The NBER Orange Book Dataset
A User's Guide

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December 2022

Linking patents to products

Patents are widely used as measures of innovation

- But mappings from **patents** to commercialized **products** are often unclear
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- Lists are published annually as the FDA's Orange Book
  - All patents (& regulatory exclusivities) associated with brand-name, small-molecule drugs

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This paper: a user's guide to the challenges and opportunities of this unique resource

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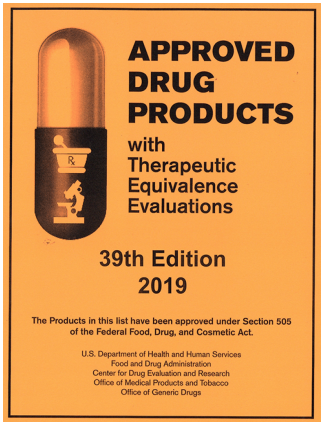
Focus on two challenges:

1. Orange Book records are self-reported by firms and not audited by the FDA
   $\Longrightarrow$ Validation exercises against external benchmarks
2. The appropriate use of the Orange Book may differ across researchers and questions
   $\Longrightarrow$ Detailed use case: calculating market exclusivity

Outline

Background



Patents and regulatory exclusivities added under **Hatch-Waxman Act (1984)**

(Drug Price Competition and Patent Term Restoration Act)

- Modern regime for competition for brand-name and generic drugs
- Includes a variety of features intended to accelerate entry of generic drugs

Patents

Eligible: Patents with > 1 claim covering drug substances, products, and methods of use

- Must list any patents that "could reasonably be asserted" [21 U.S.C. § 355(b)(1)(A)(viii)]
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Ineligible: Patents on manufacturing processes, packaging, metabolites, intermediates

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- Potential generic entrants are required to *challenge* every Orange Book patent
  - Legal certification that patent is either invalid or not infringed
  - "Paragraph IV challenges" often lead to generic entry [21 U.S.C. § 355(j)(2)(A)(vii)(IV)]

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Key feature: Infringement suits filed in response to Paragraph IV challenges

$\Longrightarrow$ Generic approval blocked for 30 months while suit is pending

Regulatory exclusivities

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Generic-blocking exclusivities

1. New chemical entity (NCE) exclusivity: **5 years**
2. Orphan drug exclusivity (ODE): **7 years**
3. Pediatric (PED) exclusivity: **6 months**
4. Generating Antibiotic Incentives Now (GAIN) exclusivity: **5 years**
5. 180-day exclusivity (Generic Drug Exclusivity): **180 days**

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Data Resources

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Four data files:

1. **FDA Drug Patents:** Full listing of patent records
   [edition, FDA application no., generic name, trade name, patent no., patent expiration]
2. **FDA Patent Use Codes**: Details on approved indications/uses [1998-present]
3. **FDA Drug Exclusivity**: Full listings of all exclusivities
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Dataset does not include all information in FDA Orange Book

- *e.g.*, the Products file, which identifies therapeutically equivalent alternatives for drugs
- Paper provides directions to expand coverage to more recent years

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* Note: does not include patent listings for biologics (some are listed in FDA's Purple Book)

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$\Longrightarrow$ Exclusivity records are **complete** and **accurate**

Patent coverage

Patent coverage reflects a mix of legal requirements and firm strategy

- Expect coverage to vary across drugs and firms
- May also vary over time: documented increase in listing of "secondary patents"
  [Kapczynski, Park, and Sampat 2012; Hemphill and Sampat 2011]

Patent coverage

Three validation exercises:

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$\Longrightarrow$ Records of all "important" drug patents are **complete**

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We investigate whether OB records reflect four changes to expiration dates:

1. Agreement on Trade-Related Aspects of IP Rights (TRIPS)
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$\Longrightarrow$ **High-level:** all changes are **accurate** except maintenance fees

- Substantial problem: $\sim$45 percent of OB patents expire before full-term
- Accurate measures of patent term require additional USPTO records

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Calculating exclusivity: combining records

The "right" calculation of market exclusivity is a function of the research question

- *Nominal*: How much market exclusivity do various legal protections confer?
- *Expected*: How long can a firm expect to be shielded from competition?
- *Realized*: How much time actually elapsed before generic entry?

