Online Appendix

To

INVESTING IN EX ANTE REGULATION: EVIDENCE FROM PHARMACEUTICAL PATENT EXAMINATION

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Background on Pharmaceutical Art Unit Examiner Hiring and Promotion

Most examiners practicing in the pharmaceutical Art Units are hired with advanced degrees and begin practicing at the Patent Office at GS-level 11. While promotions at lower pay grades—which are more relevant for examiners in non-pharmaceutical Art Units—occur within a year, promotions (e.g., promotions to GS-12, 13 or 14) at higher pay grades often require more time. For instance, over 97 percent of the promotions from GS-11 to GS-12 occur after at least a year's time, with the average length of time during GS-11 being roughly 1.2 years. Nearly 100 percent of the promotions from GS-12 to GS-13 occur at after a year's time with the average length of time at GS-12 of nearly 1.4 years. Nearly 100 percent of the promotions from GS-13 to GS-14 likewise occur after at least a year, with the average time at GS-13 being roughly 2.8 years. Factors contributing to promotions include meeting workload expectations, quality evaluations (based on random reviews of a subset of examiner work product), and the completion of additional testing or programs.

While our review of the Patent Office's personnel practices suggests that the most significant change subsequent to a promotion that bears on the examiner's decision to grant a patent application is the time allocated to review an application, there is, upon promotion to GS-14, also a change in the scrutiny of their work. Examiners at pay grades GS-13 and below must subject their decisions to a supervisory review by an examiner that has "full signatory authority." Upon promotion to GS-14, examiners are extended full signatory authority and no longer must subject their own decisions to supervisory review. The opportunity to review responses to promotions that do not carry changes in supervision allows us to help disentangle a time-allocation interpretation of our findings from a change-in-supervision interpretation. To our knowledge, nothing else changes upon GS-level promotions that would affect the manner in which examiners conduct their examinations. Through our review of examiner compensation materials made available by the Patent Office and through our interviews with former SPEs, we have determined that the basic structure of overtime and bonuses remains constant upon GS-level promotions as does the ways in which examiners earn work credits.

Additional Background on Patent Examiner Workload Expectations and Examination Time Allotments

Examiners are expected to meet certain workload goals, whereby they are expected to attain a certain number of credits, also known as "counts". Credits have historically and generally been earned upon the issuance of a first office action and at final disposal, which occurs when a patent application is allowed by the examiner or abandoned by the applicant (often after receipt of a final rejection or in anticipation of such a rejection). Quotas are set on a biweekly basis (with a second dimension of the quota system operating on a quarterly basis; the quarterly quota can be viewed as a catch-up for missed bi-weekly quota targets). By setting expectations regarding the number of credits examiners should attain over a specified period of time, the Patent Office contemporaneously sets expectations regarding the amount of time examiners should spend on applications. While examiners are free to average these time allotments over their caseload, they

are strongly encouraged to meet their credit quota through bonus- and promotion-related incentives (Frakes and Wasserman 2020).

The fact that time allocations are enforced over a bi-week period does potentially attenuate our ability to test for a differential effect of time constraints in the case of secondary relative to primary drug patents insofar as examiners may reallocate their allotments across the different patents they review in a bi-week. Nonetheless, even if they reallocate their allotments, if time constraints bind on average, it is perhaps more likely that secondary patents will bear the consequences given the greater time needed to apply the patentability standards.

Tabular Results

In Column 1 of Table A1, we present the results underlying Figure 1 of the text, allowing us to present the estimated coefficients for the covariates, except for the coefficients of the Art-Unit-by-year and experience fixed effects, which are omitted for brevity purposes. Nonetheless, to provide a sense of the estimated experience effects, later in this Online Appendix, we present a graphical depiction of the estimated coefficients of the experience effects from a specification analogous to that estimated in Column 1 of Table A1 but that includes a more modest number of experience-in-year bins.

Column 2 adds control variables with various characteristics of the patent claims. We add these in separately as we only have data for these measures for a subset of our Orange Book patents. With an already small sample size, we wanted to show results without such measures as our baseline specification. Given random assignment of applications to examiners, there is little concern over bias in estimating specifications without these controls. Nonetheless, we do offer a set of results including these measures to demonstrate the robustness of our findings to their inclusion.

Our aim with these latter controls is to account for fundamental differences in the nature of the applications that do happened to be assigned—even if by chance—to the different grade levels. Claim characteristics generally evolve over the course of the examination process, as applicants may make claim modifications to respond to examiner comments and rejections. In order to provide an exogenous measure of these characteristics—one that is not impacted by the amount of time allocated to examiners—we aim to capture claim characteristics at the time of filing. For these purposes, we turn to the Patent Claims Research Database put out by the Office of the Chief Economist at the Patent Office. The document level file of this dataset contains application-level information on the number of claims and the length of the claims. While it does not necessarily contain this information at the time of filing, it does report these measures at the time in which the application is "published" by the Patent Office, which is a decent approximation of these measures at the time of filing (Frakes and Wasserman 2020).

