Marketing Authorization and Strategic Patenting: Evidence from Pharmaceuticals

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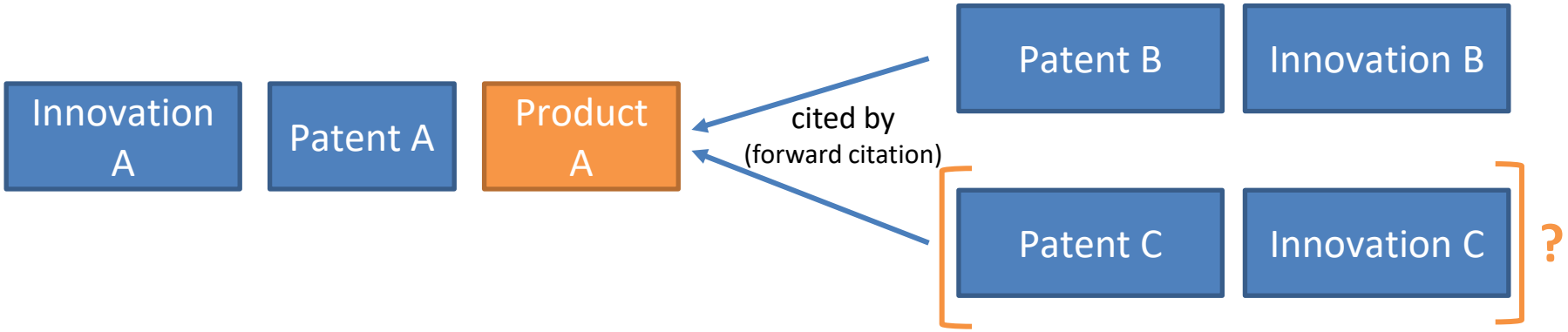
Journal of Public Economics, 2025

https://doi.org/10.1016/j.jpubeco.2025.105415

Drugs save lives, but too costly with many patents!

- Patent systems are designed to promote innovation (Mansfield 1986; Lakdawalla 2018), but strategic patenting limits drug access (EC 2009)
  - E.g., evergreening (extends length) and fencing (extends breadth)
- Trade-off: static efficiency vs. R&D incentives -> debates on patentability
  - US Supreme Court cases: Mayo 2012, Myriad Genetics 2013
- This paper: how info disclosure in market authorization (MA) affect follow-on patenting (Trial docs disclosed can function as new "prior arts")



EPO "gold standard" examination quality (Chien 2018), patent citation: follow-on patenting

Research Question:

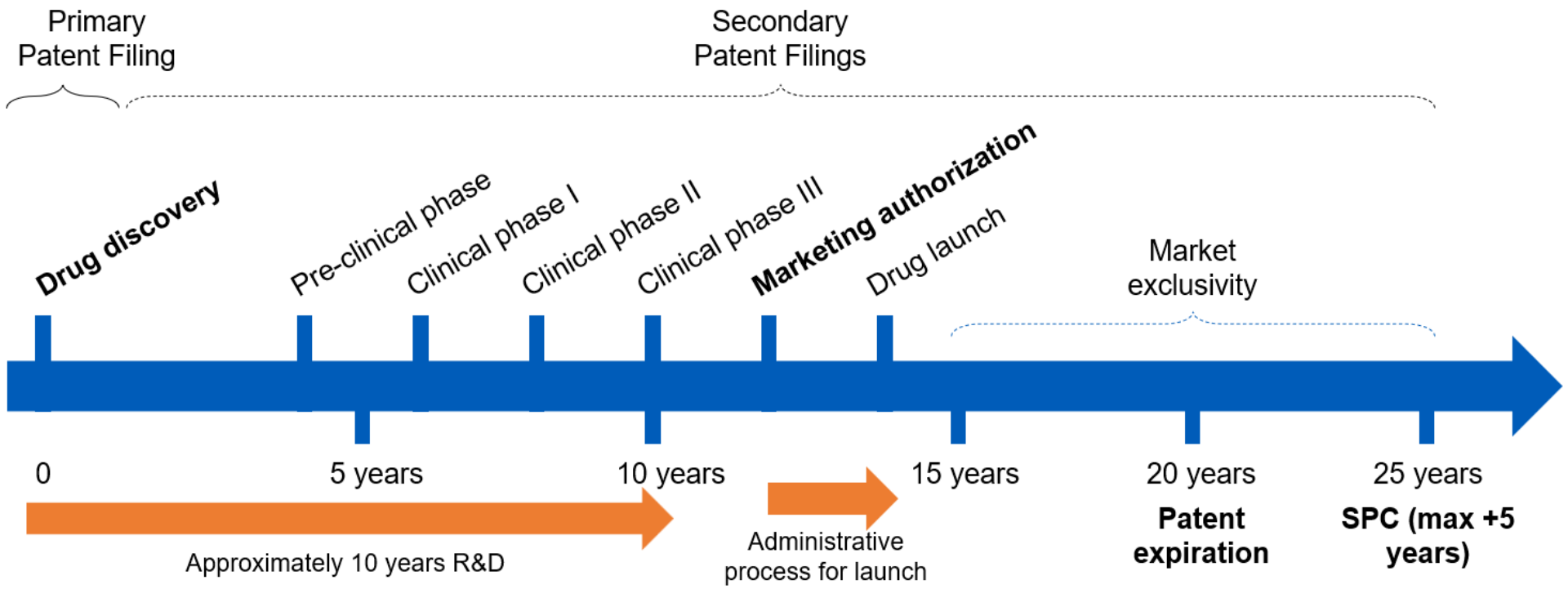
Q: How does marketing authorization of a new drug (new NME) affect follow-on innovation building upon focal drug?

- Intuitively, follow-on patenting can go either way (an empirical Q):
  - More: “Time to explore other new indications and expand the market!”
  - Less: “Time to lay flat and relax, as profit is coming in our way!”
  - Same: “I cannot decide, so maybe just good to patent as usual?”
- Exploit the authorization of new drugs to the (EU/EEA) market, utilize the variation in approval lags (that do not differ by ex-ante patent char.)
- Examine how a drug’s marketing authorization affects the rate & direction on follow-on patenting by firms (selves, related parties, others)

Literature and Contribution

- **Secondary patents**: examine the relationship btw market authorization and follow-on patenting (of different types & by different parties)
  - (Lemley & Moore 2004; Amin & Kesselheim 2012; Sampat & Shadlen 2017; Hemphill & Sampat 2011; Frakes & Wasserman 2023; Gupta 2023)
- **Intellectual property institutions and follow-on innovation**: leverage novel European institutional details and rich drug-patent dyadic data
  - (European Commission 2009; Hemphill & Sampat 2013; Sternitzke 2013; Galasso & Schankerman 2015; Gaessler et al. 2023; Sampat & Williams 2019)
- **Firm innovation strategies**: how downstream product events intertwine with upstream patenting behaviors in a heavily regulated industry
  - (Acemoglu & Linn 2004; Arcidiacono et al 2013; Budish et al. 2015; Dubois et al 2015; Gaessler & Wagner 2020; Kyle & McGahan 2012; Wang 2022)
- **Policy implication**: ex ante regulation, self-adjustment, & patent quality

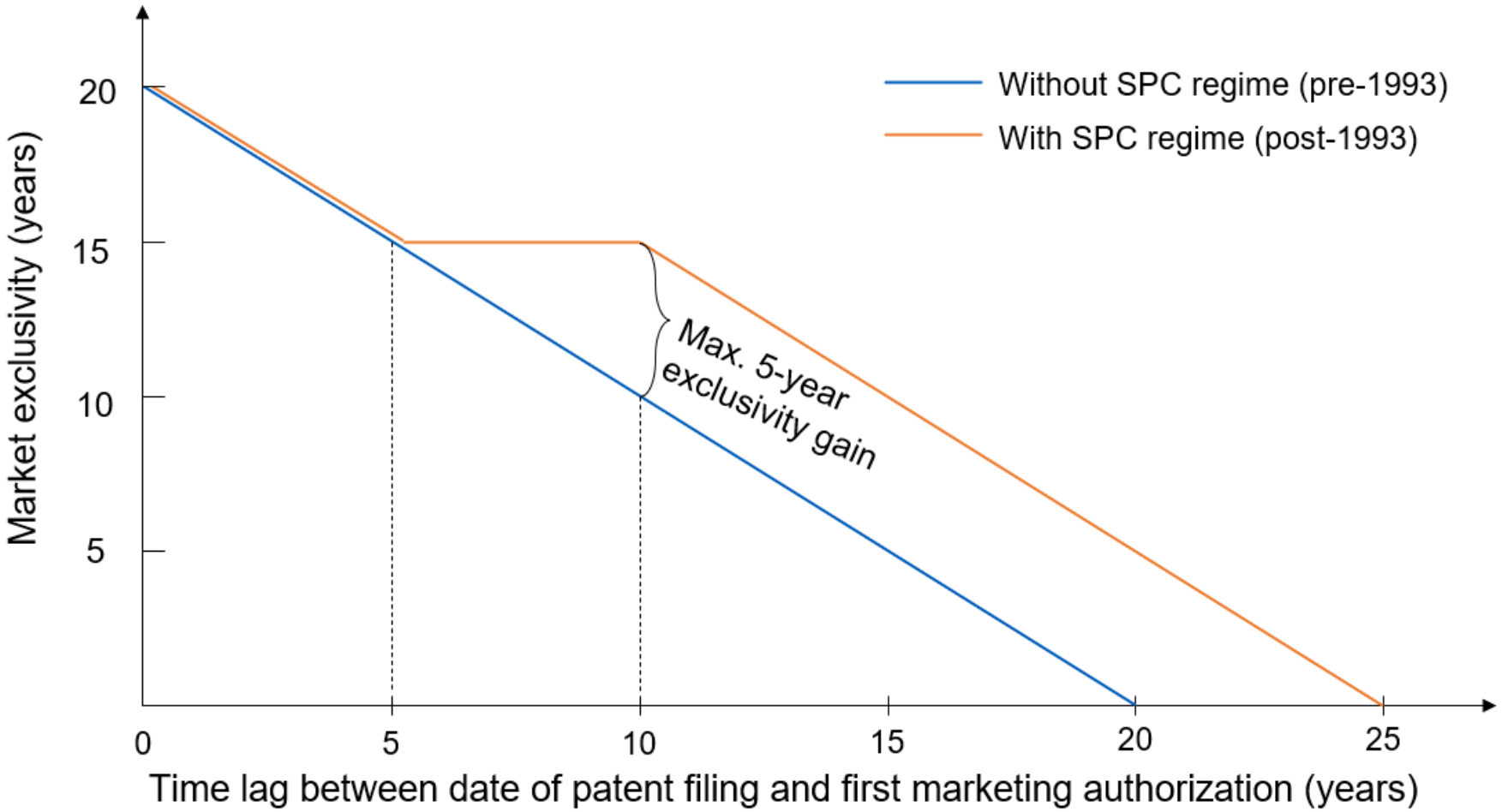
The Drug Development Process in EU (EEA)



