

Patent Pendency and Innovation in Regulated Sectors: Evidence from Pharmaceuticals and Medical Devices

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Abstract

Pharmaceutical and medical device innovators must simultaneously manage long, uncertain regulatory pathways and patent prosecution processes to ensure their inventions have a chance at entering the market. However, the relationship between the timing of patent prosecution decisions and subsequent innovation outcomes has not yet been examined in these contexts. Here, we decompose pendency at the Australian patent office into applicant-controlled delay, backlog, and examination scrutiny, relating each to follow-on innovation, commercialization, and child applications in the pharmaceutical and medical device sectors. Applicant delays are the most predictive component for positive innovation outcomes in both sectors, especially for their respective commercialization pathways. For high-regulatory-risk devices, in particular, we find that an additional year of applicant delay is associated with roughly double the odds of commercialization, highlighting the need to consider patent pendency as a composite measure to study the interaction of patent office policy and applicant strategy during prosecution.

I. INTRODUCTION

Patent systems are meant to strike a balance between two competing objectives: rewarding invention and enabling the diffusion of new knowledge. A central, and underexamined, part of that balance is patent pendency, the period between filing and final acceptance, during which an invention may already be disclosed to others while the final contours of the patent right remain unresolved. Pendency is often treated as an administrative feature of the patent system, and one that offices themselves work to measure and reduce, yet it

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can materially shape the behavior of prospective patentees.¹ For applicants, a longer pendency period may preserve option value, allowing firms to delay commitment to the prosecution process while research programs, regulatory approval, and commercial strategies progress and evolve. For rivals and other follow-on innovators, the same period may prolong uncertainty over the eventual scope of exclusionary rights. A growing body of work links the timing of examination and disclosure to cumulative innovation,² but the mechanisms through which different forms of delay affect private and social outcomes remain underexplored, especially in highly regulated sectors.

Prosecution timing can matter in any field, but it is especially consequential in pharmaceuticals and medical devices, where fixed patent terms interact with lengthy and uncertain regulatory pathways. However, the two sectors differ considerably in their research and development (R&D) processes and in the regulatory frameworks within which they operate. Pharmaceutical innovation is closely tied to long clinical and approval timelines, uniformly high regulatory stakes, and strategic concerns around exclusivity and evergreening; medical devices span a much wider range of product types and risk classes, with some technologies iterating rapidly and others confronting regulatory burdens closer to those of pharmaceuticals.

This chapter examines how patent pendency shapes both applicant-side outcomes and external follow-on innovation in pharmaceuticals and medical devices patented at IP Australia, with particular attention to the policy question of the impact of different sources of delay. If pendency systematically affects economically important downstream behavior, such as patent renewal, child application strategies,³ commercialization, or third-party innovation, then

¹ See, e.g., Ahmer Iqbal Siddiqui, “Report on Patent Backlogs, Inventories and Pendency” (IP Australia Economic Research Paper 01, 2014); Benjamin Mitra-Kahn, Alan Marco, et al., “Patent Backlogs, Inventories and Pendency: An International Framework” (joint report, UK Intellectual Property Office and U.S. Patent and Trademark Office, 2013); Charles A. W. deGrazia, Nicholas A. Pairolo, and Mike H. M. Teodorescu, “Examination Incentives, Learning, and Patent Office Outcomes: The Use of Examiner’s Amendments at the USPTO,” *Research Policy* 50, no. 10 (2021): 104315.

² Kyle Higham, Euan Richardson, and Gaétan de Rassenfosse, “Patent Pendency and Follow-on Innovation” (SSRN working paper no. 5054980, 2024). See also Joshua S. Gans, David H. Hsu, and Scott Stern, “The Impact of Uncertain Intellectual Property Rights on the Market for Ideas: Evidence from Patent Grant Delays,” *Management Science* 54, no. 5 (2008): 982–997; Deepak Hegde, Kyle Herkenhoff, and Chenqi Zhu, “Patent Publication and Innovation,” *Journal of Political Economy* 131, no. 7 (2023): 1845–1903; Alberto Galasso and Mark Schankerman, “Patents and Cumulative Innovation: Causal Evidence from the Courts,” *Quarterly Journal of Economics* 130, no. 1 (2015): 317–369.

³ A child application is a later application derived from a still-pending parent; in Australia, a divisional. Because a child inherits the parent’s priority date while remaining pending itself, applicants can use a sequence of them to keep

examination timing belongs alongside patent term and regulatory exclusivity in the standard account of how innovation incentives operate in regulated sectors. Using linked administrative and bibliographic data, we distinguish between applicant-controlled delay, backlog, and scrutiny-related delay during examination. We then relate these components to patent lapse, intra-firm follow-on innovation, child application behavior, and third-party citations in both sectors, and to commercialization in devices and Orange Book listing in pharmaceuticals. Because no regulatory risk class appears on the patent record, we also build a text classifier, trained on Therapeutic Goods Administration (TGA) registry descriptions and their assigned risk classes, that gives each device patent a probability of falling in the two highest-risk tiers. It is not validated against an external gold standard, so we treat the risk-stratified results as exploratory; it does, however, let us locate where in the device risk distribution the association between delay and commercialization is concentrated.

Each of the components we measure, whether chosen by the applicant, imposed by the office queue, or generated by examination itself, is associated with stronger applicant-side strategic outcomes and with more frequent third-party follow-on citation. The sectors differ sharply, however, in which component these associations run through. In devices, applicant-controlled delay predicts commercialization, most strongly for higher-risk products. In pharmaceuticals, examination scrutiny is associated with both Orange Book listing and intra-firm follow-on innovation. In both sectors, child applications are filed over a wider window (beyond the prosecution of the parent patent) when pendency is longer, and in neither do we find support for the view that pending rights suppress external follow-on activity.

This chapter builds on, and is distinct from, economy-wide evidence on patent pendency, and on a wider literature on how the regulatory environment shapes innovation incentives in pharmaceuticals and medical devices.⁴ Prior work using Australian administrative data establishes the average relationships between pendency components and applicant value and

claim scope open and to extend the window over which a family is enlarged, which is why we treat child applications as an outcome as well as a control.

⁴ See, e.g., Margaret K. Kyle, “Incentives for Pharmaceutical Innovation: What’s Working, What’s Lacking,” *International Journal of Industrial Organization* 84 (2022): 102850; Alberto Galasso and Hong Luo, “Tort Reform and Innovation,” *Journal of Law and Economics* 60, no. 3 (2017): 385–412.

follow-on innovation across all technology fields.⁵ However, those designs cannot address how examination timing interacts with regulatory approval clocks, why delay might be differently valuable where clinical pathways are long and uncertain, or whether pending status feeds sector-specific portfolio strategies such as evergreening through chains of child applications. Answering these questions requires the sector-specific outcome linkages we assemble here; as such, we treat pharmaceuticals and medical devices as among the settings in which the policy stakes of examination timing are at their highest, and build the analysis around the sectors’ distinctive regulatory and portfolio dynamics.

The remainder of the chapter is organized as follows. Section II reviews the literature on patent pendency, regulated innovation, and sector-specific patent-related outcomes. Section III sets out the empirical strategy and the decomposition of pendency into applicant, backlog, and scrutiny components. Section IV presents the results, and Section V discusses implications for patent policy.

II. LITERATURE REVIEW

A. Patent pendency and innovation outcomes in regulated sectors

Patent pendency, the duration between filing and a final decision, is a period of uncertainty that shapes the strategic landscape for applicants and competitors alike, and one that applicants often use to their advantage.⁶ For applicants, extended pendency can provide a period of focused internal development, allowing firms to align their patent scope with evolving commercialization strategies, R&D programs, and the market at large.⁷ However, for the broader innovation ecosystem, this duration acts as a barrier; longer pendency typically correlates with a period of delayed entry or observation, where follow-on innovators may wait until the final scope of rights is clarified.⁸ Further, clarification of rights at allowance can accelerate

⁵ Kyle Higham, Euan Richardson, and Gaétan de Rassenfosse, “Patent Pendency and Applicant Innovation Outcomes” (working paper, Motu Economic and Public Policy Research, 2024); Higham et al., “Patent Pendency and Follow-on.”

