Marketing Authorization and Strategic Patenting: Evidence from Pharmaceuticals

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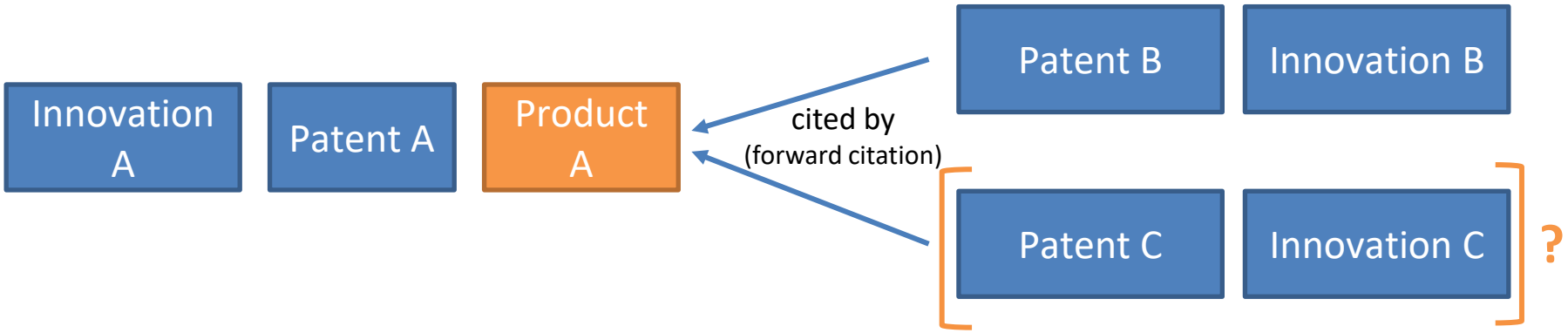
Drugs save lives, but too costly with many patents!

- 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")



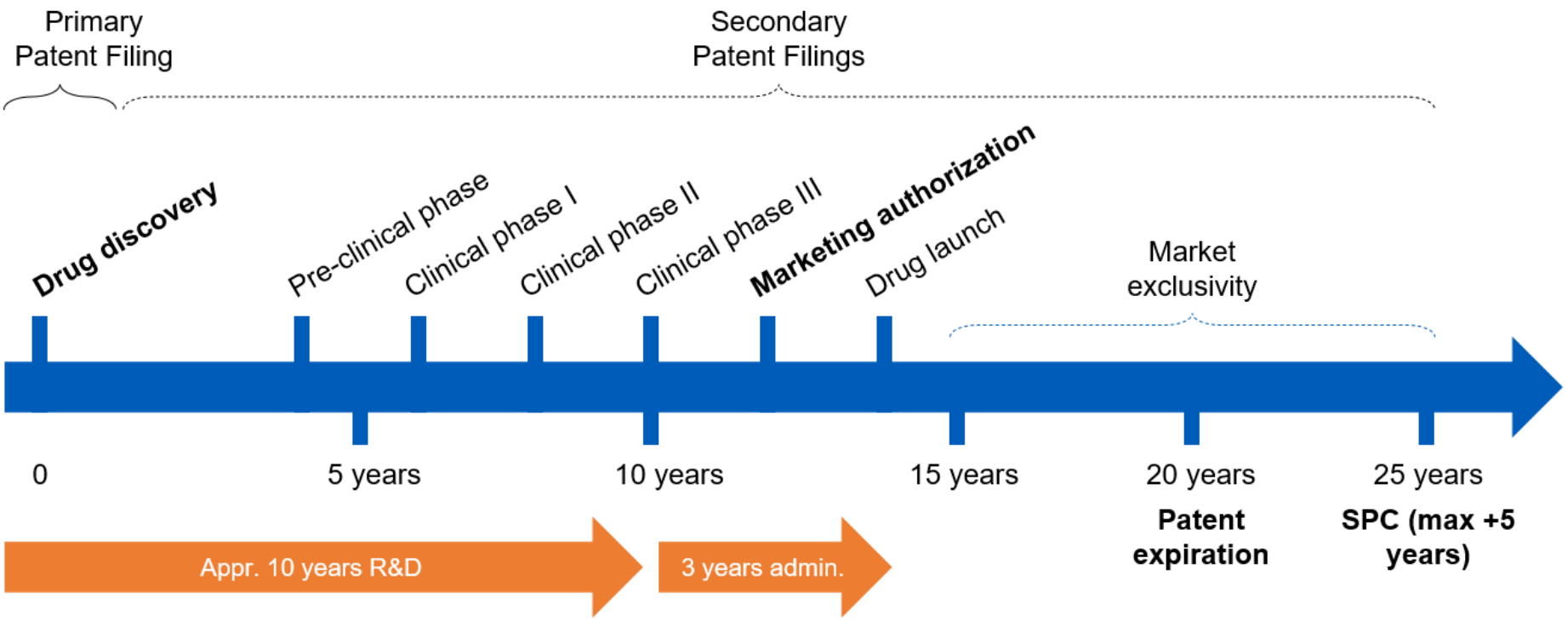
EPO "gold standard" examination quality (Chien 2018), patent citation: follow-on patenting

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)