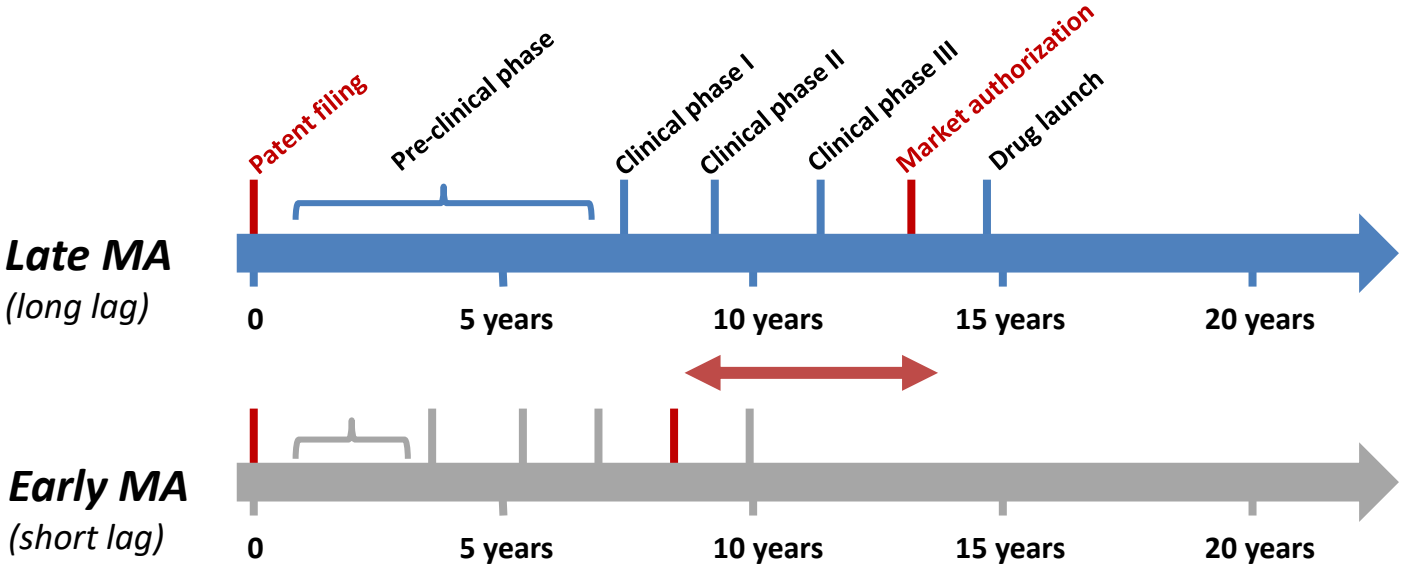
- In European Economic Area (EU+Iceland, Liechtenstein, Norway), originators submit applications for market authorization to European Medicines Agency (/national)
  - verifies safety, efficacy, quality; drugs can then be sold for approved indications
- Market exclusivity: firms hold exclusive right to market/sell a patented drug

EU Patent Term Extension (SPC Regime)

- Supplementary Protection Certificates (SPC) regime, 1993- : extension capped at 5 years; market exclusivity constant for patents w/ 5-10 years' approval lag
- SPC term (≤5 years)= date of 1st MA in EEA – filing date of basic patent – 5



It takes a long & uncertain time to develop a drug…



- Approval lag *cannot* be predicted perfectly at the time of the patent filing: whether/when the drug will be on the market (à la Gilchrist 2016)
  - Scientific uncertainty: drug R&D process is highly uncertain & non-linear
    - e.g., mRNA technology was viewed as non-promising for decades until Covid
    - e.g. (small molecule drugs w long lags): Prozac, Lipitor, Plavix, Gleevec, …
  - Organizational factors: mergers & acquisitions, $, licensing, transfer, …
- Meanwhile, the patent system rewards "first-to-file" as the patent owner
  - Firms often file patents once a molecule of $-interest is *vaguely* identified
  - Strategic delay of MA is costly: later product entry (lost 1st-mover advantage)

Data Construction: primary patent-drug dyadic data

- **Patent-drug linkage**: data on primary patent covering an NME (new molecular entity) and the approved drug from public registers.
  - SPC data from the German Patent Office – i.e., Deutsches Patent- und Markenamt (DPMA): originator specifies the core (basic) patent for a drug
  - Restrictions: 1) exclude patents filed 20+ years before data collection (1997+); 2) only keep SPCs on the 1st drug rel. to primary patents (unique patent family-drug links)
  - **Approval lag**: lag btw original filing date of focal drug's primary patent (priority date) and the 1st EU market authorization (allow 5+ years post approval periods)
- **Patent data**: patent info on the primary patents from EPO PATSTAT
  - Link via appl_no w patent info at patent family level; EPO search report
- **Drug data**: Cortellis, link by patent family id, tag pharma cites; categorize product, process, 2ndary patents; crosswalk conditions w WHO ICD-9 code

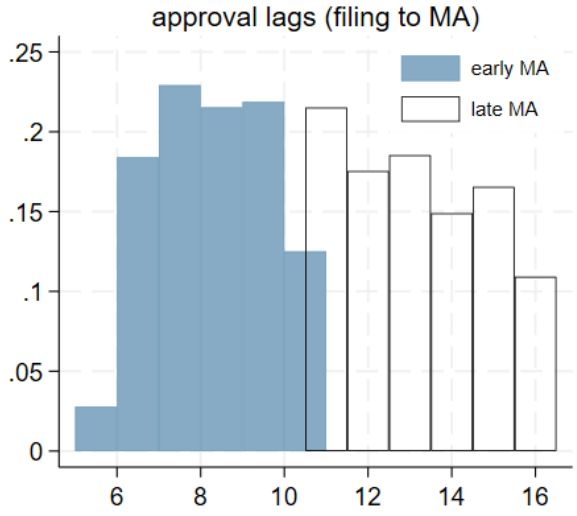
Deutsches Patent- und Markenamt

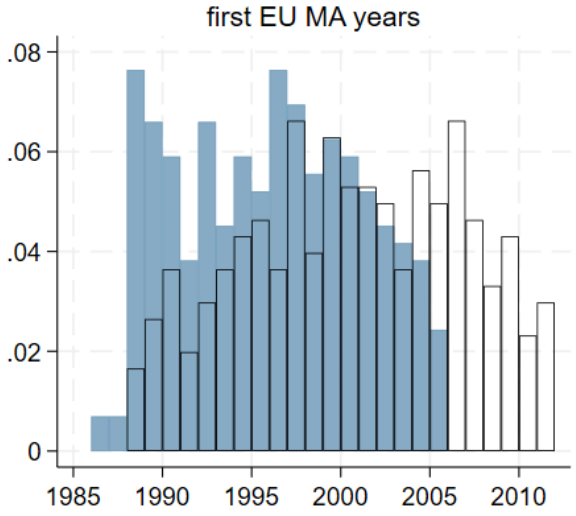
Europäisches Patentamt
European Patent Office
Office européen des brevets

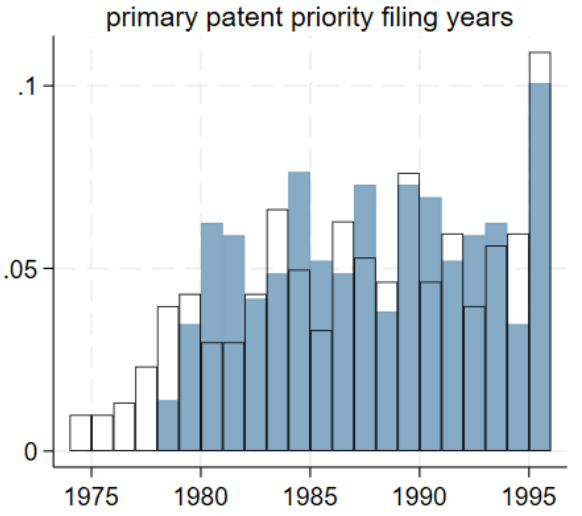
Clarivate Cortellis™

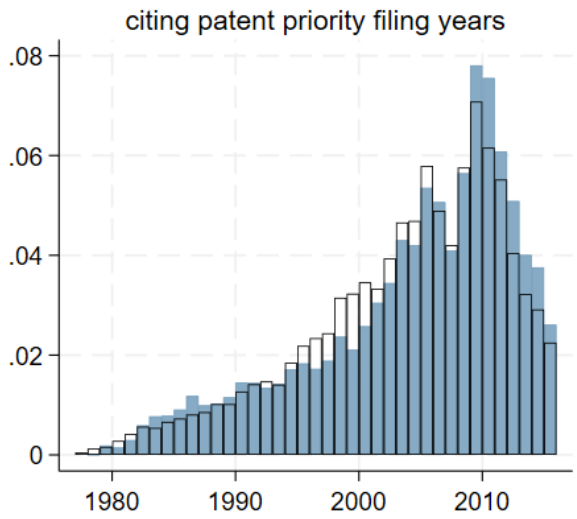
Distribution of timing-related variables

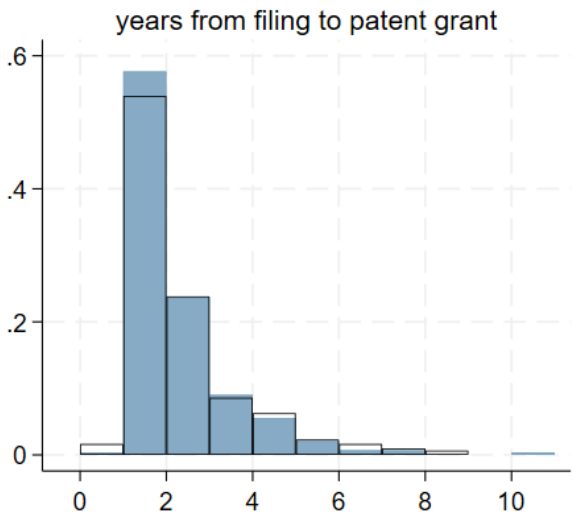
Patents with early vs. late MA (split approval lag at median) are similar regarding priority time, time span at the patent offices (time to patent grant), technological nature (e.g., ICD-9, complexity, resubmissions), and ex-ante drug/disease/patent characteristics (t-test across many metrics).