⁶ Alfons Palangkaraya, Paul H. Jensen, and Elizabeth Webster, “Applicant Behaviour in Patent Examination Request Lags,” *Economics Letters* 101, no. 3 (2008): 243–245.

⁷ Cesare Righi, Davide Cannito, and Theodor Vladasel, “Continuing Patent Applications at the USPTO,” *Research Policy* 52, no. 4 (2023): 104742.

⁸ Higham et al., “Patent Pendency and Follow-on.”

cooperative licensing, so pendency shapes the timing of commercialization as well as of follow-on invention.⁹

In regulated industries like life sciences, the impact of pendency is further complicated by the interaction between the patent clock and regulatory approval lags. Because (non-extended) patent terms are fixed at 20 years from the filing date (extensions of term, discussed below, are available only in narrow circumstances), lengthy clinical trial and regulatory review periods erode effective market life¹⁰ and create a significant distortion in research investment. Previous work has found that a typical drug spends around 9.1 years in clinical development before approval, so a large share of the nominal term is consumed before market entry,¹¹ and firms accordingly underinvest in research with long horizons such as cancer prevention and early-stage treatment.¹² Where appropriability is perceived as insecure, launch in a given jurisdiction may be slowed altogether.¹³ Stronger effective exclusivity does not necessarily suppress later entry, however. In the United States, longer first-in-class exclusivity is associated with more subsequent approvals in the same class, concentrated among imitative follow-on products.¹⁴

B. Sector-specific proxies for value and strategy

Capturing commercialization and strategic behavior in these sectors requires data linkages specific to each. For medical devices, Virtual Patent Marks (VPMs) can proxy commercialization, since device firms have been found to use them heavily to signal patent protection on marketed products and deter infringement.¹⁵ For pharmaceuticals, the U.S. Food and Drug Administration (FDA) Orange Book links approved drugs to the patents protecting

⁹ Gans, Hsu, and Stern, “The Impact of Uncertain Intellectual Property Rights.”

¹⁰ C. Scott Hemphill and Bhaven N. Sampat, “Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals,” *Journal of Health Economics* 31, no. 2 (2012): 327–339.

¹¹ Dean G. Brown, Heike J. Wobst, Abhijeet Kapoor, Leslie A. Kenna, and Noel Southall, “Clinical Development Times for Innovative Drugs,” *Nature Reviews Drug Discovery* 21, no. 11 (2022): 793–794.

¹² Eric Budish, Benjamin N. Roin, and Heidi Williams, “Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials,” *American Economic Review* 105, no. 7 (2015): 2044–2085.

¹³ Iain M. Cockburn, Jean O. Lanjouw, and Mark Schankerman, “Patents and the Global Diffusion of New Drugs,” *American Economic Review* 106, no. 1 (2016): 136–164.

¹⁴ Duncan S. Gilchrist, “Patents as a Spur to Subsequent Innovation? Evidence from Pharmaceuticals,” *American Economic Journal: Applied Economics* 8, no. 4 (2016): 189–221.

¹⁵ While a mark indicates the transition from legal right to actively marketed asset, VPMs do not capture every instance of commercial use: marking is voluntary and concentrated among larger firms with formal intellectual property management, so commercialization is understated, and understated non-randomly. See Gaétan de Rassenfosse, “Notice Failure Revisited: Evidence on the Use of Virtual Patent Marking” (working paper, National Bureau of Economic Research, 2018).

them.¹⁶ Those entries identify the patents most likely to block generic entry, which makes them a workable measure of a drug's potential market life and commercial value.¹⁷

Because regulatory delay erodes the effective statutory term, the Australian Patent Term Extension (PTE) regime compensates applicants for time spent obtaining registration on the Australian Register of Therapeutic Goods (ARTG).¹⁸ Extensions are limited to “pharmaceutical substances per se,” so a PTE request identifies the primary patents most critical to a drug's commercial success. Granted PTEs are too rare in Australia to serve as a dependent variable, though the availability of the mechanism here and elsewhere suggests a high premium on effective patent life. In the United States, similarly extended patents serve as bellwether indicators for generic entry, and about one-third of them are secondary rather than primary patents, so commercially decisive rights can themselves arise from follow-on filing strategies.¹⁹ Whether extension remains the right instrument, or instead interacts with portfolio-building in ways that entrench exclusivity beyond the core inventive contribution, is contested in Australia as elsewhere.²⁰

Portfolio strategy after grant responds to regulatory risk and to follow-on filing opportunities. In devices, a product's likely risk classification sets the level of scrutiny health regulators apply, which may in turn shape applicant strategy in the parallel patenting process. In both sectors, the main instrument in such a strategy is the continuing application, through which applicants build thickets of overlapping rights.²¹ Small-molecule drugs are commonly protected by multiple patents,²² and the resulting portfolios have been read as an arms race of strategic

¹⁶ U.S. Food and Drug Administration, “Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book),” <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>.

¹⁷ Jacob S. Wharton, “Orange Book Listing of Patents under the Hatch-Waxman Act,” *Saint Louis University Law Journal* 47 (2003): 1027; Maya Durvasula, C. Scott Hemphill, Lisa Larrimore Ouellette, Bhaven Sampat, and Heidi L. Williams, “The NBER Orange Book Dataset: A User's Guide,” *Research Policy* 52, no. 7 (2023): 104791.

¹⁸ Patents Act 1990 (Cth) ch 6 pt 3 (Austl.).

¹⁹ Victor L. Van de Wiele, Aaron S. Kesselheim, Sarosh Nagar, and S. Sean Tu, “The Prevalence of Drug Patent Term Extensions in the United States, 2000–2018,” *Nature Biotechnology* 41, no. 7 (2023): 903–906.

²⁰ Allison Sadick, “The Dispute of the Patent Term Extension in Australia,” *Journal of Intellectual Property Law & Practice* 14, no. 9 (2019): 699–715.

²¹ Michael A. Carrier and S. Sean Tu, “Why Pharmaceutical Patent Thickets Are Unique,” *Texas Intellectual Property Law Journal* 32 (2023): 79.

²² Lisa Larrimore Ouellette, “How Many Patents Does It Take to Make a Drug? Follow-on Pharmaceutical Patents and University Licensing,” *Michigan Telecommunications and Technology Law Review* 17 (2010): 299.

legal activity rather than a reflection of therapeutic advance.²³ The secondary patents these filings yield tend to arrive late, five or more years after priority,²⁴ and can add several years of nominal life through formulation and method-of-use claims.²⁵ That nominal extension is unevenly realized, since higher-sales drugs accumulate more patents and longer nominal terms even as effective market life stays much shorter, secondary patents being disproportionately challenged.²⁶ Disclosing no new technological matter, these patents nonetheless leave claim boundaries unsettled, and the resulting uncertainty raises transaction costs for competitors and prolongs the exclusionary power of the original invention.²⁷

III. EMPIRICAL STRATEGY

Our strategy integrates administrative records with specialized commercial data and a granular decomposition of pendency duration, to isolate the mechanisms through which the pendency components shape the tension between private strategic value and broader technological spillovers. All variables not introduced below are described, with their construction, in Online Appendix A.