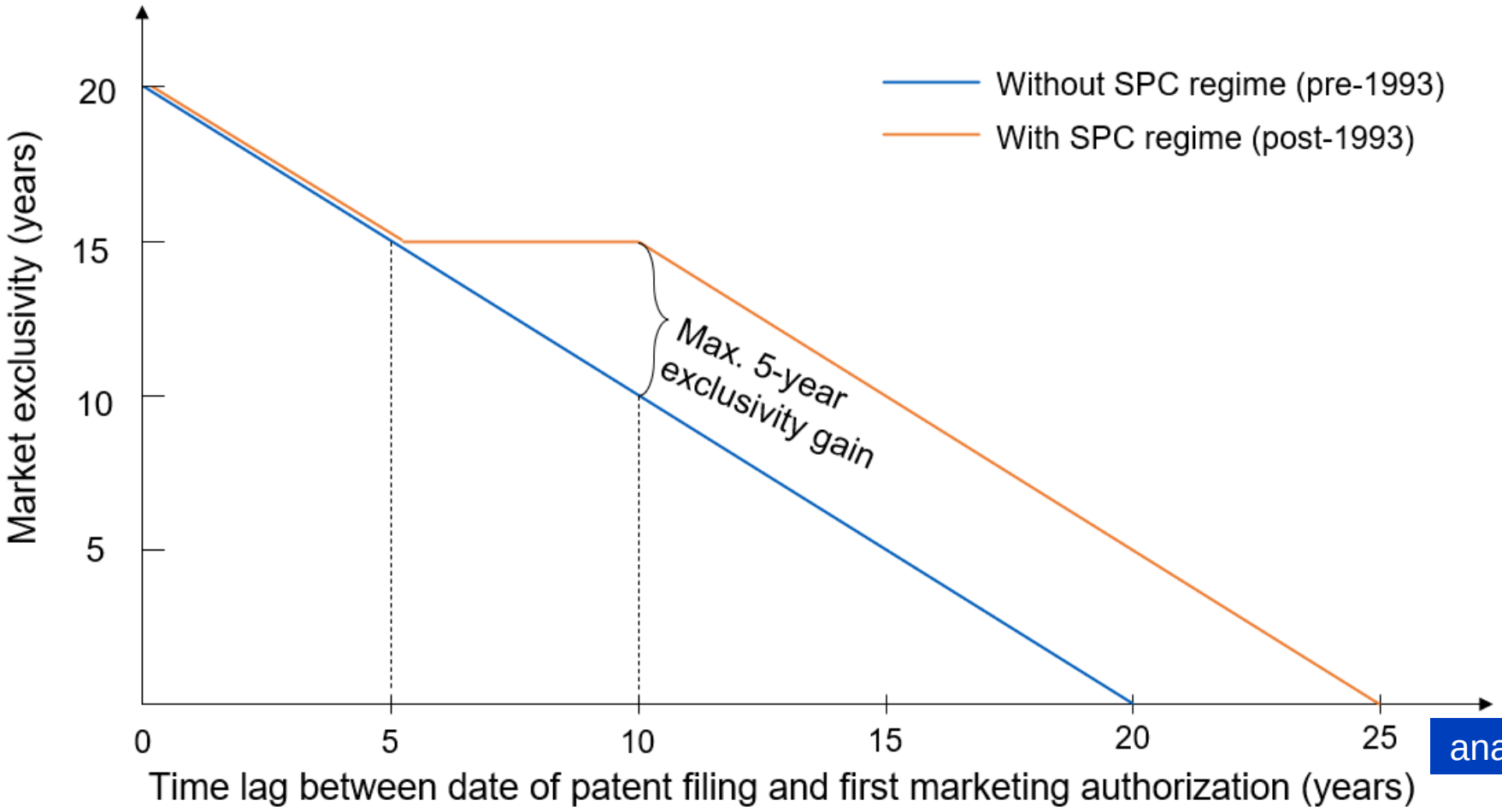
The Drug Development Process in EU (EEA)



- 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

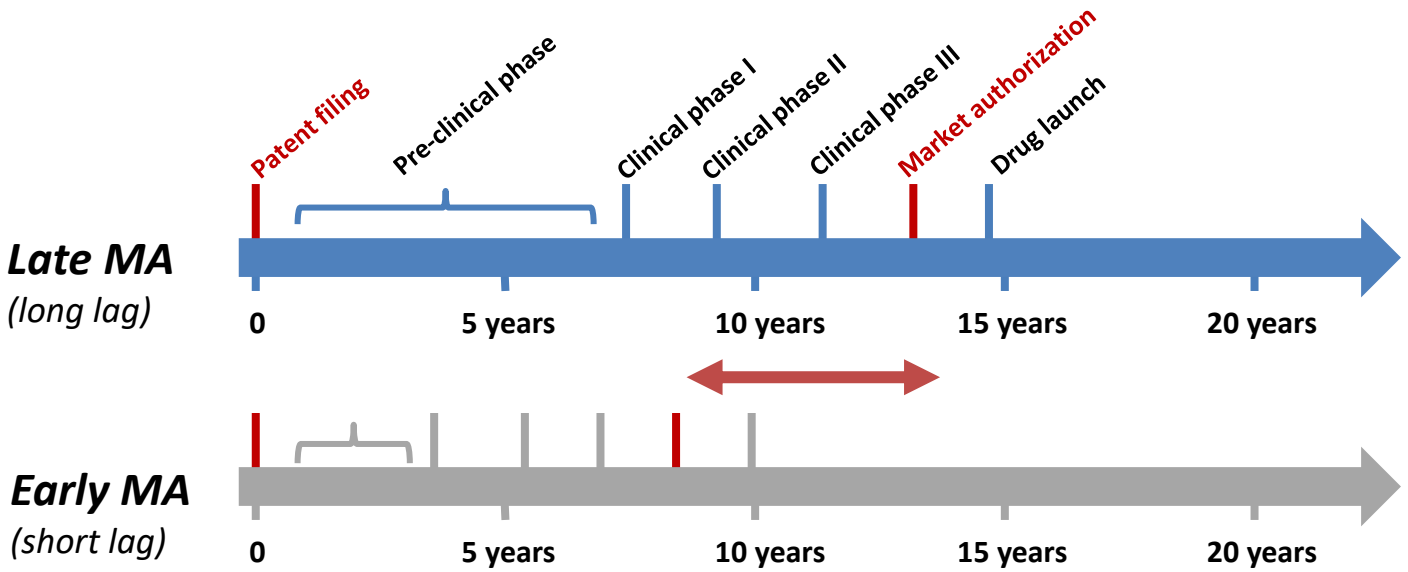
EU Patent Term Extension (SPC Regime)

