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Patents as Weapons in Pharmaceutical Competition

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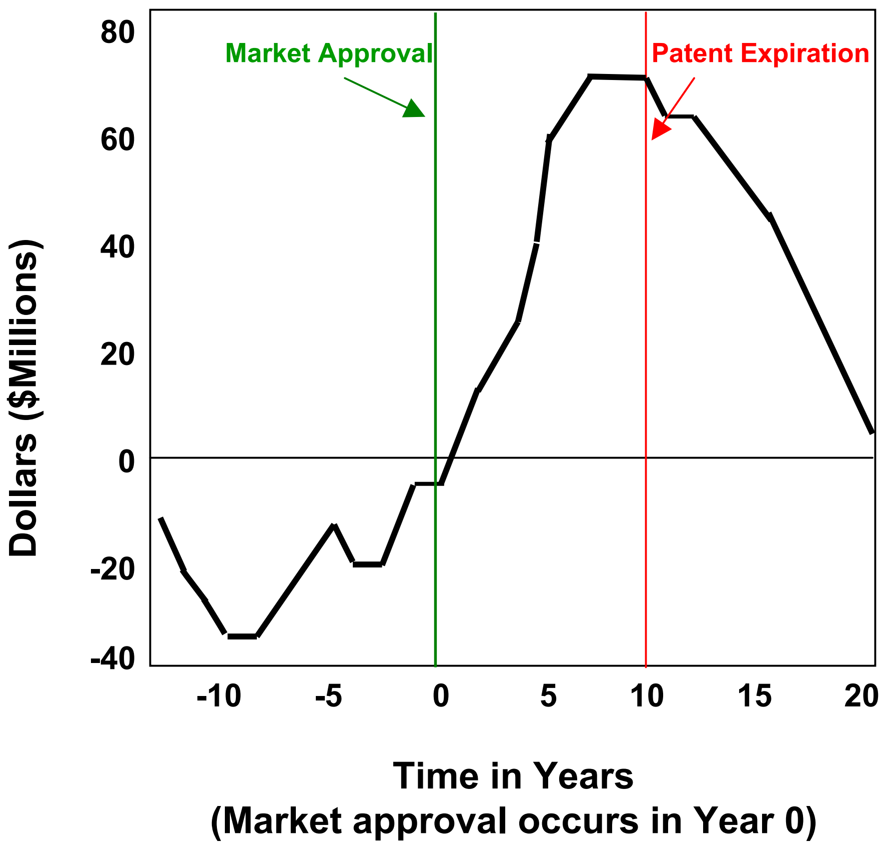
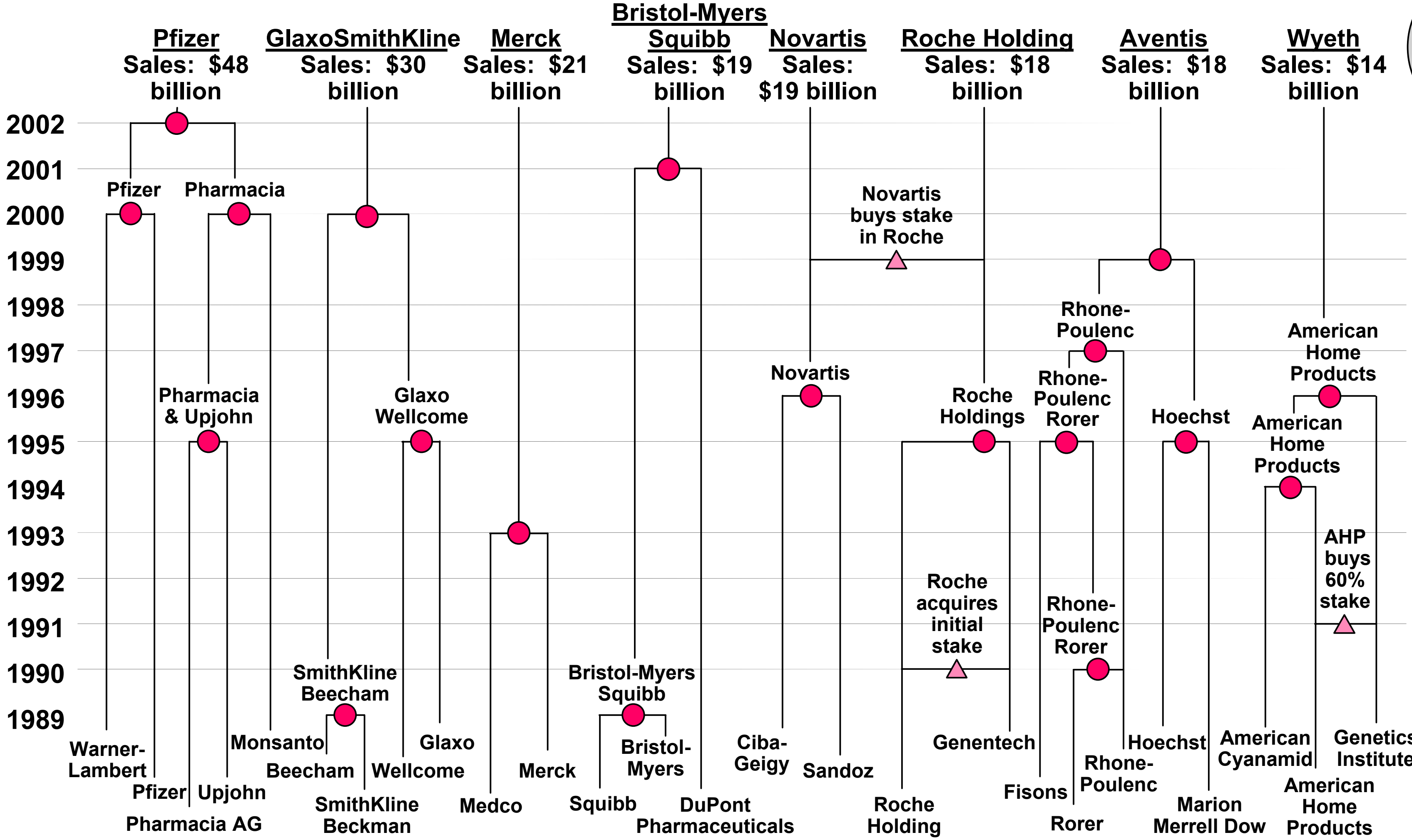
Hypothetical Life Cycle of R&D Investment and Revenues