A. Special considerations for the medical sector

Estimating the relationship between pendency and outcomes in the medical sector requires addressing the misalignment between statutory patent terms and effective commercial lifecycles. In both sectors, the 20-year term is eroded by mandatory pre-market phases, including clinical trials and (in Australia) TGA approval, but only pharmaceutical applicants can, in some cases, request an extension of term to compensate for that erosion. For pharmaceuticals, primary patents are often granted years before the drug reaches the market, and because the Australian patent term runs from the filing date and regulatory exclusivity runs from marketing approval, a later grant has minimal impact on effective protection. As such, the more relevant consideration

²³ Maya Durvasula and Lisa Larrimore Ouellette, “Beyond the Pharmaceutical Patent Arms Race” (SSRN working paper no. 5229897, 2025).

²⁴ S. Sean Tu, “The Long Con: An Empirical Analysis of Pharmaceutical Patent Thickets,” *University of Pittsburgh Law Review* 86 (2024): 213.

²⁵ Amy Kapczynski, Chan Park, and Bhaven Sampat, “Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of ‘Secondary’ Pharmaceutical Patents,” *PLOS ONE* 7, no. 12 (2012): e49470.

²⁶ C. Scott Hemphill and Bhaven N. Sampat, “Patents, Innovation, and Competition in Pharmaceuticals: The Hatch-Waxman Act after 40 Years,” *Journal of Economic Perspectives* 39, no. 2 (2025): 27–52.

²⁷ Righi et al., “Continuing Patent Applications”; Tu, “The Long Con.”

is the period of uncertainty during which patent scope is not settled, which is also the period when firms must decide how much to invest in development and whether to license.²⁸

Within the medical device sector, the regulatory burden is highly heterogeneous. The complexity and duration of regulatory approval are closely tied to a device’s invasiveness and risk profile,²⁹ and applicants may time the prosecution of related patents around that regulatory timeline. To control for this heterogeneity, we stratify our medical device sample by regulatory risk. We employ a text-based classifier, trained on device summaries published by the TGA and their assigned risk classes, to score each patent on how likely it is to describe a device in one of the two higher-risk regulatory classes. The score is continuous, and we use it both as a control for the prosecution and strategic idiosyncrasies of high-risk devices and, in Section IV, as the basis for splitting the device sample. Its construction is described in Online Appendix B.

Finally, empirical designs must account for child application strategy. Treating child patents as independent observations would double-count the same underlying invention, so we restrict the focal analysis to the first Australian filing within a given simple family, as defined in the European Patent Office (EPO) master documentation database (DOCDB), and instead capture that behavior through a control for the number of child applications in the family, our proxy for the applicant’s child application strategy. This isolates the initial pendency period while still controlling for broader portfolio management. The same count is an outcome in Section IV, where we model child application behavior directly.

B. Outcomes

To evaluate the private value and strategic utility of a patent, we examine several applicant-side outcomes. First, we model *lapse risk* by measuring the survival time from grant until the applicant’s failure to pay renewal fees, right-censored at the end of our observation window, which leaves 23% of device and 19% of pharmaceutical patents still in force at that

²⁸ Brown et al., “Clinical Development Times”; Gans, Hsu, and Stern, “The Impact of Uncertain Intellectual Property Rights.”

²⁹ Ariel Dora Stern, “Innovation under Regulatory Uncertainty: Evidence from Medical Technology,” *Journal of Public Economics* 145 (2017): 181–200; Matthew Grennan and Robert J. Town, “Regulating Innovation with Uncertain Quality: Information, Risk, and Access in Medical Devices,” *American Economic Review* 110, no. 1 (2020): 120–161; Elaine Blair, “Australian Medical Device Regulatory Framework: An Overview,” in *Medical Regulatory Affairs*, ed. Jack Wong and Raymond Tong (New York: Jenny Stanford Publishing, 2025).

date. Second, we construct sector-specific binary indicators for *commercialization*. For medical devices, commercialization is defined by linkage to the IPProduct database, denoting whether the patent is marked on a marketed product.³⁰ For pharmaceuticals, we proxy approved therapeutic value through existing linkage data to the FDA Orange Book via U.S. family equivalents.³¹ The Orange Book lists patents on drugs approved through new drug applications, so patents on biologics, which are licensed through a separate pathway, are not registered in this source even when the product is marketed. Our listing data also end in 2016, so later filings have had less time to be listed, and the filing-year fixed effects absorb the resulting differences between cohorts. Finally, we measure *intra-firm follow-on* innovation using a binary indicator for whether the focal patent is cited by the applicant’s subsequent filings, capturing the degree to which the patent supports cumulative internal R&D.

To assess broader technological spillovers and market impact, we examine third-party follow-on innovation. This is captured through forward citations, excluding assignee self-citations. Because citation data are highly skewed, we measure *citation incidence* as a binary variable indicating whether a patent receives at least one forward citation from a third party. To add context to this measure, we also examine two specific sub-types of citations: X/Y citations, which indicate strong technological proximity by threatening novelty or inventive step, and competitive citations, which are those found both in the text of the patent and on the front page.³² Beyond mere incidence, we also model *citation timing*, defined as the duration from the focal patent’s first publication to its first third-party citation. The model is estimated on the full sample, with patents not yet cited right-censored at the end of 2022. Because fewer than one in ten is ever cited by a third party, most observations are censored.³³

³⁰ IPProduct, “IPProduct Database,” <https://ipproduct.io>.

³¹ Durvasula et al., “The NBER Orange Book.” Australia has no equivalent register: patent linkage here operates through certificates required of generic applicants at the point of marketing approval, with no public list of patents covering approved products. Therapeutic Goods Act 1989 (Cth) ss 26B–26C (Austl.). The U.S. linkage is nonetheless informative for Australian filings, since a listing attaches to the invention: the compound worth listing in the United States is the compound claimed in the Australian member of the same family.

³² Higham et al., “Patent Pendency and Follow-on.”

³³ Kyle Higham and Sadao Nagaoka, “Language Barriers and the Speed of International Knowledge Diffusion,” *Nature Human Behaviour* 10, no. 5 (2026): 860–872.

C. Pendency variables

While we define *total pendency* as the gross duration from the Australian filing date to the date of final acceptance, treating this period as a single variable masks the fundamentally different incentives and actors driving the delay. Therefore, we partition total pendency into three mutually exclusive components: one attributable to the applicant and two attributable to the patent office.

First, *applicant-side pendency* captures the aggregate time strictly controlled by the applicant. This includes pre-examination delays, such as the time taken to formally lodge a Request for Examination (RFE),³⁴ as well as within-examination delays, such as the time taken to draft and file responses to adverse office actions. This kind of delay can serve as a deliberate strategic tool to preserve option value and adapt claim scope while waiting for clinical trial results or regulatory feedback.³⁵

Second, we decompose office-side delay into administrative and substantive phases. *Backlog pendency* represents administrative queueing time, measured as the lag between the applicant's RFE and the issuance of the First Examination Report by the patent office. Because little active examination occurs during this period, it functions as a largely exogenous administrative delay.

Finally, *scrutiny pendency* captures the duration of active examination. Calculated as the total office-controlled time minus the backlog period, it covers the substantive exchange between examiner and applicant, as distinct from time spent in the queue. Australian prosecution is closer to U.S. than to European practice in having no cap on the number of reports and no per-report fee, so the number of rounds reflects the applicant's willingness to keep negotiating as much as the examiner's objections. The exchange is constrained instead by the deadline to reach acceptance, which is 21 months from the first report where examination was requested before

³⁴ Australian applicants must actively request examination; the office does not begin of its own motion. A request may be made at any time up to five years from the filing date, and if none is made the office issues a direction, after which the applicant has two months to comply or the application lapses. Patents Act 1990 (Cth) s 44; Patents Regulations 1991 (Cth) reg 3.15 (Austl.). Directions are common, so part of the variation in when examination begins is not itself an applicant choice.

³⁵ Mark A. Lemley and Kimberly A. Moore, "Ending Abuse of Patent Continuations," *Boston University Law Review* 84 (2004): 63.

