

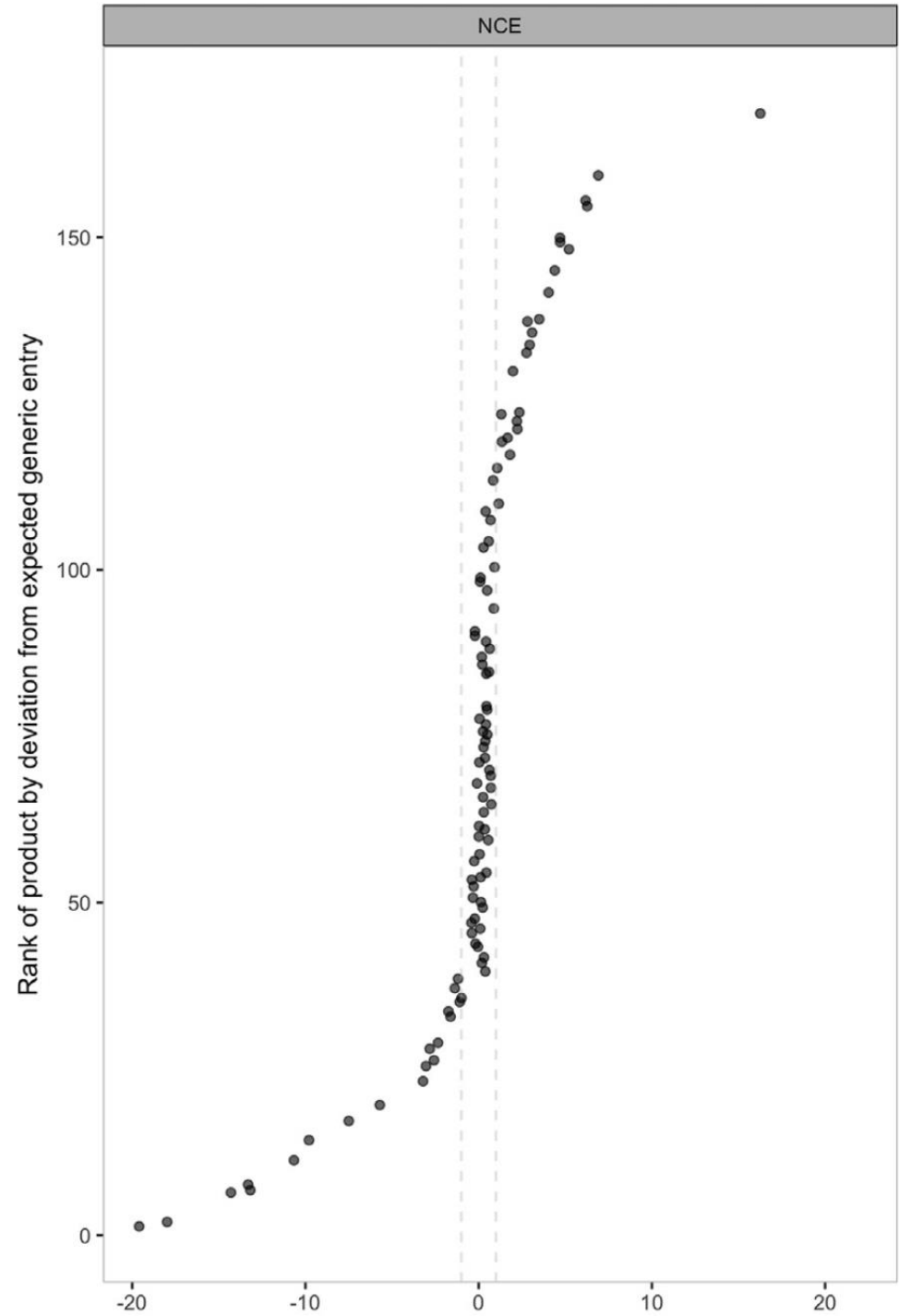


Healthcare Access and Innovation

S. Sean Tu
National Institutes of Health Care Management
December 11, 2024

Primary Patents

- Generic Market Entry
 - Active Ingredients
 - PTE Patents
-



The NEW ENGLAND JOURNAL *of* MEDICINE

- See Dave C, Hartzema A, Kesselheim AS. Prices of Generic Drugs Associated with Numbers of Manufacturers. *New England Journal of Medicine* 327(26): 2597-2598 (2017).