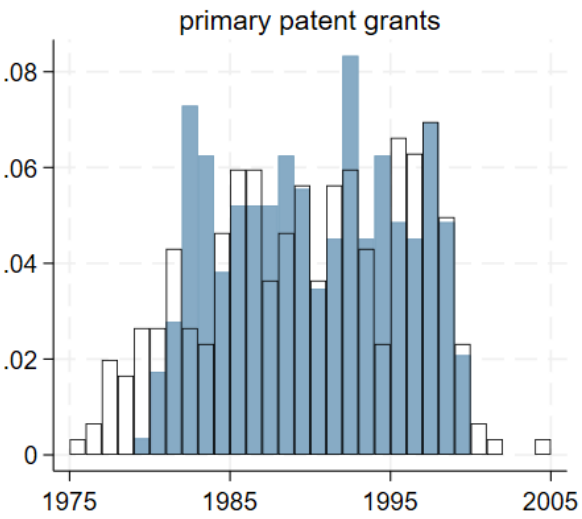












Empirical Strategy: Event Studies (à la S&S 2023)

- Drugs that never been approved should not be valid counterfactuals; rather, drugs approved but with early/later MAs (within drug comparison)
- Staggered event study exploits the variation in approval lags & end-binning (Schmidheiny & Siegloch, 2023)
  - Robust to count data models e.g., PPML; other DiD estimators, e.g., stacked

$$\mathbf{E}[y_{it}|\, X_{it}] = \exp[\alpha + \sum_{j=\underline{j}}^{\bar{j}} \beta_j\, MA_{it}^{j} + \sum_{j=\underline{j}}^{\bar{j}} \gamma_j\, patent_{it}^{j} + \sum_{j=\underline{j}}^{\bar{j}} \eta_j\, SPC_{it}^{j} + \delta_t + \theta_i]$$

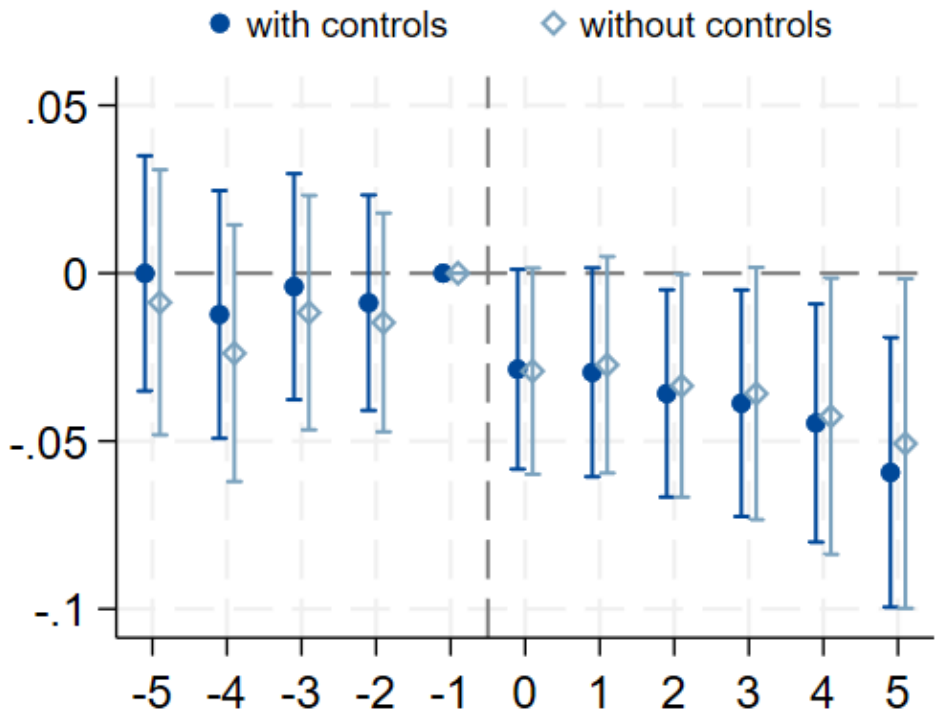
- y_{it} : # of forward citations (other DVs: examiner citations, self, other, etc)
- MA_{it}^{j}: drug approval happening j periods away from t
- δ_t & θ_i: citation year and patent fixed effects (drug-patent 1-1 level)
- Baseline: no patent and SPC controls; preferred: with demanding patent grant and SPC grant controls; estimates w a “partial effects” interpretation

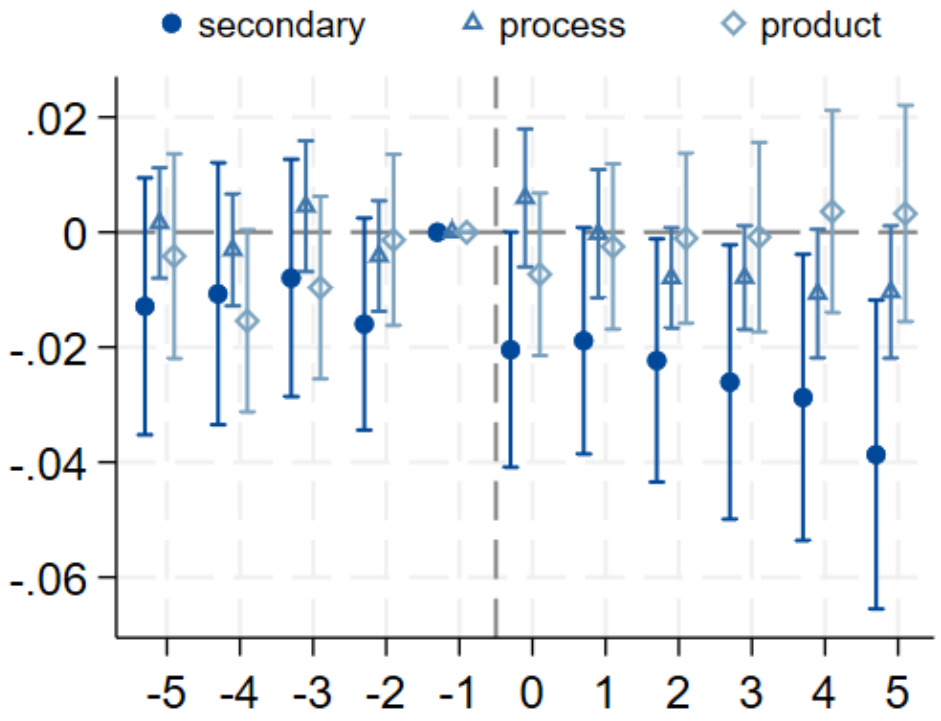
Market Authorization & self-citations: by type of patent

Secondary: e.g., new formulations, dosage forms, combinations, or use.

Process: e.g., new manufacturing process.

Product: e.g., new products, macromolecule.



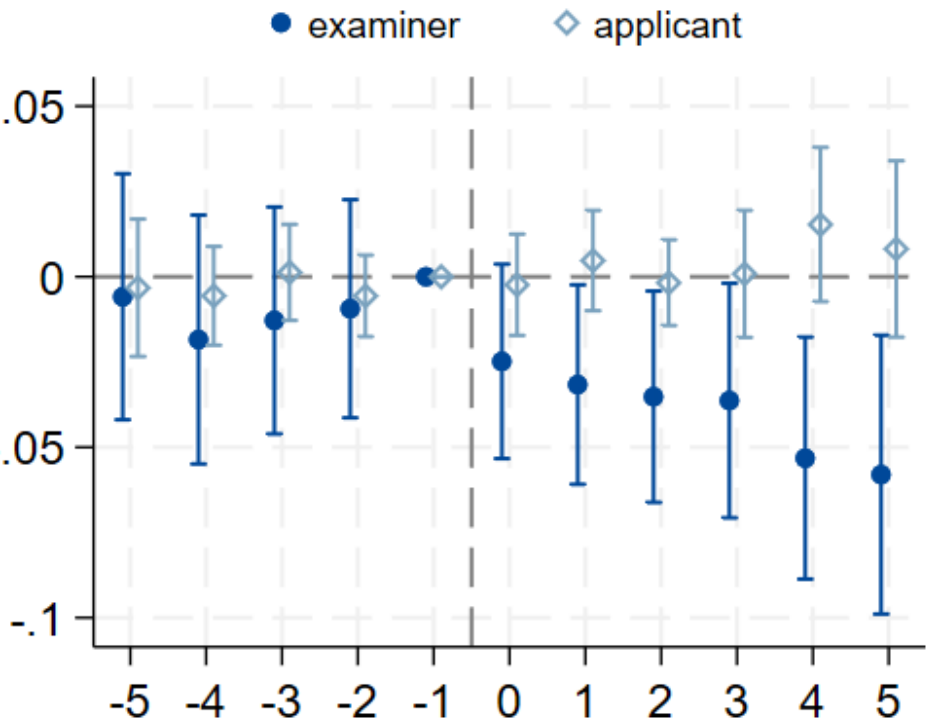


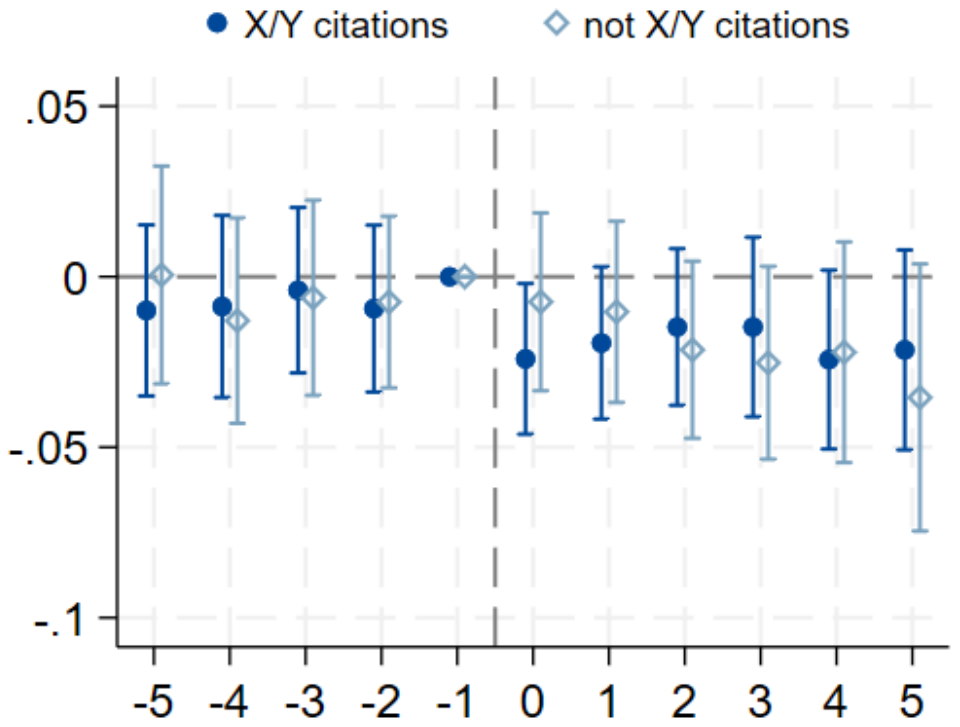
Marketing authorization & self-citations: by source/type

Self-citations added by **examiners** (high quality, majority of EP citations)

Self-citations added by **applicants**

X/Y-ref.: suggest legally "weak" patents as they increase the likelihood of a post-grant validity challenge (Wagner & Wakeman, 2016)