April 15, 2013, and 12 months thereafter.³⁶ Because the number of adverse reports is among our strategy controls, the scrutiny estimates in our preferred specification compare applications with the same number of rounds, and so reflect how long those rounds took. This kind of delay can indicate the existence of a complex technological landscape or contentious claim boundaries that require significant clarification before grant.

D. Econometric models and specifications

All models are estimated separately for the pharmaceutical and medical device subsamples, given the different market structures, innovation cycles, and regulatory frameworks governing the two sectors. Binary outcomes, namely commercialization, intra-firm follow-on, and third-party citation incidence, are estimated by logistic regression, with exponentiated coefficients reported as odds ratios (ORs). Outcomes with a temporal dimension are estimated by survival analysis. For the timing of third-party follow-on we use accelerated failure time models with a log-normal distribution, which suits the skewed distribution of citation lags and accounts for right-censoring at the end of the observation window in 2022.³⁷ For patent lapse we use a hazard model, which captures the applicant's ongoing cost-benefit calculus, since failure to pay renewal fees indicates that maintenance cost has exceeded perceived option or market value.³⁸

Identification rests on within-cohort and within-technology variation. All specifications include filing-year fixed effects and 35 World Intellectual Property Organization (WIPO) technology class fixed effects,³⁹ so that the comparison is between applications filed in the same year and classified in the same field, mitigating impacts of any macroeconomic shocks, statutory changes, secular trends in patenting behavior, and baseline citation propensities across technological sub-fields. What remains is variation in when a given applicant requested examination, how long the queue for that field was, and how much examination followed. We do not claim that this residual variation is exogenous, and we read the estimates as conditional

³⁶ Patents Act 1990 (Cth) s 142(2)(e); Patents Regulations 1991 (Cth) reg 13.4(1)(b) (Austl.).

³⁷ Janet M. Box-Steffensmeier and Bradford S. Jones, *Event History Modeling: A Guide for Social Scientists* (Cambridge: Cambridge University Press, 2004).

³⁸ Ariel Pakes, "Patents as Options: Some Estimates of the Value of Holding European Patent Stocks" (working paper, National Bureau of Economic Research, 1984); Jean O. Lanjouw, Ariel Pakes, and Jonathan Putnam, "How to Count Patents and Value Intellectual Property: The Uses of Patent Renewal and Application Data," *Journal of Industrial Economics* 46, no. 4 (1998): 405–432.

³⁹ Ulrich Schmoch, "Concept of a Technology Classification for Country Comparisons" (working paper, WIPO, 2008).

associations throughout. The primary applicant-outcome and citation analyses report three specifications, adding first baseline and then strategy controls to the pendency components. The last is our preferred specification throughout unless otherwise stated. In the tables that follow, baseline and strategy control coefficients are estimated but not reported, and these control sets are listed in Online Appendix A. Standard errors are clustered by applicant, since applicants file repeatedly and prosecution strategy is a firm-level choice.

E. Data

1. Sources

We draw on a combination of administrative patent records, global bibliographic databases, and external linkages to construct our variables. Our primary source for Australian patent administrative data is the IP Government Open Data (IPGOD) provided by IP Australia.⁴⁰ IPGOD supplies all critical dates and examination milestones (e.g., filing dates, requests for examination, and the issuance of adverse reports) as well as legal status events such as post-grant renewals and lapses. To construct patent families and extract bibliographic details, we rely on the EPO’s Worldwide Patent Statistical Database (PATSTAT Spring 2026).⁴¹ PATSTAT allows us to map DOCDB family structures and accurately link Australian filings to their international equivalents, which is necessary for tracking global prosecution strategies.

To capture our sector-specific commercial and regulatory outcomes, we integrate three external databases. The IPROduct database identifies device commercialization⁴² and the FDA Orange Book, linked via U.S. family equivalents, identifies pharmaceutical regulatory approval,⁴³ while historical TGA device summaries and their risk classifications provide the training data for the risk classifier of Online Appendix B.⁴⁴

⁴⁰ IP Australia, “Intellectual Property Government Open Data 2022 (IPGOD),” <https://data.gov.au/data/dataset/ipgod2022>.

⁴¹ European Patent Office, “PATSTAT,” <https://www.epo.org/en/searching-for-patents/business/patstat>.

⁴² IPROduct, “IPROduct Database.”

⁴³ Durvasula et al., “The NBER Orange Book.”

⁴⁴ Therapeutic Goods Administration, “Australian Register of Therapeutic Goods (ARTG),” <https://www.tga.gov.au/resources/artg>.

2. Sample construction

To construct our final sample, we apply several structural restrictions. First, we restrict our observation window to applications filed between 2004 and 2016. This specific window allows us to observe patents under a relatively modern examination regime while allowing sufficient post-grant observation time (right-censored at the end of 2022) for longer-term outcomes such as lapse and third-party citations to accrue. The third-party citation models instead use the year of first publication anywhere in the family, since citations that plausibly reflect knowledge flow can only accrue once the disclosure is public; the two windows select overlapping but not identical sets of applications. We explicitly limit the sample to standard patents, excluding Australian “innovation patents” (a now-phased-out, lower-inventive-step right) to ensure all observations underwent substantive examination.

To ensure independence among observations, we retain only the first Australian filing within each DOCDB family as the focal invention, as described in Section III.A.

Finally, we assign the remaining focal patents to our two sectors using Cooperative Patent Classification (CPC) codes. The pharmaceutical cohort is uniquely identified using the subclass A61P (specific therapeutic activity of chemical compounds or medicinal preparations).⁴⁵ The medical device cohort comprises patents falling within the broader A61 class, strictly excluding A61P (therapeutics) and A61D (veterinary instruments). We note that this approach differs from some previous definitions,⁴⁶ in that A61K patents that are not also classified under A61P are considered part of our medical device cohort. These include patents for novel dental filling compounds, cosmetics, and other preparations with no specific therapeutic component.

IV. RESULTS

A. Summary statistics

Table 1 sets out how medical patents differ from a non-medical baseline (included in this table only, and omitted from all analyses hereafter) and how the two medical sectors differ from

⁴⁵ Colleen Cunningham and David Hall, “Linking Medical Device Technologies and Product Markets” (working paper, 2025).

⁴⁶ See, e.g., IP Australia, “A Patent Analytics Study on the Australian Pharmaceutical Industry” (2015).

each other.⁴⁷ Relative to non-medical patents, medical patents remain in force for less time yet more often support subsequent in-house follow-on innovation, and both medical sectors carry longer applicant-side pendency.

⁴⁷ These patents meet all the same criteria as the medical sector patents, except that they are not in the patent classes mentioned.

Table 1. Summary statistics

	Non-device/non-pharma		Medical devices		Pharmaceuticals	
	Mean	Std. dev.	Mean	Std. dev.	Mean	Std. dev.
<i>Applicant outcomes</i>						
Renewal time (years)	6.51	3.44	6.38	3.29	6.00	3.36
Commercialization (fraction)	0.010	0.101	0.038	0.191	0.011	0.106
Intra-firm follow-on (fraction)	0.391	0.488	0.475	0.499	0.520	0.500
<i>Pendency components (years)</i>						
Applicant-side pendency	3.10	1.20	3.58	1.11	3.77	1.06
Office backlog	0.85	0.45	0.69	0.40	0.83	0.42
Examination scrutiny	0.06	0.08	0.06	0.08	0.06	0.09
<i>Third-party follow-on outcomes</i>						
First citation, any (fraction)	0.063	0.244	0.084	0.277	0.060	0.237
First citation, X/Y (fraction)	0.017	0.130	0.028	0.164	0.020	0.139
First citation, competitive (fraction)	0.002	0.046	0.003	0.051	0.009	0.095
Years to first citation, any	3.54	2.54	3.38	2.58	3.63	2.49
Years to first citation, X/Y	3.94	2.63	3.94	2.64	3.80	2.67
Years to first citation, competitive	3.48	2.28	3.17	2.27	3.77	2.29
<i>Reported control</i>						
High-risk probability	—		0.305	0.152	—	
Observations	123,374		26,899		32,812	

Notes: Mean and standard deviation for the main analytical cohorts. Non-device/non-pharma represents the baseline pool of standard patent applications. Descriptive statistics for control variables whose coefficients are not reported are omitted; the control sets are listed in Online Appendix A.

