

The role of patents in research and development

Promoting Innovation in the Life Science Sector and Supporting Pro-Competitive Collaboration:
The Role of Intellectual Property

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Technological innovation is a key determinant of economic and public health progress

Overall and disease-specific mortality, morbidity improvements

- Heart disease and stroke
- Various cancers
- HIV / AIDS and HAART
- Hepatitis C
- Next generation potential examples: gene and cell therapies
- Many other examples

Buxbaum JD, Chernew ME, Fendrick AM, Cutler DM. Contributions Of Public Health, Pharmaceuticals, And Other Medical Care To US Life Expectancy Changes, 1990-2015. *Health Aff (Millwood)*. 2020;39(9):1546-1556.

Lichtenberg, FR, Virabhak S. Pharmaceutical-embodied technical progress, longevity, and quality of life; drugs as “equipment for your health.” *MDE. Manage Decis Econ*. 2007;28(4-5):371-92.

Robust evidence that innovation responds to economic incentives

Firms' expectations drive investment necessary to bring products to market

- New molecular entities and clinical trial activity (Acemoglu and Linn 2004; Blume-Kohout and Sood 2013; Dubois 2015)
- Vaccines (Finkelstein 2004)
- Certain oncology projects (Budish, Roin and Williams 2004)
- Other examples across markets, health care and non-health care

Patents play an essential role for drugs

Economics of drug development make patents particularly important

- Process of developing, approving and commercializing new drugs is lengthy, costly, and risky; invention and development costs are very high
- Costs of imitation are generally very low
- The few approved drugs which are commercially successful fund R&D costs, including failures
- Without patents and/or other forms of IP protection, few firms would be likely to make such investments
- In addition, patents and IP expectations play key roles in funding and partnership opportunities for early-stage firms

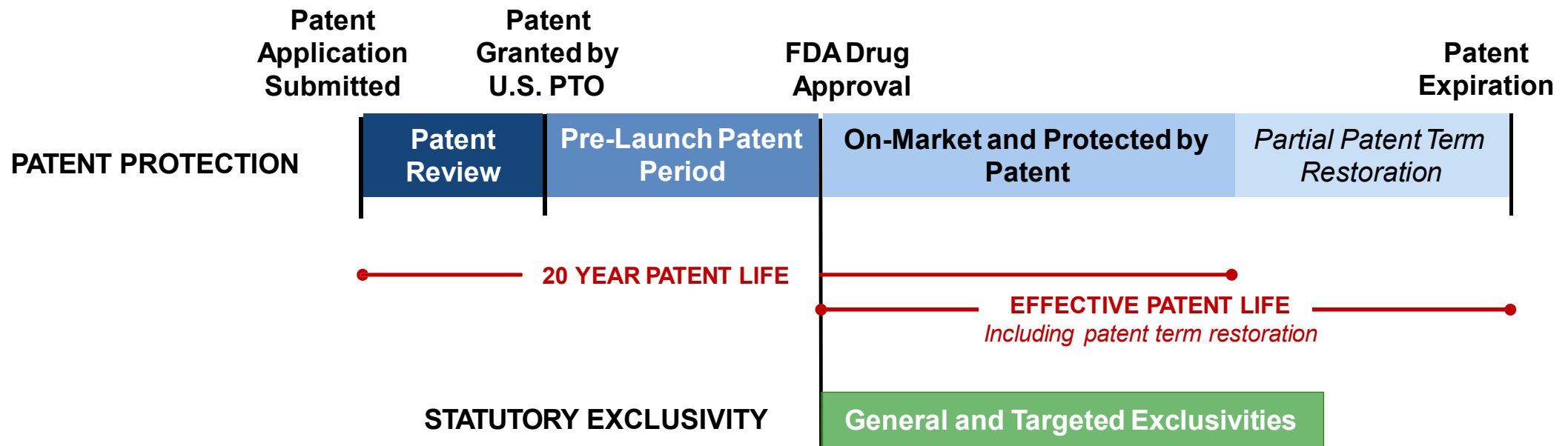
The core patent trade-off

Static inefficiency of reduced access today vs dynamic efficiency of increased development of new products in the future

- Patents award a time-limited period of exclusive marketing – they confer the right to exclude competitors for a limited time within a given scope; require disclosure
- During this period of exclusive marketing, prices to consumers are higher than otherwise
- The essential rationale for patent protection is that long-term benefits in the form of future innovation outweigh short-term restrictions on imitative cost competition (generic drugs):