- 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



analysis

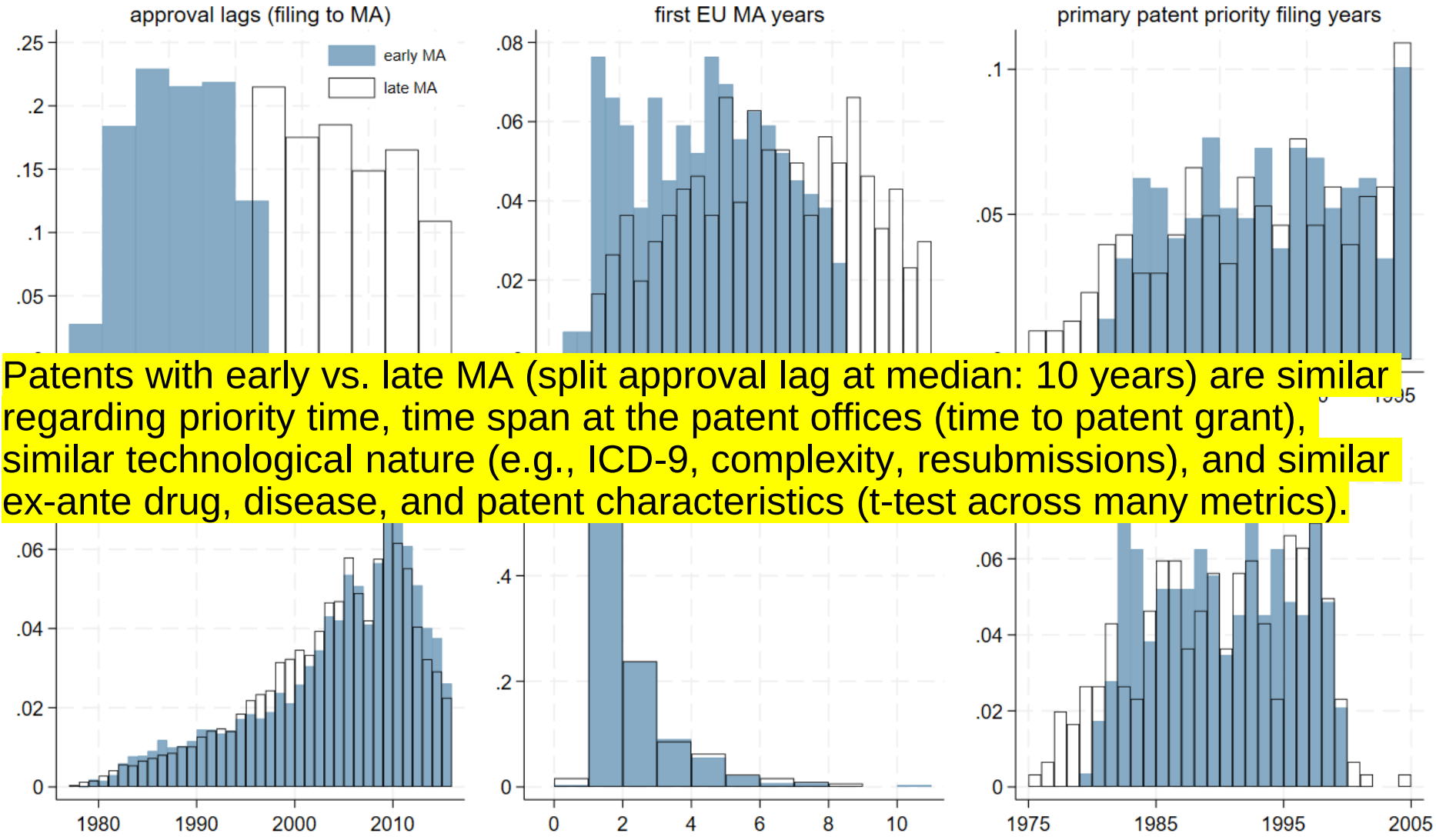
It takes a long & uncertain time to develop a drug…



- 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 & organizational factors: finance, M&A, $, licensing, …

- **Data**: 1) patent-drug linkage: SPC data from DPMA; 2) patent data on primary patents from EPO PATSTAT, family level patent info; 3) drug data: Cortellis, link by family id; 4) crosswalk diseases w WHO ICD-9.

Distribution of characteristics (split by median MA)



Patents with early vs. late MA (split approval lag at median: 10 years) are similar regarding priority time, time span at the patent offices (time to patent grant), similar technological nature (e.g., ICD-9, complexity, resubmissions), and similar ex-ante drug, disease, and 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

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

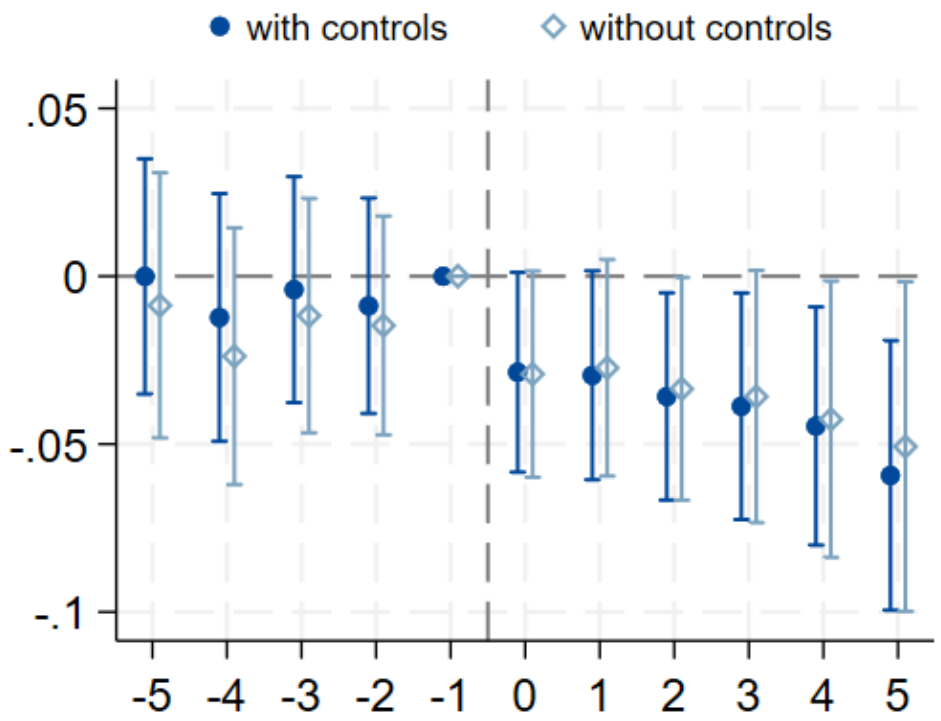
- y_{it} : # of forward citations (other DVs: examiner citations, self, other, etc)
- MA_{it}^{j}: drug approval happening j periods away from t
- δ_t & θ_i: citation year and patent fixed effects (drug-patent 1-1 level)
- Baseline: no patent and SPC controls; preferred: with demanding patent grant and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