In the interests of brevity, we present these results only for the case of secondary Orange Book patents.

Additional Reference:

Frakes, Michael, and Melissa Wasserman. 2020. "Procrastination at the U.S. Patent Office?" *Journal of Public Economics* 183.

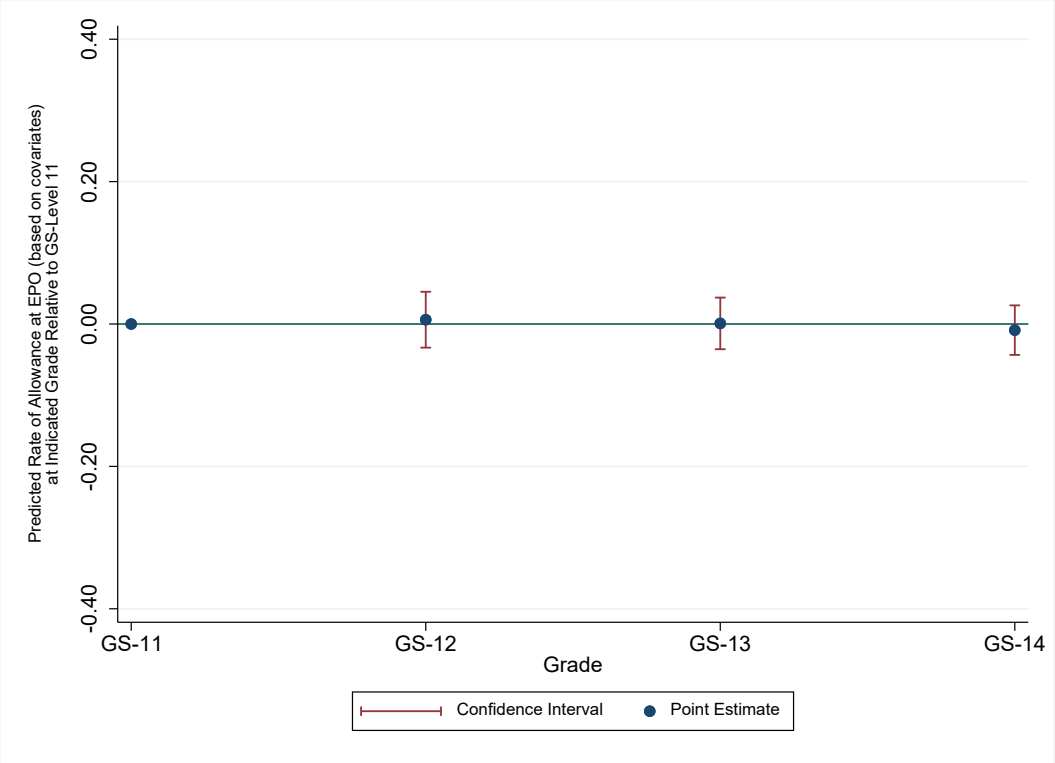
TABLE A1. FULL RESULTS: RELATIONSHIP BETWEEN LIKELIHOOD OF EPO ALLOWANCE OF TWIN OF U.S.-ISSUED SECONDARY ORANGE BOOK PATENT AND GRADE LEVEL OF EXAMINER ASSIGNED TO RELEVANT U.S. PATENT

Omitted: GS-11		
GS-12	-0.054	-0.068
	(0.029)	(0.042)
GS-13	-0.069	-0.072
	(0.037)	(0.054)
GS-14	-0.096	-0.117
	(0.044)	(0.059)
Omitted: (Tenure < 2 Years)		
Tenure 2-4 Years	-0.340	-0.189
	(0.156)	(0.101)
Tenure 4-6 Years	-0.153	0.027
	(0.131)	(0.067)
Tenure (6-8 Years	-0.204	-0.028
	(0.133)	(0.056)
Tenure 8-10 Years	-0.207	-0.018
	(0.165)	(0.056)
Tenure 10+ Years	-0.184	-
	(0.130)	
Omitted: (Hiring Cohort 1980-1985)		
Hiring Cohort 1985-1990	0.036	0.044
	(0.094)	(0.104)
Hiring Cohort 1990-1995	0.051	0.001
	(0.154)	(0.151)
Hiring Cohort 1955-2000	0.082	0.065
	(0.199)	(0.174)
Hiring Cohort 2000-2005	0.022	-0.057
	(0.227)	(0.187)
Hiring Cohort 2005-2010	0.029	-0.057
	(0.256)	(0.211)
Hiring Cohort 2001+	-0.000	-0.143
	(0.311)	(0.273)
Small Entity Applicant	-0.123	-0.095
	(0.038)	(0.052)
Number of claims (100s)	-	-0.601
		(0.554)
Number of dependent claims (100s)	-	-0.031
		(0.043)
Total number of words in claims (10000s)	-	0.214
		(0.123)
Total number of words in dependent claims (10000s)	-	0.111
		(0.159)
Minimum number of words per claim across claims (1000s)	-	0.081
		(0.100)
Minimum number of words per claim across dependent claims (1000s)	-	-0.887
		(2.520)
Average number of words per claim (1000s)	-	-0.152
		(0.094)
Average number of words per dependent claim (1000s)	-	-0.555
		(0.428)
Art-Unit-by-Year Fixed Effects	YES	YES
Experience-In-Single-Year Fixed Effects	YES	YES
Number of Observations	2466	1856