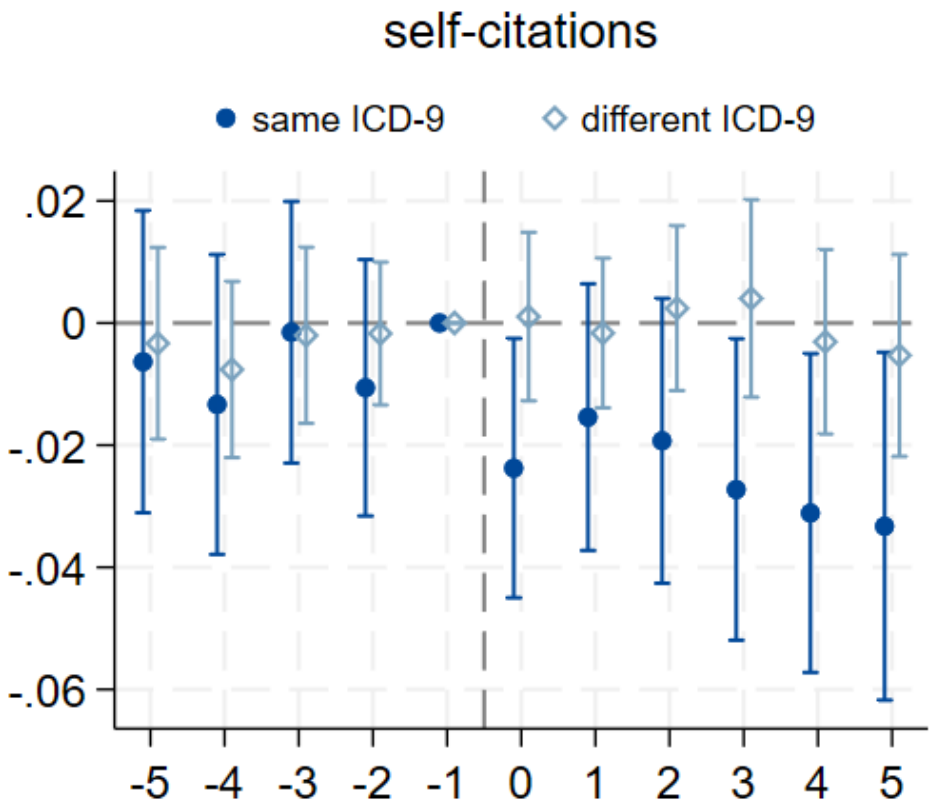
(X: a single prior patent doc can undermine the novelty/inventiveness of claimed invention; Y: do so in combination w/ other docs)

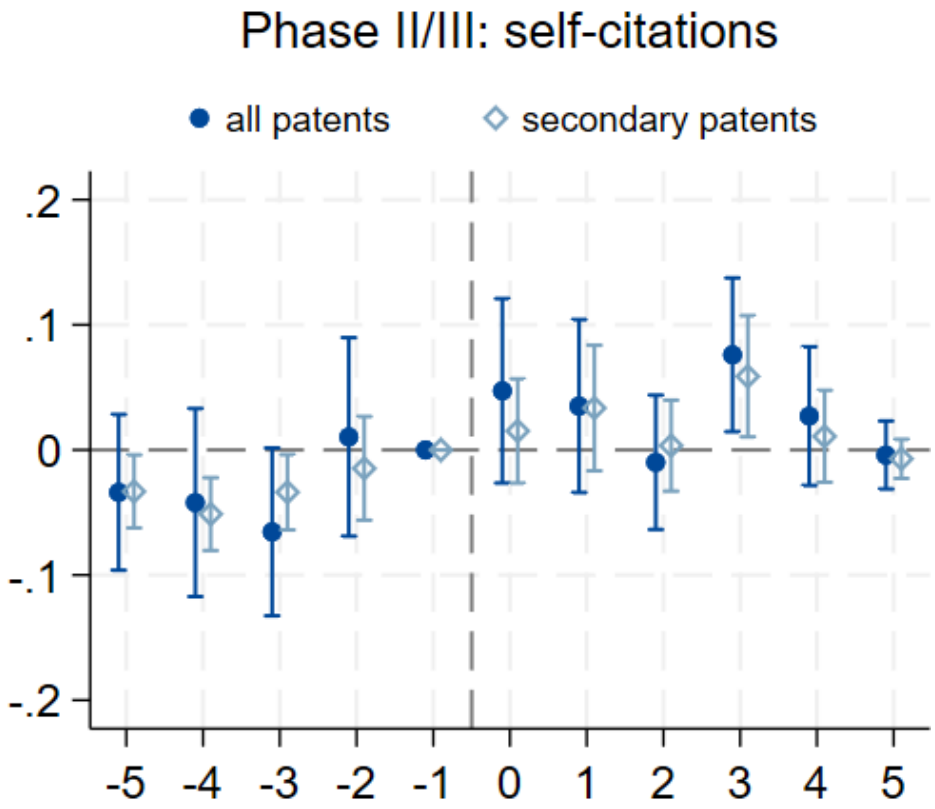
MA & self-citations: by disease; & placebo events

Same disease area as the approved drug

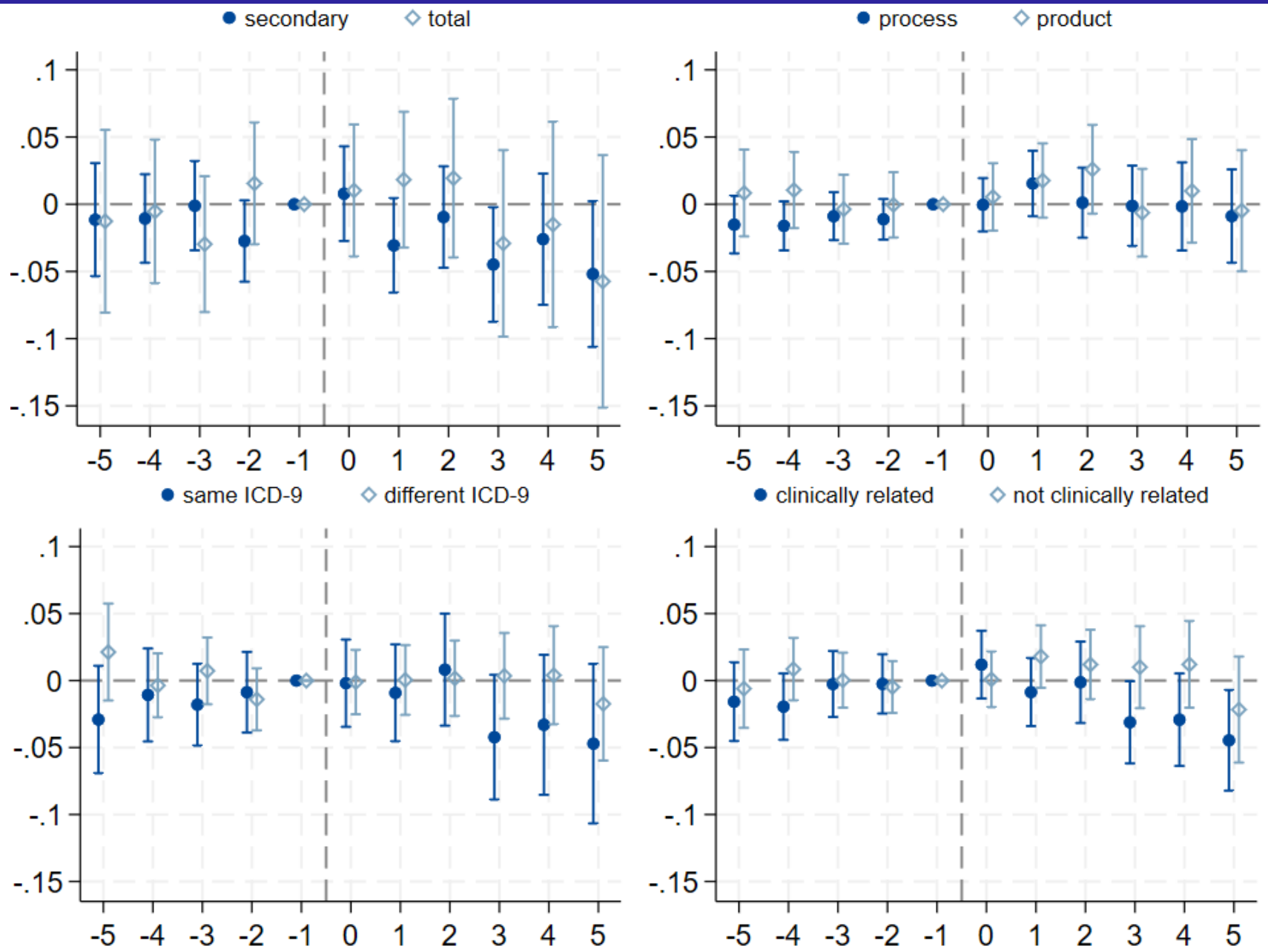
Different disease areas from the focal drug

Use end of phase II/start of phase III as a major (**placebo**) milestone event to test the mechanism (disclosure/enforceability)