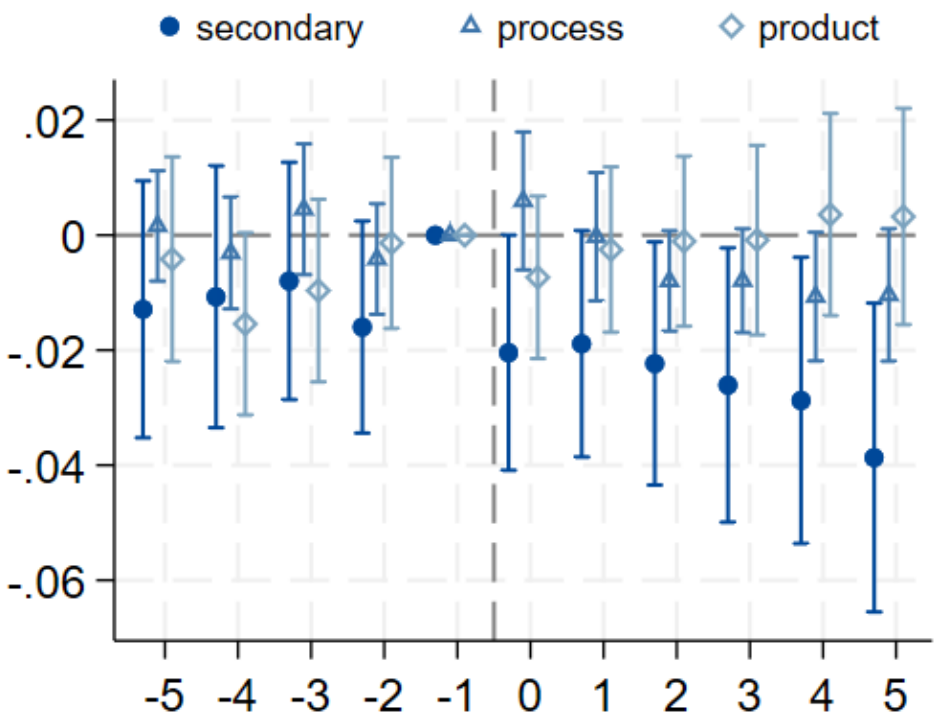
Market Authorization & self-citations: by type of patent

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

Process: e.g., new manufacturing process.

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



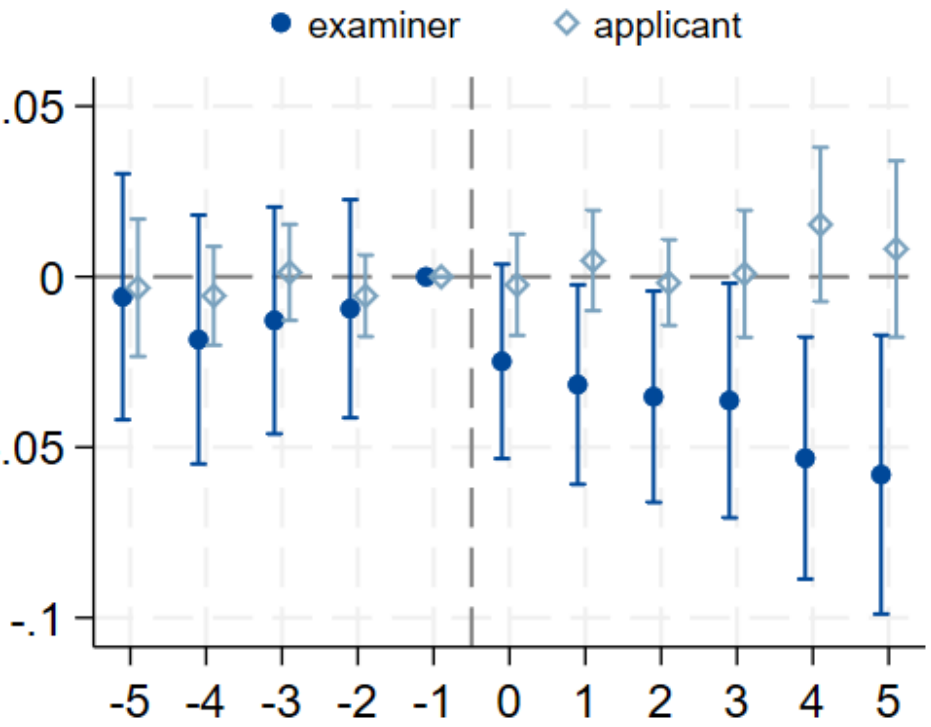


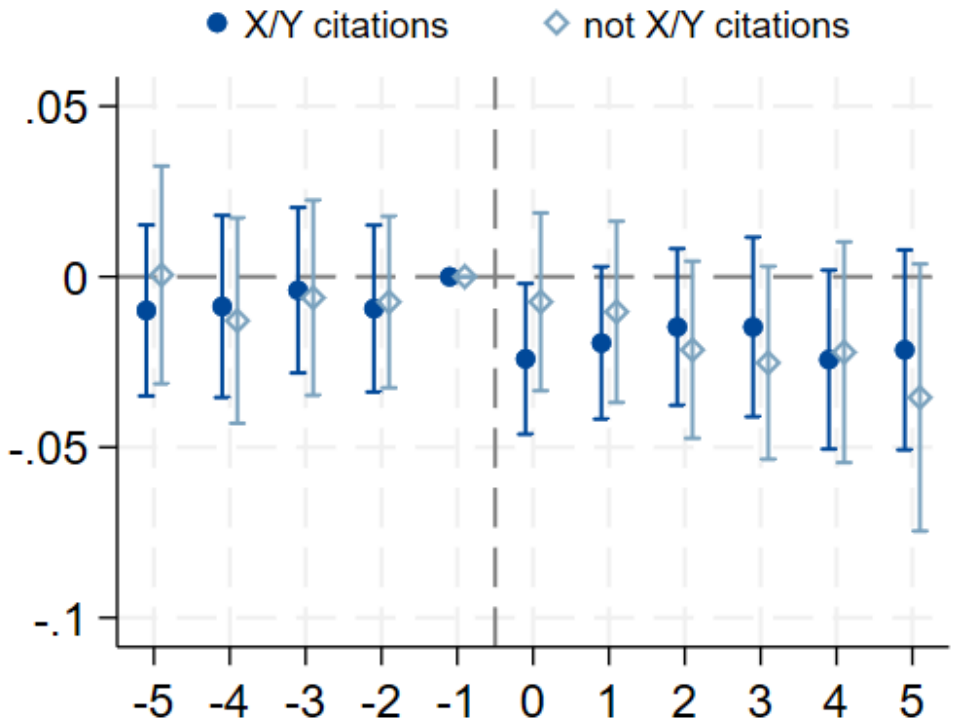
Marketing authorization & self-citations: by source/type

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)





