

Morgan Lewis

Analysis of Innovation in Merger Investigations: The Role of Counsel

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May 12, 2010

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Innovation Market Analysis for Pharmaceutical Mergers

Pfizer Agrees to Acquire Wyeth – Jan. 26, 2009



Wyeth

PFIZER TO ACQUIRE WYETH, CREATING THE WORLD'S PREMIER BIOPHARMACEUTICAL COMPANY

NEW YORK, NY and MADISON, NJ--January 26, 2009 – Pfizer (NYSE: PFE) and Wyeth (NYSE: WYE) today announced a definitive agreement under which Pfizer will acquire Wyeth for \$42 billion in cash, \$10 billion per share, or a total of 240 million shares. The transaction has been approved by the boards of directors of both companies.

The combination of Pfizer's and Wyeth's development projects in diabetes, pain, as well as significant number of compounds in development. These will be managed by Pfizer for Alzheimer's disease to use in targeted therapies.

The new company will have units tailored to patient needs, from development from clinical trials to commercialization. This approach will allow for rapid decision-making and a more efficient use of resources and, as a result, will enhance the company's ability to invest in long-term opportunities. The combination will also provide additional high quality and high volume manufacturing capabilities, including Wyeth's Grange Castle, Ireland facility, the largest integrated biotechnology manufacturing facility in the world.

The combination also brings together a robust pipeline of biopharmaceutical research and development projects, including programs in diabetes, inflammation/immunology, oncology and pain, as well as significant opportunities in Wyeth's Alzheimer's disease pipeline, which has a number of compounds in development, including phase three biotech compound Bapineuzumab.

Commissioner J. Thomas Rosch, “Antitrust Regulation of Innovation Markets,” Feb. 5, 2009

III. PRACTICAL CONSIDERATIONS OF REGULATING INNOVATION MARKETS UNDER ANTITRUST LAWS

Next I would like to discuss the practical considerations of regulating innovation markets. I have

First, the most fundamental practical

standpoint, the application of antitrust laws to innovation markets provides consumers with better products or products that are developed more quickly. Critics of applying

antitrust laws to regulate “innovation markets” assert

that increases in concentration do tend to detract

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pools are formed.

[T]he most fundamental practical consideration is whether ... the application of antitrust laws to innovation markets provides consumers with better products or products that are developed more quickly

Is it better to lock scientists from competing firms in a room and let intellectual fermentation occur? **Will that result in more innovation or at least quicker innovation than challenging such collaboration as a violation under Section 1 or Section 7?** Or ... are consumers better off when agencies use antitrust laws to increase competition’s role in innovation because innovation declines when concentration increases? The jury is still out on that fundamental question.

Comanor and Scherer, AAI, Memorandum on the Proposed Acquisition by Pfizer of Wyeth, Feb. 11, 2009

Unfortunately, we have no evidence on the extent to which the two companies have prospective products in research, development or testing that would be rivals if and when they receive FDA approval. To the extent that there are developmental overlaps, an innovation market analysis should be undertaken, and if the overlaps are large, that would provide a further basis for opposing the merger. In addition,

The Pace of Pharmaceutical Innovation

In recent years, it has become increasingly clear that pharmaceutical R&D productivity has declined sharply. Iain Cockburn states

By many accounts, the pharmaceutical industry's productivity is declining. More and more new drugs are introduced but the rate of reporting in trade journals and medical literature is falling. There are "strangled" pipelines, and as the FDA's drug approvals, the New York Times concluded ... that the research "throughput" had grown worse.

The reverse side of this same story is the increasing research cost of pharmaceutical

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New Considerations in Pharmaceutical Mergers

- ***Will the combination of the parties harm innovation in the pharmaceutical industry?***
 1. Innovation for specific therapeutic areas (Potential Competition Analysis)
 - Common issue in pharmaceutical mergers
 2. Innovation across the pharmaceutical industry (Innovation Market Analysis)
 - No precedent
 - Became major focus after Pfizer-Wyeth was announced on Jan. 26, 2009

The Role of Counsel: Addressing the Commission's Concerns

1. What are necessary conditions for a merger to reduce incentives for R&D in the pharmaceutical industry?
2. Address market structure and innovation:
 - Examine Potential Benefits for Innovation from the Merger
 - Examine Potential Harm to Innovation from a Merger
3. Break the analysis into two parts:
 - Innovation across the pharmaceutical industry
 - Innovation for specific therapeutic areas