Standard errors are indicated in parenthesis and are clustered at the unit of assignment—i.e., at the Group Art Unit level to account for correlation in unobservables within assignment groups. The dependent variable indicates the incidence of allowance at the EPO among the sample of U.S.-issued secondary Orange Book patents that are part of a family of applications between the U.S. Patent Office and the EPO.

Covariate Balance in Exploration of Relationship between Likelihood of EPO Allowance of Twin of U.S.-Issued Secondary Orange Book Patent and Grade Level of Examiner Assigned to Relevant U.S. Patent

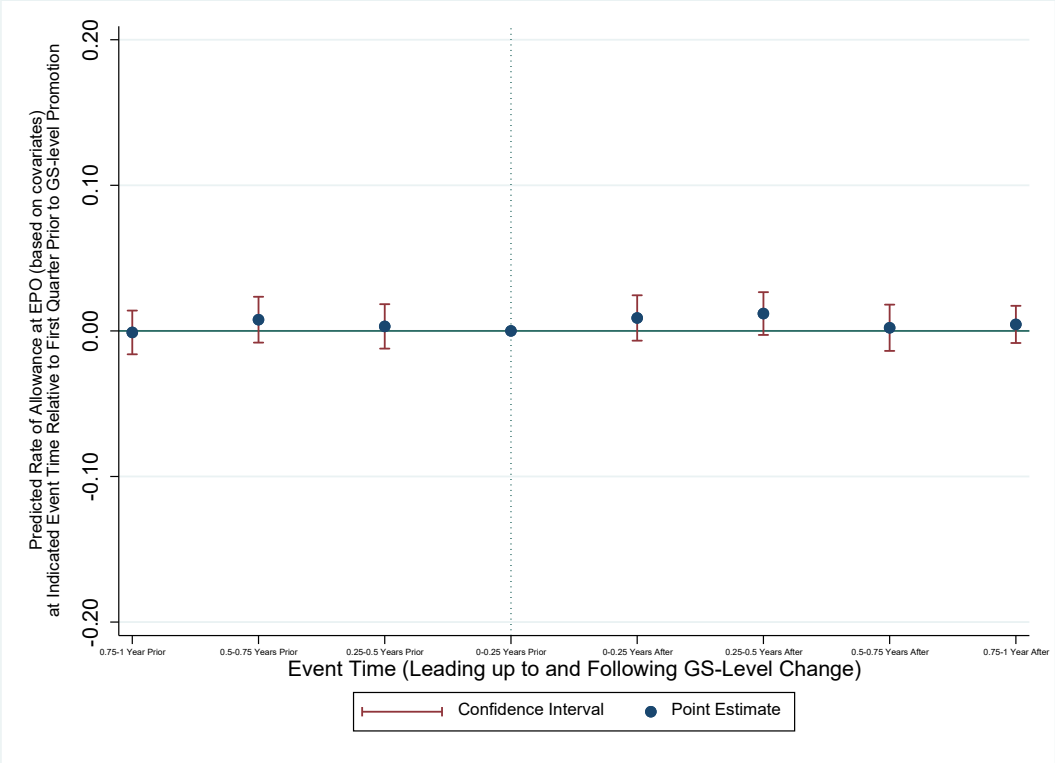
FIGURE A1. COVARIATE-BALANCE ANALYSIS: RELATIONSHIP BETWEEN PREDICTED LIKELIHOOD OF EPO ALLOWANCE OF TWIN OF U.S.-ISSUED ORANGE BOOK PATENT AND GRADE-LEVEL OF EXAMINER ASSIGNED TO RELEVANT U.S. PATENT



Notes: results are from a sample of Orange Book patents (secondary and primary) issued in the U.S. and part of a family of applications at both the U.S. Patent Office and the European Patent Office. For each such patent, we form a predicted likelihood of allowance at the EPO based on a regression of the incidence of EPO allowance on the full set of covariates and on Art-Unit-by-year fixed effects. We then regress this predicted measure on the set of GS-level dummies and plot the resulting coefficients.