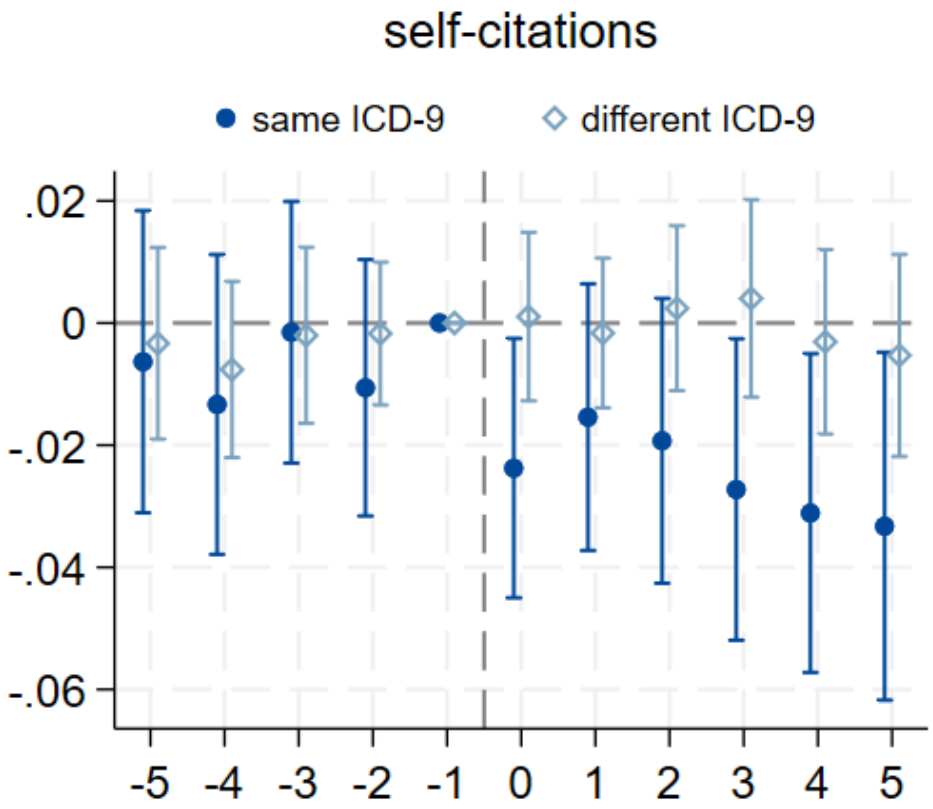
(X: a single prior patent doc can undermine the novelty/inventiveness of claimed invention; Y: do so in combination w/ other docs)

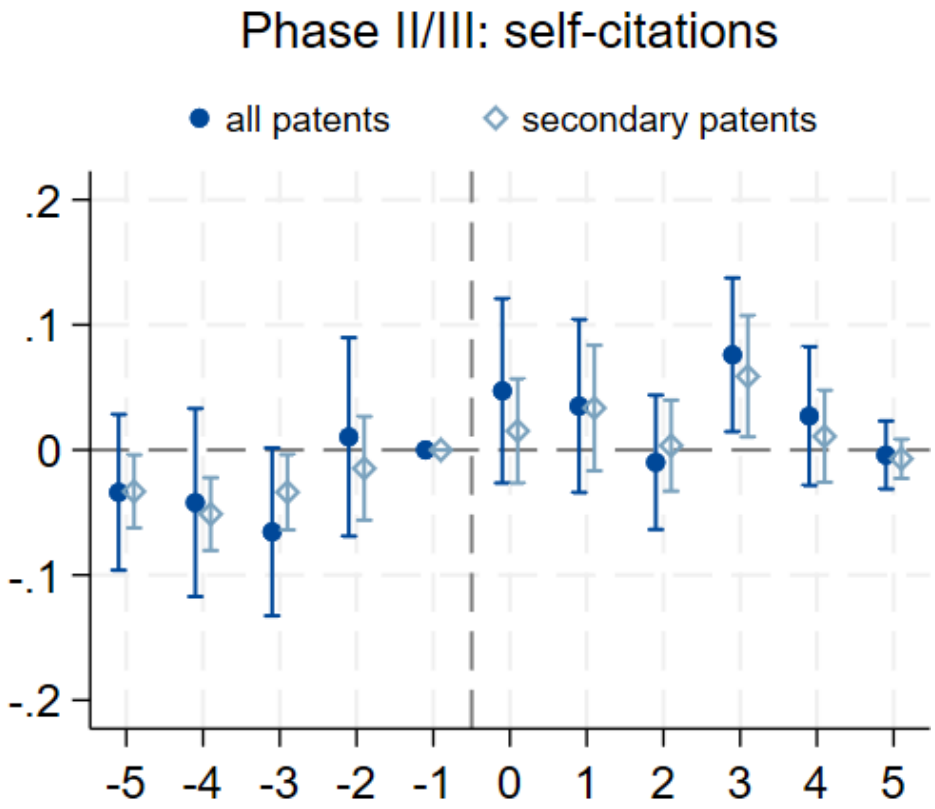
MA & self-citations: by disease; & placebo events