Source: *Pharmaceutical R&D: Costs, Risks and Rewards, Office of Technical Assessment, February 1993.*

Acquisition Often Follows Failure to Sustain a Drug Development Pipeline

Genealogy of the Drug Industry—Europe and America



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The 1984 Hatch-Waxman Act was intended to balance society's competing desires for continual innovation and low-cost generic drugs.

Provisions of the Hatch-Waxman Act:

- **180-day period of exclusivity**

  First generic company to file an ANDA is given the exclusive right to market its generic version of a patented drug for 180 days

- **30-month stay protection**

  When a generic company files an ANDA, the brand-name company has 45 days to decide whether to sue the company for patent infringement.

  Filing the lawsuit stays FDA's approval of ANDA until the earliest of:

  - Date of patent expiration
  - Final determination of non-infringement or patent invalidity by a court
  - Expiration of 30 months from the receipt of notice of the paragraph IV certification

  Brand-name companies may obtain additional 30-month stays when they add new patents for the same drug to the Orange Book list. The company initiates a new 30-month stay with each patent listing.

"Beyond any doubt, Hatch-Waxman has increased generic drug entry. Generic drugs now comprise more than 47 percent of the prescriptions filled for pharmaceutical products" **– FTC Study**

Strategies Used by Pharmaceutical Companies to Extend the Patent's Life or Reduce Competition from Generics

- **Extending Exclusivity**
  - Patenting a new delivery system (*e.g.*, immediate release and extended release)
  - Patenting a purified version of the drug
  - Patenting a manufacturing process

- **Transferring value to a new product**
  - Introducing a new generation drug (*e.g.* maximum strength)
  - Introducing an over-the-counter version of the drug