Covariate Balance for Dynamic Event-Study Analysis

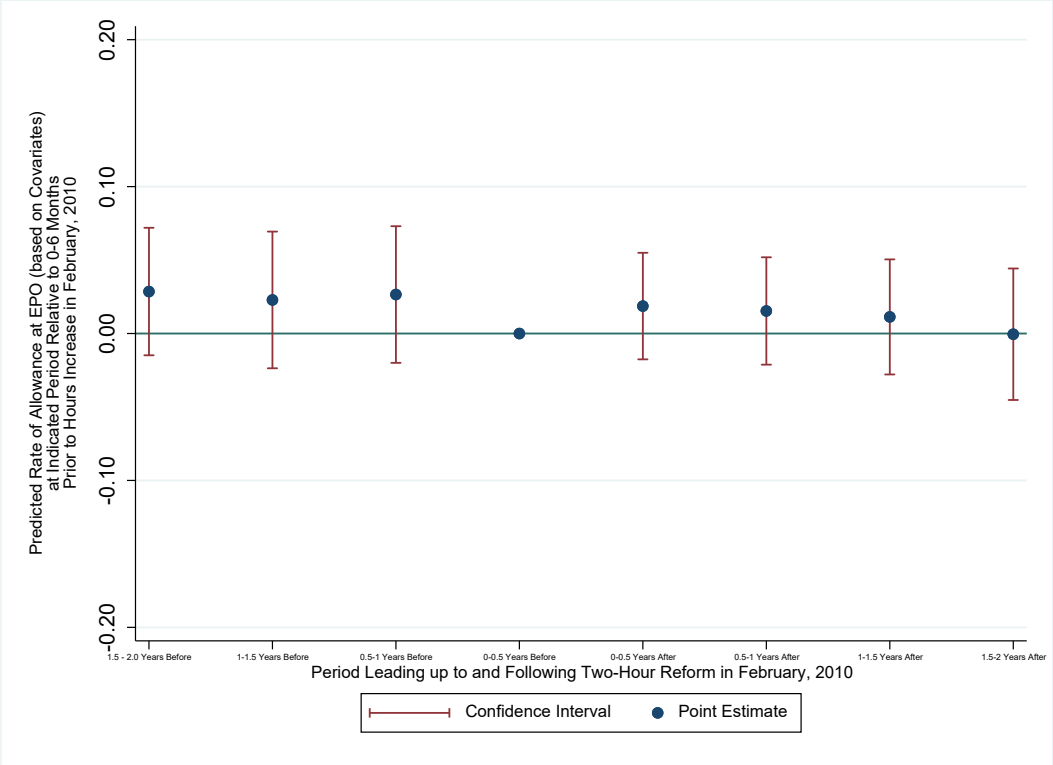
FIGURE A2. COVARIATE-BALANCE ANALYSIS FOR DYNAMIC EVENT-STUDY ANALYSIS: TREND IN PREDICTED EPO-ALLOWANCE LIKELIHOOD IN PERIOD OF TIME LEADING UP TO AND FOLLOWING GS-LEVEL PROMOTION, SECONDARY PATENTS



Notes: predicted EPO allowance outcomes are calculated as in Figure A1. Figure A2 then plots the trend in these predicted outcomes over a generalized event window centered around GS-level promotions (in quarter increments).

Covariate Balance for Dynamic Event-Study / 2010 Reform Analysis

FIGURE A3. FALSIFICATION TEST FOR 2010 TIME-ALLOCATION REFORM EVENT STUDY



Notes: predicted EPO allowance outcomes are calculated as in Figure A1. Figure A3 then plots the trend in these predicted outcomes over an event window centered around the reform in February 2010 in which examiners were extended two additional hours to review applications.

2010 Reform Analysis

Over the course of our sample, the Patent Office enacted a reform—effective in February, 2010—extending all examiners (regardless of grade level or technology) an additional two hours of review per application.[1] As an additional exercise, we consider a simple event-study analysis where we track the likelihood that twin applications of U.S.-issued Orange Book patents are also allowed at the EPO in the period of time before and after the effective date of this reform.

This approach is not without important caveats. Lacking a control group, our modest aim here is to simply conduct a validation exercise in which we attempt to detect a jump in EPO allowance outcomes upon this one-time increase in time allotments, rather than to nail down with precision the steady-state improvement in quality that arises from this time expansion. Since we are drawing on time-series variation only and since EPO allowances outcomes will be changing over time for other reasons, we are inclined not to embrace a comparison window that is too wide. Nonetheless, considering an already small sample of Orange Book patents, we cannot consider an observation window that is too small. To balance these concerns, we elect to look for a change in outcomes in a window characterized by two years prior to and subsequent to the two-hour reform in February, 2010. This approach entails focusing on only roughly 20% of our original Orange Book sample.