Necessary Conditions

1. The Merger must combine R&D Activities directed to potentially competing new products
2. The Merger must represent a large share of the R&D expenditures directed to new products that may compete in a relevant market
3. Barriers to entry into R&D directed to the new products in a relevant market must be high
4. Spillovers from successful discovery and benefits from information sharing must be low

Potential Benefits

- Appropriation Effects
 - Larger share of the benefits from R&D investments
 - Minimizes first to market advantage (*e.g.*, statins)
- Better Information
 - R&D Information from two firms is better than one
 - New knowledge about potential drug effectiveness and safety
- Effective Spending
 - Reduction in R&D spending \neq Reduction in innovative output
 - Focused spending on programs with the greatest potential benefit (*e.g.*, Sutent)

Potential Harm

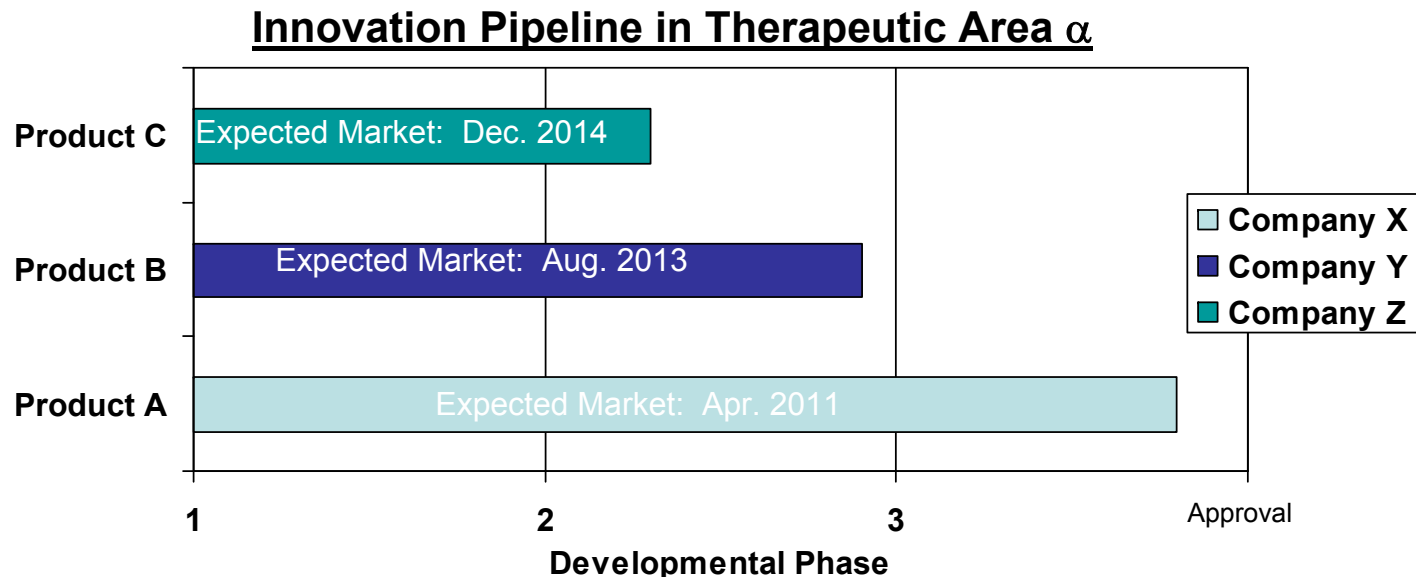
- Does the combined firm have less incentive to innovate and replace existing products?
 - Pharmaceutical companies have added incentives to develop complimentary products (e.g., co-marketing)
- Does the combined firm have less incentive to invest in new product development?
 - The same incentives would exist post-merger; the pharmaceutical industry is not a “winner-take-all” R&D industry
- Is the merger likely to result in coordinated effects in R&D?
 - Difficult to assess R&D activities across the industry (e.g., Medivation)
 - Difficult to assess the status of specific programs
- Will the merger affect bidding for promising new drugs?
 - No, because numerous “qualified” alternatives exist



Innovation for Specific Therapeutic Areas

Hypothetical Acquisition of Overlapping Pipeline Product

- Companies X, Y, and Z are the only competitors with pipeline products (A, B, and C) to treat Therapeutic Area α in Phase 2 or 3



- Company X agrees to purchase Company Y
- FTC claims that the combination of Companies X and Y will harm innovation for products to treat Therapeutic Area α

