Antitrust Issues Involving Mergers, Acquisitions & Exclusive Licensing in Pharma and Biotech

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ACI Pharmaceutical Antitrust Conference
May 21, 2008

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Roadmap

- Market Definition
- Competitive Effects Analysis
  - Horizontal Theories
  - Vertical Theories
- Entry
- IP Defenses
- Efficiencies
- Strategic Acquisitions
- Remedies
- Where Merger Enforcement May Head
Analytical Framework

- Will discuss substantive merger analysis more generically here, followed by applications to pharma/biotech transactions.
- Additional discussion of consent decree “precedent” is not terribly useful.
  - Most important precedents are where the FTC does not challenge deals.
  - Most enforcement actions are easily distinguishable or obviously *sui generis*.
  - FTC staff can provide insights into decrees *ad nauseam*.
  - Change in administration could have significant impact, leaving past enforcement decisions less insightful.
- But we will discuss towards the end where enforcement could be headed with respect to pharmaceutical transactions and what obstacles the FTC might have to overcome.
- Procedural/tactical advice for each step along the way.
Market Definition

• First, essential and often outcome-determinative step in merger analysis. More art than science.
• Focus is generally on product market definition, though geographic market definition can sometimes make a significant difference.
• Has often been the graveyard for recent DOJ and FTC challenges to mergers in federal courts.
• Increasing agreement among enforcers and defense bar that market definition is a tool, not an end in itself, and should be a flexible, open inquiry based on all credible evidence.
• Bottom Line: Rigid application of product market definition approach in the Horizontal Merger Guidelines approach is not useful.
Overview of Market Definition in Pharma/Biotech

- Number of different approaches:
  - Mechanisms of action
  - Medical condition/indications
  - Administration methods
  - Dosage forms, duration of action
- Often based on market reports, confirmed in documents and corroborated by physicians and health plans.
- Need to be pragmatic and creative. Example: actual usage/switch patterns over significant period of time in patient outcome studies.
- FTC view: product market definition can depend on stage of product’s life.
- Generally, FTC approach in merger context is consistent with “best available evidence” approach to market definition and rejection of rigid approaches.
Potential Anticompetitive Effects of Horizontal Mergers

• Coordination
  • Almost never relevant outside generic-generic deals.

• Unilateral Effects
  • More appropriate for differentiated product markets like pharma, biotech, diagnostics, and devices.

• Potential Competition
  • Frequent in cases involving highly concentrated segments where one of the parties has product relatively close to market (i.e., Phase III+).

• Pure Innovation Markets
  • Very rare.
Coordinated Effects: General Framework

- Applicable primarily to homogenous product markets where:
  - Nonprice competition unimportant;
  - Entry infrequent or unlikely;
  - Tacit coordination on price is easy to achieve and monitor, and deviations from tacit agreement easy to punish.
- For merger to make a difference, must make this tacit collusion easier, perhaps by reducing competitively significant asymmetries or eliminating a “maverick” - a firm with the ability and incentive to compete aggressively and successfully.
Coordinated Effects: Pharmaceuticals

- Generic-generic transactions (significant number of FTC enforcement actions over the past two years).
- Question is whether combination makes any incremental competitive difference. As number of firms grows smaller, theoretically possible. But empirically true?
  - What about entry?
  - What about powerful buyers?
  - And what about less transparency due to multi-product discounting and bundling?
- Are there ever generic mavericks?
- Do new therapeutic treatments remain competitive constraints?
Unilateral Effects: General Overview

• Applicable to differentiated product markets.
• Central question: are the products of the merging firms the closest substitutes for a significant number of consumers?
  • Greater than 35% combined share?
  • What is “significant?”
• Look at scanner data, product attribute surveys, interaction and switching indices, and merger simulations using this data (along with information about firm margins).
• Must take into account repositioning and efficiencies even if econometrics show that postmerger price increase likely.
• Arguably need to incorporate diversion to products outside market to perform appropriate merger simulations.
Unilateral Effects: Pharmaceutical Mergers