In Table A2, we demonstrate results from a specification similar to that of speciation (1) but focusing on this more limited sample and including an indicator for the 2010 reform.[2] As demonstrated by Column 1, we find a statistically-significant post-reform increase of 9.1 percentage points—or roughly 11 percent relative to the mean—in the likelihood that the twin application of a secondary U.S.-issued Orange Book Patent is also allowed at the EPO. As demonstrated by Column 2, we document no such increase in the case of active-ingredient Orange Book patents, with a near-zero point estimate of the reform coefficient.[3]

TABLE A2. CHANGE IN EPO ALLOWANCE RATE OF TWIN OF U.S.-ISSUED ORANGE BOOK PATENT FOLLOWING 2010 REFORM INCREASING TIME ALLOTMENTS BY TWO HOURS (FOUR-YEAR WINDOW)

	(1)	*(2)*
	SECONDARY PATENTS	ACTIVE INGREDIENT PATENTS
Post Hours Reform	0.089	-0.002
	(0.046)	(0.033)
Number of Observations	520	193

Notes: results are from a sample of secondary (Column 1) and primary (Column 2) Orange Book patents disposed of in a four year (two on each side) event window around the February 2010 reform extending all examiners two additional hours to review applications. Specifications include the control variables indicated in specification (1) in addition to GS-level fixed effects. Standard errors are reported in parentheses and are clustered at the Art-Unit level.

[1] Otherwise, the time-allotment schedule remained entirely fixed over the sample period.

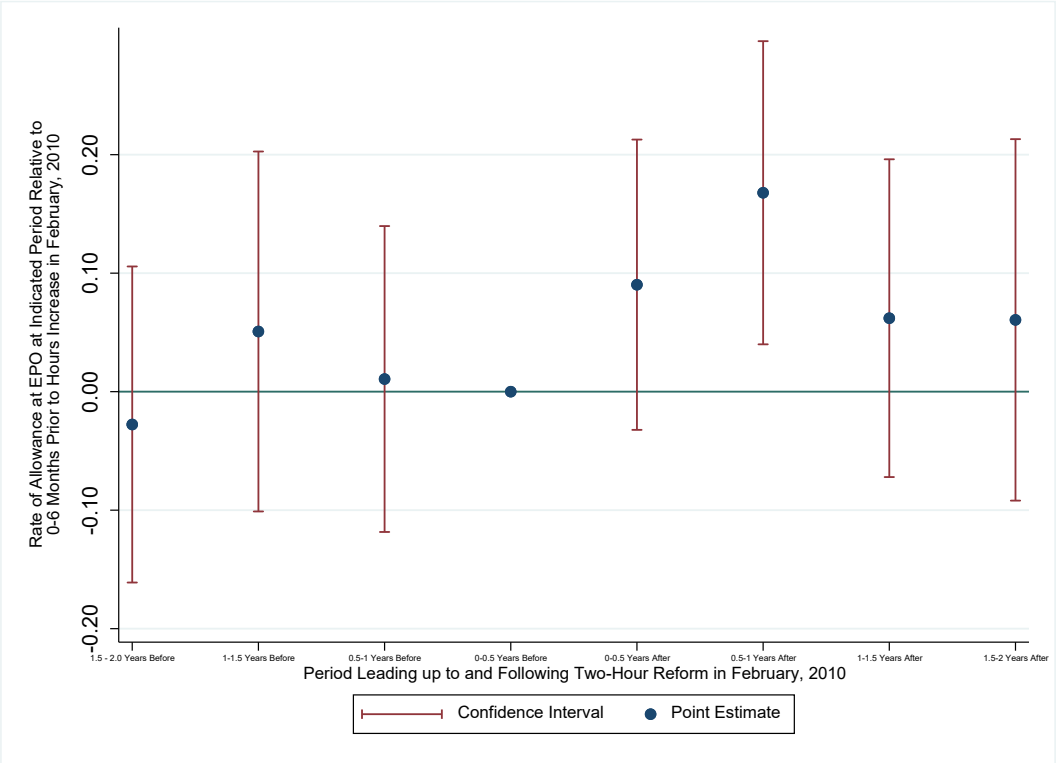
[2] We include GS-level dummies as controls in this specification. Instead of including Art-Unit-by-year fixed effects, however, we only include Art-Unit fixed effects, since Art-Unit-by-year fixed effects would subsume our reform regressor of interest. We also include fixed effects for calendar months—e.g., a fixed effect for January (generically—i.e., not specific to any year), etc.

[3] We acknowledge, of course, that with a standard error of 3.3 percentage points, we cannot rule out that a meaningful increase in this validity marker for the active-ingredient patents is possible.

In Figure A4, we take a dynamic approach to this event-study analysis, where we replace the reform dummy with a series of event-time indicator variables capturing periods leading up to and following the February 2010 reform (using half-year groups as the incremental observation period). Given our aim to use this approach as a robustness check on the findings from Table A2, we focus only on the sample of secondary Orange Book patents. Encouragingly, we find no evidence that the post-reform increase in validity suggested by Table A2 materialized prior to the reform, instead finding a jump at the moment of the reform. Given the small sample size entailed by looking at the window around 2010 and given the relatively taxing dynamic specification, our estimates in Figure A4 are somewhat imprecise. Though the point estimate of the first post-reform event indicator suggests a strong jump in EPO allowance outcomes, this estimate is not statistically distinguishable from zero. The second post-reform event indicator, however (signifying the 6-12 month period following the reform) is statistically distinguishable from zero.

