

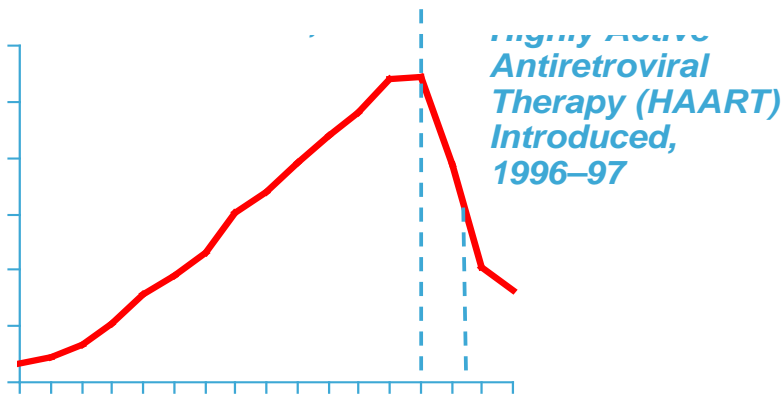


Assessing the Economic Case for Patents for Biopharmaceuticals 4th Annual CPIP Conference - GMU

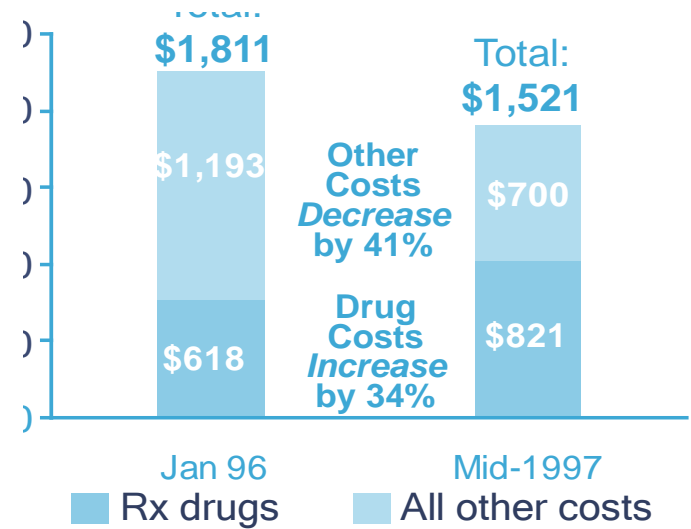
Richard Manning, PhD

October 7, 2016

Advances in HIV therapy illustrate impact of innovation on cost and medical outcomes



HIV Mortality Declined Dramatically After Introduction of First Antiretrovirals...