“During this time period, the high prices curtail some access to valuable medicines. However, this reduced access today is deliberately traded off for the development of new products in the future. These new products provide access to patients for whom there would otherwise be no treatment.” (C Garthwaite, testimony)

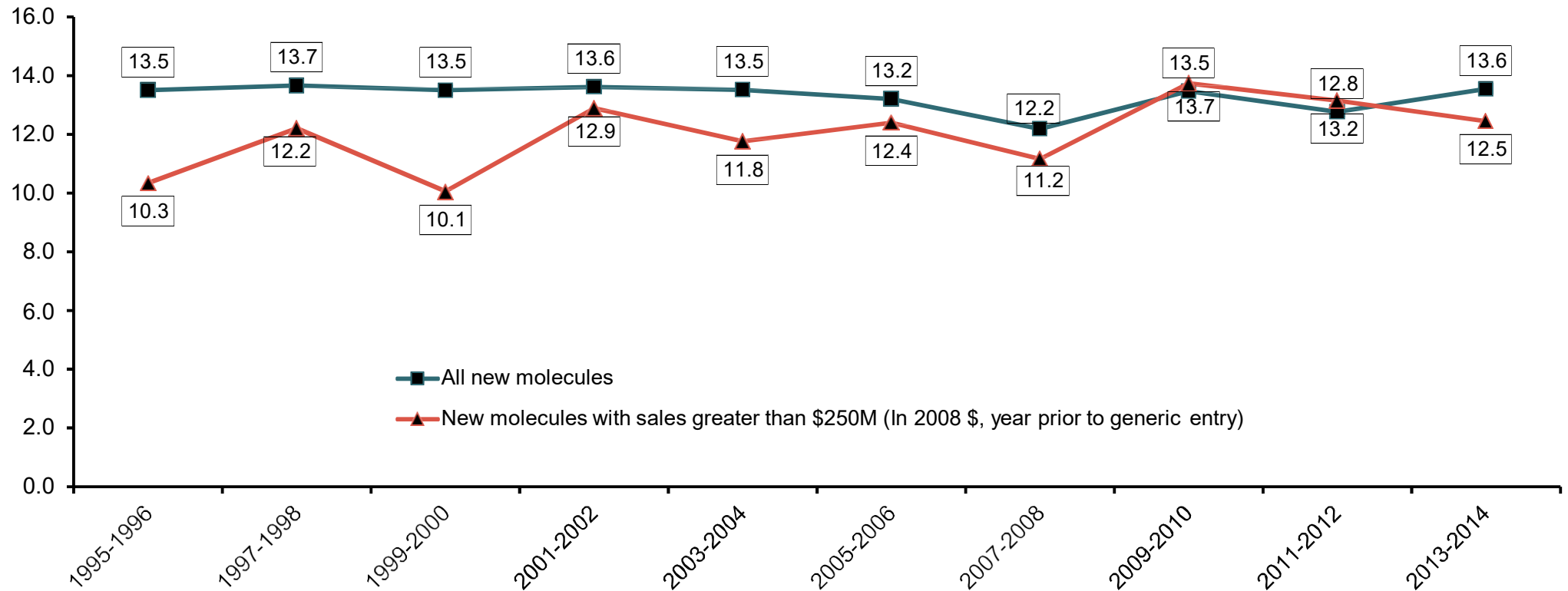
Patents are a foundational element of the U.S. system of drug innovation financing – and operate in tandem with other IP provisions



- Patents run from application - statutory exclusivity runs from FDA approval
- Patent and statutory exclusivity periods run in parallel – they are not additive
- Together with market entry decisions, they jointly determine the Market Exclusivity Period