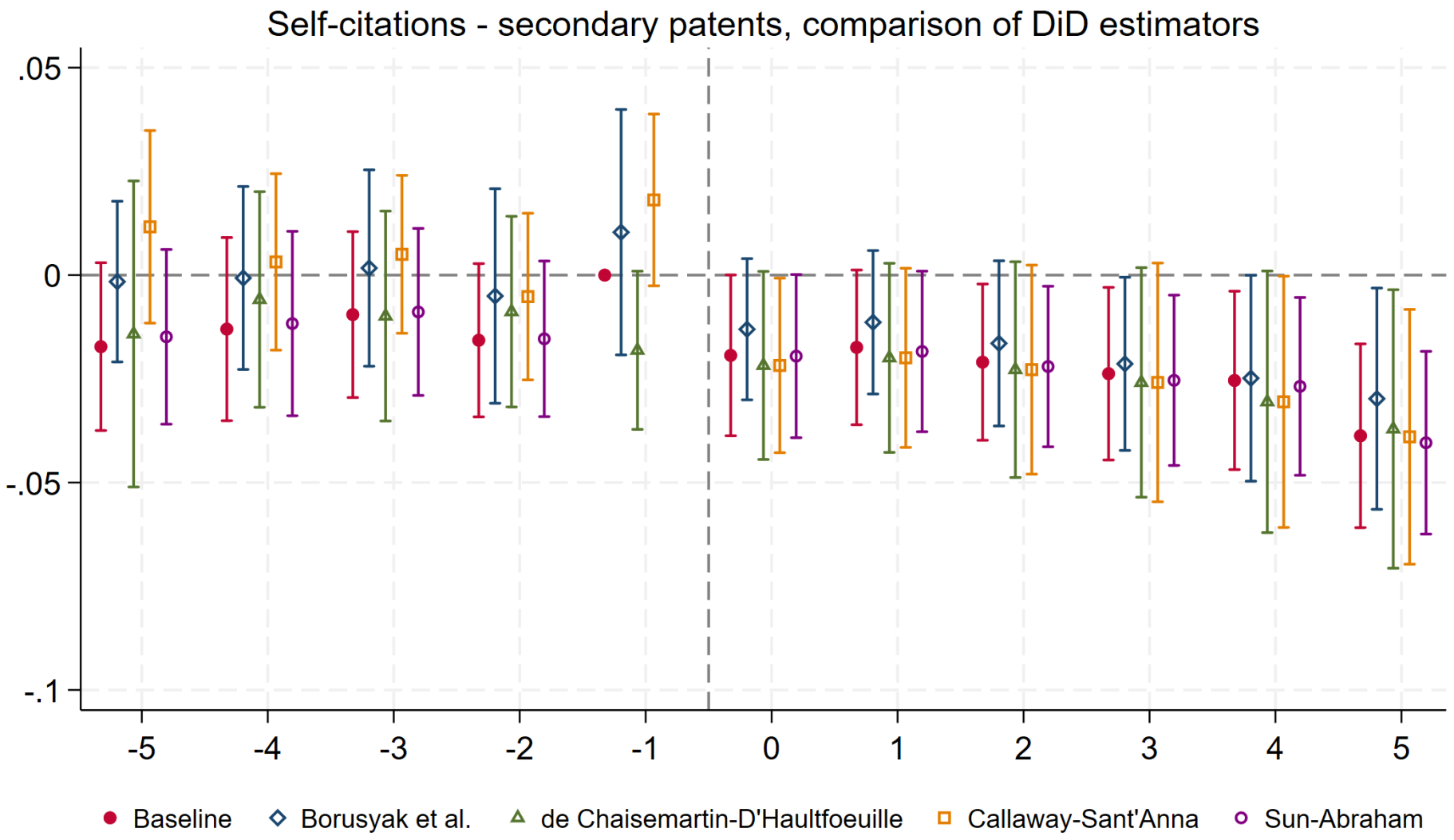




MA & **other** parties' forward citations: big picture



Robustness Checks: Alternative DiD Estimators



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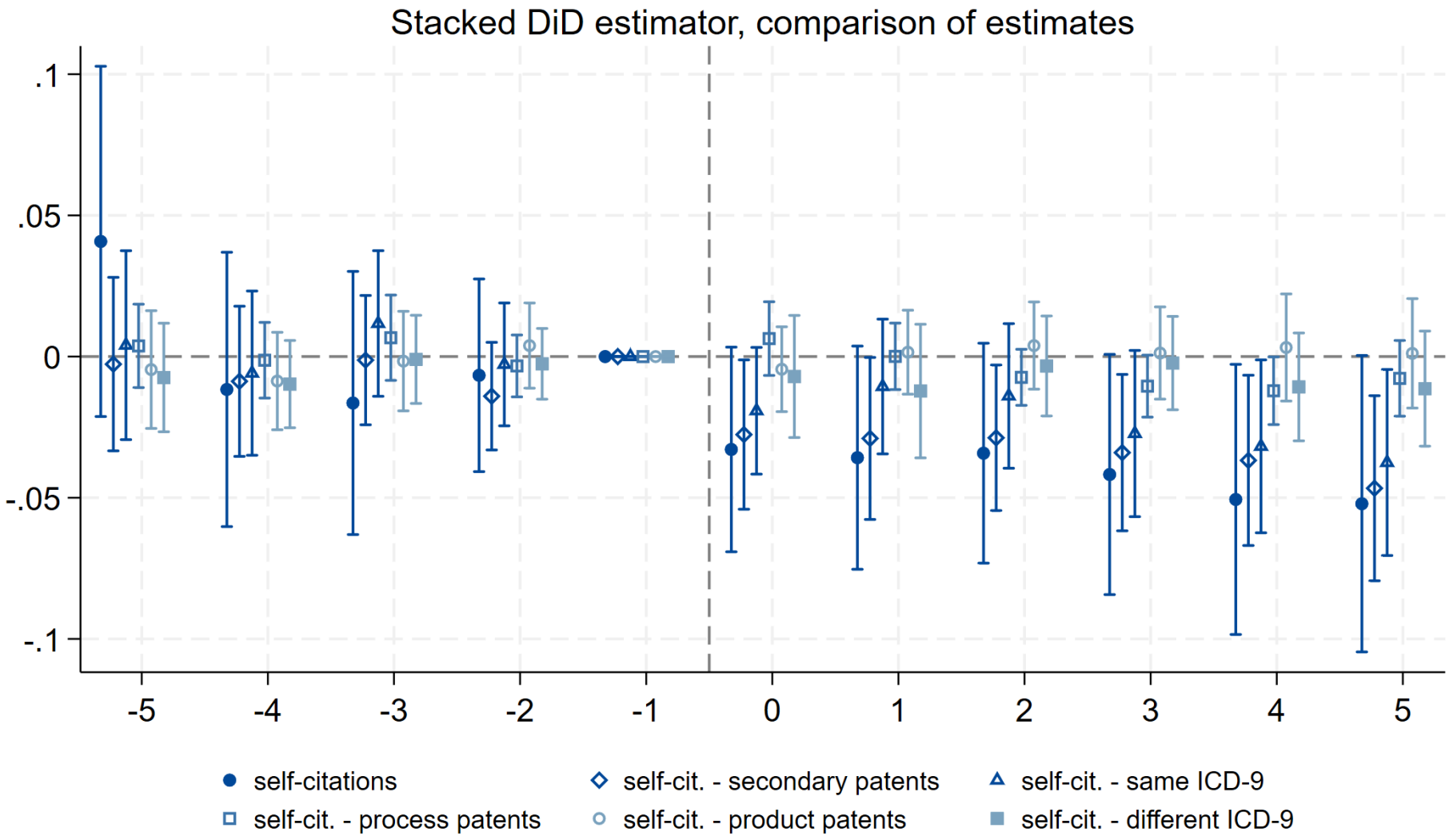
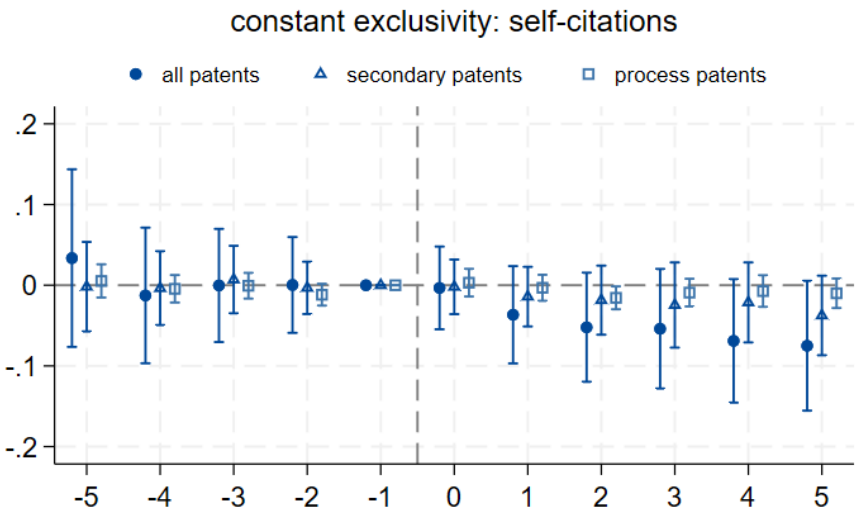
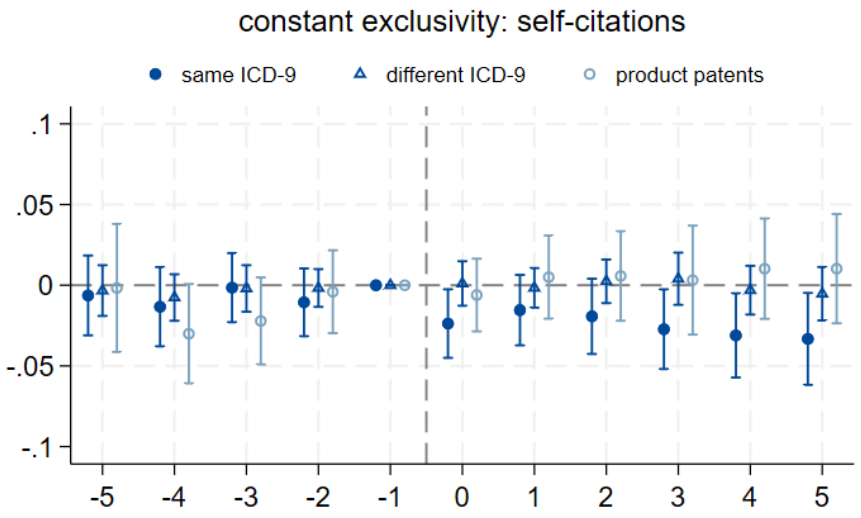
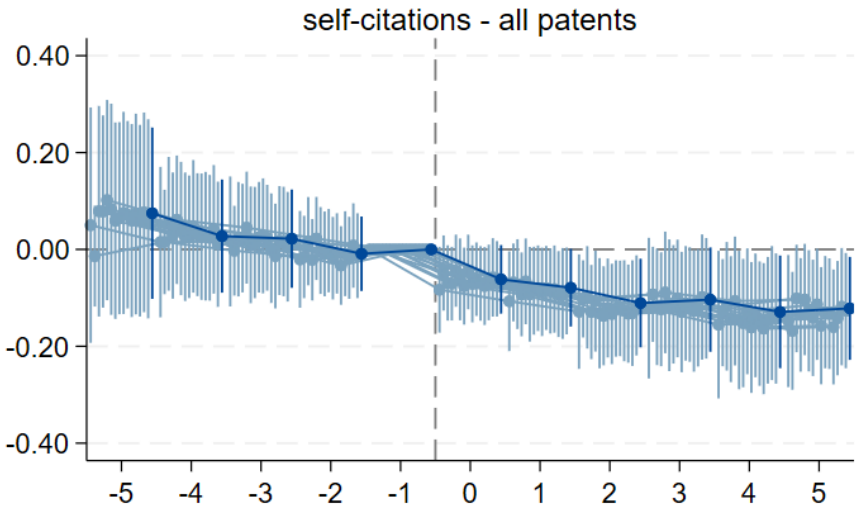


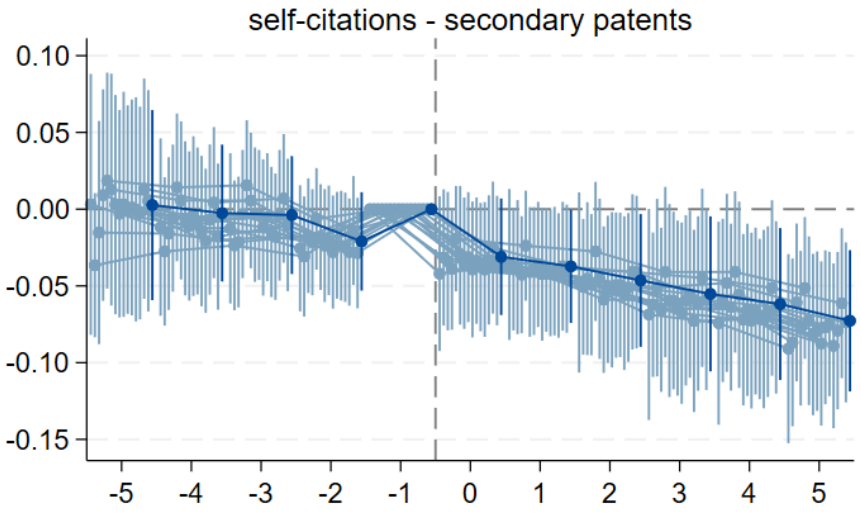
Robustness: Short Approval Lags & Leave-1-out

To isolate MA effects (focus on the event) from potential confounding effects from approval lags (periods)





