Orange Book Stories

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The challenge

- Saying something new about Orange Book patenting
  - Lots of great papers out there
  - Lots of great data out there
- Finding Recent data
  - No two papers seem to use the same data
  - Even the best data sets are outdated
  - PatEx stops in 2022, which means losing years of granted patents and new applications

The Solution – update it all

- Step 1 – Build the full Orange Book list
- Step 2 – Update PatEx
- Step 3 – Find something interesting and new to say

Step 1 – Building the Orange Book List the lazy scholar's way

- Grab all the patents listed in the NBER Orange Book database (~5500)
  - This is very good on the older patents, but stops in 2016
- Grab all the patents listed as Orange Book in Lexis Total Patent One (~9950)
  - This is very good on newer patents, but is missing many older patents
- Join the two

- Current total ~11,000 Orange Book patents

Step 2: Extending PatEx – the not so lazy way

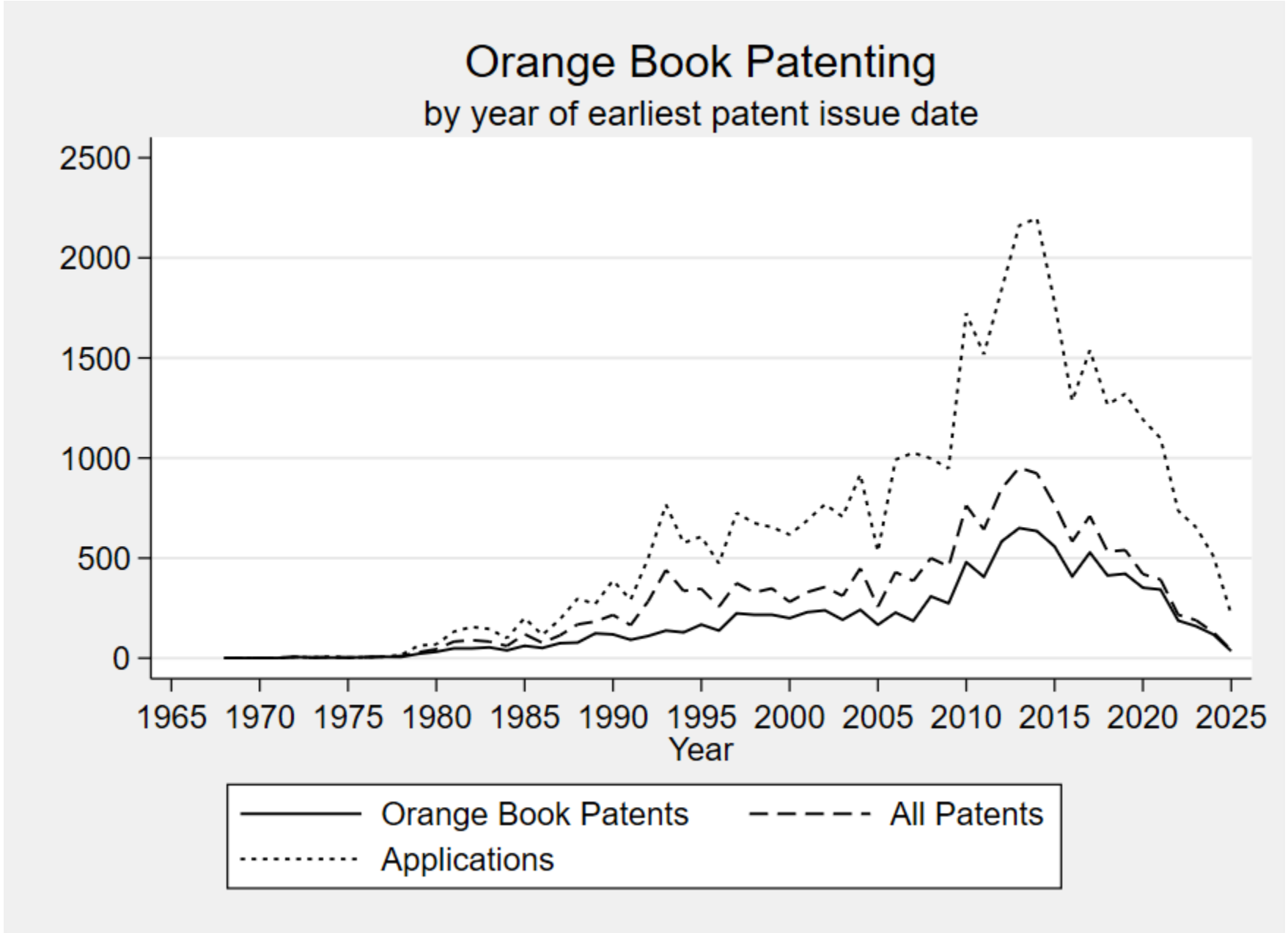
- Download bulk Patent File Wrapper data from PTO (JSON format)
- Develop streaming JSON reader to convert each application record into several CSV files with unique key
- Import CSV files into Stata and format variables to match PatEx Database
- Merge imported files into PatEx, updating existing records and adding new
  - e.g. add issued patents, new parents, new children
  - e.g. add new applications that were not published as of 2023 PatEx release
- Rinse and repeat for each year, testing to see whether changes justify the time

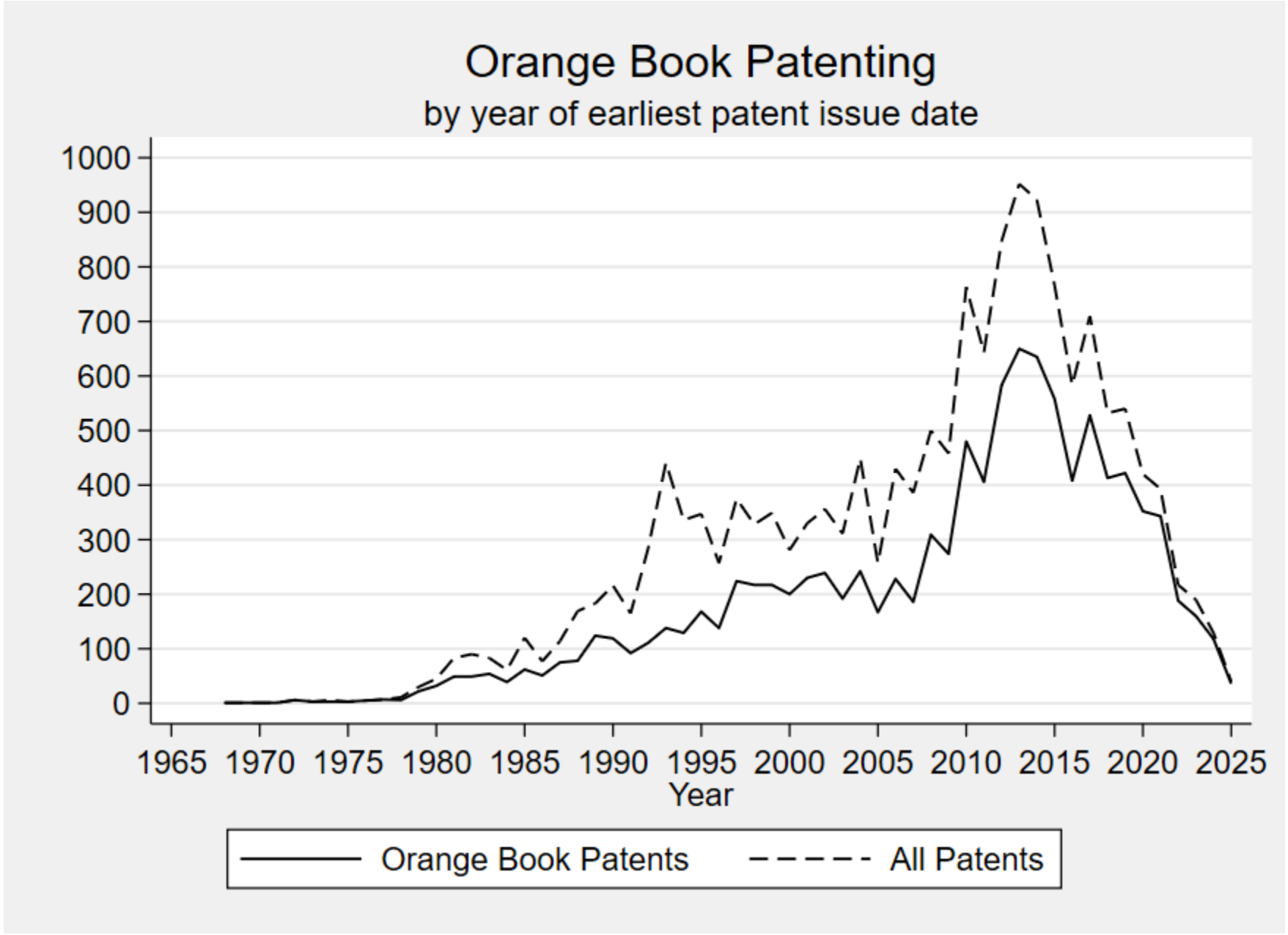
- Final tally: Added updated records from 2018-2025 to system
  - 2019 added 13,000 new patents, nearly 20% of applications
  - 2018 added only 2,000 new patents, good enough for me
  - 300 of 11000 OB patents still missing from updated PatEx
    - Will likely import <2017 at some point

Step 3 – Anything interesting?

