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Webinar: Balancing Innovation, Access, and Affordability

Intellectual Property Protections, Market Exclusivity Periods, and Innovation

Genia Long
Analysis Group, Inc.

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Topics

1. Biopharmaceutical innovation and intellectual property protection
2. The Hatch-Waxman framework
3. Market exclusivity periods: Definition and recent research
4. Some potential implications for biologics and biosimilars

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Intellectual property protections are essential to the development of new medicines

- The development of new drugs involves large R&D investments, over many years, with uncertain clinical and financial results
- Copying them (i.e., developing and launching generic drugs) is generally straightforward and much less expensive
- Without intellectual property protections, innovators would not expect to recover the fixed investment in R&D before losing sales to generic competitors
- Therefore, without market exclusivity protections, firms would not invest in developing innovative new drugs

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The 1984 Hatch-Waxman Act balances dual goals

"The American public has a great stake in achieving the twin ends of the 1984 law. These goals are:

First, making available today's medicines at the most competitive and affordable prices; and,

Second, encouraging the development of tomorrow's breakthrough cures."

Statement of Sen. Orrin Hatch, before the Committee on the Judiciary, United States Senate, One Hundred Seventh Congress, May 24, 2001.

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The framework created the modern U.S. generic drug industry

For Generic Manufacturers:	For Brand Manufacturers:
▪ Created a regulatory approval pathway for generic drugs (ANDA) that greatly reduced the cost of generic entry ▪ Created an innovator Orange Book patent list and generic firm patent challenge process ▪ Provided a patent infringement safe harbor for testing before the brand patent expires ▪ Provided additional incentive in the form of 180-day exclusivity for first-filing successful ANDA filer	▪ Restored a portion of lost patent term protection (due to lengthening testing and approval time) ▪ Allowed exclusivities for innovator firms (5 years of data exclusivity, 3 years for new clinical investigations) ▪ Separate legislation created orphan drug and pediatric exclusivity incentives

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The Market Exclusivity Period

- Market exclusivity period (MEP) = the time between brand launch and initial generic entry
- Length of the MEP is determined by multiple factors:
  - Innovator launch timing relative to patents
  - Statutory IP protections for the innovator
  - Patent challenge outcomes
- It is the commercially relevant lifetime for the branded drug, and a key metric
  - Longer MEP provides more time for brand manufacturers to recover the cost of innovating new drugs, provides greater incentives for investment
  - Shorter MEP accelerates potential cost savings from generic entry

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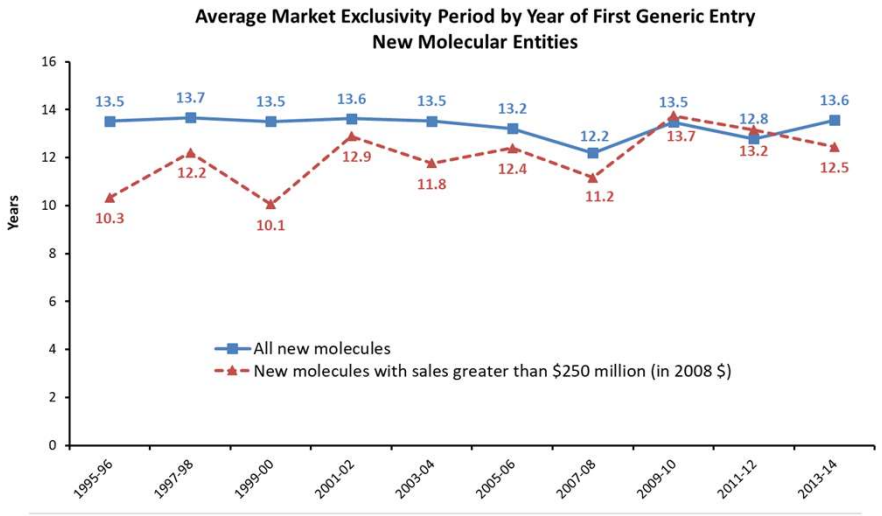
Market exclusivity periods average ~ 12-14 years overall



Source: Grabowski HG, Long G, Mortimer R, Boyo A. Updated trends in US brand-name and generic drug competition. J Med Econ. 2016 Sep;19(9):836-44. [6]

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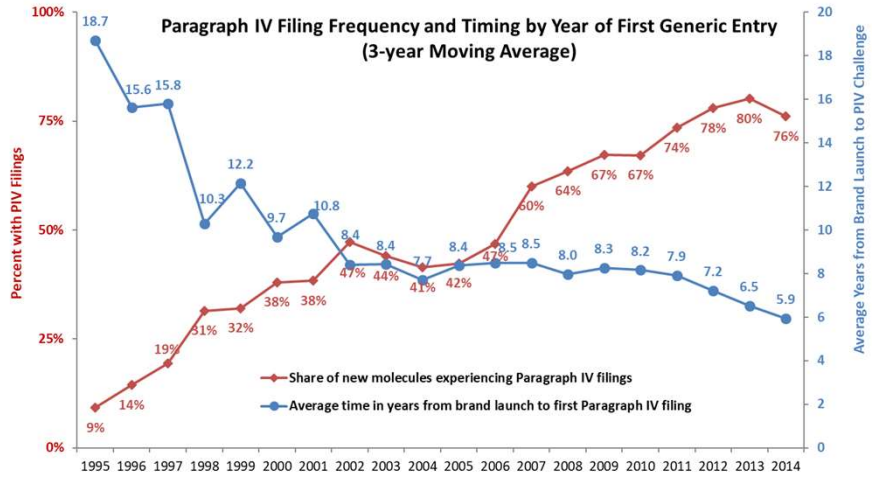
Generic patent challenges happen more often, earlier