Within the medical sector, device patents are observed commercializing at three to four times the rate of either comparison group, in part because virtual patent marking is heavier in that sector and, for pharmaceuticals, the listing data end in 2016. Pharmaceutical patents, for their part, are around three times more likely than device patents to attract competitive citations from third parties, although those citations tend to arrive later.

B. Applicant outcomes

We present the results for applicant-side outcomes in Tables 2 and 3, estimated independently for the medical device and pharmaceutical subsamples, respectively. Across both cohorts we report time to patent lapse (where a hazard ratio (HR) above one indicates a higher hazard of lapse and therefore a shorter patent life), commercialization (measured for devices by linkage to a VPM and for pharmaceuticals by Orange Book listing), and intra-firm follow-on innovation (whether the focal patent supports cumulative internal R&D).

Table 2. Applicant outcomes for medical devices

Specification	Pendency component			Reported controls		N
	Applicant	Backlog	Scrutiny	High-risk	Child applications	
<i>Panel A. Lapse hazard (HR)</i>						
(1) Pendency only	1.062*** (0.02)	1.081** (0.03)	1.027 (0.08)			26,885
(2) + Baseline	1.062*** (0.02)	1.088*** (0.03)	1.043 (0.09)	0.979 (0.09)		25,213
(3) + Strategy	1.057** (0.02)	1.057* (0.03)	0.953 (0.08)	0.950 (0.08)	0.936*** (0.01)	25,213
<i>Panel B. Commercialization (OR)</i>						
(1) Pendency only	1.171*** (0.06)	1.171 (0.15)	0.484 (0.27)			26,525
(2) + Baseline	1.234*** (0.08)	1.257 (0.18)	0.527 (0.30)	1.200 (0.54)		24,871
(3) + Strategy	1.353*** (0.12)	1.332** (0.19)	0.732 (0.39)	1.074 (0.47)	1.240*** (0.07)	24,830
<i>Panel C. Intra-firm follow-on (OR)</i>						
(1) Pendency only	1.038 (0.03)	1.010 (0.06)	0.921 (0.16)			26,885
(2) + Baseline	1.136*** (0.03)	1.106* (0.07)	1.067 (0.21)	2.854*** (0.38)		25,213
(3) + Strategy	1.159*** (0.04)	1.164** (0.07)	1.271 (0.25)	2.804*** (0.38)	1.687*** (0.06)	25,213

Filing-year and WIPO class fixed effects included in every specification.

Notes: Panel A reports hazard ratios for patent lapse; Panels B and C report odds ratios. Rows are specifications, adding control blocks cumulatively; columns are the pendency components and the controls whose coefficients we report; panels are outcomes. Each cell reports one coefficient from a single model, with its standard error directly beneath; the pendency components are measured in years. Baseline controls cover applicant type and technology environment, and strategy controls add filing and prosecution behavior (Online Appendix A). * $p < 0.10$; ** $p < 0.05$; *** $p < 0.01$. Standard errors are clustered by applicant. The high-risk probability is a composition control, reported for transparency rather than interpreted as an effect of risk class.

Table 3. Applicant outcomes for pharmaceuticals

Specification	Pendency component			Reported control	
	Applicant	Backlog	Scrutiny	Child applications	N
<i>Panel A. Lapse hazard (HR)</i>					
(1) Pendency only	0.998 (0.01)	1.000 (0.02)	0.878** (0.05)		32,798
(2) + Baseline	0.998 (0.01)	1.005 (0.02)	0.897* (0.05)		31,512
(3) + Strategy	0.991 (0.01)	0.962** (0.02)	0.816*** (0.06)	0.926*** (0.01)	31,465
<i>Panel B. Orange Book listing (OR)</i>					
(1) Pendency only	0.990 (0.07)	0.724* (0.12)	1.846** (0.51)		30,552
(2) + Baseline	1.030 (0.07)	0.685** (0.12)	2.086*** (0.50)		29,357
(3) + Strategy	1.331*** (0.14)	0.791 (0.14)	2.432*** (0.64)	1.315*** (0.09)	29,300
<i>Panel C. Intra-firm follow-on (OR)</i>					
(1) Pendency only	1.073** (0.03)	1.202*** (0.05)	0.863 (0.13)		32,799
(2) + Baseline	1.170*** (0.02)	1.239*** (0.05)	1.245 (0.17)		31,513
(3) + Strategy	1.186*** (0.03)	1.399*** (0.06)	1.612*** (0.26)	1.572*** (0.04)	31,466

Filing-year and WIPO class fixed effects included in every specification.

Notes: As for Table 2, except that the high-risk probability applies only to medical devices and is therefore absent here.

1. Medical devices

For medical devices, the results displayed in Table 2 separate by outcome rather than by pendency component. In our fully specified model, a one-year increase in applicant-side pendency is associated with a 35.3% increase in the odds of commercialization (OR = 1.353, $p < 0.01$) and a 15.9% increase in the odds of intra-firm follow-on (OR = 1.159, $p < 0.01$), and backlog shows similar associations with both (OR = 1.332 and OR = 1.164, each $p < 0.05$). Both components are also associated with a higher hazard of lapse once the full control set is included (HR = 1.057 for each, at $p < 0.05$ for applicant-side delay and $p < 0.10$ for backlog), while examination scrutiny is uninformative throughout. Delay in the device sector therefore tracks commercial application and internal cumulative innovation, along with a modestly shorter period of maintenance. The estimates for applicant-side delay and office backlog are of similar magnitude despite the two differing in who controls them, a similarity we return to below.

2. Pharmaceuticals

The dynamics of pendency operate very differently in the pharmaceutical sector, as shown in Table 3. Unlike in medical devices, applicant-side delay has no statistically significant association with the hazard of lapse in the pharmaceutical sample ($HR = 0.991$). It does, however, remain a strong predictor of high-value strategic outcomes, associating with 33.1% higher odds of an Orange Book listing ($OR = 1.331$, $p < 0.01$) and increased intra-firm cumulative innovation ($OR = 1.186$, $p < 0.01$). The largest difference between the sectors lies in examination scrutiny. For pharmaceuticals, longer scrutiny is a strong predictor of both Orange Book listing ($OR = 2.432$, $p < 0.01$) and intra-firm follow-on innovation ($OR = 1.612$, $p < 0.01$).⁴⁸ This pattern is consistent with the possibility that commercially important pharmaceutical patents spend longer in examination,⁴⁹ which may partly explain why they are both more likely to be maintained over time and associated with commercially consequential outcomes. Longer scrutiny is also associated with a significantly lower hazard of lapse for the broader pharmaceutical sample ($HR = 0.816$, $p < 0.01$), implying longer patent life. The same specification shows a lower hazard of lapse for backlog ($HR = 0.962$, $p < 0.05$), so pharmaceutical patents that spent longer in the queue are also held marginally longer once granted.

C. Child application strategy and evergreening

In our main specifications, we include the count of child applications as a predictor of a patent's private value. However, child application strategies, which are frequently employed in the life sciences to build patent thickets or facilitate “evergreening,”⁵⁰ are intrinsically linked to the pendency of the original patent. Under Australian patent law, divisional applications can be filed at any time while the parent application is pending, or up to three months from the date of

⁴⁸ Dropping the 8,439 applications (25.7% of the pharmaceutical sample) that carry a CPC code associated with biologics (Online Appendix C) removes 8 of the 372 Orange Book listings. The preferred-specification odds ratios become 1.367 for applicant-side delay ($p < 0.01$), 0.796 for backlog ($p = 0.22$), and 2.701 for scrutiny ($p < 0.01$), against 1.331, 0.791, and 2.432 in Table 3.