Key difference from other studies

- This study is based on patent families, not drugs
  - ~4700 families <> number of drugs
- There could be single families that apply to multiple Orange Book entries
- There could be multiple families that apply to single Orange Book entries
- Dates will not match
  - Most studies use approval date
  - This study uses filing and grant dates, which can be offset one way or the other
- Nonetheless, a cursory comparison to other papers shows that the trends are the same over similar time periods


Orange Book Patenting
by year of earliest patent issue date
2500
2000
1500
1000
500
0
1965 1970 1975 1980 1985 1990 1995 2000 2005 2010 2015 2020 2025
Year
Orange Book Patents
All Patents
Applications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by year of earliest patent issue date
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900
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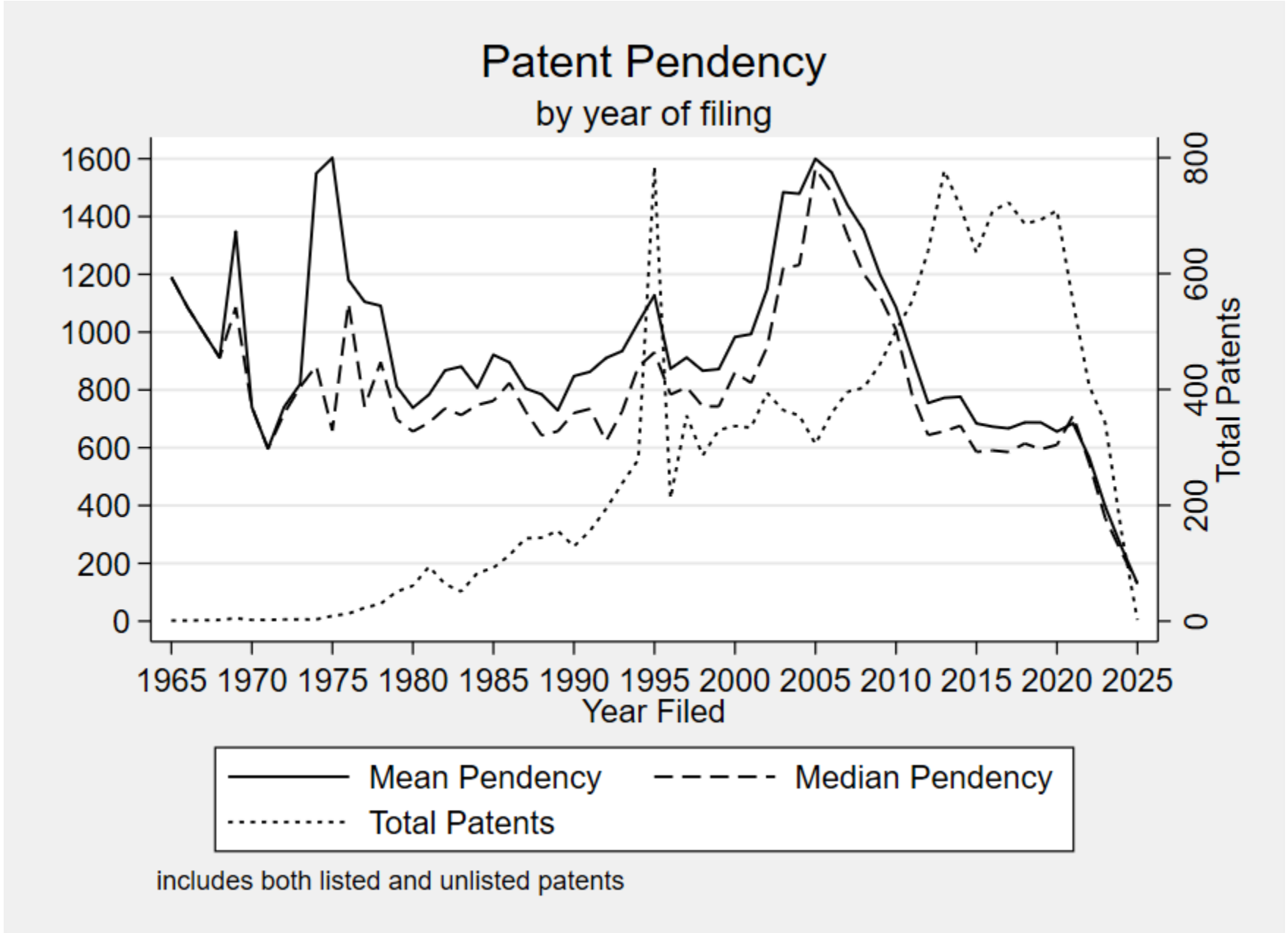
2025
Year
Orange Book Patents
All Patents