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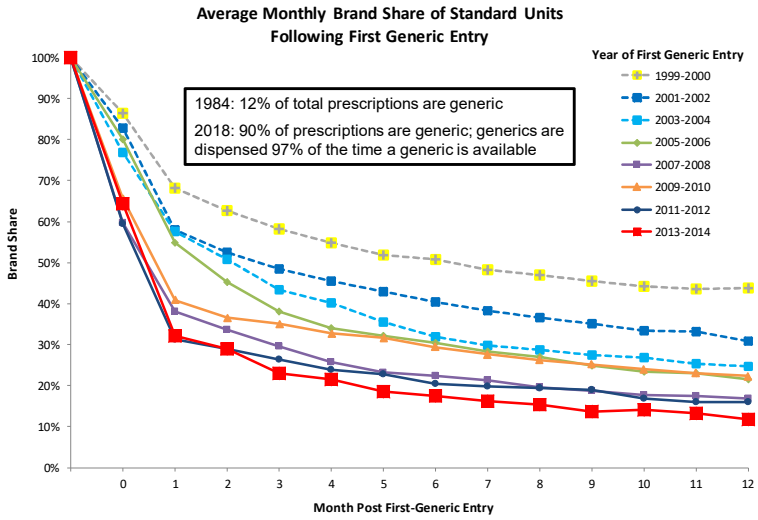
Brand erosion after generic entry has accelerated



Source: Grabowski HG, Long G, Mortimer R, Boyo A. Updated trends in US brand-name and generic drug competition. J Med Econ. 2016 Sep;19(9):836-44. 8

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Biologics Price Competition and Innovation Act (BPCIA)

- Enacted in 2010 as part of federal health care reform law
- Amends the Public Health Service Act and establishes new 351(k) pathway for follow-on biologics:
  - Biosimilar vs. interchangeable biological products
  - FDA determines standards for approval
- 12 years of exclusivity
  - 4 years until biosimilar application can be submitted
  - 8 additional years until application can be approved
  - No additional protection for new indications, routes of administration, dosing, delivery
- 1 year exclusivity for first interchangeable-rated biosimilar
- "Patent dance" patent dispute mechanism

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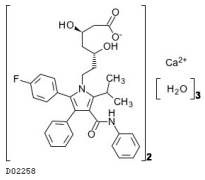
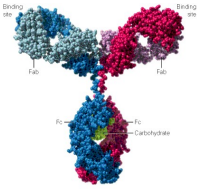
Differences -- Small Molecules and Biologics

	Small Molecules	Biologics
Source	Chemical synthesis	Cultures of living cells
Form	Generally oral solids	Injected or infused
Reimbursement	Pharmacy benefit	Often a medical benefit
Example	Lipitor (anti-cholesterol)  LIPITOR MW = 558.64	Herceptin (breast cancer)  HERCEPTIN MW = 185,000

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Differences – Generics and Biosimilars

	Generic Drugs	Biosimilars
Governing Law	Hatch-Waxman	BPCIA
Clinical Trials	No clinical trials	Clinical trials likely necessary
Substitution	Typically automatic pharmacy substitution	No biosimilar approvals to date are interchangeable
Manufacturing Costs	Capital costs low Manufacturing costs low	Capital costs high Manufacturing costs high
Marketing Costs	Generally N/A	Expected to be significant

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Differences – Some Market Implications

	Generic Drugs	Biosimilars (expected)
Economic Model	Established over 35 years	Emerging
Competitive Model	Price-based competition	Combined quality and price-based competition
Market Entrants	Low entry costs and often many entrants	Higher entry costs and fewer entrants
Share of Molecule	High share of molecule, achieved rapidly	Slower uptake and variation across therapeutic area, indication, specialty, etc., at least initially

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U.S. biosimilar approvals

Product	Number of Approved Biosimilars	First Biosimilar Approval	First Biosimilar Launch
Neupogen (Amgen)	2	Mar 2015	Sep 2015
Remicade (Janssen)	3	Mar 2016	Nov 2016
Enbrel (Amgen)	2	Aug 2016	—
Humira (AbbVie)	3	Sep 2016	—
Avastin (Roche)	1	Sep 2017	—
Herceptin (Roche)	4	Dec 2017	—
Procrit (Janssen) / Epogen (Amgen)	1	May 2018	—
Neulasta (Amgen)	2	Jun 2018	Jul 2018
Rituxan (Roche)	1	Nov 2018	—

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