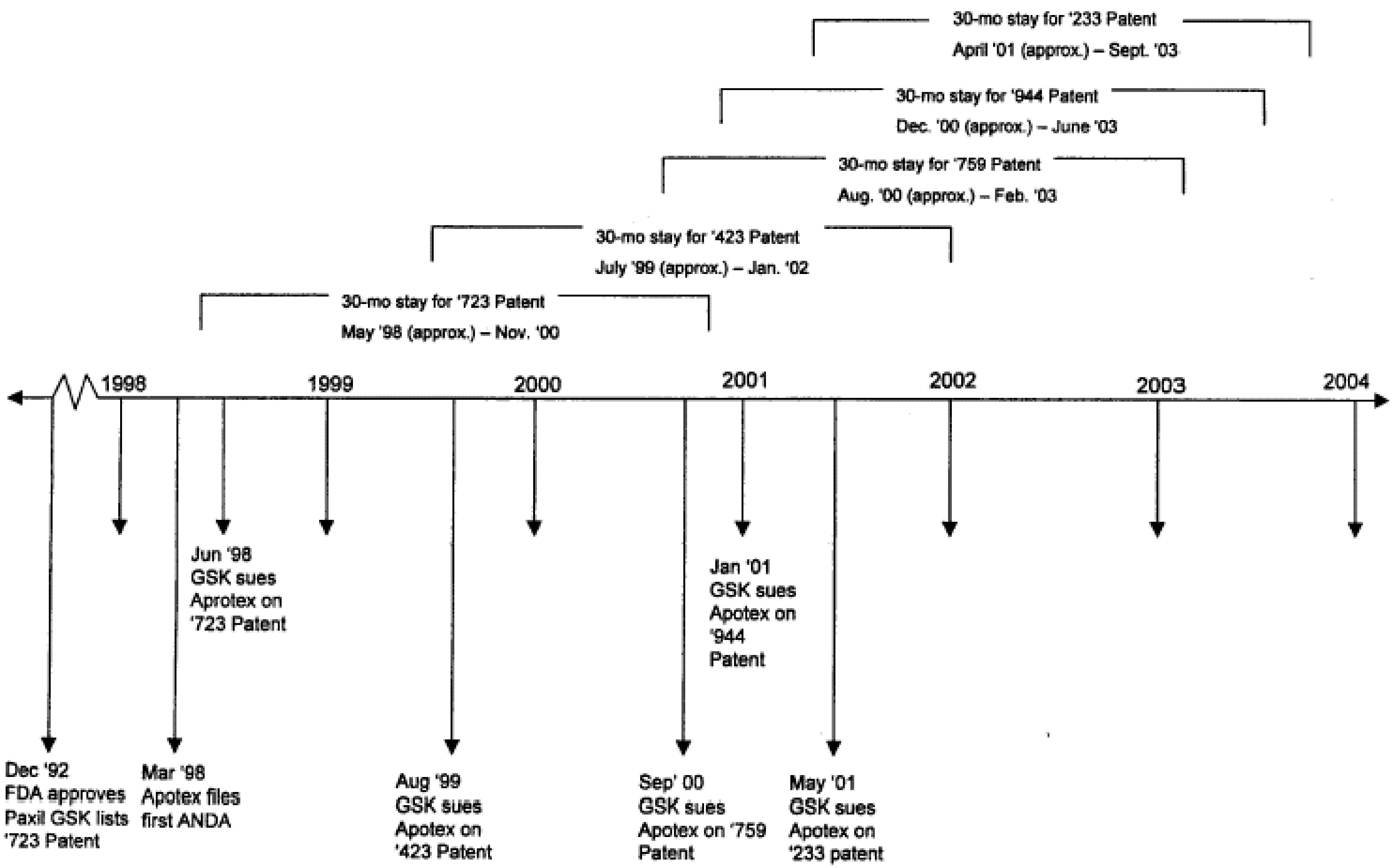
Strategies Being Investigated by the FTC as Potentially Anticompetitive