In Figure A3 of this Online Appendix (see above), we demonstrate balance in observable application characteristics throughout this event window, again plotting a corresponding event trend in *predicted* EPO allowance rates.

FIGURE A4. 2010 TIME-ALLOCATION REFORM EVENT STUDY



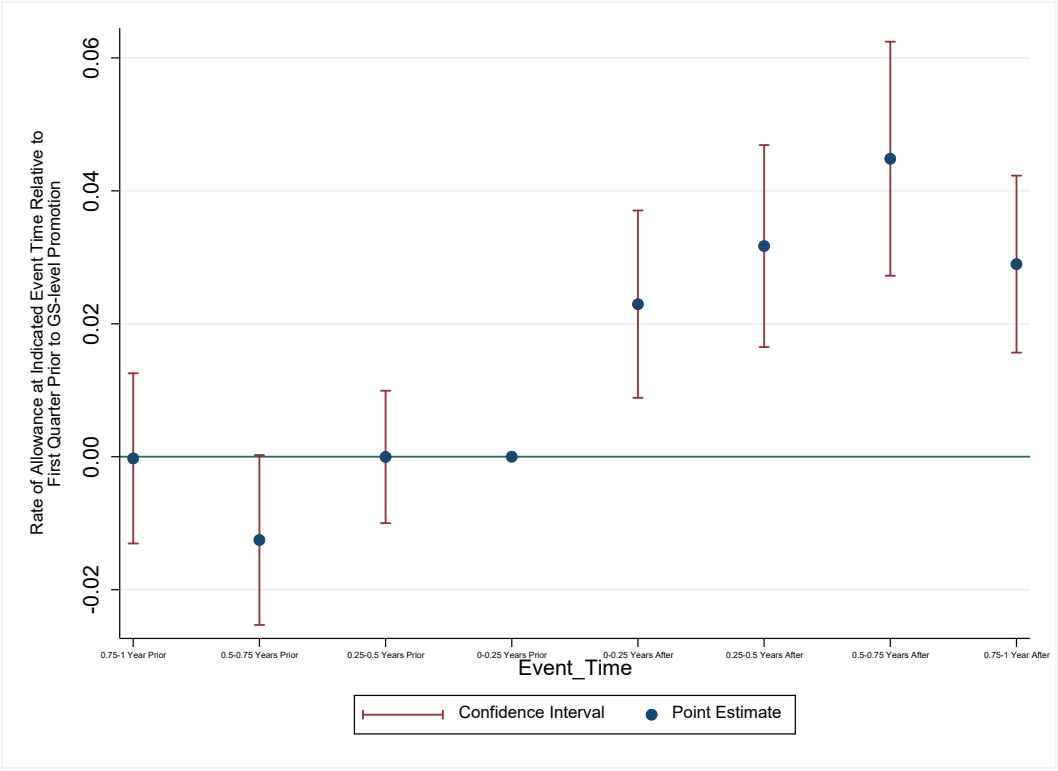
Notes: results are from a sample of secondary Orange Book patents disposed of in a four year (two on each side) event window around the February 2010 reform extending all examiners two additional hours to review applications. Specifications include the control variables indicated in specification (1) in addition to GS-level fixed effects. 95% confidence intervals are indicated by the vertical bars and are clustered at the Art-Unit level.

Altogether, the results from this 2010-reform analysis complement the comparison of secondary and primary patent results in providing suggestive evidence that the GS-level results derived above are reflective of a story in which binding time constraints are leaving patent examiners to allow invalid secondary patents on the margin.

Additional Grant-Rate Findings

We supplement Figure 4 from the text with a grant-rate counterpart to Figure 2b in the text (for simplicity given the notably larger sample size used in this grant-rate analysis, we focus on the simple event-study framework without using promoted-out GS-14 examiners as controls). That is, we also estimate a specification where we (i) consider applications reviewed in 2-year (1-year on either side) event windows around each promotion, (2) stack sub-samples of all such events and (3) estimate event-study specifications within these event windows that allow us to observe the evolution of the grant-rate in the quarters leading up and following a GS-level promotion. As demonstrated by Figure A5, we document a sharp increase in the grant rate that emerges at the moment of the promotion event.

FIGURE A5. EVENT-STUDY ANALYSIS: TREND IN LIKELIHOOD OF APPLICATION ALLOWANCE IN PERIOD OF TIME LEADING UP TO AND FOLLOWING GS-LEVEL PROMOTION



Notes: results are from a stacked sample of pharmaceutical patent applications disposed of in a two-year (one on each side) event window around the reviewing examiners' promotions to GS-12, 13 and 14 (N=122,706). The plotted coefficients represent the estimated coefficients of the event-time indicators from specification (3). 95% confidence intervals are indicated by the vertical bars.