Patent Pendency
by year of filing
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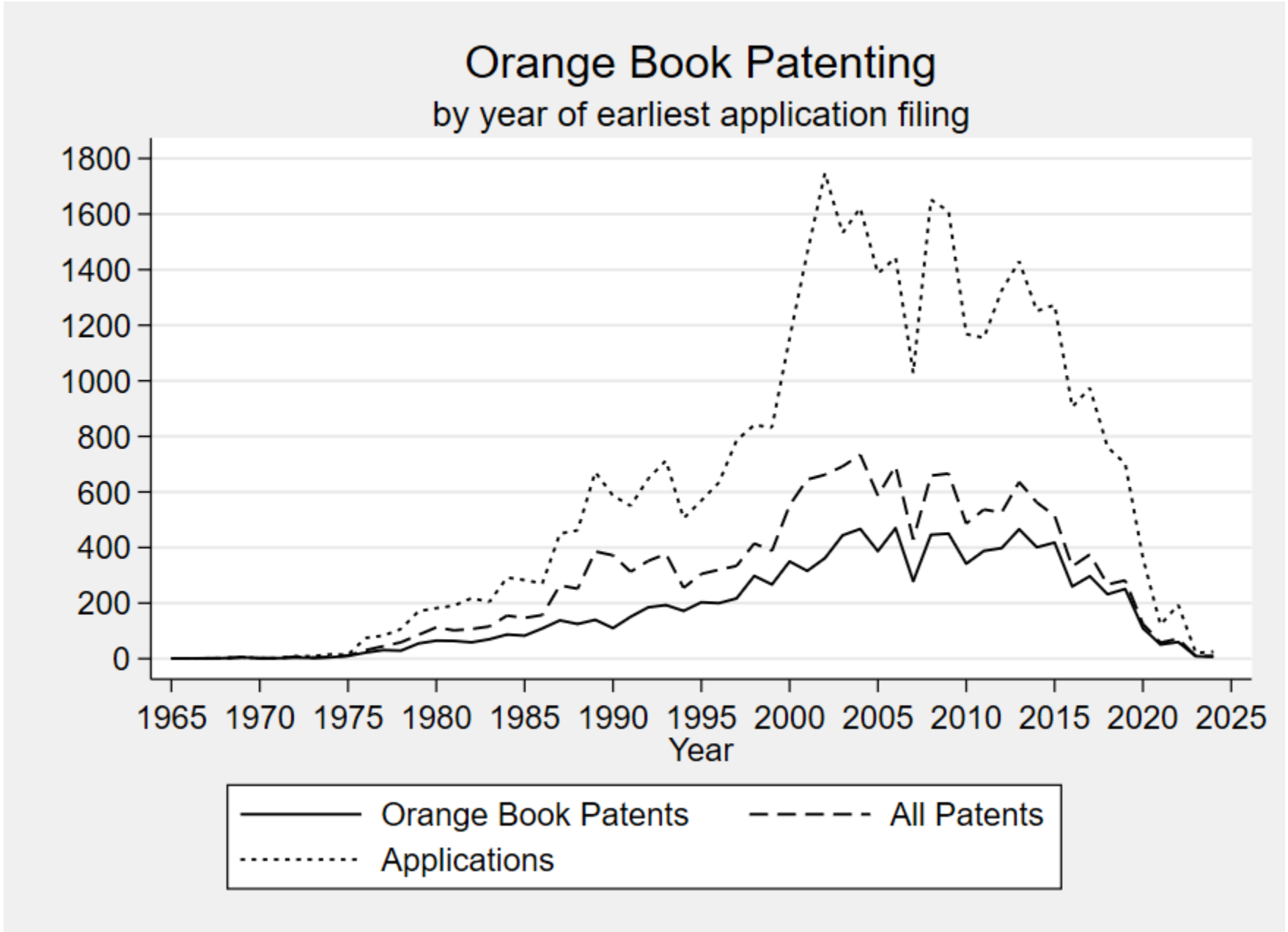
1400
1200
1000
800
600
400
200
0
800
600
400
200
0
Total Patents
1965 1970 1975 1980 1985 1990 1995 2000 2005 2010 2015 2020 2025
Year Filed
Mean Pendency
Median Pendency
Total Patents
includes both listed and unlisted patents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by year of earliest application filing
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1600
1400
1200
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800
600
400
200
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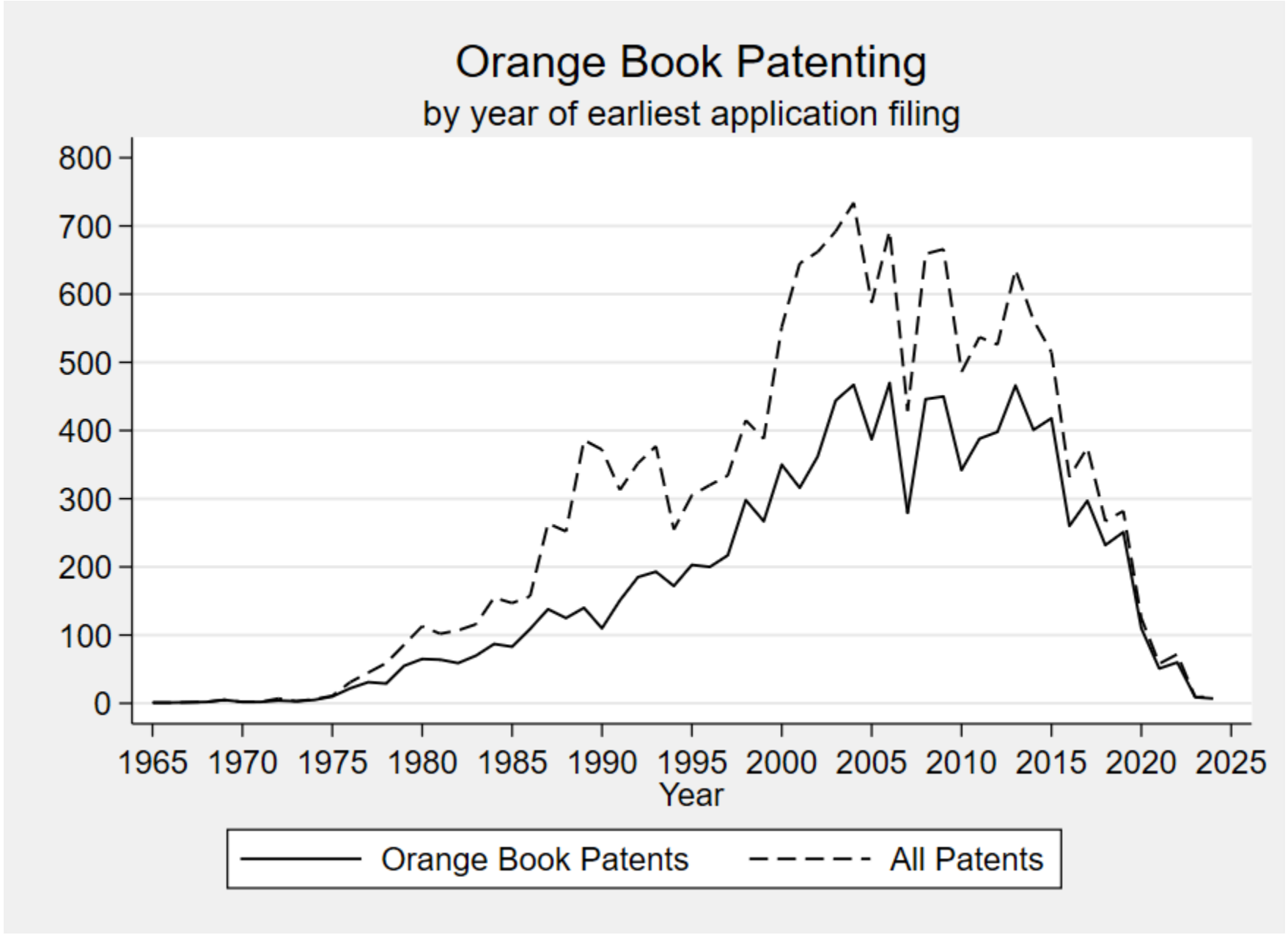
Year
Orange Book Patents
All Patents
Applications


Orange Book Patenting
by year of earliest application filing
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700
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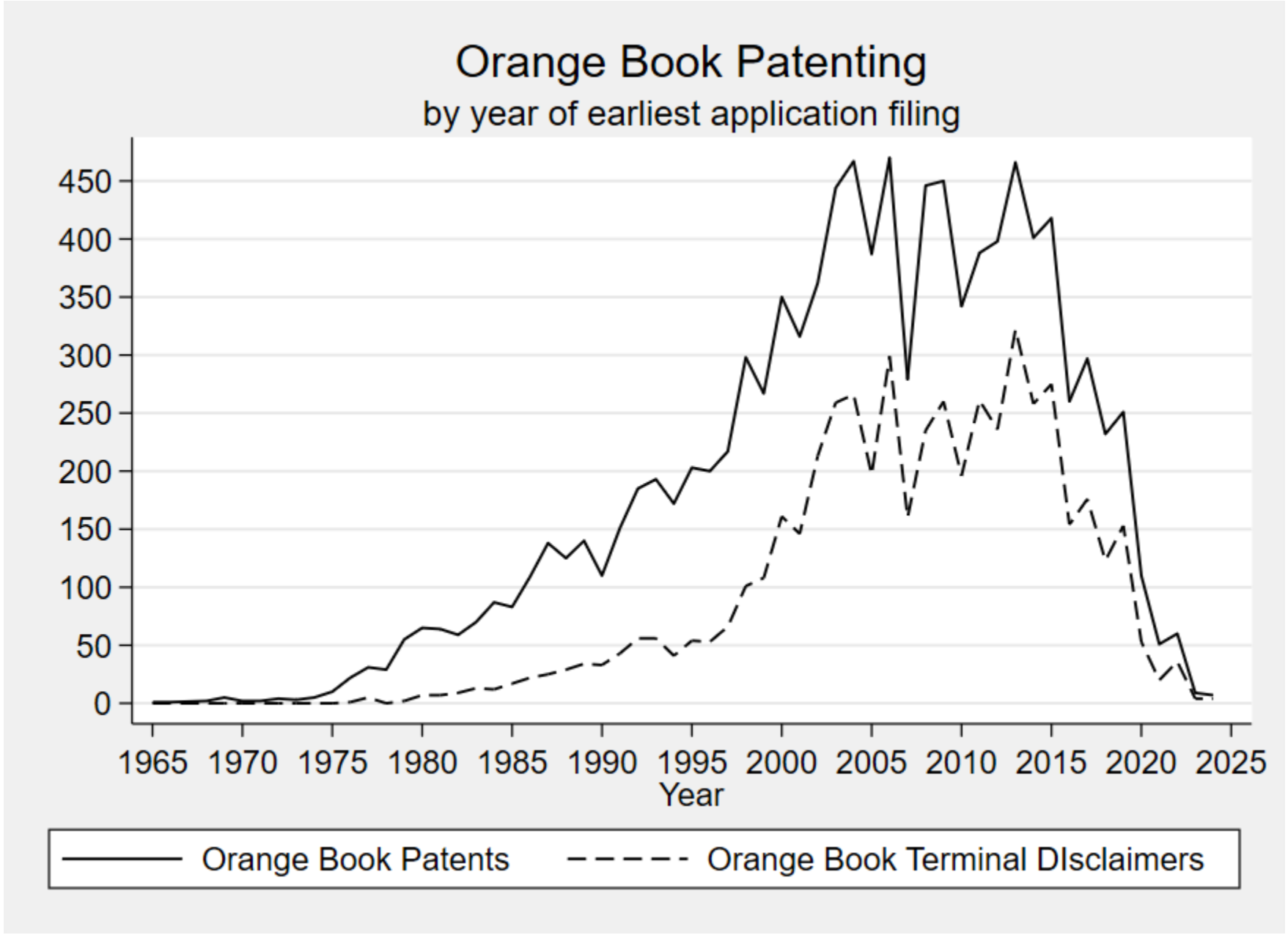
2025
Year
Orange Book Patents
All Patents