- **Agreements between brand-name and generic companies that delay entry of the generic product that would otherwise trigger 180-day marketing exclusivity**
  - ***Abbot Laboratories v. Geneva Pharmaceuticals (Hytrin)***
    - Five 30-month stays initiated by Abbot in response to ANDA filings by Geneva.
    - Geneva and Abbot entered into an agreement "whereby Geneva agreed not to market its generic tablets or capsules until the '207 patent litigation was finally concluded" (FTC study) or another generic company entered the market. Abbot paid Geneva $4.5 million per month in exchange.
  - ***Biovail v. Mylan and Pfizer (Procardia)***
    - Pfizer sued first ANDA filer Mylan for infringement.
    - Pfizer and Mylan entered agreement in which Pfizer licensed its product to Mylan, which would market Pfizer's licensed product rather than its generic product.
    - Because neither a court judgment was rendered on the patent nor did Mylan begin to market its generic product, the 180-day market exclusivity could not be triggered.

Strategies Being Investigated by the FTC as Potentially Anticompetitive

- **Use of multiple 30-month stays by invoking Orange Book patent listings after the first generic applicant filed its ANDA**
  - ***IVAX v. Bristol-Myers Squibb Co. (Taxol)***
    - Bristol sued first ANDA filer IVAX and triggered 30-month stay
    - CAFC affirmed lower court's decision on invalidity of two patents.
    - American Biosciences obtained a related patent, which Bristol listed in the Orange Book, threatening another 30-month stay.
  - ***Andrx Pharm. Inc. v. Biovail Corp. Int'l (Tiazac)***
    - Andrx filed ANDA for a generic version of Tiazac and sent its paragraph IV certification to Biovail, which sued for infringement.
    - Before the CAFC's decision, Biovail listed a second patent in the Orange book.
    - Andrx filed a second paragraph IV certification and Biovail sued, thus triggering a second 30-month stay.
  - ***Nichols, et al. v. SmithKline Beecham Corporation (Paxil)***
    - SmithKline Beecham (GSK) sued first ANDA filer Apotex Corp., triggering a 30 month stay.
    - "Four additional 30-month stays have prevented FDA approval of generic competition against Paxil for approximately 65 months" – *FTC study*

30-Months Stays Obtained for Paxil



Source: *Generic Drug Entry Prior to Patent Expiration: An FTC Study*

Pharmaceutical Innovation
F. R. Lichtenberg, 2002

- **The benefits to society of introducing new drugs outweigh the costs:**
  - **Increased longevity**

Cost per life year gained	\$424
Economic value of a life year (Murphy and Topel)	\$150,000

  - **Improved quality of life (reduced limitation at work and other activities)**

Per patient increase in cost from switching to newer drugs	\$71
Value of the reduction of work-loss days	\$143

  - **Reduced total medical expenditure**

Per prescription increase in cost from switching to newer drugs	\$18
Value of reduction of hospitalization, home health care and other non-drug expenditures	\$71

Economic Value of Medical Research
K. M. Murphy and R. Topel, 1999

- **There is significant economic value in improving health and life expectancy**
  - From 1970 to 1990, the historical gains from increased longevity have been on the order of $2.8 trillion per year, of which more than half ($1.5 trillion) can be attributed to reduction in mortality from heart disease.
  - Eliminating deaths from heart disease would generate approximately $48 trillion, while curing cancer would be worth about $47 trillion. An innovation that reduced the cancer death rate by only 1% would generate about $500 billion.
- **Investment in pharmaceutical R&D outpaces investment in other areas of medical research**
  - The level of R&D to sales for medical care as a whole (3.5%) is small relative to the level of R&D to sales for the drug sector (10.4%).
  - Drug related research is primarily privately funded, other areas of medical research are primarily funded from federal sources.
- **Murphy and Topel conclude that the higher ratio of R&D spending in pharmaceutical is a result of the greater ability to patent innovations in that sector.**

The Value of R&D in Medical Care Will Increase Over Time

According to Murphy and Topel, the economic gains from increasing life expectancy are greater:

(i) the larger is the population,

(ii) the higher are the lifetime incomes,

(iii) the greater is the existing level of health (thus, advancements in health are complementary), and

(iv) the closer the population is to the age of onset of disease,

All of these are expected to grow over time.

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