Examiner Fixed Effects

In the grant-rate analysis, we use examiner fixed effects, taking advantage of the fact that each examiner reviews a large number of drug patents over their career. The ability to use examiner fixed effects when focusing on the Orange Book sample is threatened by the fact that individual examiners tend to review a small number of patents in our sample frame that wind up being listed in the Orange Book. Roughly half of the Orange Book sample consists of patents reviewed by examiners that have reviewed four or fewer patents in this Orange Book sample. For this reason, when analyzing the Orange Book sample, we do not include examiner fixed effects, but include a rich set of other examiner characteristics including experience-in-years fixed effects, hiring-year cohort fixed effects and ultimate-tenure-at-PTO-in-years fixed effects, in addition to Art-Unit-by-year fixed effects. Frakes and Wasserman's (2017) analysis of the relationship between GS-level promotions and grant rates demonstrates that the inclusion of these effects produces nearly identical results to the examiner fixed effects specification.

Nonetheless, in this Online Appendix, we do present results from an examiner fixed effects approach on the Orange Book sample, in connection with our investigation into the effects of GS-level promotions on the quality of reviews (as captured by the EPO benchmarking approach) of secondary drug patents. For the sake of brevity and in consideration of the taxing nature of this estimation, we show results from the binary event-study analysis underlying Table 2 in the text but now including examiner effects. As demonstrated, the results are consistent with that presented in Table 2.

TABLE A3: RELATIONSHIP BETWEEN LIKELIHOOD OF EPO ALLOWANCE OF TWIN OF U.S.-ISSUED ORANGE BOOK PATENT AND GRADE-LEVEL PROMOTION EVENT, STACKED EVENT STUDY RESULTS (ONE-YEAR PRE- AND POST-EVENT), WITH EXAMINER FIXED EFFECTS

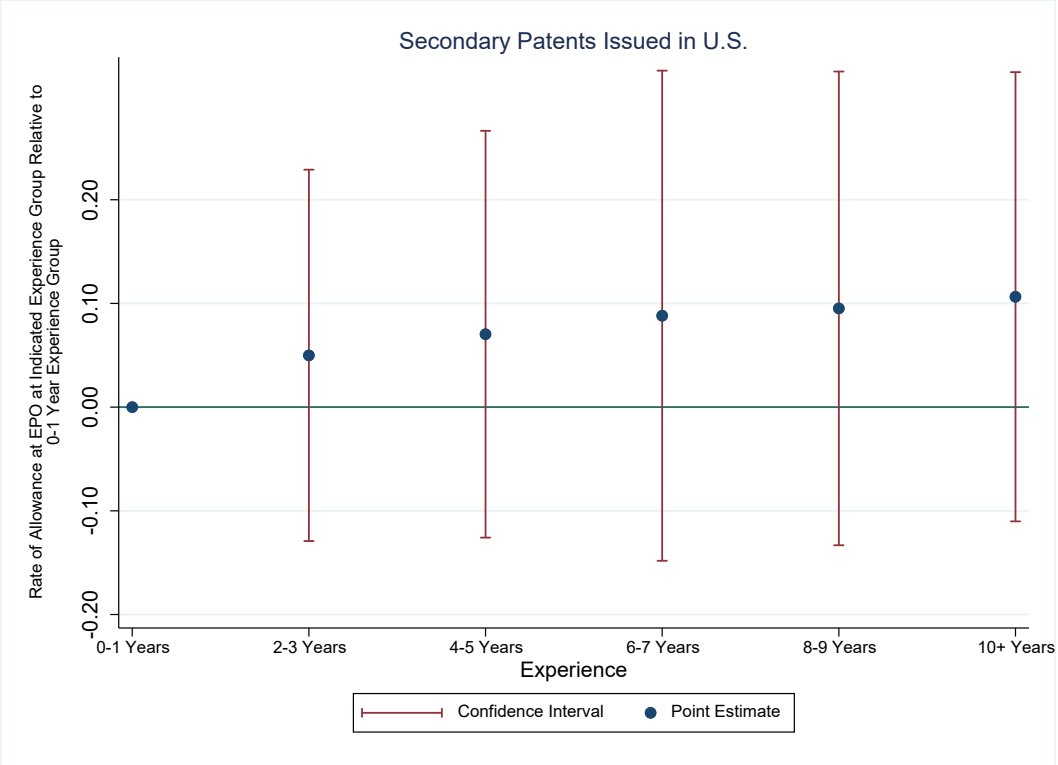
	(1)	**(2)**	
	Secondary Patents	**Primary (Active-Ingredient) Patents**	**Difference in Promotion Effect between Secondary and Primary Patents**
Post Promotion Event	-0.073	-0.011	-0.061
	(0.022)	(0.037)	(0.037)
N	930	152	1,082
Mean of Dependent Variable	0.86	0.96	0.87

Notes: results are from a stacked sample of secondary (Column 1) and primary (Column 2) Orange Book patents disposed of in a two-year (one on each side) event window around the reviewing examiners' promotions to GS-12, 13 and 14. The estimated specification also include the control variables indicated in specification (2) along with examiner fixed effects. Standard errors are reported in parentheses and are clustered at the Art-Unit level.