Same disease area as the approved drug

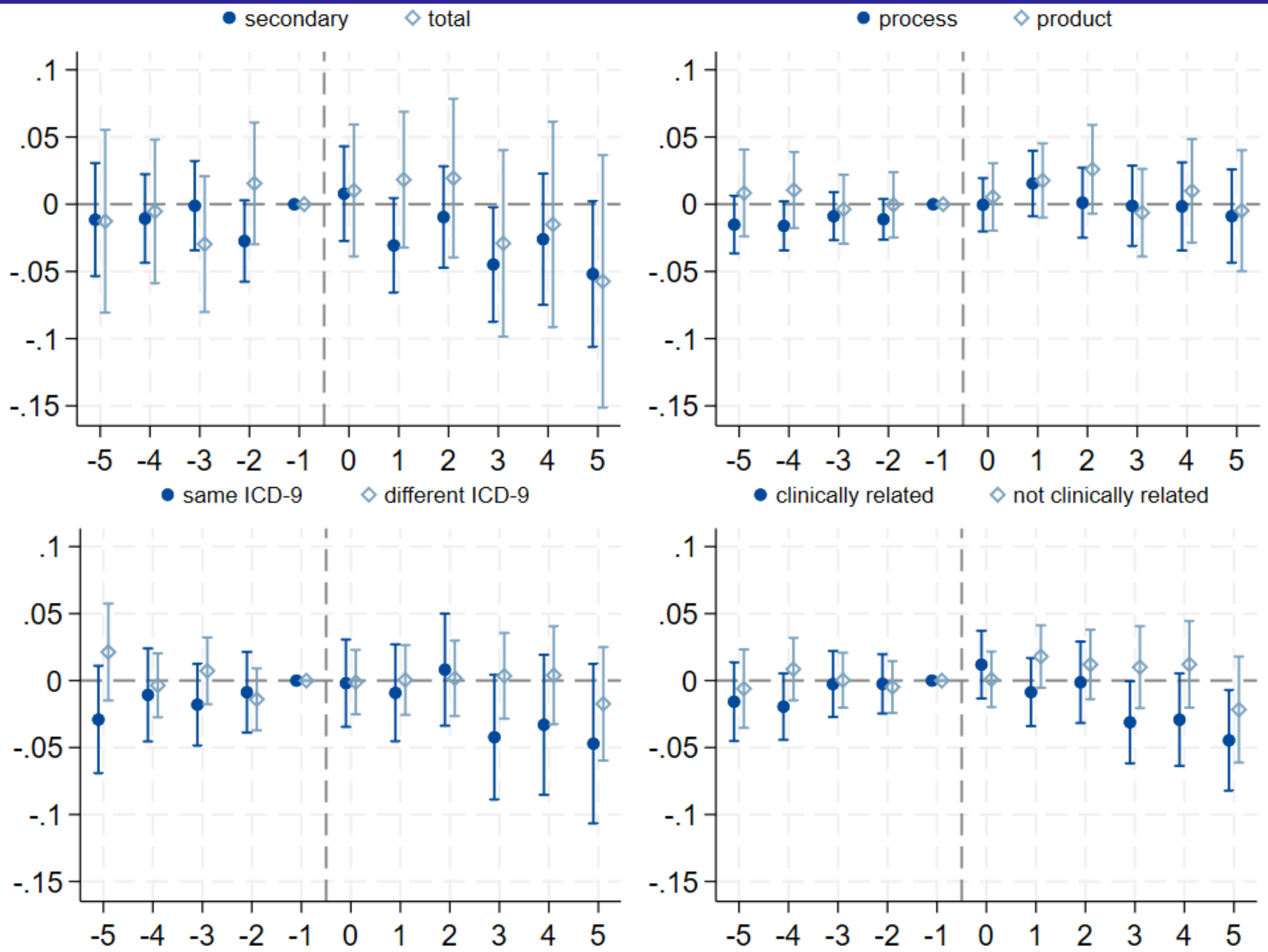
Different disease areas from the focal drug