⁴⁹ Mark A. Lemley, Doug Lichtman, and Bhaven Sampat, “What to Do about Bad Patents?” *Regulation* 28 (2005): 10.

⁵⁰ Hemphill and Sampat, “Evergreening, Patent Challenges”; Hazel V. J. Moir, “Exploring Evergreening: Insights from Two Medicines,” *Australian Economic Review* 49, no. 4 (2016): 413–431; Hazel V. J. Moir, “Pharmaceutical Patents and Evergreening,” in *The Cambridge Handbook of Investment-Driven Intellectual Property* (Cambridge: Cambridge University Press, 2023), 133–152.

advertisement of its acceptance.⁵¹ Because Australian double-patenting laws are relatively generous, prohibiting only strict redundancy of claiming, applicants can legally file a sequence of divisionals. Maintaining a pending divisional provides option value: applicants can respond to attempts to design around the parent claims, pursue broader protection where parent claims were limited during examination, or adapt as the invention develops.

To understand whether pendency acts merely as a correlated attribute or as a direct mechanism facilitating these strategies, we model child application behavior directly as a function of our pendency components. We analyze two family-level outcomes, restricted to Australian filings. First, we model the *child application count* (the total number of child applications in the family) using Poisson regression, reporting incidence rate ratios (IRRs). Second, we model the *child application span* (the temporal span of the strategy, measured as the lag in years between the first and last filing in the family) using ordinary least squares (OLS), conditional on the family containing at least one child application. Selection into that sample is itself associated with pendency. The results are displayed in Table 4.

⁵¹ The three-month limit dates from the Raising the Bar reforms, applying to divisional applications made on or after April 15, 2013; previously a divisional could be filed at any time before the parent lapsed or was refused, withdrawn, or granted. The earlier rule, which covers much of our filing window, ties the available window still more closely to the parent's pendency.

Table 4. Child application strategy outcomes

	Medical devices		Pharmaceuticals	
	Count (IRR)	Span (OLS, years)	Count (IRR)	Span (OLS, years)
<i>Pendency components</i>				
Applicant-side pendency	1.249*** (0.05)	0.924*** (0.05)	1.195*** (0.03)	0.849*** (0.04)
Office backlog	1.505*** (0.15)	1.465*** (0.14)	1.375*** (0.08)	0.973*** (0.09)
Examination scrutiny	1.728** (0.38)	1.358*** (0.47)	1.346** (0.20)	0.236 (0.42)
<i>Reported control</i>				
High-risk probability	1.603** (0.34)	0.065 (0.32)	—	—
Baseline controls	Yes	Yes	Yes	Yes
Filing-year fixed effects	Yes	Yes	Yes	Yes
WIPO class fixed effects	Yes	Yes	Yes	Yes
Observations	25,213	3,131	31,466	4,462

Notes: Count is the number of child applications filed at IP Australia, reported as an incidence rate ratio from a Poisson model. Span is the number of years between the first filing in the family and the most recent child application, reported as an OLS coefficient and estimated on families with at least one child application. These models carry baseline controls only, and the constant is estimated but not shown. Otherwise as for Table 2.

For medical devices, all forms of pendency are strongly associated with a higher volume of child applications. A one-year increase in applicant-side pendency is associated with a child application rate 25% higher (IRR = 1.249, $p < 0.01$), and a one-year increase in backlog with a rate 50% higher (IRR = 1.505, $p < 0.01$). The association with active examination is the strongest of the three. Translated to a weekly basis, its annualized coefficient (IRR = 1.728) corresponds to an expected child application count approximately 1.1% higher for each additional week of active scrutiny.

Longer pendency is associated with both the volume of filings and the span of time over which these families are built. Each year of applicant delay (+0.924 years) and of backlog delay (+1.465 years) is associated with a wider gap between the first and last filing in the family (both $p < 0.01$), and each additional week of scrutiny with a child application span about 1.4 weeks wider. That is, in the device sector prolonged pendency goes hand in hand with persistent, multi-year portfolio expansion, which is consistent with maintaining pending child applications where rapid technological iteration can leave the parent's claims behind.

For the pharmaceutical sector, very similar patterns are observed. A one-year increase in applicant pendency ($IRR = 1.195$, $p < 0.01$) and a one-year increase in backlog ($IRR = 1.375$, $p < 0.01$) are each associated with a higher child application count, as is active scrutiny, where each additional week of examination corresponds to a child application rate approximately 0.6% higher ($p < 0.05$).

The temporal spread of these filings, however, follows a slightly different pattern from devices. Pharmaceutical applicants' own strategic delays (+0.849 years) and backlog (+0.973 years) are both associated with a longer child application window (both $p < 0.01$), while active scrutiny pendency shows no statistically significant association with child application span.

This contrast is consistent with a different use of the child application system across the two sectors. In pharmaceuticals, the evergreening window stretches further where administrative queueing and early strategic delay are longer, which may reflect applicants waiting for lengthy clinical trials to resolve. Longer examination scrutiny, by contrast, is associated with a larger number of child filings but not with a longer calendar timeline over which they are filed. That is consistent with applicants filing concurrent child applications to meet immediate examiner objections, such as lack of unity across Markush groups, or to pursue broader protection where parent claims are being limited, rather than with scrutiny extending the window over which the family can be enlarged.

D. Risk heterogeneity in medical devices

High-risk devices, such as life-sustaining implants (TGA Class IIb and Class III), face stricter clinical trial requirements and higher regulatory hurdles than low-risk consumables like basic surgical tools (Class I and Class IIa). To ensure our results are robust to the large volume of low-risk devices, we use our text-based risk classifier to test for differences across risk profiles. We re-estimate the applicant outcome models in two ways, first by interacting the pendency variables with the continuous predicted high-risk probability in the full sample, and second by splitting the sample at a predicted probability of 0.5 into low-risk ($N \approx 22,000$) and high-risk ($N \approx 3,000$) devices, retaining the continuous probability as a control within each group. The results of these regressions are displayed in Table 5.

Table 5. Applicant outcomes by medical device risk heterogeneity

Sample	Pendency component			Reported control	
	Applicant	Backlog	Scrutiny	High-risk	N
<i>Panel A. Lapse hazard (HR)</i>					
Interaction, full sample	1.028 (0.03)	1.085* (0.05)	0.768 (0.14)	0.688 (0.16)	25,213
× high-risk prob.	1.096* (0.06)	0.917 (0.11)	2.183 (1.18)		
Low-risk devices	1.061*** (0.02)	1.073** (0.03)	0.947 (0.09)	0.993 (0.12)	22,213
High-risk devices	1.030 (0.04)	0.928 (0.07)	0.980 (0.26)	1.245 (0.33)	3,000
<i>Panel B. Commercialization (OR)</i>					
Interaction, full sample	1.202 (0.15)	1.628* (0.41)	1.394 (1.50)	0.453 (0.56)	24,830
× high-risk prob.	1.474 (0.37)	0.511 (0.40)	0.120 (0.41)		
Low-risk devices	1.273** (0.12)	1.251 (0.19)	0.647 (0.36)	0.710 (0.36)	21,852
High-risk devices	2.059*** (0.34)	2.003* (0.74)	2.495 (3.26)	9.545** (10.41)	2,640
<i>Panel C. Intra-firm follow-on (OR)</i>					
Interaction, full sample	1.212*** (0.06)	1.282** (0.16)	1.379 (0.58)	5.935*** (3.11)	25,213
× high-risk prob.	0.866 (0.10)	0.733 (0.22)	0.751 (0.99)		
Low-risk devices	1.159*** (0.04)	1.154** (0.08)	1.229 (0.25)	2.341*** (0.44)	22,213
High-risk devices	1.120 (0.09)	1.299* (0.20)	1.986 (1.46)	6.122*** (3.76)	2,996

Baseline and strategy controls, filing-year and WIPO class fixed effects included throughout.