Orange Book Patenting
by year of earliest application filing
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400
350
300
250
200
150
100
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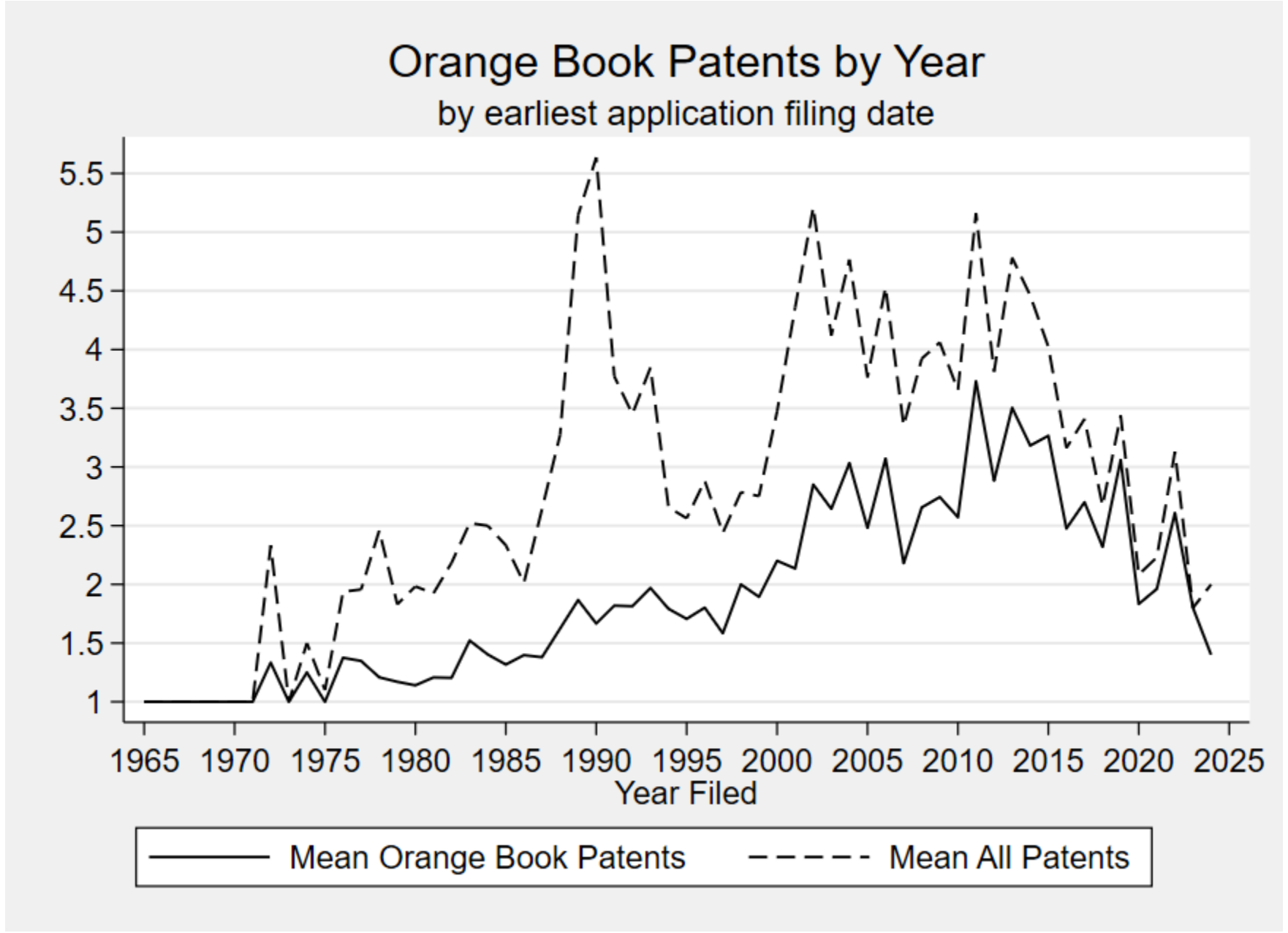
2015
2020
2025
Year
Orange Book Patents
Orange Book Terminal DIsclaimers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by earliest application filing date
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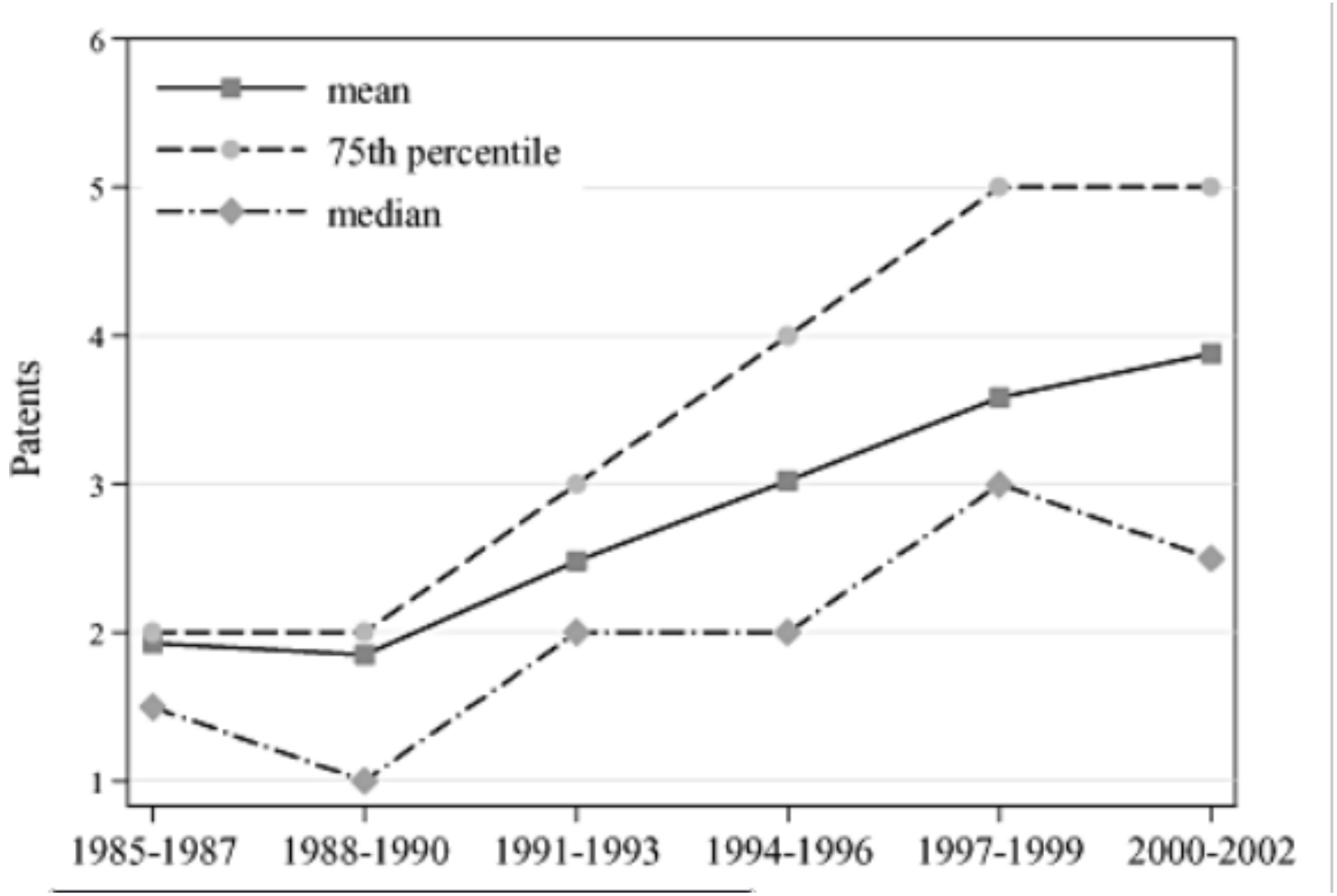
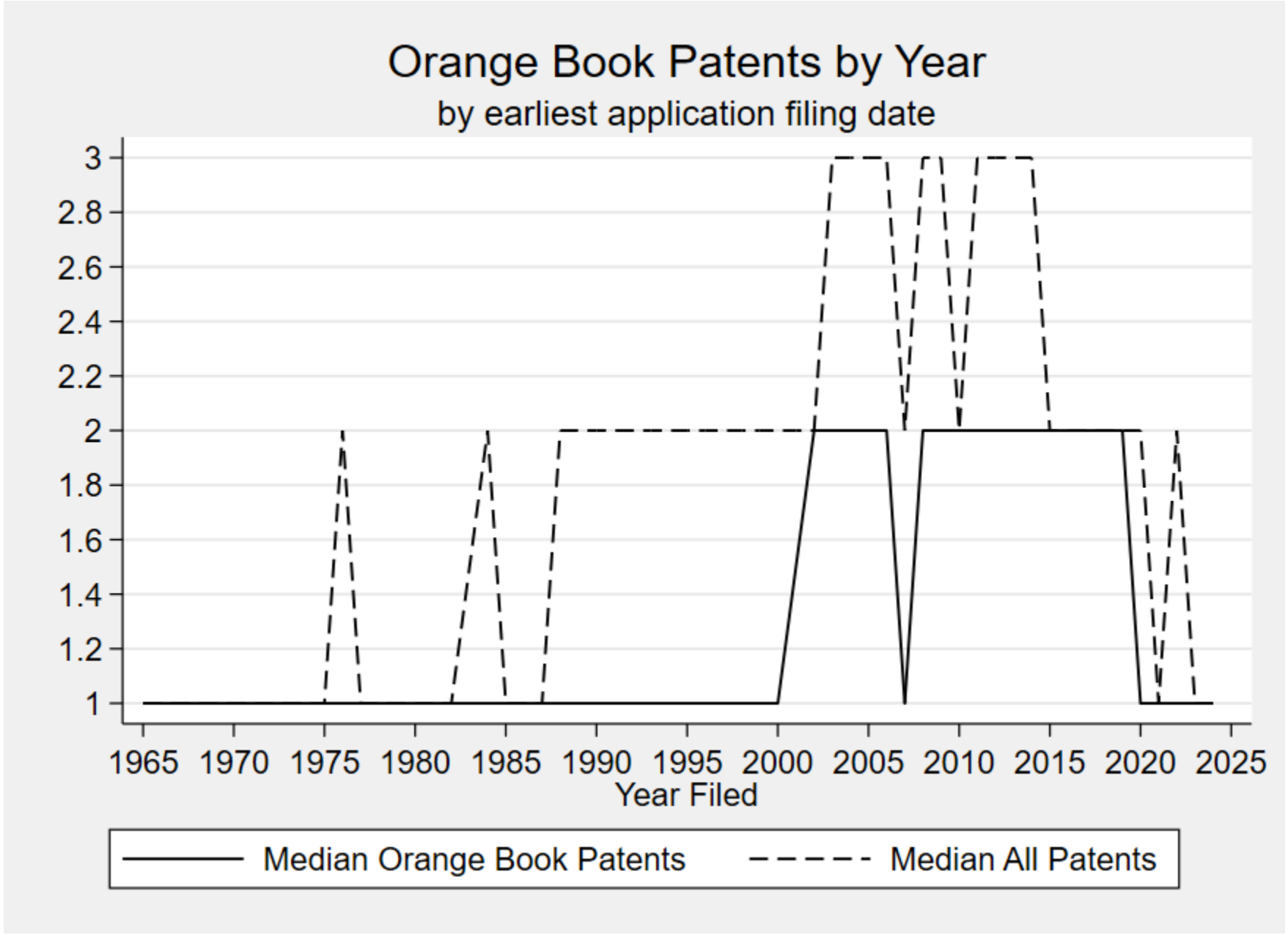
5
4.5
4
3.5
3
2.5
2
1.5
1
1965 1970 1975 1980 1985 1990 1995 2000 2005 2010 2015 2020 2025
Year Filed
Mean Orange Book Patents
Mean All Patents