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

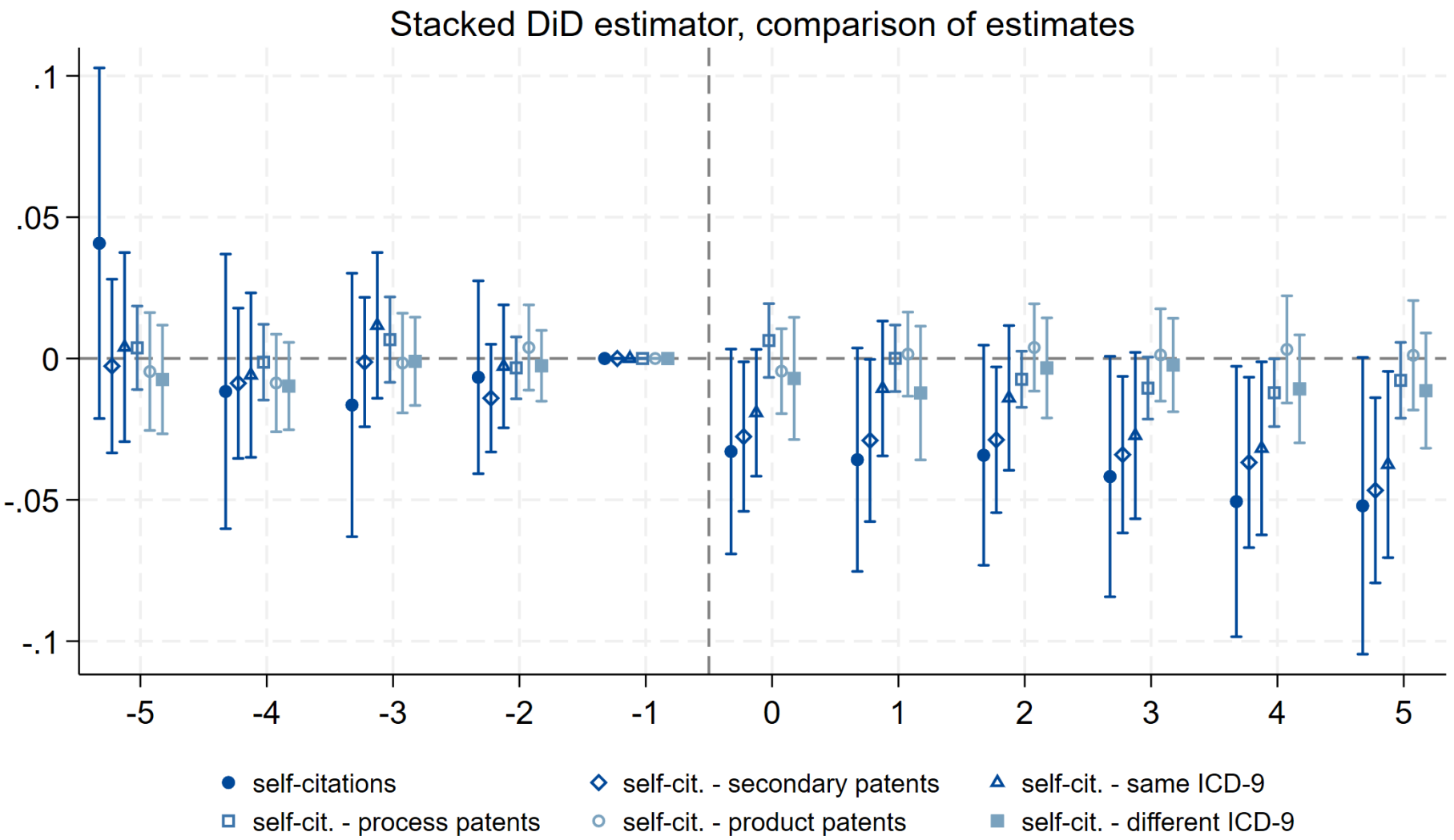




MA & **other** parties' forward citations: big picture

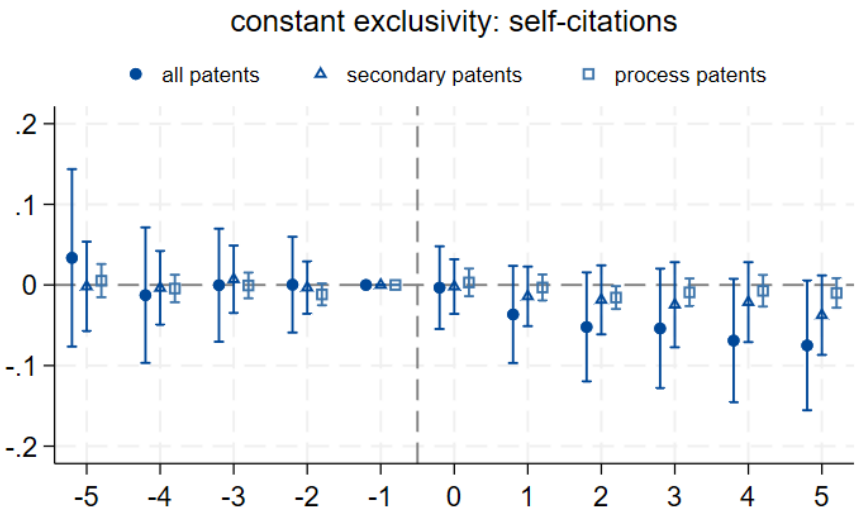


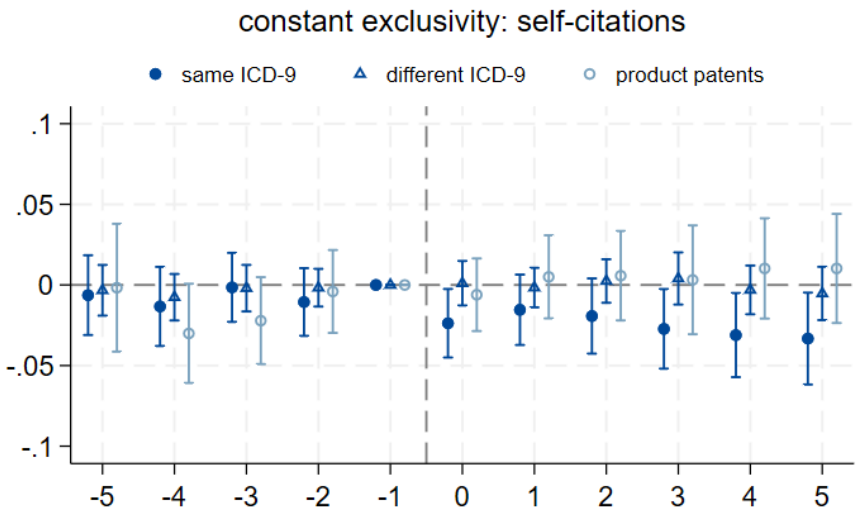
Robustness Checks: Alternative DiD Estimators

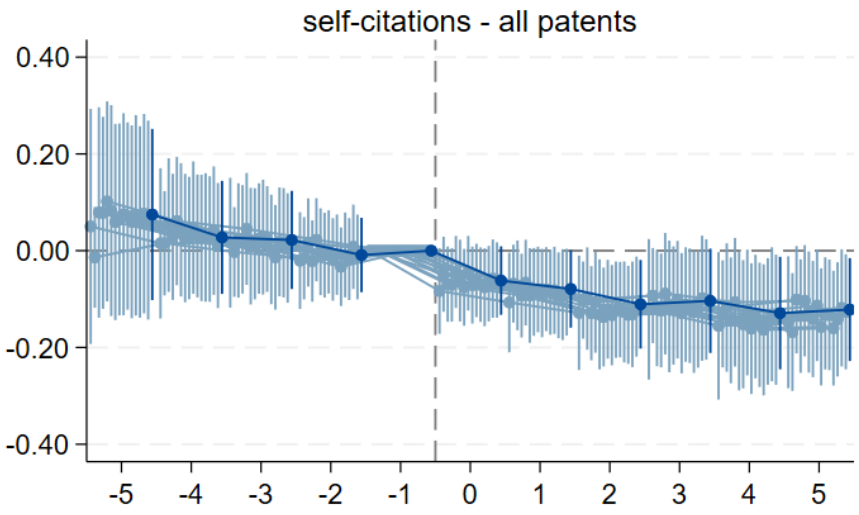


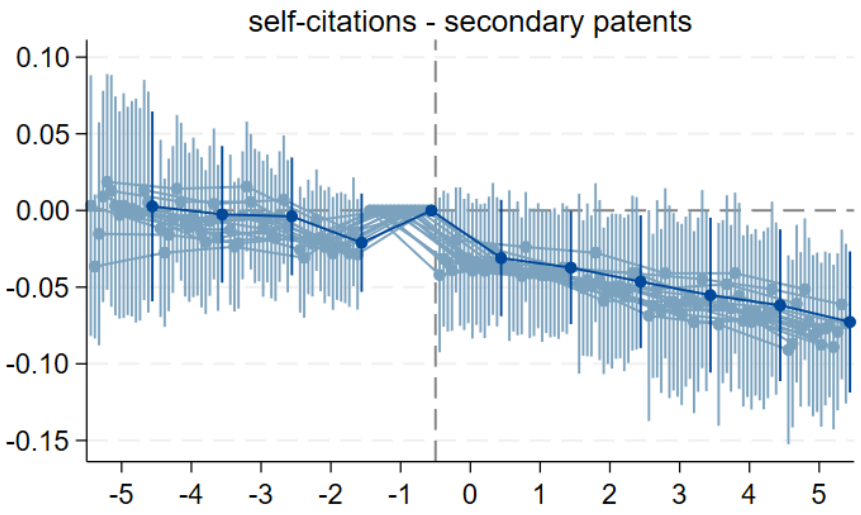
Robustness: Short Approval Lags & Leave-1-out

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









Additional analyses account for **non-European market incentives**, **firm-specific** factors, and **IV for delays**.

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! (contact: Lucy Xiaolu Wang at xiaoluwang@umass.edu)