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Paper provides detailed advice for calculation of "legal protection periods"

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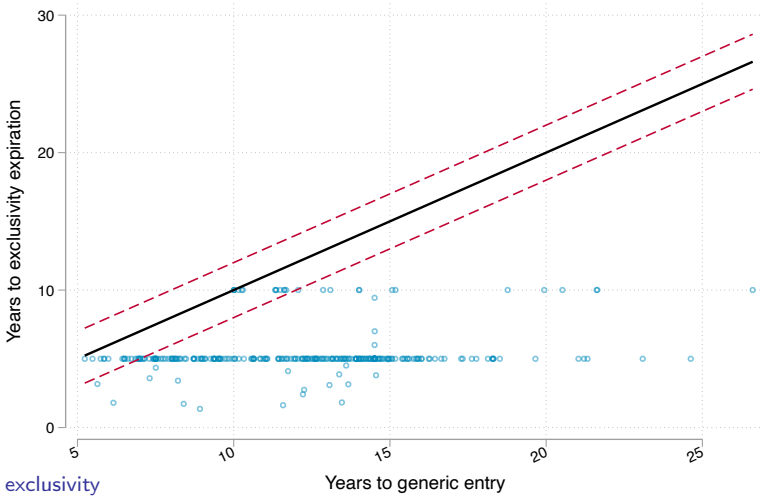

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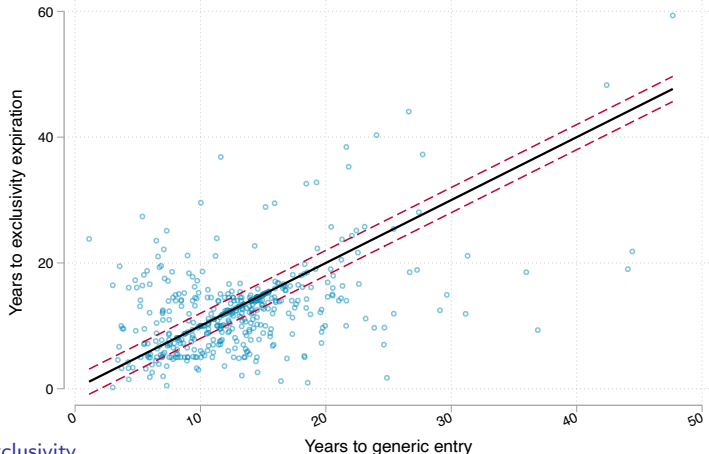

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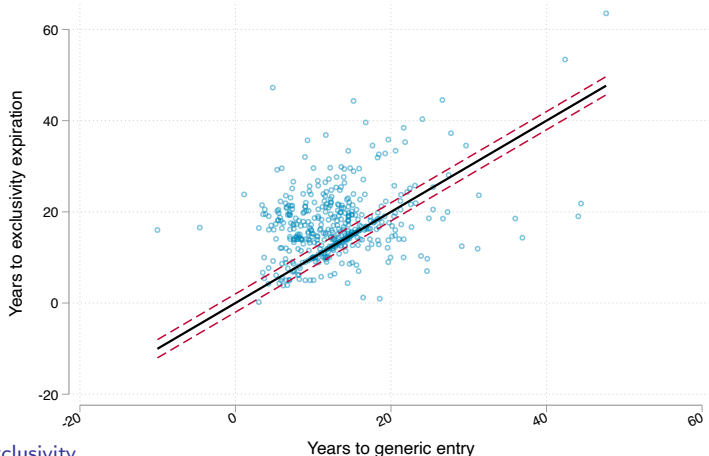

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Using the Orange Book for research

Key advantages:

- Unique opportunity to study linkages between patents and products
  - Rich resource for understanding pharmaceutical markets
- Variables facilitate a wide variety of linkages to other datasets
  - Drug name, sponsor, patent number, FDA application number
- *Good news:* Records are generally complete and accurate
  - Exception: maintenance fee non-payment

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"Calculating exclusivity" $\Longrightarrow$ Appropriate use of data is based on questions of interest