Hemphill & Sampat 2011

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by earliest application filing date
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2.2
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1.6
1.4
1.2
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1985
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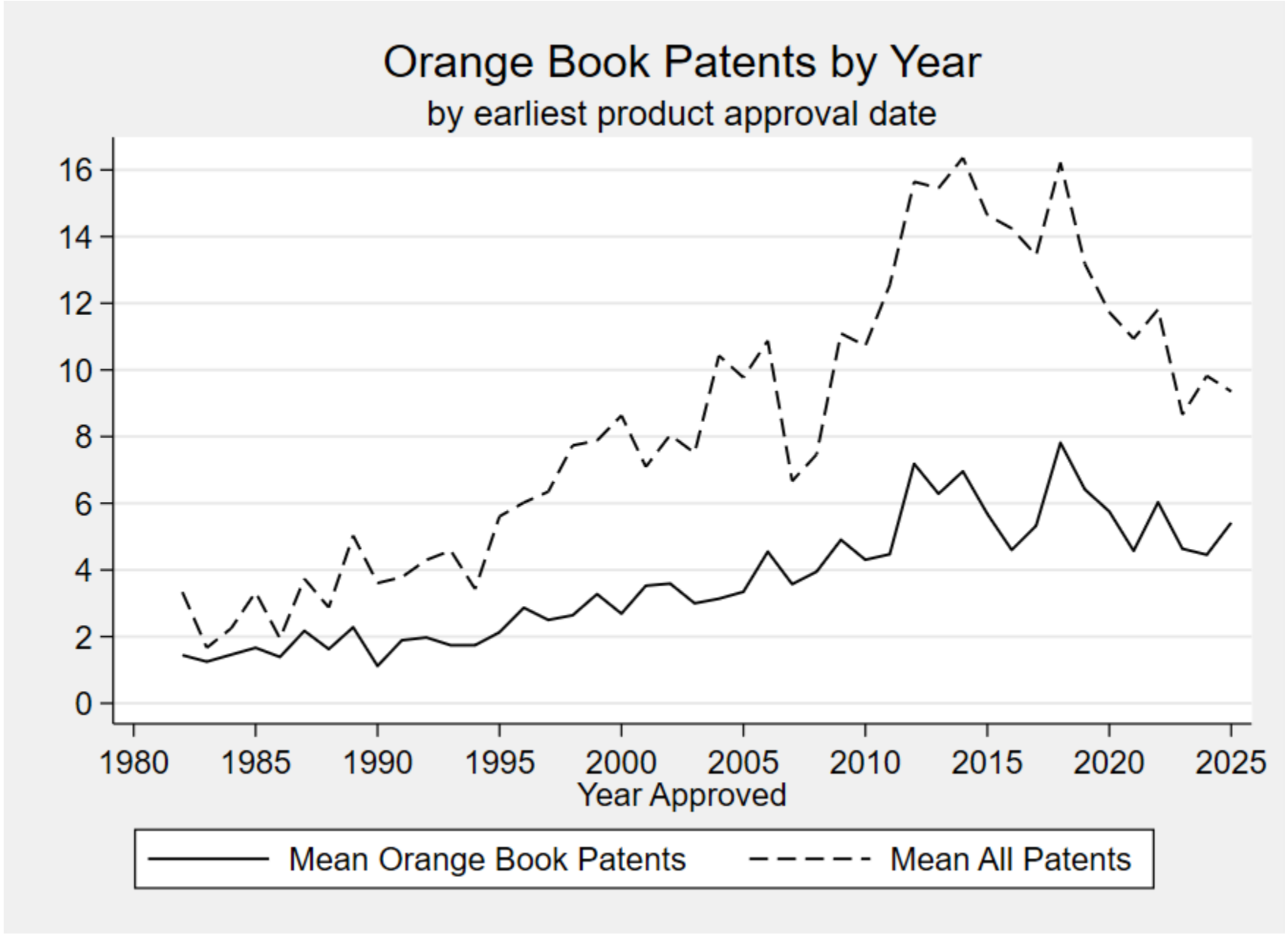
2025
Year Filed
Median Orange Book Patents
Median All Patents