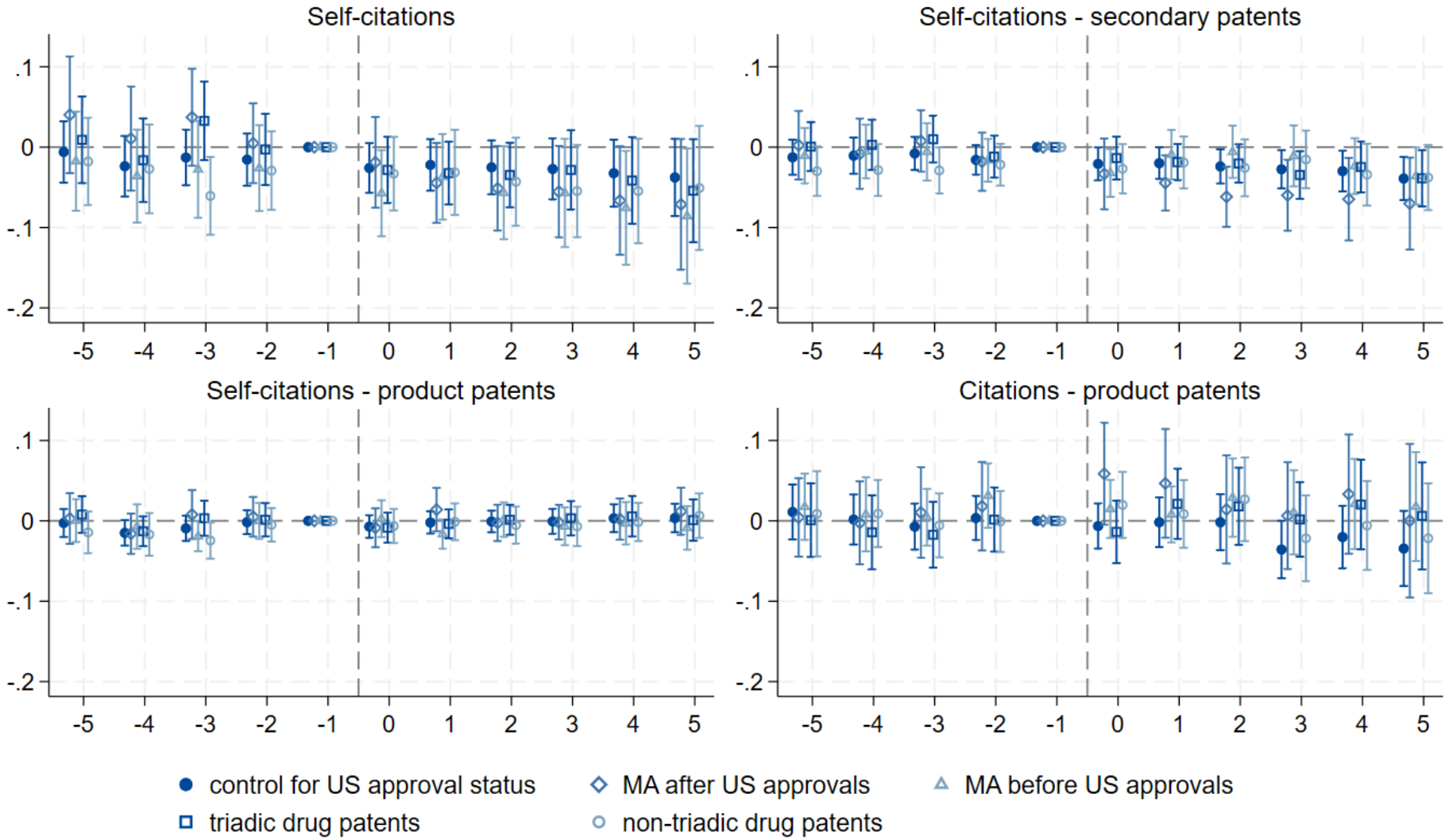




Leave-one-out analysis: whether results are driven by a few disease areas? No, pretty robust.

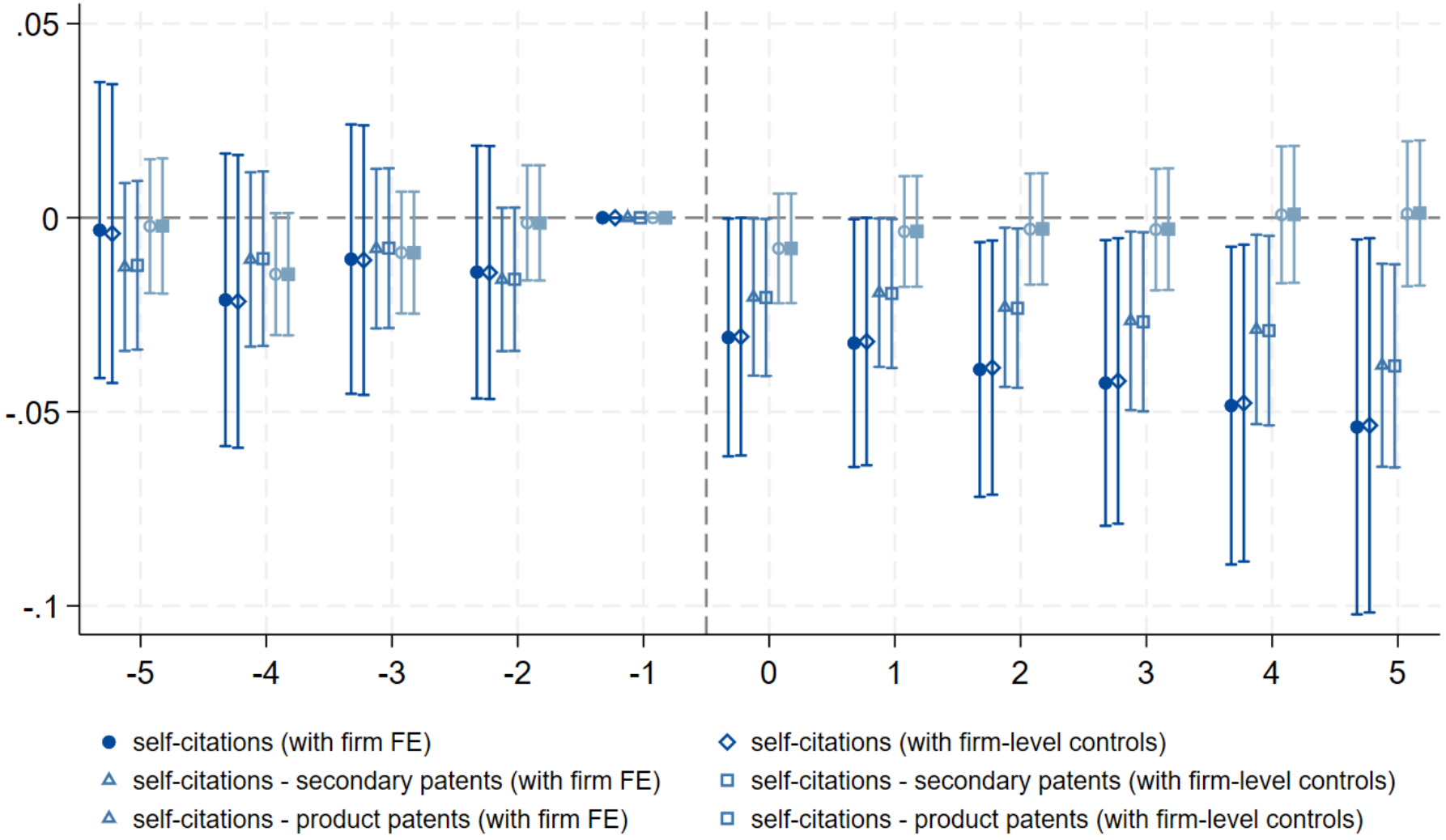
Non-European Market Incentives

US market incentives (e.g., US approvals) are important, but won't explain away our results. Robust to control for US approvals and in subsamples of US approvals before/after MA, or by triadic patent (filed for the same invention in all 3 major patent offices: EPO, USPTO, JPO) status.



Firm-specific characteristics

Robust to control for firm fixed effects or firm-level observable controls, e.g., number of prior drug approvals, years in the industry. Overall result patterns are very similar to benchmark models.



Delays in Approvals: IV Estimation

- IV approach: time from patent filing to the beginning of phase 1 trial (IV) is the most random part able to predict the whole lag (à la Gilchrist 2016)
  - cross-sectional data using the total # of self-cites as Y, IV (file to 1st trial) for the time to approval; IV estimates > OLS (oppos. to the worry of upward bias)
  - Results suggest our event study estimates are conservative (likely l.b.)

Log/Linear	(1)	(2)	(3)	(4)	(5)	(6)
DV: Log Self Citations	IV: Time to Phase I Trials			IV: Time to Phase III Trials		
	OLS	Reduced Form	IV	OLS	Reduced Form	IV
Time to Approval (Priority)	0.049		0.290*	0.045		0.060
	(0.051)		(0.169)	(0.040)		(0.055)
IV: Time Phase I		0.082*				
		(0.044)				
IV: Time Phase III					0.047	
					(0.044)	
Priority Year FE	Yes	Yes	Yes	Yes	Yes	Yes
Patent Grant Year FE	Yes	Yes	Yes	Yes	Yes	Yes
Patent Controls	Yes	Yes	Yes	Yes	Yes	Yes
Underidentification test			9.18			36.99
Weak identification test			9.34			82.33
Observations	77	77	77	125	125	125

Conclusion, & Discussion

- We find that strategic follow-on patenting **decreases** after a drug's market authorization, when follow-on drug patents are harder to obtain
  - More drop for less novel patents; No change in meaningful patents
  - Both originators and other firms adjust similarly, at different speeds
  - Empirical test indicates it's harder to obtain enforceable patents post-MA

- *Policy implications*: leveraging existing regulatory disclosure requirements may provide a practical approach to improving patent quality without changing formal patentability standards

Thank you! (corresponding author: Wang: xiaoluwang@umass.edu)

Full published paper: https://doi.org/10.1016/j.jpubeco.2025.105415

MPI discussion paper: https://ssrn.com/abstract=4638115

Backup slides

- Included additional figures for visual result summary
- Please check the manuscript for complete tables ☺