Notes: Each panel reports the fully specified model for the interaction sample and for the low-risk and high-risk subsamples, where the split is a predicted high-risk probability above 50%. Rows marked × high-risk prob. give the interaction terms from the full-sample model directly beneath the corresponding main effects. Otherwise as for Table 2.

In the commercialization panel, the association between applicant-side delay and higher patent value holds across both risk tiers. The association is much larger for complex, high-risk devices. A one-year increase in applicant-side pendency is associated with odds of commercialization 27.3% higher for low-risk devices (OR = 1.273, $p < 0.05$), and 106% higher for high-risk devices (OR = 2.059, $p < 0.01$). This suggests that applicant-controlled delay may be especially valuable when a firm is navigating long, uncertain clinical and regulatory pathways.

The lapse associations sit in the low-risk majority and do not separate by risk class. Among low-risk devices both applicant-side delay (HR = 1.061, $p < 0.01$) and backlog (HR = 1.073, $p < 0.05$) are associated with a higher hazard of lapse, while the corresponding interactions with predicted risk are small and imprecise (HR(interaction) = 0.917 for backlog and 1.096, $p < 0.10$, for applicant-side delay). The point estimates sit close to one throughout, and the high-risk subsample holds 3,000 observations against 22,213, so the contrast between the tiers is likely one of precision rather than of magnitude. Examination scrutiny remains uninformative for all outcomes across both groups.

E. External outcomes: third-party follow-on innovation

To examine whether longer pendency is associated with external follow-on activity, we estimate logistic regressions (reporting odds ratios) in each sector for the incidence of any third-party citation, of an X/Y citation, and of a competitive citation.

1. Medical devices

In the medical device sample, the third-party results run through applicant-side delay, as shown in Table 6. In our preferred specification, a one-year increase in applicant-side pendency is associated with higher odds of receiving any citation (OR = 1.108, $p < 0.01$) and of an X/Y citation (OR = 1.136, $p < 0.10$). Backlog is positively signed for all three citation types but fails to reach conventional significance levels in any of them once the full control set is included (OR = 1.082, 1.189, and 1.311, respectively). The evidence for scrutiny pendency is similarly limited.⁵²

⁵² Unreported log-normal accelerated failure time models for the time from publication to first third-party citation point the same way, with applicant-side delay the clearest predictor: longer applicant-controlled delay is associated with faster arrival of a first citation of every type, while backlog reaches significance only without the full control set and scrutiny pendency shows no robust association.

Table 6. Third-party citation incidence for medical devices

Specification	Pendency component			Reported controls		N
	Applicant	Backlog	Scrutiny	High-risk	Child applications	
<i>Panel A. Any citation (OR); 2,204 cited families</i>						
(1) Pendency only	1.069*** (0.03)	1.173** (0.09)	1.117 (0.27)			25,551
(2) + Baseline	1.063** (0.03)	1.127 (0.08)	1.097 (0.26)	1.282 (0.20)		25,521
(3) + Strategy	1.108*** (0.04)	1.082 (0.09)	1.028 (0.24)	1.103 (0.17)	1.358*** (0.04)	25,521
<i>Panel B. X/Y citation (OR); 730 cited families</i>						
(1) Pendency only	1.113*** (0.04)	1.311** (0.16)	1.679* (0.49)			25,453
(2) + Baseline	1.099** (0.04)	1.249* (0.15)	1.587 (0.46)	0.968 (0.26)		25,423
(3) + Strategy	1.136* (0.07)	1.189 (0.15)	1.427 (0.44)	0.744 (0.20)	1.268*** (0.05)	25,423
<i>Panel C. Competitive citation (OR); 70 cited families</i>						
(1) Pendency only	0.937 (0.13)	1.206 (0.55)	0.564* (0.19)			17,053
(2) + Baseline	0.919 (0.13)	1.173 (0.52)	0.577 (0.21)	2.277 (1.92)		17,028
(3) + Strategy	0.836 (0.17)	1.311 (0.60)	0.656 (0.24)	1.699 (1.47)	0.924 (0.21)	17,028

Publication-year and WIPO class fixed effects included in every specification.

Notes: Odds ratios from logistic regression predicting the incidence of third-party forward citations. Otherwise as for Table 2, except that the fixed effects are for publication year rather than filing year.

2. Pharmaceuticals

For pharmaceuticals, the results in Table 7 do not support a deterrence interpretation. As for medical devices, we find that longer pendency is generally associated with greater third-party follow-on activity. In the incidence models, applicant-side delay is positively associated with the likelihood of receiving any citation (OR = 1.179, $p < 0.01$) and an X/Y citation (OR = 1.145, $p < 0.05$) in the preferred specification, though not with competitive citations. Backlog is more strongly predictive, with higher odds of any citation (OR = 1.226, $p < 0.01$), of an X/Y citation (OR = 1.297, $p < 0.05$), and of a competitive citation (OR = 1.700, $p < 0.01$). Scrutiny pendency is also positively associated with competitive citation incidence (OR = 2.072, $p < 0.01$), while its relationship with general and X/Y citation incidence is less stable across specifications. The overall pattern therefore runs counter to a spillover-suppression story, since pharmaceutical

patents experiencing longer pendency, especially greater backlog, are more likely to receive, and to receive sooner, subsequent third-party citations.⁵³ One reading is that applications with longer prosecution have features that draw more attention from later inventors and competitors; however, we cannot separate knowledge diffusion from rivalry within the current empirical design.

⁵³ The corresponding pharmaceutical models also point to faster follow-on: applicant-side delay and backlog are each associated with earlier first general and X/Y citations, backlog with markedly earlier first competitive citations, and scrutiny pendency with faster arrival of a first competitive citation.

Table 7. Third-party citation incidence for pharmaceuticals

Specification	Pendency component			Reported control	
	Applicant	Backlog	Scrutiny	Child applications	N
<i>Panel A. Any citation (OR); 1,942 cited families</i>					
(1) Pendency only	1.105*** (0.03)	1.187** (0.08)	1.250 (0.21)		31,625
(2) + Baseline	1.109*** (0.03)	1.173** (0.08)	1.247 (0.21)		31,625
(3) + Strategy	1.179*** (0.05)	1.226*** (0.09)	1.322 (0.23)	1.280*** (0.04)	31,583
<i>Panel B. X/Y citation (OR); 638 cited families</i>					
(1) Pendency only	1.119*** (0.05)	1.216* (0.14)	1.597* (0.40)		31,581
(2) + Baseline	1.121*** (0.05)	1.212 (0.14)	1.544* (0.39)		31,581
(3) + Strategy	1.145** (0.08)	1.297** (0.15)	1.489 (0.41)	1.228*** (0.06)	31,539
<i>Panel C. Competitive citation (OR); 302 cited families</i>					
(1) Pendency only	1.078 (0.07)	1.689*** (0.28)	1.706** (0.42)		26,344
(2) + Baseline	1.079 (0.07)	1.601*** (0.27)	1.774** (0.44)		26,344
(3) + Strategy	1.141 (0.11)	1.700*** (0.29)	2.072*** (0.51)	1.105 (0.09)	26,296

Publication-year and WIPO class fixed effects included in every specification.

Notes: As for Table 6, except that the high-risk probability applies only to medical devices and is therefore absent here.

V. CONCLUSIONS

Decomposing delay into applicant-side pendency, backlog, and scrutiny, we find that different sources of delay relate differently to innovation outcomes, and that the pattern varies markedly across the two medical sectors. Longer pendency tends to be associated with commercially and strategically salient applicant-side outcomes throughout, and the pattern does not support the simpler claim that delay insulates patentees from outside competition or suppresses cumulative innovation.