Orange Book Patents by Year
by earliest product approval date
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14
12
10
8
6
4
2
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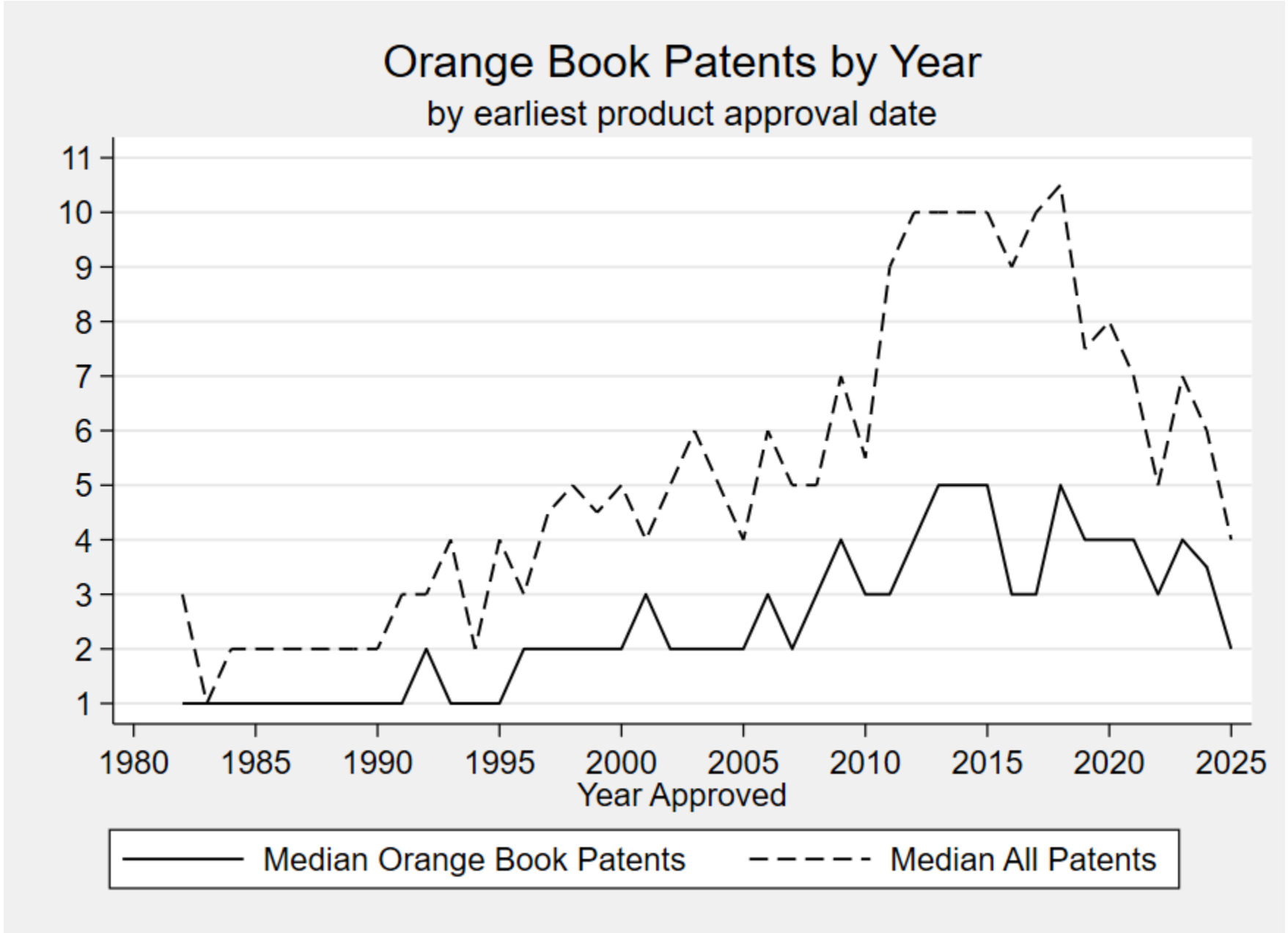
1985
1990
1995
2000
2005
2010
2015
2020
2025
Year Approved
Mean Orange Book Patents
Mean All Patents


Orange Book Patents by Year
by earliest product approval date
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8
7
6
5
4
3
2
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1985
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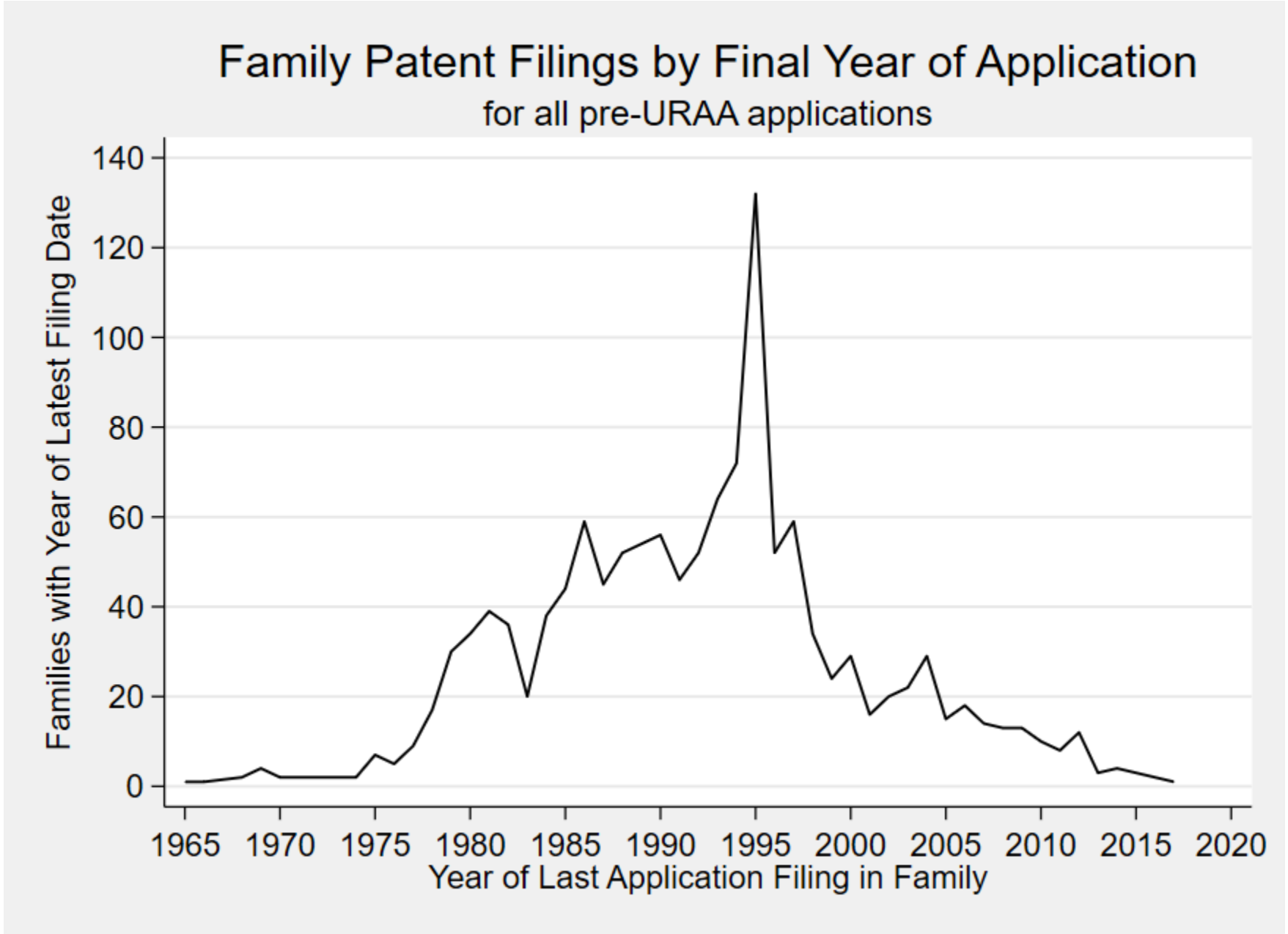
2000
2005
2010
2015
2020
2025
Year Approved
Median Orange Book Patents
Median All Patents