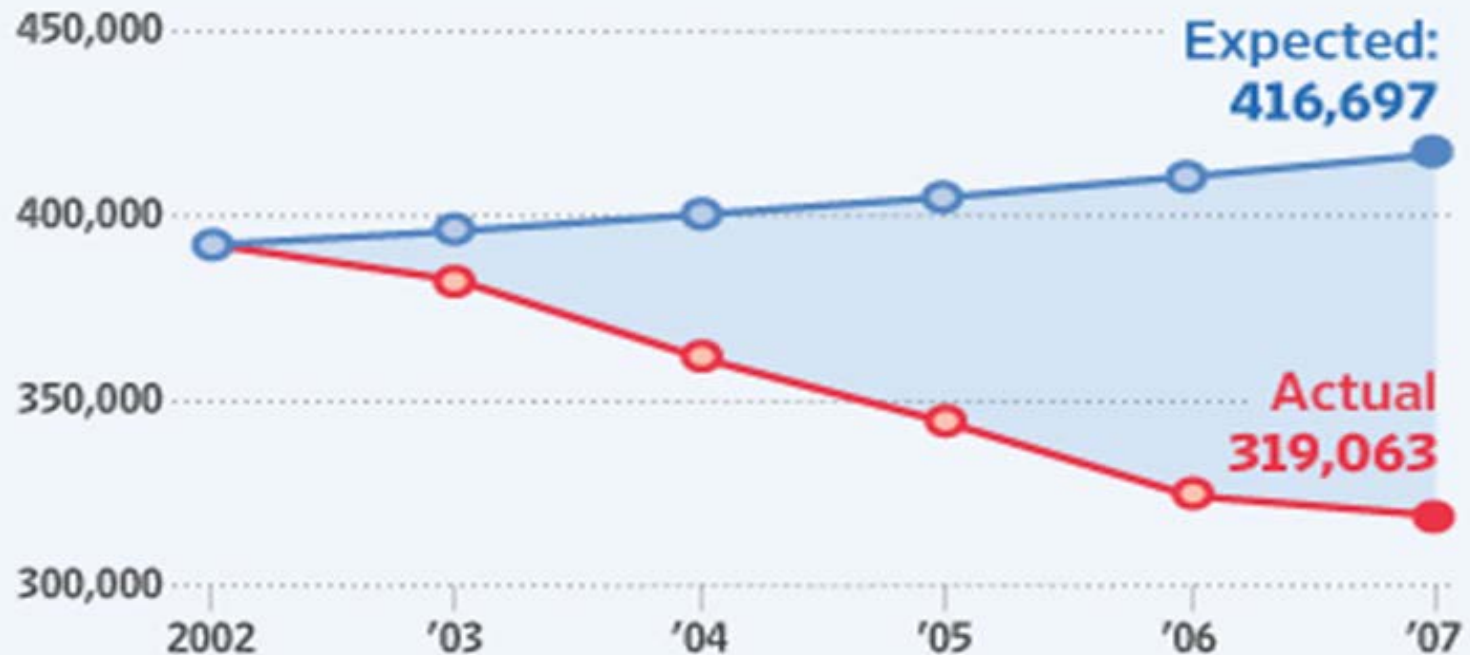


...While Monthly Costs for AIDS Patients Decreased by 16% After HAART Introduced

for the care of HIV-infected patients in the era of highly
817-23; 2) Mortality – National Center for Health
3) Drug development data – PhRMA and the NIH Office

Heart-Attack Hospitalizations Drop

Decline in admissions for acute myocardial infarction for Medicare patients.



Note: Combines actual heart-attack admissions among Medicare fee-for-service patients and estimated admissions for Medicare managed-care patients. The expected trend reflects a constant rate of heart attacks per 100,000 people.

Source: Jersey Chen, Yale University

The unique economics of innovation in biopharmaceuticals have typically led to “high” prices for innovative drugs

- Markets lead to pricing based on value delivered to patients
 - Definition of “high priced” is fluid – Diflucan, Zithromax and Lipitor were once considered expensive
 - Innovation can (and will) be highly valuable
 - ◆ HAART for HIV
 - ◆ Hepatitis C cures
 - ◆ Oncology
 - ◆ Alzheimer's
 - But when innovation doesn't deliver value, new products don't succeed
 - ◆ Inhalable insulin
 - ◆ Weekly Prozac
 - ◆ PCSK9 inhibitors (TBD)
- High value and high prices lead to concerns
 - Profitability
 - Access to innovative treatments

UN High Level Panel on Access to Medicines (Sept. 2016)

- Observation:
 - “Market-driven R&D has been credited by some for producing a number of important health technologies that have improved health outcomes significantly worldwide. However, significant gaps in health technology innovation and access persist. Under the prevailing model, the biomedical industry, **with the help of intellectual property and data protections**, in addition to benefitting from public funding for research, recoups the costs of its R&D and marketing through **high product prices protected by patent monopolies and data and market exclusivities.**”
- Policy recommendation:
 - “the United Nations Secretary-General should initiate a process for governments to negotiate global agreements on the coordination, financing and developments of health technologies. This includes negotiations for a **binding R&D Convention that delinks the costs of research and development from end prices** to promote access to good health for all.”