• Strikingly different than usual unilateral effects cases. No scanner data; little or no opening for econometrics.
• Usually focus on whether physicians, patients and health insurers view products from the merging firms as closer to each other than to other competitors.
• Highly inelastic demand could mean that consumers do not switch much at all.
• Theoretically, unilateral effects analysis in pharma context can also focus on “most distant substitutes” if staff becomes concerned about how postmerger firm could reduce blunt and combative positioning between divergent approaches within same therapeutic category.
Potential Competition: Overview

- Basic Theory of Harm: combining an actual competitor with a likely entrant would reduce competition that would have occurred by delaying entry or reducing price/innovation/quality pressure on incumbent firms.
- Entry must be reasonably likely in the foreseeable future.
- Market must be highly concentrated or otherwise showing indicia of sclerotic competition.
  - Recent FTC statement in Google/DoubleClick: entrant “must be uniquely positioned to have a competition-enhancing effect.”
- Internal documents showing likely positioning of entrant and response from incumbents highly probative.
- Because there is no actual interaction between potential entrants and incumbents, harder for targets to show they would NOT compete closely or significantly.
Potential Competition: Pharmaceutical Mergers

- Frequent theory of harm in pharmaceutical mergers.
- Usually applied when one of the merging parties has one of the few products on the market, the other party has one of only a handful of products in or past Phase III, and few other firms are likely to enter in the foreseeable future.
- Neither staff nor Commission has required that new entrant be “uniquely positioned” to have a procompetitive effect on the market, but as a practical matter, that is what staff investigates, whether “uniquely” means product attributes, likely competitive strength, or time-to-market.
- As a practical matter, should investigate any compounds in pipelines at Phase II or further.
- For targets with small patient populations, look at Phase I and IP portfolio.
Innovation Markets

• Usually applied only in pharmaceutical and defense industries, where actual product markets may not yet exist but where future competitive landscape is fairly predictable.

• Theory is that combination could reduce timing, quality or intensity of innovation by putting leading R&D efforts under same roof.
  
  • Epitomizes continuing hostility of antitrust law to Schumpeterian theory, which focuses on large, dominant firms as continuing hothouses for innovation.

• Pure innovation market theory applied only once in pharmaceuticals, to Ciba/Sandoz.

• FTC statement in Genzyme/Novazyme implied additional internal restraints on use of doctrine in investigations.

• But cannot be excluded as potential theory when targets involve small patient populations or high-priority conditions.
Potential Anticompetitive Effects of Vertical Mergers

- Combination will enhance ability and/or incentive of merged firm to exclude or impair actual or potential competitors in one market in which one of the merger partners competes.
  - E.g., essential input or complement used by one or more rivals becomes controlled by a competitor. (Digene/Cytyc; Monsanto/DPL)
  - E.g., combination of IP results in broader potential exclusion than either merging party would have or could have pursued absent transaction. (Ciba/Sandoz and the “killer patent portfolio”)
- Also vertical theories involving coordination or misuse via information.
- Generally requires significantly greater market power at one market level than threshold for concern in horizontal merger cases.
- Increasingly significant issue in biotech/device markets where there is and often must be cooperation among a number of parties.
- Generally a lower enforcement priority in Bush II v. Clinton I.
Entry

• Generally but not always treated under the same standard used to analyze whether merging parties are potential competitors. Unless Phase II or further, potential entrants not considered to be competitively significant.

• Legal standard: must be timely, likely and sufficient to reverse or deter anticompetitive effect in question.
  • Chicago Bridge & Iron decision in Fifth Circuit affirmed FTC approach to requiring entry to be of sufficient scale to deter anticompetitive effects.

• Regulatory approval process (FDA, EPA and/or others) usually a significant, transparent and predictable barrier here.

• IP can also be a significant barrier to entry.

