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Industry Collaborations to Co-Develop Therapies: The Antitrust Issues

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Presentation overview

- The potential antitrust concern
- Sources of antitrust guidance
- Antitrust analytical framework
- DOJ/FTC *Competitor Collaboration* Guidelines: R&D safety zone
- Some concluding observations

The potential antitrust concerns

- Antitrust is premised on the view that competition will lead to the optimum allocation of resources and maximize consumer welfare
- If competitors coordinate their activities, it could lead to:
  - Higher prices
  - Lower quality
  - Reduced innovation
- Could have an impact on market for
  - Products or services
  - Technology
  - Innovation – R&D directed to particular new or improved goods or processes where capabilities to engage in relevant R&D can be associated with specialized assets and or characteristics of specific firms
- Nevertheless, antitrust recognizes that collaborations among competitors can lead to efficiencies
  - Especially long history of collaborative R&D ventures among competitors in many fields
  - Most are undertaken without serious antitrust scrutiny

Sources of antitrust guidance

- Sherman Act   1 – prohibits every "contract combination. . . or conspiracy in restraint of trade."
  - But very little case law, especially with respect to R&D collaborations
- DOJ and FTC *Antitrust Guidelines for Collaborations Among Competitors* (2000), available at FTC.GOV
- National Cooperative Research Act of 1984 and National Cooperative Research and Production Act of 1993
  - Provides for Rule of Reason treatment
  - Limits liability to single damages if JV is filed with the FTC and DOJ

Antitrust analytical framework

- Agreement involving *per se* conduct such as naked agreement to fix prices or allocate markets can be summarily condemned.
- But if agreement is reasonably related and necessary to achieve procompetitive benefits of an "efficiency-enhancing integration of economic activity," then "rule of reason" applies
  - Flexible inquiry – is agreement likely to harm competition by increasing incentive or ability to raise price or reduce output, quality, service or innovation below what would prevail in absence of agreement?
  - Consider
    - Nature of the agreement
    - Whether participants have market power – i.e. high market shares with entry barriers
    - Likelihood of competitive harm
    - Likely procompetitive benefits (i.e. efficiencies)
    - Existence of less restrictive alternatives

DOJ/FTC *Collaboration Guidelines*: Application to R&D joint ventures

- "Through the combination of complementary assets, technology and know-how, an R&D collaboration may enable participants more quickly and efficiently to research and develop new or improved goods, services or production processes"
- Central question – will collaboration slow down pace at which R&D efforts are pursued?
- Anticompetitive concerns greater where:
  - Collaboration or participants already posses market power over an existing product and the new R&D effort might cannibalize their supra-competitive earnings
  - R&D efforts are confined to firms with specialized characteristics or assets

DOJ/FTC *Collaboration Guidelines*: Safety zone for R&D competition analyzed in terms of innovation markets

- Applies where there are 3 or more independently controlled research efforts in addition to those of the collaboration that possess the required specialized assets and incentives to engage in R&D that would be a close substitute of activity the collaboration
- In defining close substitutes, consider:
  - Nature, scope and magnitude of R&D efforts
  - Access to financial support
  - Access to IP, skilled personnel, or other specialized assets
  - Timing
  - Ability, either alone or with others, to commercialize innovations

Other important considerations

- Extent to which collaborators will be able to compete with each other in commercializing invention
- Any other collateral restraints?
- Combination therapies
  – Will individual components continue to compete with each other?
  – How will combination products be priced relative to the individual components?

Concluding observations

- Fewer antitrust concerns with R&D venture where
  - There are several other comparable ongoing R&D efforts
  - Collaborators do not already have entrenched products
  - Collaboration is limited to core research efforts, with collaborators free to independently commercialize
  - Possible to demonstrate very convincing benefits from collaboration that could not be achieved independently
- Possible to obtain prior guidance from DOJ or FTC
- Antitrust attorneys are used to advising on R&D efforts – should not be an insurmountable barrier on most collaborations

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