E.g., EGFr-tk Inhibitors for the Treatment of Cancer (Pfizer-Warner Lambert)

Pipeline Compounds: Costs and Probabilities

- No empirical evidence that consumers benefit from the race to approval
 - High cost to develop + Low probability of reaching market
 - Companies benefit from shared information: Enhanced knowledge of safety (e.g., side effects) and effectiveness
- Costs and transitional probabilities for investigational compounds (costs in millions of 2000 dollars)*:

Testing Phase	Mean Cost	Standard Deviation	Probability of Entering Phase	Expected Cost through end of Phase
Phase I	15.2	12.8	100.0	15.2
Phase II	23.5	22.1	71.0	31.9
Phase III	86.3	60.6	31.4	59.0

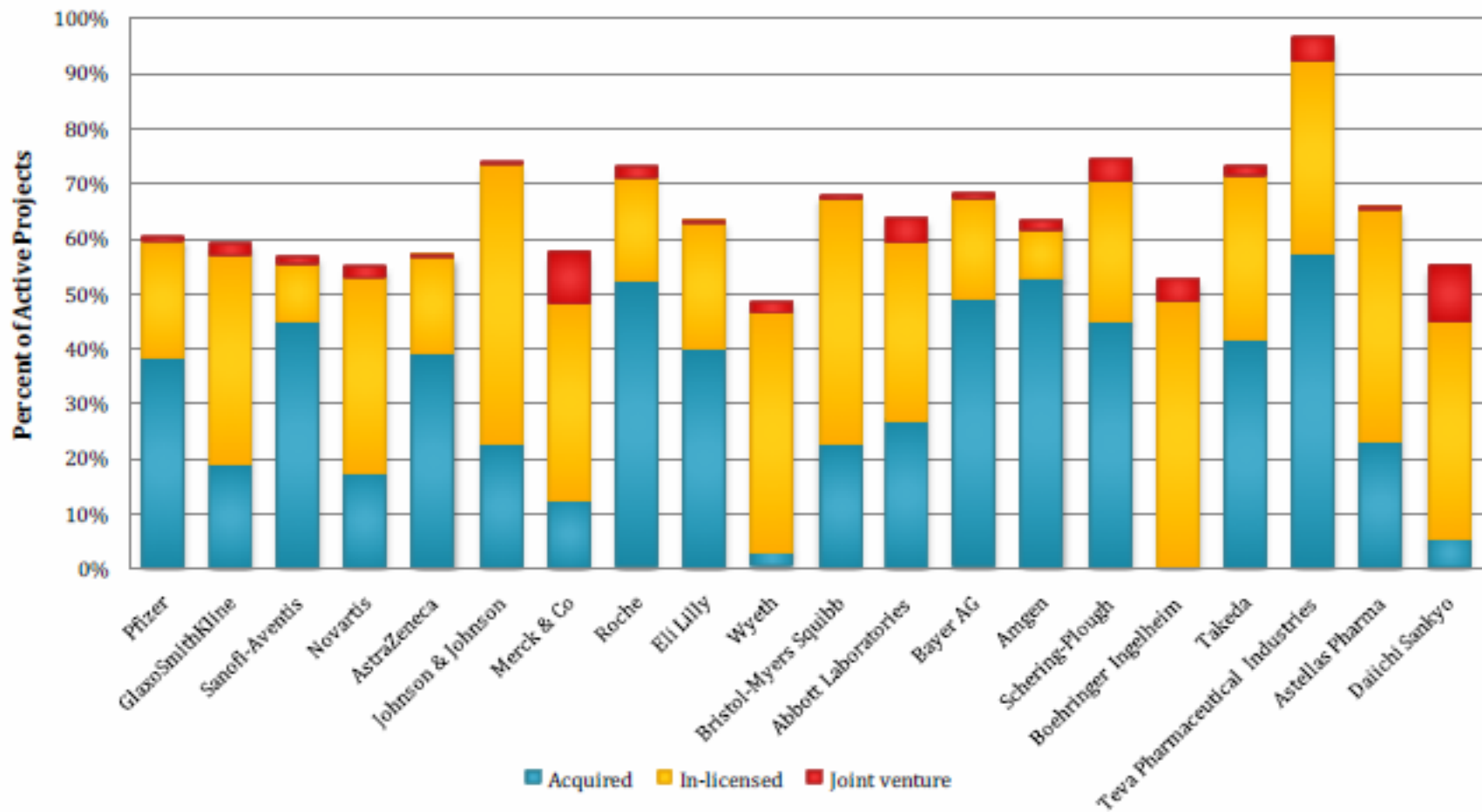
*Data from Journal of Health Economics (2003)