Full paper: https://ssrn.com/abstract=4638115

Backup slides

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

Similar Ex-Ante Drug & Patent Characteristics

Early MA vs Late MA	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Early MA (N = 288)			Late MA (N = 302)				
	Mean	Median	Std. Err	Mean	Median	Std. Err	Diff	p-value
Time to approval	8.26	8	1.3	13.21	13	1.7	4.94	0.000***
Time to patent grant	2.33	2	1.2	2.44	2	1.4	0.11	0.322
Patent priority year	1987.38	1987	5.1	1987.00	1987	5.8	-0.39	0.394
First patent grant year	1989.66	1990	5.4	1989.36	1990	6.3	-0.30	0.533
First MA year	1995.64	1996	5.0	2000.17	2000	6.1	4.53	0.000***
Market exclusivity	15.00	15	0.0	12.88	13	1.7	-2.12	0.000***
Initial forward cit.	0.66	0	1.1	0.64	0	1.1	-0.02	0.812
Initial self cit.	0.27	0	0.5	0.28	0	0.5	0.02	0.684
Initial other cit.	0.40	0	0.9	0.36	0	0.8	-0.04	0.586
Initial same ICD9 cit.	0.25	0	0.5	0.25	0	0.5	0.00	0.967
Initial other ICD9 cit.	0.03	0	0.2	0.04	0	0.2	0.00	0.915
Initial biotech patent cit.	0.00	0	0.0	0.00	0	0.1	0.00	0.329
Initial secondary patent cit.	0.13	0	0.4	0.10	0	0.3	-0.03	0.334
Initial process patent cit.	0.02	0	0.2	0.03	0	0.2	0.00	0.875
Initial product patent cit.	0.19	0	0.4	0.21	0	0.5	0.02	0.544
Size of patent family	26.83	24	16.7	24.77	24	14.6	-2.06	0.112
Number of applicants	1.09	1	0.3	1.10	1	0.3	0.01	0.827
Transn. patent family	0.87	1	0.3	0.85	1	0.4	-0.01	0.630
Triadic patent family	0.52	1	0.5	0.56	1	0.5	0.05	0.268
Tech area organic chem.	0.44	0	0.5	0.50	1	0.5	0.07	0.110
Tech area pharma.	0.47	0	0.5	0.36	0	0.5	-0.10	0.010***
Tech area biotech.	0.06	0	0.2	0.10	0	0.3	0.05	0.035**
Tech area material chem.	0.01	0	0.1	0.01	0	0.1	-0.00	0.616
Applicant country US	0.36	0	0.5	0.33	0	0.5	-0.03	0.497
Applicant country Europe	0.47	0	0.5	0.43	0	0.5	-0.04	0.311

Mean comparison – similar disease characteristics

- Similar early/late MA mean by ICD-9 categories (& leave-one-out analyses)
  - Small size diff in 1) early: endocrine/immun. & mental disorders; 2) *late: skin diseases

Early MA vs Late MA	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Early MA (N = 288)			Late MA (N = 302)				
	Mean	Median	Std. Err	Mean	Median	Std. Err	Diff	p-value
Number of ICD9	2.32	2	2.4	2.26	2	2.4	-0.06	0.790
Infectious/parasitic diseases	0.23	0	0.4	0.26	0	0.4	0.03	0.470
Neoplasms	0.14	0	0.4	0.15	0	0.4	0.00	0.905
Endocrine/immun. disorders	0.12	0	0.3	0.18	0	0.4	0.06	0.066*
Blood diseases	0.03	0	0.2	0.02	0	0.2	-0.01	0.482
Mental disorders	0.05	0	0.2	0.09	0	0.3	0.04	0.061*
Nervous system diseases	0.12	0	0.3	0.11	0	0.3	-0.01	0.633
Circulatory system diseases	0.17	0	0.4	0.15	0	0.4	-0.03	0.435
Respiratory system diseases	0.07	0	0.3	0.05	0	0.2	-0.02	0.321
Digestive system diseases	0.06	0	0.2	0.04	0	0.2	-0.02	0.405
Genitourinary diseases	0.08	0	0.3	0.12	0	0.3	0.04	0.192
Pregnancy/childbirth	0.00	0	0.1	0.00	0	0.1	-0.00	0.952
Skin diseases	0.07	0	0.3	0.02	0	0.2	-0.04	0.017**
Musculoskeletal diseases	0.07	0	0.3	0.09	0	0.3	0.01	0.578
Conditions perinatal period	0.04	0	0.2	0.02	0	0.1	-0.02	0.213
Ill-defined conditions	0.09	0	0.3	0.08	0	0.3	-0.02	0.542
Ijury/poisoning	0.08	0	0.3	0.07	0	0.2	-0.01	0.541

MA and forward citations: results summary

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	DV: Log Forward Citations							
	All	Self	Other	Secondary	Process	Product	= ICD9	≠ ICD9
n years before MA	-0.006	0.006	-0.012	-0.024	-0.018	0.014	-0.026	0.017
	(0.038)	(0.021)	(0.037)	(0.026)	(0.013)	(0.020)	(0.025)	(0.022)
4 years before MA	-0.023	-0.015	-0.010	-0.019	-0.022*	0.003	-0.016	-0.011
	(0.031)	(0.020)	(0.028)	(0.020)	(0.011)	(0.017)	(0.021)	(0.015)
3 years before MA	-0.034	-0.005	-0.035	-0.009	-0.008	-0.005	-0.014	0.008
	(0.028)	(0.018)	(0.027)	(0.020)	(0.011)	(0.015)	(0.018)	(0.015)
2 years before MA	0.003	-0.009	0.009	-0.040**	-0.018*	0.006	-0.010	-0.013
	(0.026)	(0.017)	(0.024)	(0.018)	(0.009)	(0.014)	(0.018)	(0.014)
Year of MA	-0.023	-0.027*	-0.001	-0.015	0.002	0.003	-0.022	-0.001
	(0.026)	(0.016)	(0.025)	(0.019)	(0.012)	(0.014)	(0.017)	(0.014)
1 year after MA	-0.017	-0.029*	0.006	-0.049***	0.012	0.017	-0.024	0.001
	(0.028)	(0.016)	(0.026)	(0.019)	(0.013)	(0.015)	(0.019)	(0.014)
2 years after MA	-0.024	-0.036**	0.001	-0.036*	-0.010	0.022	-0.014	0.002
	(0.032)	(0.017)	(0.030)	(0.020)	(0.014)	(0.018)	(0.022)	(0.016)
3 years after MA	-0.084**	-0.040**	-0.050	-0.075***	-0.015	-0.011	-0.073***	0.003
	(0.037)	(0.019)	(0.035)	(0.022)	(0.016)	(0.018)	(0.024)	(0.018)
4 years after MA	-0.074*	-0.046**	-0.037	-0.058**	-0.015	0.006	-0.068**	-0.002
	(0.040)	(0.021)	(0.039)	(0.025)	(0.017)	(0.020)	(0.027)	(0.020)
n years after MA	-0.120**	-0.053**	-0.076	-0.090***	-0.019	-0.009	-0.083**	-0.027
	(0.049)	(0.025)	(0.047)	(0.028)	(0.019)	(0.024)	(0.032)	(0.023)
Patent Grant	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SPC Grant	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Patent-Drug FE	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Citation Year FE	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Observations	12390	12390	12390	12390	12390	12390	12390	12390
Cluster	590	590	590	590	590	590	590	590