Family Patent Filings by Final Year of Application
for all pre-URAA applications
Families with Year of Latest Filing Date
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20
40
60
80
100
120
140
1965
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1975
1980
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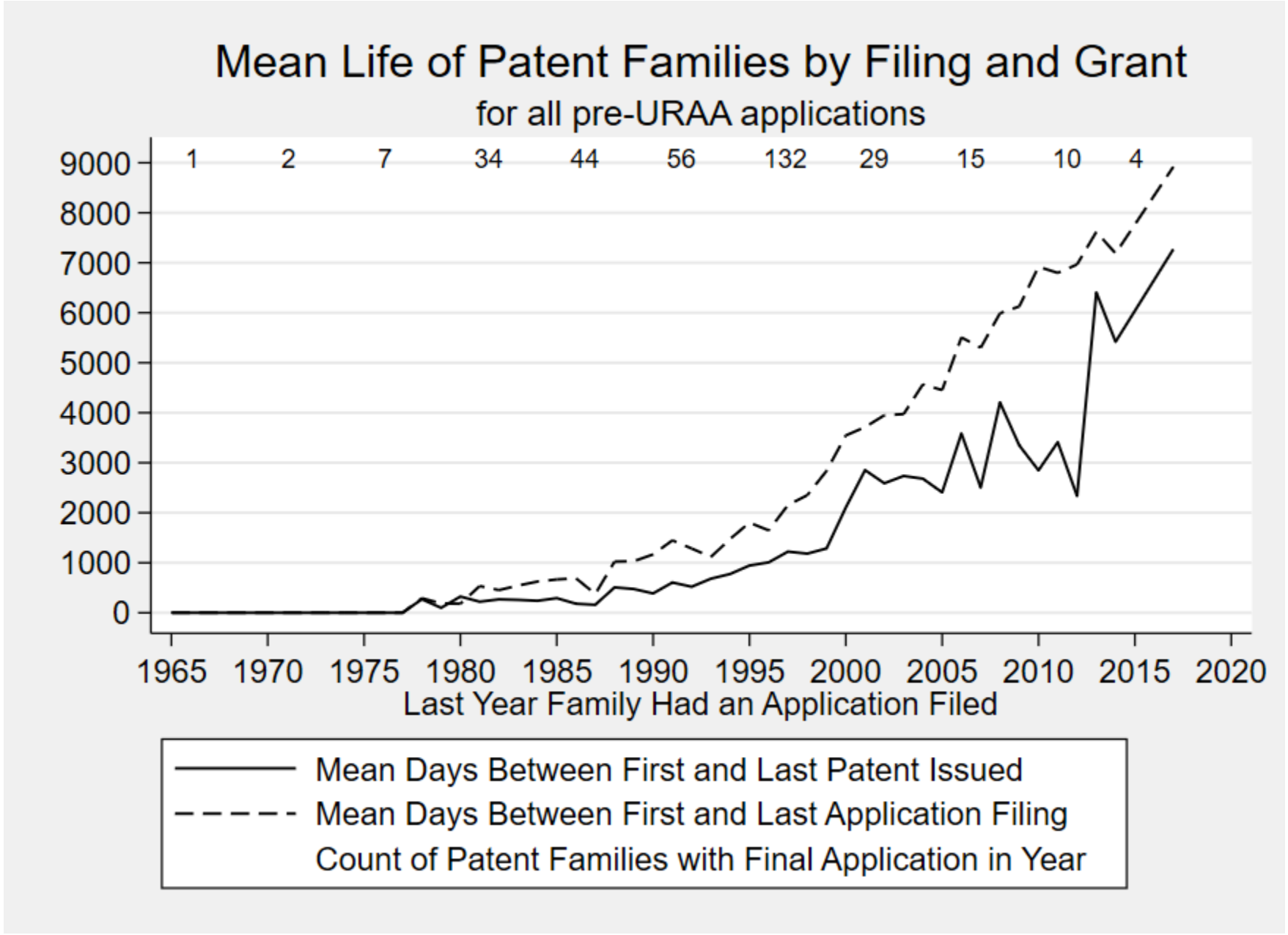
2015
2020
Year of Last Application Filing in Family


Mean Life of Patent Families by Filing and Grant
for all pre-URAA applications
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2
7
34
44
56
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29
15
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4
9000
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7000
6000
5000
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1965
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2020
Last Year Family Had an Application Filed
Mean Days Between First and Last Patent Issued
Mean Days Between First and Last Application Filing
Count of Patent Families with Final Application in Year

Inventor Overlap

	Frequency	Percent
All Inventors The Same		
0	1,883	48.51%
1	1,999	51.49%
Total	3,882	100.00%

	Frequency	Percent
Some Overlap Among All Patents		
0	426	10.97%
1	3,456	89.03%
Total	3,882	100.00%

Sanity Check

Hypocalcaemic Peptides And Process For Their Manufacture

DOCUMENT ID	DATE PUBLISHED
US 4347242 A	1982-08-31

INVENTOR INFORMATION

NAME	CITY	STATE	ZIP CO
Neher; Robert	Binningen	N/A	N/A
Riniker; Bernhard	Frenkendorf	N/A	N/A

ASSIGNEE INFORMATION

NAME	CITY	STATE	ZIP CO
Ciba-Geigy Corporation	Ardsley	NY	N/A

TYPE CODE
02

APPLICATION NO	DATE FILED
05/889066	1978-03-22

Hypocalcaemic Peptides And Process For Their Manufacture

DOCUMENT ID	DATE PUBLISHED
US RE32347 E	1987-02-03

INVENTOR INFORMATION

NAME	CITY	STATE	ZIP CODE	COUNTRY
Neher; Robert	Binningen	N/A	N/A	CH
Riniker; Bernhard	Frenkendorf	N/A	N/A	CH