Innovation Across the Pharmaceutical Industry

Bidding for New Drugs

- Numerous alternative “qualified” bidders exist*:

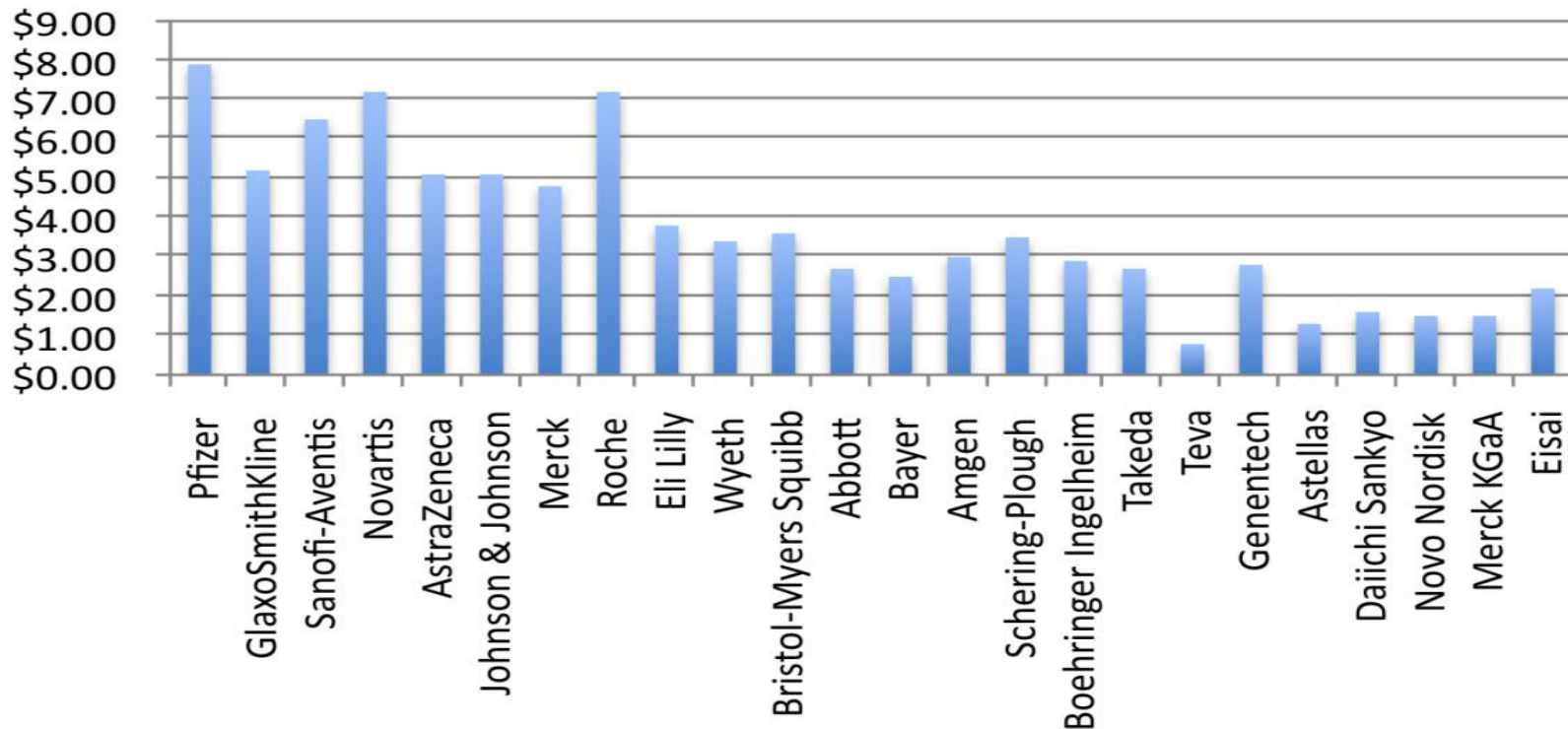


*Data from EvaluatePharma

Big Budget Pharma R&D Programs

- Eight companies boasted R&D budgets > \$4 billion in 2008:

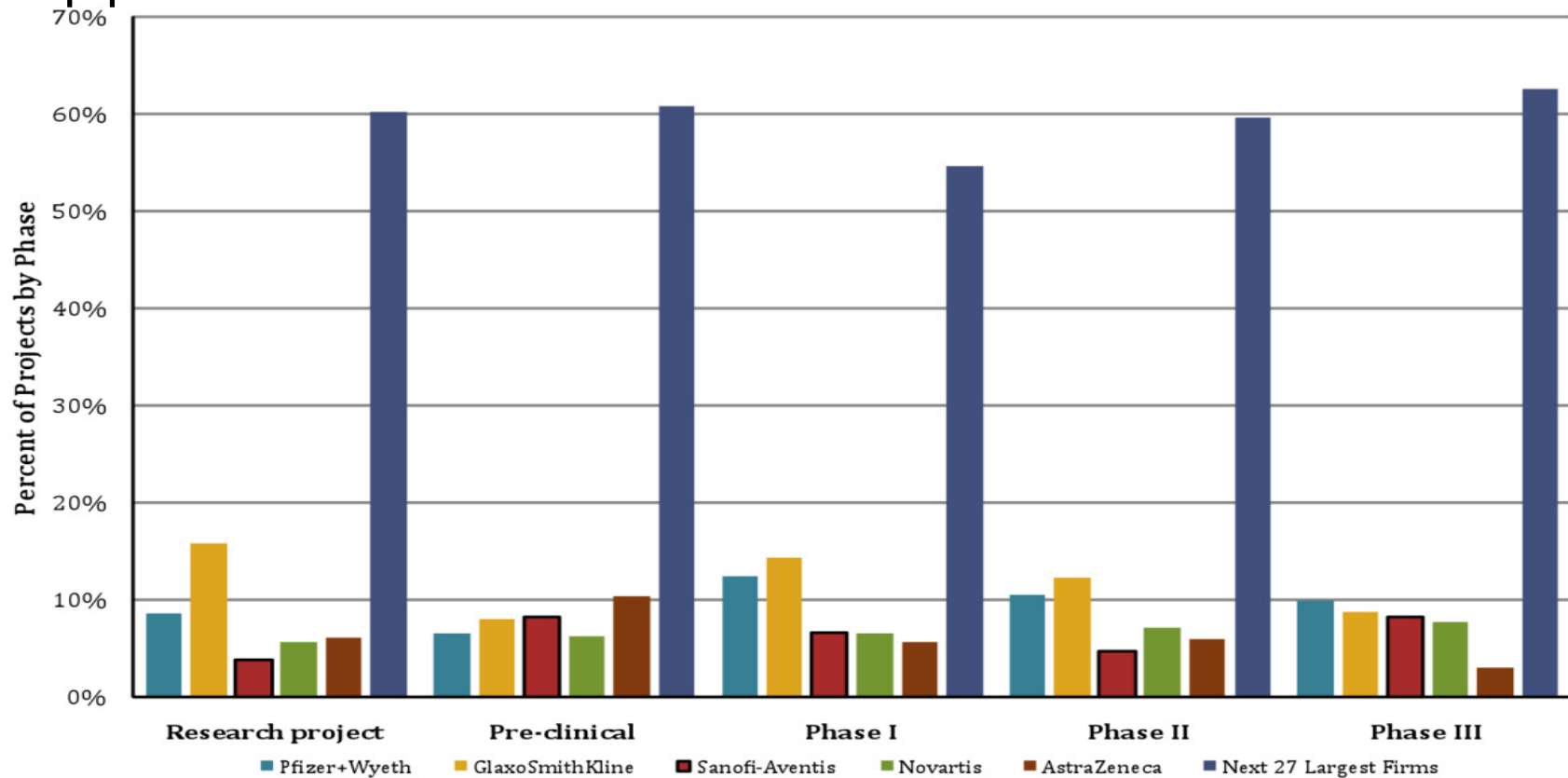
Annual 2008 R&D spend by major pharmaceutical firms (\$ billions)*



*Data from www.pharmexec.com

Innovation Occurs at All Stages Throughout the Pharmaceutical Industry

- Shares of company R&D at different stages of the R&D pipeline*:



*Data from EvaluatePharma



Questions Remain

Questions Going Forward

- FTC ultimately agreed that Pfizer-Wyeth did not pose a competitive threat in the market for innovation
- Questions remain...
 1. How do you define and analyze an innovation market across the pharmaceutical industry?
 2. What is meant by *innovation*?
 - Research *and* Development? Research *or* Development?
 3. Where does innovation occur?
 - Can an innovation market be limited to major pharmaceutical companies?
 4. How do you measure competitive effects in an innovation market?