  - Merger Commentary
  - Merger Data Release
- FTC/DOJ Merger Guidelines
  - Market definition and share
  - Competitive effects
  - Entry
  - Efficiencies

# FTC Biotech Investigations

- Phases under Hart-Scott-Rodino Review
  - Initial waiting period (first 30 days)
  - Second Request
  - Full Commission review
- Tools – Biotech is Different from Other Industries
  - Company information (pipeline, business plans, interviews)
  - “Opinion Leaders”
  - FDA
  - Subpoena authority
- Outcomes
  - No action
  - Consent
  - Litigation

# FTC Merger Review – All Industries

- When does the FTC actually challenge (*i.e.*, obtain a consent or sue to block) a deal?

7 to 6:	18%
6 to 5:	38%
5 to 4:	60%
4 to 3:	72%
3 to 2:	85%
2 to 1:	97%

- Key factors:
  - Concentration/Number of significant competitors
  - “Hot Documents”
  - Complaining customers

# FTC Merger Review – Pharma/Biotech

- When does the FTC actually challenge (*i.e.*, obtain a consent or sue to block) a deal?

7 to 6:	0%
6 to 5:	0%
5 to 4:	0%
4 to 3:	30% (3 of 10)
3 to 2:	60% (6 of 10)
2 to 1:	100% (8 of 8)

# Theories of Anticompetitive Harm: Biotech Merger Cases Studies

- Actual Competition (Amgen/Immunes)
- Potential Competition (Amgen/Immunes)
- Platform Technologies (Ciba/Sandoz)
- Innovation Markets (Genzyme/Novazyme)

# Case Study Actual Competition: Amgen/Immunex (2002 – Consent)

- Product market:
  - Neutrophil regeneration factors – treats neutropenia
- Competition:
  - Amgen – Neupogen and Neulasta
  - Immunex – Leukine
- FTC Analysis:
  - Only two companies with products on market
  - Entry – requires lengthy trials and FDA approval (likely 6-10 years and over \$200m)
  - Thus, merger likely to cause harm by eliminating “actual, direct, and substantial competition between the only two firms in the market”
- Consent Provision: Divest Immunex product

# Case Study Potential Competition: Amgen/Immunex (2002 – Consent)

- Product market:
  - IL-1 inhibitors (block inflammation cascade)
- Stage of Development:
  - Amgen -- Kineret on market; R&D on second generation
  - Immunex – Phase 1
  - Regeneron – Phase 2, but likely blocked
- FTC Analysis:
  - Merger would cause “significant anticompetitive effects . . . by eliminating Amgen’s most significant (and likely only) potential competitor, Immunex”
  - Cites concerns relating to “potential” competition, as well as “ongoing R&D” between the companies
- Consent Provision:
  - Amgen to license certain patents to Regeneron

# Case Study Platform Technologies: Ciba-Geigy/Sandoz (1997 – Consent)

- Product markets:
  - “Gene therapy technology” and “R&D for gene therapies”
  - R&D for four specific gene therapies
- FTC alleged two bases for anticompetitive harm:
  - Innovation in gene therapies
    - Combined patent position post-merger would be so dominant that others would have to invent around or license
    - Result -- Reduction or delay in research due to combining two dominant gene therapy firms
  - Specific markets: generally two most advanced companies in R&D for these specific products
- Consent:
  - Gene therapy – licensing of gene therapy IP
  - Specific products – licensing and divestitures (herbicides and flea-control)

# Case Study Innovation Markets: Genzyme/Novazyme (2004 - Closed)

- Product market:
  - Enzyme replacement treatment for Pompe disease
- Stage of Development:
  - Both programs early pre-clinical (at time deal was consummated)
- Key Issues:
  - Consummated merger - FTC can review deal even if under HSR thresholds
  - Merger to monopoly - is there a presumption of anticompetitive harm?
  - Race to market - does presence of competing R&D program create incentives to get to market faster
  - Efficiencies

# General Guidance on Biotech Mergers

- Very Early Development Cases (e.g., Innovation or Platform Technology)
  - Enforcement unlikely, because harm is too speculative
  - Possible exception where: merger to monopoly, or patent portfolio concerns
- “Potential” Competition Cases
  - Key is assessment product market (who competes or may compete), and
  - Whether merging programs are “closest competitors”
- “Actual” Competition Cases
  - Analysis much more similar to other product markets
  - Concerns focus on price and output