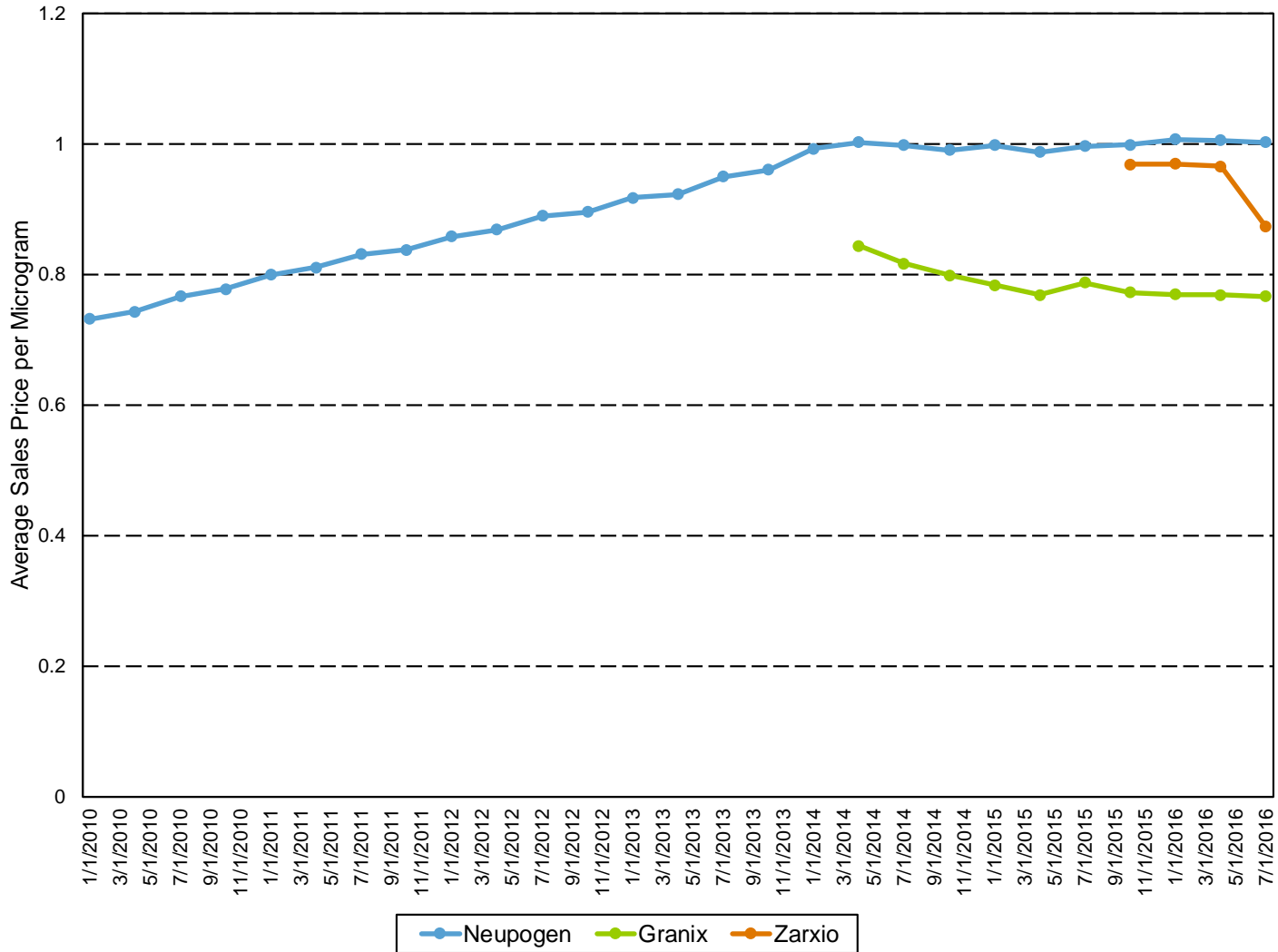
Is the patent model broken?

- Ideally, patents (combined with pricing freedom) align consumer and producer interest
 - Patents are most effective when markets work
 - Sometimes market incentives fail to produce efficient levels of innovation
 - ◆ Basic research, antibiotics, neglected tropical diseases (diseases of poverty)
 - Do companies need to enforce patents in LDCs?
- Many alternatives to patents have been proposed
 - Prizes
 - Patent pools
 - Marketing exclusivity divorced from patents
 - Philanthropic development
 - Public purchase of critical patents?
 - Academic “R” followed by Public “D”
 - ◆ All IP in public domain
 - Compulsory licensing/Technology transfer requirements
 - ◆ Sometimes with “equitable” royalty payments
- Despite certain successes and the hopes of some, no proven alternative model has emerged

Key issues involving patents

- Brands v. Generics: The well known Hatch Waxman story
 - The rise of Paragraph IV challenges
 - Reverse settlements/Pay for delay
 - ◆ How can it **not** be an antitrust violation to pay a competitor not to enter the market? – perhaps it's not that simple
 - ◆ Actavis decision
 - Should primary patents be presumed valid, but secondary patents not?
 - ◆ Incentivising valuable secondary innovation
- Biologics v. Biosimilars:
 - The Patent Dance – a question for the Supreme Court?
 - What has happened abroad?
 - What is likely to happen here?
 - ◆ Not separate sectors/industries
 - ◆ Uptake dictated by complex interactions
 - Payer/Providers/Patients
 - Regulatory interchangeability

ASP for Neupogen (filgrastim), Granix and Zarxio (biosimilar)



Key issues involving patents (cont.)

- Product hopping
 - Real incremental innovation v. brand extension
 - Can the market distinguish between real innovation and clever marketing?
 - Visibility of discounts and rebates
- Price spikes for generic medicines
- Etc.

Thank You

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