Fig. A2 Distribution of expected market exclusivity

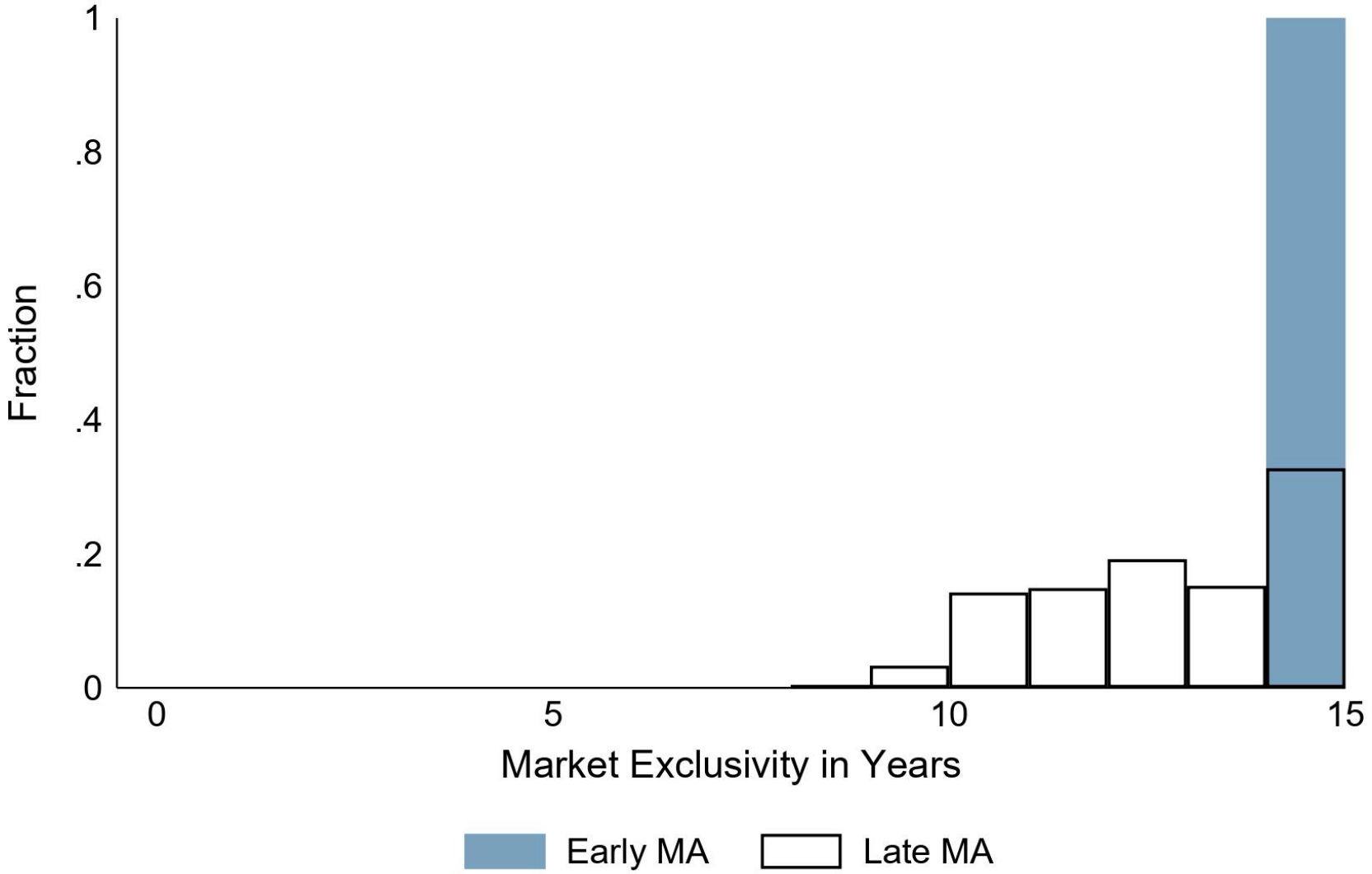
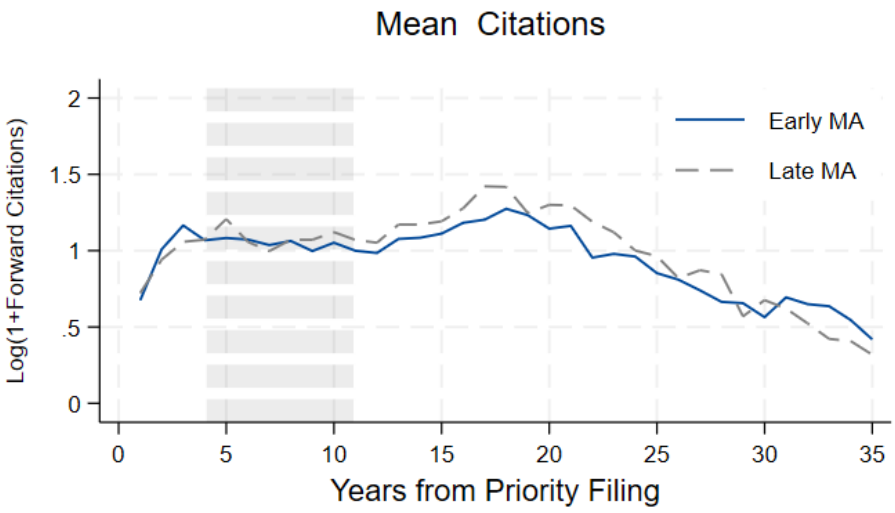
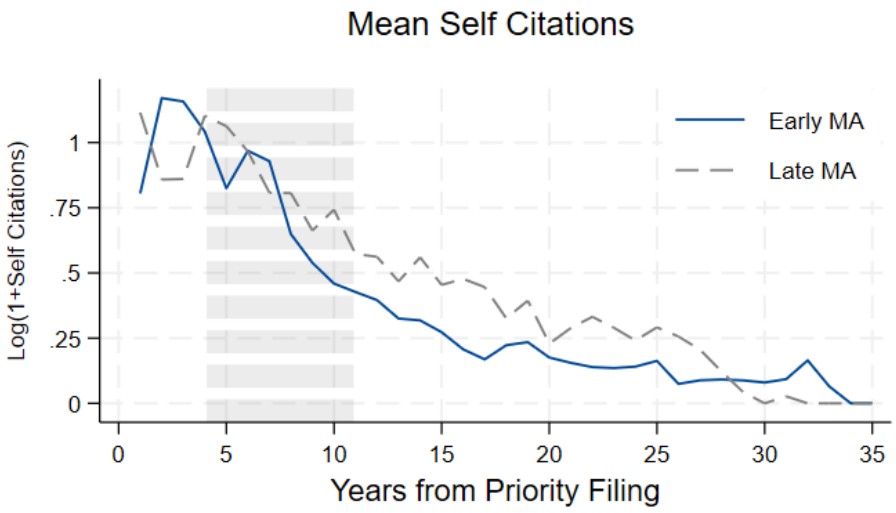
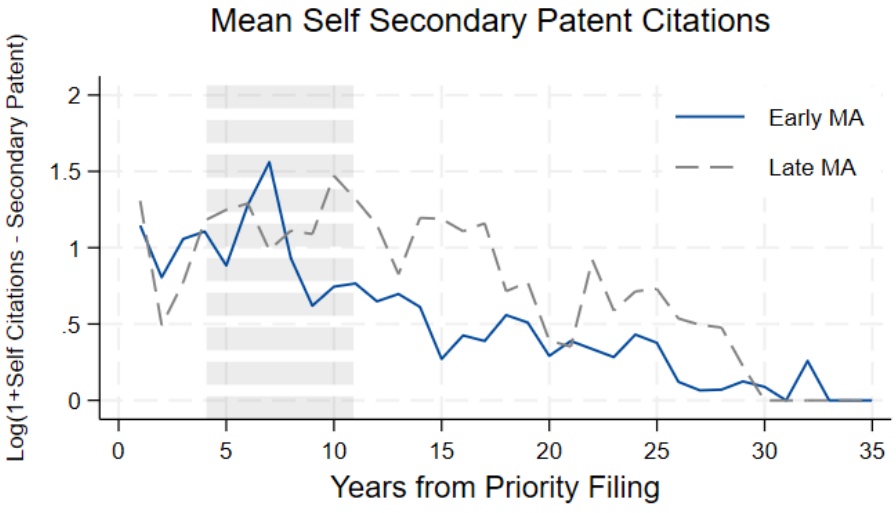


Fig. A3: citations by approval lag: early/late half







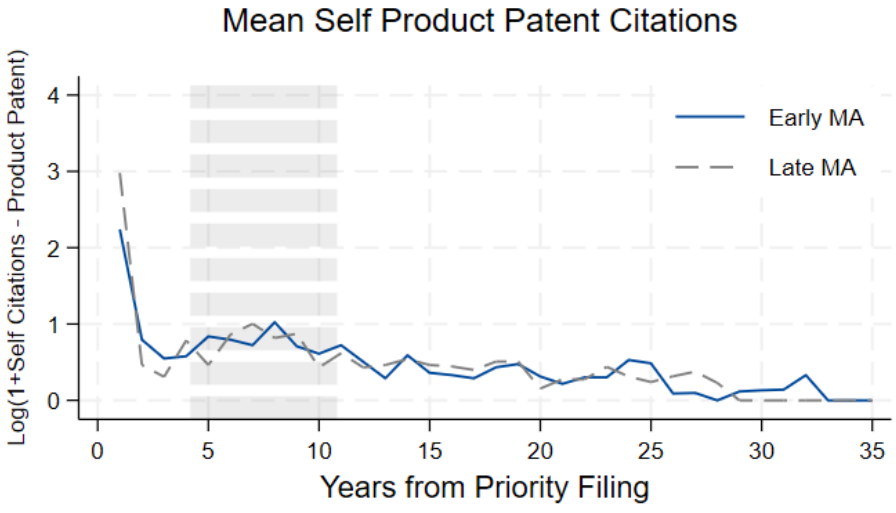
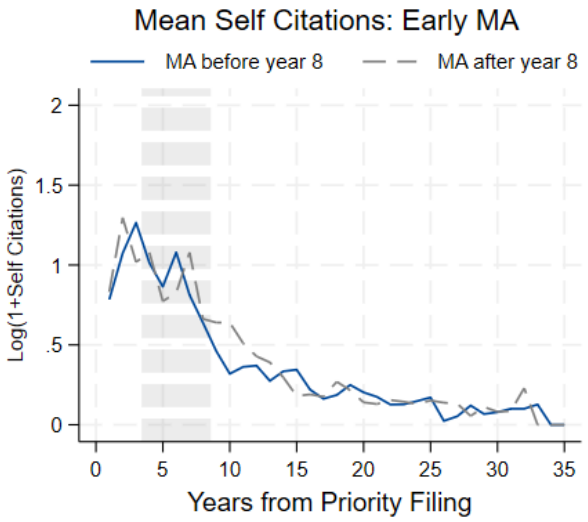
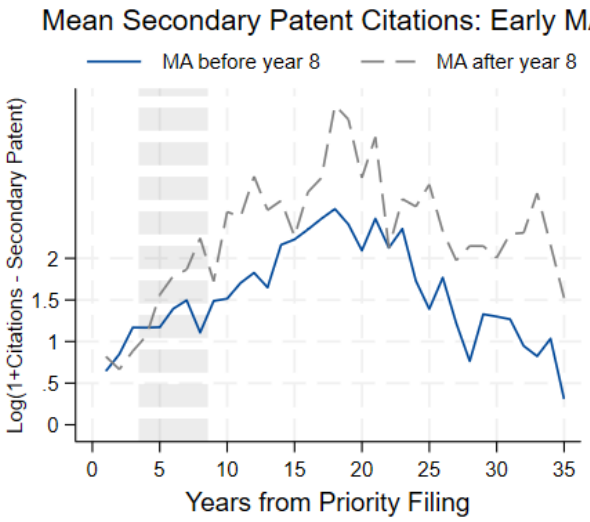
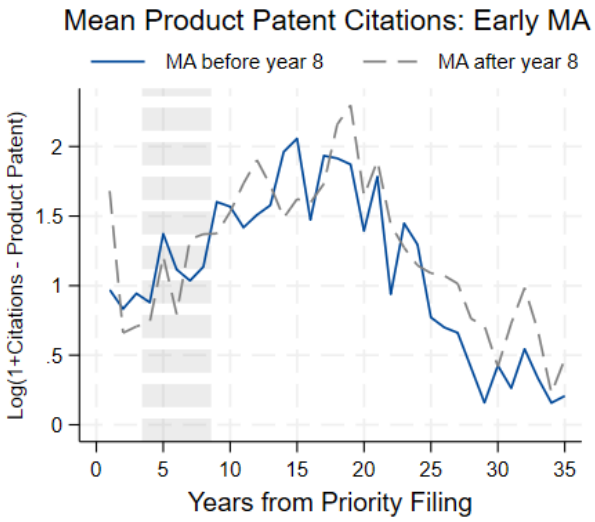
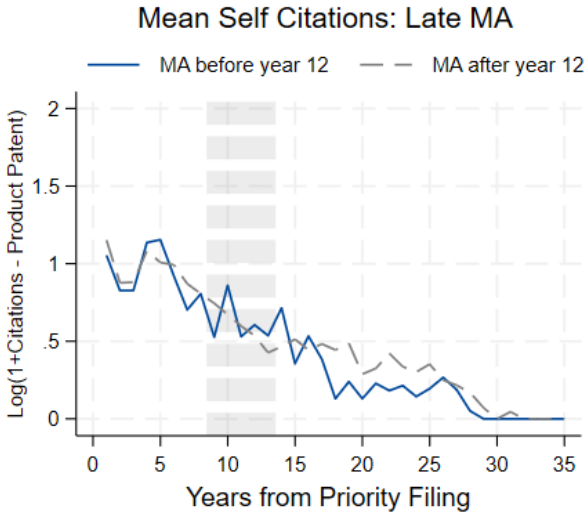