In pharmaceuticals, applicant delay and scrutiny predict outcomes consistent with the protection of commercially important assets, while applicant delay and backlog also track child application behavior that can extend the strategic life of the family. These results are expected for a setting in which applicants use pending status to preserve flexibility while long clinical,

regulatory, and market processes unfold. In medical devices, delay is again associated with stronger applicant-side outcomes, but the value of applicant-controlled delay is most pronounced among higher-risk devices, where commercialization pathways are longer and less certain. Device-sector pendency also tracks persistent child application activity, which points to multi-year portfolio management (such as that seen in so-called complex technology fields)⁵⁴ rather than passive administrative delay.

In neither sector do the results support a general spillover-suppression account in which longer office-side delay leads to weaker or slower third-party follow-on innovation. If anything, longer pendency is often associated with more frequent third-party citations, and in the device sector that association runs through applicant-controlled delay rather than through the queue. This does not make delay socially costless, and not all follow-on citations represent valuable knowledge diffusion; some will reflect strategic monitoring or contestation around commercially salient technologies. Even so, pendency appears to shape the timing and pattern of follow-on activity rather than freezing it, which may sit awkwardly with a policy debate that treats office delay as a straightforward trade-off between legal certainty and administrative inefficiency.⁵⁵

These findings describe systematic empirical relationships, not causal mechanisms. Of particular importance for interpretation is the fact that the components of delay we measure are not independent of the value of the underlying invention. Longer applicant-side delay may reflect deliberate deferral on assets a firm already judges valuable, which will attract citations as rivals compete for space around a lucrative market, and longer backlog may reflect a crowded field in which examiner capacity lags filing demand. The similar magnitudes we observe for applicant delay and backlog in the device sector are consistent with such a common cause. Citation measures cannot perfectly distinguish learning from rivalry, even with the X/Y and competitive distinctions, nor can commercialization proxies capture every form of market success. Child

⁵⁴ Georg von Graevenitz, Stefan Wagner, and Dietmar Harhoff, “Incidence and Growth of Patent Thickets: The Impact of Technological Opportunities and Complexity,” *Journal of Industrial Economics* 61, no. 3 (2013): 521–563.

⁵⁵ For the framing of pendency as straightforward cost, see Mark F. Schultz and Kevin Madigan, “The Long Wait for Innovation: The Global Patent Pendency Problem” (Center for the Protection of Intellectual Property, George Mason University, 2016). For the case that delay is neither uniform in its effects nor necessarily wasteful, see Pierre Régibeau and Katharine Rockett, “Innovation Cycles and Learning at the Patent Office: Does the Early Patent Get the Delay?” *Journal of Industrial Economics* 58, no. 2 (2010): 222–246; and Joachim Henkel and Florian Jell, “Patent Pending: Why Faster Isn’t Always Better” (SSRN working paper, 2010).

application behavior may reflect real adaptation to evolving technology as much as strategic efforts to maintain uncertainty. The device risk measure is a text-based classifier rather than an official assignment and, while manually sanity-checked, is not validated against a gold standard, so the risk-stratified results should be considered exploratory. That said, the classifier's output behaves as one would expect of a genuine risk measure, in that predicted high-risk probability is strongly associated with intra-firm follow-on throughout (Tables 2 and 5), and the applicant-delay association is largest precisely where regulatory pathways are longest. Future work could link patent timing more directly to regulatory approval milestones, pricing and entry outcomes, litigation, or family-level claim evolution, and ideally within a design aimed at causal identification. Litigation, in particular, would allow a test of the argument that more thorough examination is not worth its cost because few patents are ever litigated or licensed⁵⁶ (although in our data active examination averages about three weeks of the more than four years an application spends across the three phases we measure).

A first implication is that pendency has policy relevance beyond case-processing speed. In pharmaceuticals, deferred examination systems such as Australia's can create a strategic window in which applicants preserve option value and expand patent families. Because child applications remain available while rights are pending, longer applicant delay and backlog postpone certainty while extending the period over which patentees can refine claims, react to competitors, and broaden coverage around commercially important products. We make no claim here about abuse of the system, nor about how these patterns would look outside regulated industries with long and uncertain development timelines; the point is that pendency settings affect the scope for portfolio-extension behavior, including evergreening-type strategies, and should be assessed with that possibility in view. Among high-sales drugs, the originator-held secondary patents with the highest private value are concentrated in delivery mechanisms and alternative formulations, the claim categories most often associated with evergreening.⁵⁷ Where effective patent life is squeezed by protracted clinical timelines, firms may lean more heavily on

⁵⁶ Mark A. Lemley, "Rational Ignorance at the Patent Office," *Northwestern University Law Review* 95 (2001): 1495–1532.

⁵⁷ Andrew F. Christie, David M. Studdert, and Chris Dent, "Evidence of 'Evergreening' in Secondary Patenting of Blockbuster Drugs," *Melbourne University Law Review* 44, no. 2 (2011): 537–564.

secondary and follow-on patents, and these large portfolios can generate considerable uncertainty and litigation without correspondingly clear gains in social value.⁵⁸

Second, the device results caution against a blanket anti-delay stance: longer applicant-side delay and backlog are often associated with stronger applicant-side outcomes, and the positive relationship between applicant-controlled delay and commercialization is especially pronounced among higher-risk devices, which face more demanding and uncertain development and approval pathways. A policy agenda aimed solely at compressing pendency could therefore have uneven effects across applicants and technologies. In parts of the device sector, faster resolution may remove flexibility that is economically valuable for bringing complex products to market. The relevant policy question concerns which forms of delay are most harmful, for whom, and under what regulatory conditions.

Third, the results imply that examination timing should be considered alongside sector-specific regulatory timing rather than in isolation. In both pharmaceuticals and higher-risk devices, pending-patent status appears most valuable in settings where product development and regulatory approval are lengthy, uncertain, and costly. The welfare consequences of examination settings (the deferral window, the acceptance deadline, the availability of expedited examination) therefore depend on how they sit against TGA approval timelines, and processing-speed targets alone will miss that interaction. Settings that look inefficient in the abstract may have different consequences for a high-risk implant than for a low-risk consumable, since for the former the effective commercial life is already heavily shaped by approval delays.

Finally, policy evaluation should look beyond applicant outcomes alone, since follow-on research is a central channel through which disclosed patent information generates social value. Office-side delay is not associated with weaker or slower third-party follow-on in the aggregate. The external effects of delay are therefore more complex than a deterrence story suggests, and delay cannot be assumed harmless on that basis, because pendency may alter who responds, when, and whether the response is cumulative innovation, strategic monitoring, or competitive crowding. In pharmaceuticals especially, any assessment of longer pendency must weigh the possibility that delay feeds a broader system of overlapping rights and strategic contestation,

⁵⁸ Sadick, “The Dispute”; Durvasula and Ouellette, “Beyond the Pharmaceutical Patent.”

alongside the more familiar considerations of applicant flexibility and effective exclusivity.⁵⁹ Disentangling these behaviors would be a fruitful line of inquiry for future research.

Taken together, these findings suggest that patent offices considering reform should distinguish carefully between applicant-controlled delay, passive backlog, and active scrutiny, which do not appear to be interchangeable. Policies that reduce backlog may still be desirable on administrative grounds, but their innovation consequences should not be assumed to mirror those of restricting applicant flexibility or intensifying examination. More broadly, any assessment of patent-office performance in regulated sectors should account for strategic family management, regulatory timing, and external follow-on effects, rather than treating faster grant as an unambiguous objective in itself.

⁵⁹ Van de Wiele et al., “The Prevalence of Drug”; Durvasula and Ouellette, “Beyond the Pharmaceutical Patent.”