Patents Gamesmanship

Evergreening

Patent Thickets

Product Hops



Patent Thickets

- Patent Thickets Deter or Delay Strategy
- More Patents on Same Active Ingredients
- Increased Frequency of Method of Use Patents
- Increased Use of CONs



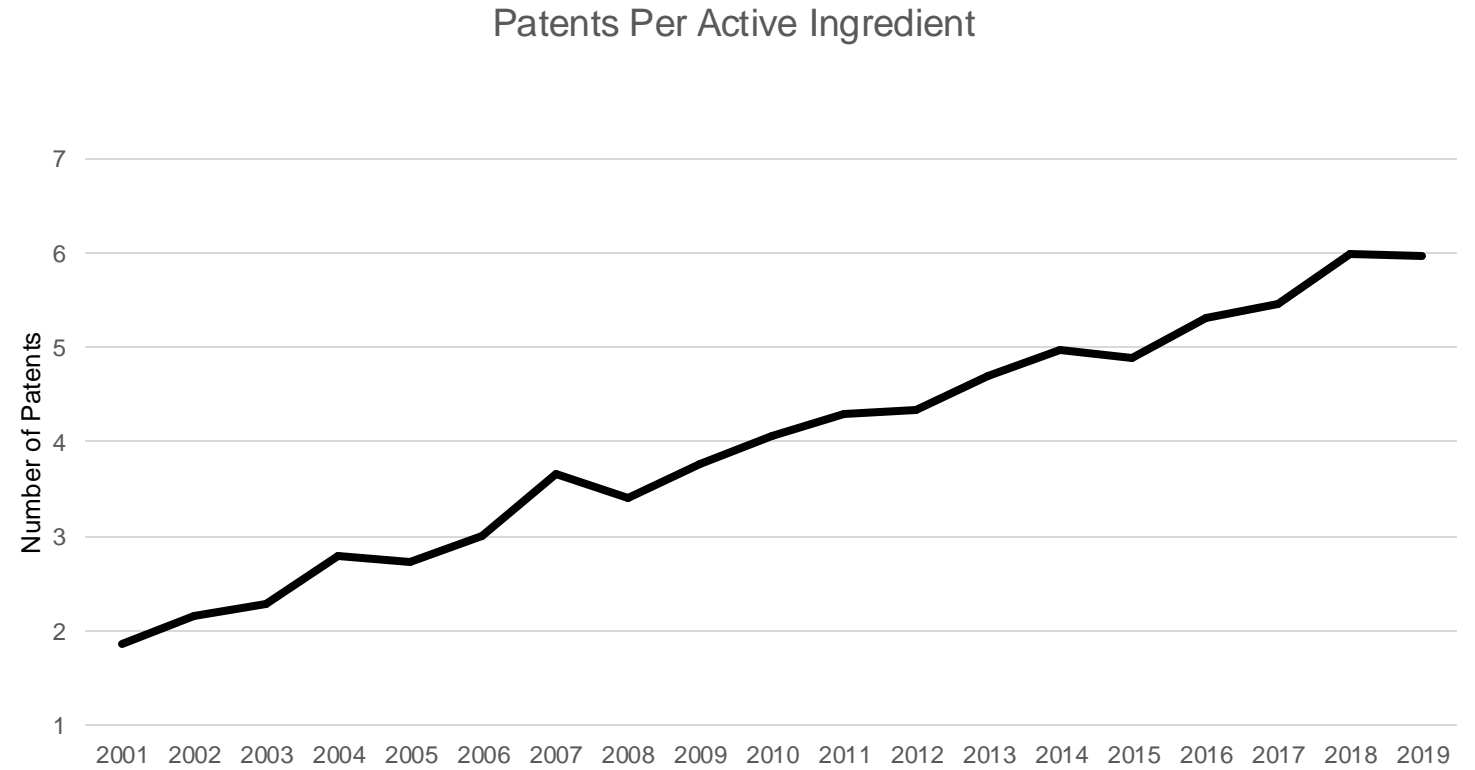
Typical Thicket Claims

- **US 8,629,111**: Topical ophthalmic emulsion comprising cyclosporin A, polysorbate 80, acrylate, water, and castor oil.
- **US 8,648,048**: Method of increasing tear production in eye comprising: administering cyclosporin A, polysorbate 80, acrylate, water, and castor oil.
- **US 8,685,390**: Method of treating dry eye disease comprising administering cyclosporin A, polysorbate 80, acrylate, water and castor oil.
- **US 9,248,191**: Method of treating keratoconjunctivitis sicca comprising administering cyclosporin A, polysorbate 80, acrylate, water and castor oil.



Increasing Use of Patent Thickets

- Increased Number of Patents per Active Ingredient
- Three-Fold Increase



Increased Healthcare Cost: Patents and Product Hops

See Wouters O, Feldman W, Tu SS. Product Hopping in the Drug Industry- Lessons from Albuterol. *New England Journal of Medicine* 387(13):1153-1156 (2022).

Humira Thickets

See Chao B, Whalen R, Kesselheim AS, Tu SS.
Clearing Dense Drug Patent Thickets. *New England
Journal of Medicine* (Published Online November 27,
2024).