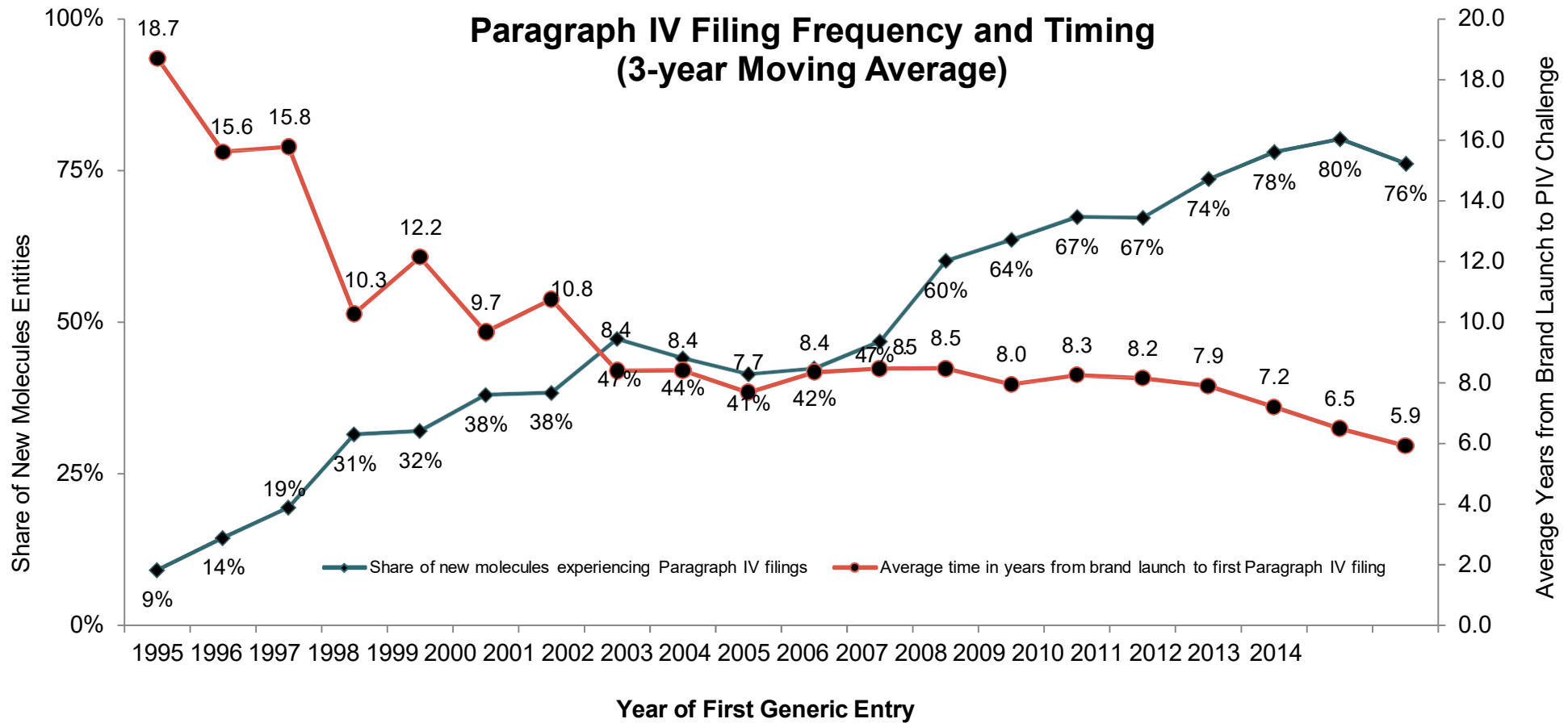
Results: Average Market Exclusivity Periods are substantially shorter than 20 year patent term and have remained fairly constant over two decades

**Average Market Exclusivity Period by Year of First Generic Entry
New Molecular Entities**



Grabowski H, Long G, Mortimer R, Boyo A. Updated trends in US brand-name and generic drug competition. *J Med Econ.* 2016;19(9):836-844.

Over the same period, patent challenges have increased and accelerated



Grabowski H, Long G, Mortimer R, Boyo A. Updated trends in US brand-name and generic drug competition. *J Med Econ.* 2016;19(9):836-844.

Special issues: Vaccines and diagnostics

Some patent and economic issues for vaccines and diagnostics

- **Vaccines**

- Value: Individual health (cost reductions, work productivity gains), population health (herd immunity), other societal economic gains (lower birth rates, increased investments in education, reduced antibiotic resistance, greater economic stability and growth)
- Patents: Production process versus product patents
- Economic value drivers: Inclusion in recommended immunization schedules; reimbursement policies among public and private payers

- **Diagnostics**

- Value: Option value of information
- Patent and economic issues: Patentability issues, lab-based tests, reimbursement challenges