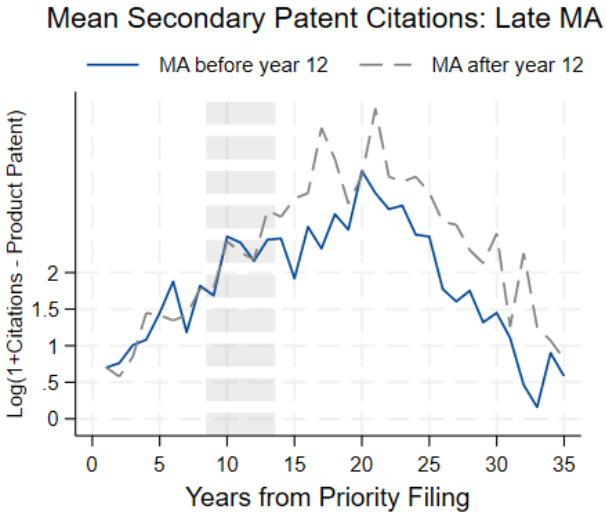
Fig. A4: citations by approval lag: early/late subgroup











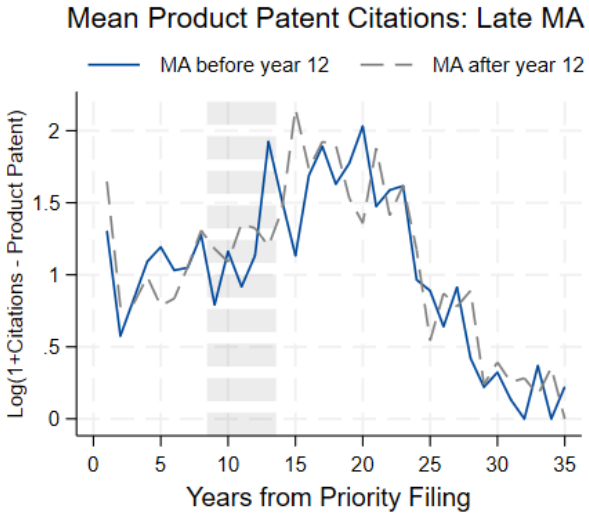
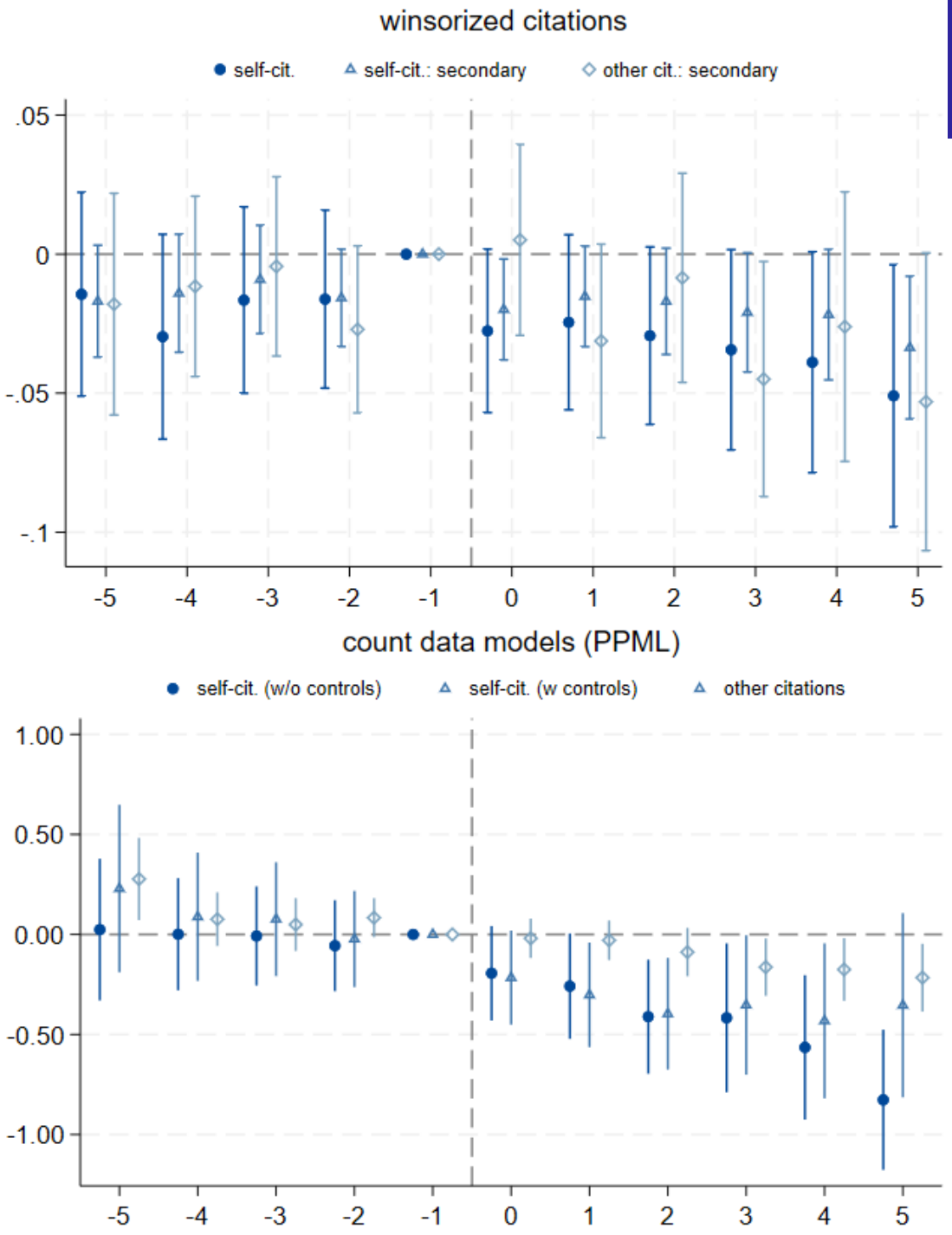


Fig. A5


winsorized citations
self-cit.
self-cit.: secondary
other cit.: secondary
.05
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-5
-4
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5
count data models (PPML)
self-cit. (w/o controls)
self-cit. (w controls)
other citations
1.00
0.50
0.00
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Fig. A6: impact of MA on citations: long post periods

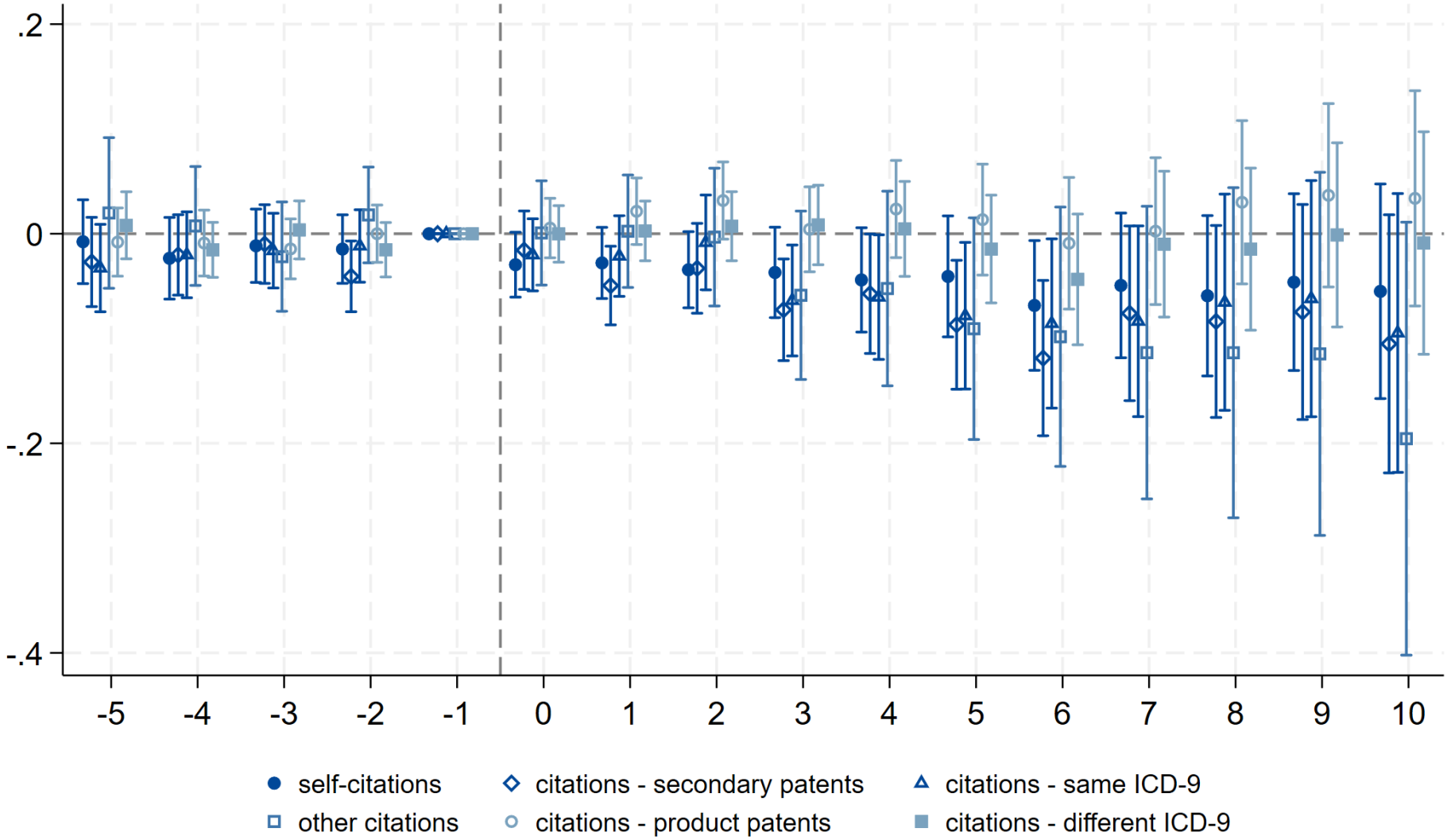

Fig. A7: citations from US patents