ASSIGNEE INFORMATION

NAME	CITY	STATE	ZIP CODE	COUNTRY
Ciba-Geigy Corp.	Ardsley	NY	N/A	N/A

TYPE CODE
02

APPLICATION NO	DATE FILED
06/644696	1984-08-27

Sanity Check

PCT#

PCT/US13/23312

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PCT#

PCT/US13/23315

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Sanity Check

Application #

17/831,209

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Application #

16/387,504

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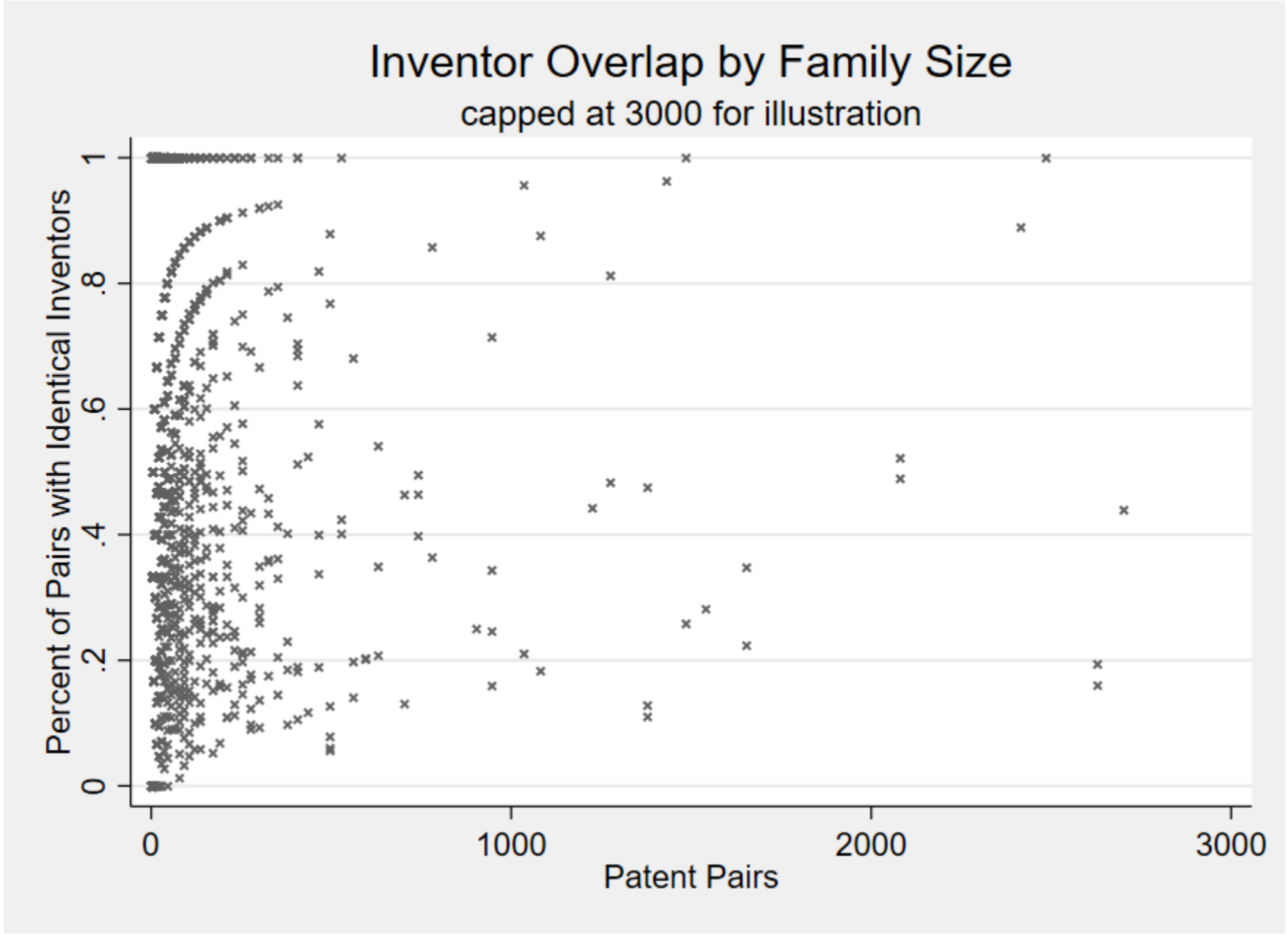
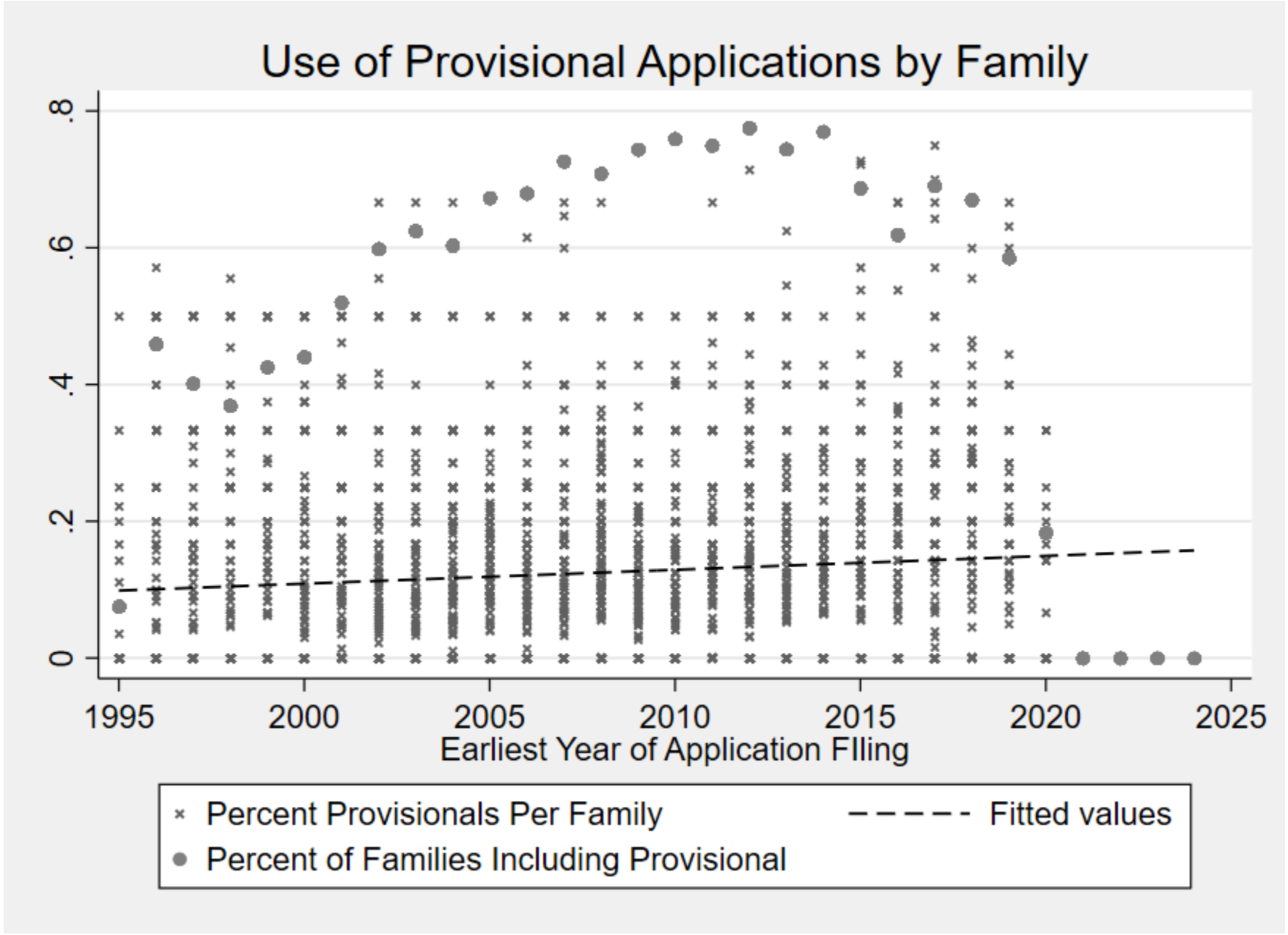

Inventor Overlap by Family Size
capped at 3000 for illustration
Percent of Pairs with Identical Inventors
0
.2
.4
.6
.8
1
0
1000
2000
3000
Patent Pairs


Use of Provisional Applications by Family
0
.2
.4
.6
.8
1995
2000
2005
2010
2015
2020
2025
Earliest Year of Application FIling
Percent Provisionals Per Family
Percent of Families Including Provisional
Fitted values

Possible next steps

- Break down by product?
  - Challenge: substantial patent overlap
- Does family size deter generic entry/ANDA litigation?
  - Challenge: timing of patents v. timing of litigation
  - Challenge: including sales (see, e.g. Hemphill & Sampat 2011)
- Did 2003 changes to listing rules affect listing volume?
- Timing analysis – are patents expiring later?
  - Challenge – comparing families withing NDA grouping
- Compare with litigation and IPR outcomes
  - Cf. Tu & Lemley
- Other stuff?