• But . . . .
Horizon Issue: IP Defenses

• IP can also theoretically be a defense to a transaction that appears to involve a significant overlap.
• But the agencies have been generally reluctant to permit an “IP Defense” to what would otherwise be problematic transaction when it is one of the merging parties, not potential entrants, facing potential exclusion from IP.
  • Commissioner Rosch speech.
  • Atypical asymmetric treatment by staff.
• Could be characterized multiple ways, with implications for burden of proof:
  • Not horizontal competitors?
  • Efficiency?
  • Failing firm?
Where IP Defenses Are Likely to Head in this Context

- Agency will continue to either reject the defense or impose burden of proof on parties.
- When the issue gets litigated in a merger case, agency will have to face law created under *Baker Hughes* re: evidentiary standards and burden of proof and under *Tamoxifen* and *Schering Plough* on antitrust/IP.
- If IP defense is part of competitive effects analysis, agency likely to argue that parties would have licensed each other in absence of merger, just as it has pressed “less restrictive settlement” option in *Schering* and *Tamoxifen* amicus.
- Or FTC staff could argue that parties should prove that the IP defense is an efficiency, i.e., only a partial offset to potential anticompetitive effects that can be produced only through merger, not through cross-licensing or other less restrictive transactions.
Efficiencies in Pharmaceutical Transactions

- Examples: R&D, production, marketing and sales cost savings; R&D synergies.
- Part of Merger Guidelines, but rarely makes a difference in pharma or other transactions.
- Efficiencies have to be cognizable, verifiable, merger-specific and often market-specific.
- Arguably, large efficiencies from other portions of pharma transactions should be used to offset potential anticompetitive effects – usually the same purchasers are buying the relevant products.
- But neither staff nor the Commission approves this approach, especially in pharma, where different markets often involve entirely different downstream patient populations.
- But presenting efficiencies as part of a transactional overview is often useful in providing the agency with a positive and appropriate context for analyzing the deal.
Hybrid Theories: Product Improvement Acquisitions

- There are, however, some efficiencies that may look positive from both a corporate and patient perspective, which nevertheless raise antitrust concerns at the FTC.
- Product line extensions and improvement acquisitions, particularly when occurring in the context of a litigation settlement, have attracted interest from FTC staff, esp. with Health Care nonmerger staff.
- This is consistent with larger interest in strategic IP transactions, reflected in Commissioner Rosch’s 2007 speech.
- FTC investigations have included Lilly/Sepracor and Cima/Cephalon; other nonpublic investigations.
- Antitrust injury holding in *Eastman Chemical* (Federal Circuit) makes it likely that FTC intervention will continue with respect to strategic and potentially exclusionary IP acquisitions.
- Key defenses here could be accelerated time-to-market, as well as elimination of blocking IP.
- Remedies can involve licensing generic entry, as in *Cima*. 
Remedies

- *Cima* reflects pragmatism of Mergers I staff and increasing openness of Commission to novel, practical remedies.
- This is one area of the law where the enforcement agencies generally enjoy a tremendous amount of latitude – remedies can usually include everything up to and including the sale of all assets relating to an overlapping business, perhaps even on a global basis when necessary to preserve domestic competition.
- IP licensing alone, however, remains the exception to the general rule requiring full divestiture.
- One area requiring additional examination is whether, how and when divestiture of indirect interests must occur.
Indirect Coordination Remedies

- Divestiture of minority equity interests has become a major component of pharmaceutical antitrust enforcement (and indeed, of overall merger enforcement).
- Can often lead to significant holdup by other corporate entities with incentive and ability to delay consummation of generally efficient and procompetitive transactions.
- The law does permit the FTC to investigate and remedy such indirect interests (as Sixth Circuit recently confirmed in *Dairy Farmers of America*).
- But if the anticompetitive theories are remote (as is often the case with very low levels of equity interests) or easily remedied through firewalls (which are often imposed in any event), then it is not clear why such interests should be used to delay consummation of large transactions which could result in significant consumer benefits.
The Horizon

- As we have discussed, recent decisions have given agencies more flexibility with respect to entry, efficiencies and remedies.

- Reason to believe that agency could expand investigations of strategic acquisitions, particularly if Democrats win in November; recent arguments about underenforcement with respect to mergers over the past eight years.

- The real question is what might happen when a pharma merger finally gets litigated, which generally becomes more likely if and when government remedies seem unpalatable.
  - Government defeats involving product market definition and competitive effects analysis could end up affecting pharma merger enforcement.

- But not likely to have much of an effect on day-to-day enforcement because the FTC’s merger analysis in this field is generally within the mainstream of modern antitrust law, and remains cutting-edge compared to merger enforcement in other industries, particularly in dealing with multiple probabilities and uncertainties (as discussed in Shelanski/Katz 2007 article).
Questions?