Experience Effects

In Figure A6, we present estimated experience effects from specification (1) from the text, focusing on the sample of secondary Orange Book patents. These serve as a complement to Figure 1 of the text which presents the estimated GS-level effects from the same specification

FIGURE A6. RELATIONSHIP BETWEEN LIKELIHOOD OF EPO ALLOWANCE OF TWIN OF U.S.-ISSUED ORANGE BOOK PATENT AND EXPERIENCE LEVEL (IN YEAR BLOCKS) OF EXAMINER ASSIGNED TO RELEVANT U.S. PATENT



Alternative Windows for Event-Study Analysis, Secondary Patent Analysis

In the proceeding figures, we replicate the event-study analysis depicted in Figure 2b of the text, but using different event windows. For simplicity, we show this robustness in the case of the simple stacked event-study analysis without using promoted-out GS-14 examiners as controls (in a difference-in-difference framework), though we note that the robustness demonstrated here holds as well when using alternative event windows for this difference-in-difference counterpart.

First, we focus on the 1-year window around the promotion—i.e., the half-year prior and the half-year post—focusing on how EPO allowance rates evolve in 45-day increments. As demonstrated by Figure A7, we continue to see a drop in EPO allowance rates that arises upon the GS-level promotion and not prior, consistent with a causal response to the promotion. However, the confidence intervals grow with this approach, leaving us with less ability to make inferences in the period by period movements. This loss of precision is to be expected given that this tighter window requires us to drop even more secondary patents from the investigation and given that our use of shorter increments leaves us with smaller samples per increment. It is nonetheless encouraging—and thus supportive of the results from the broader window—that we document a similar pattern of point estimates in the period of time surrounding the promotion event.

Second, we focus on the 4-year window around the promotion—i.e., two years prior and two years post—focusing on how EPO allowance rates evolve in 6-month increments.

FIGURE A7. EVENT-STUDY ANALYSIS: TREND IN EPO-ALLOWANCE LIKELIHOOD IN PERIOD OF TIME LEADING UP TO AND FOLLOWING GS-LEVEL PROMOTION, SECONDARY PATENTS (45-DAY INCREMENTS, 1-YEAR WINDOW)

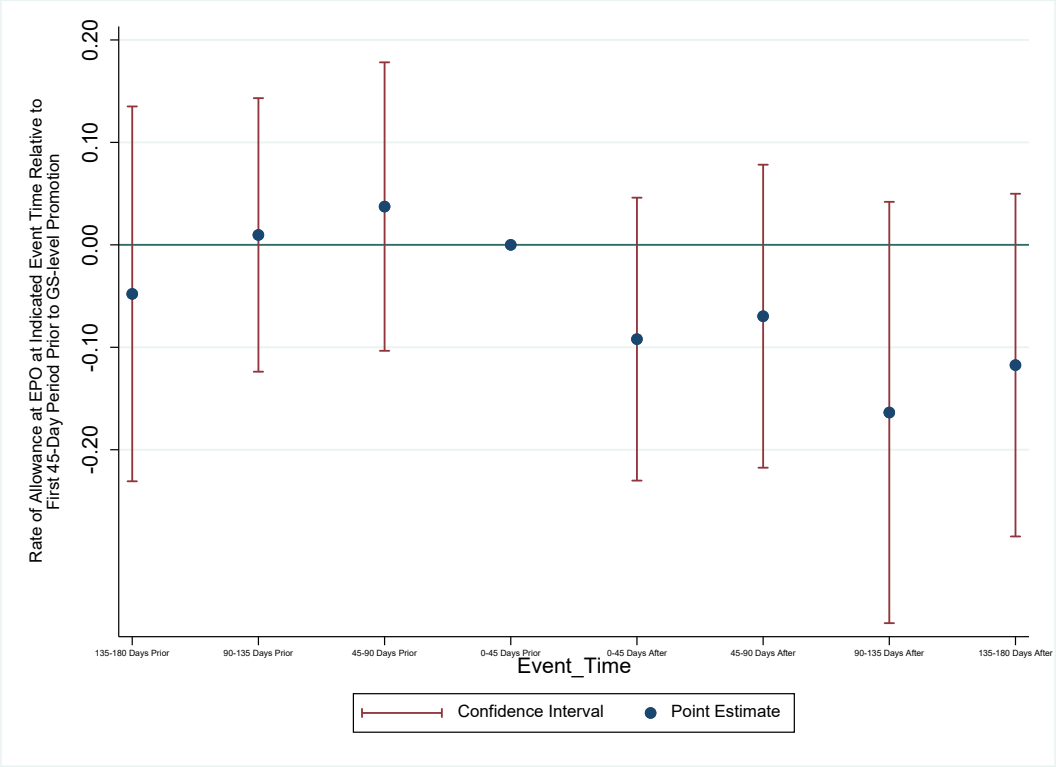
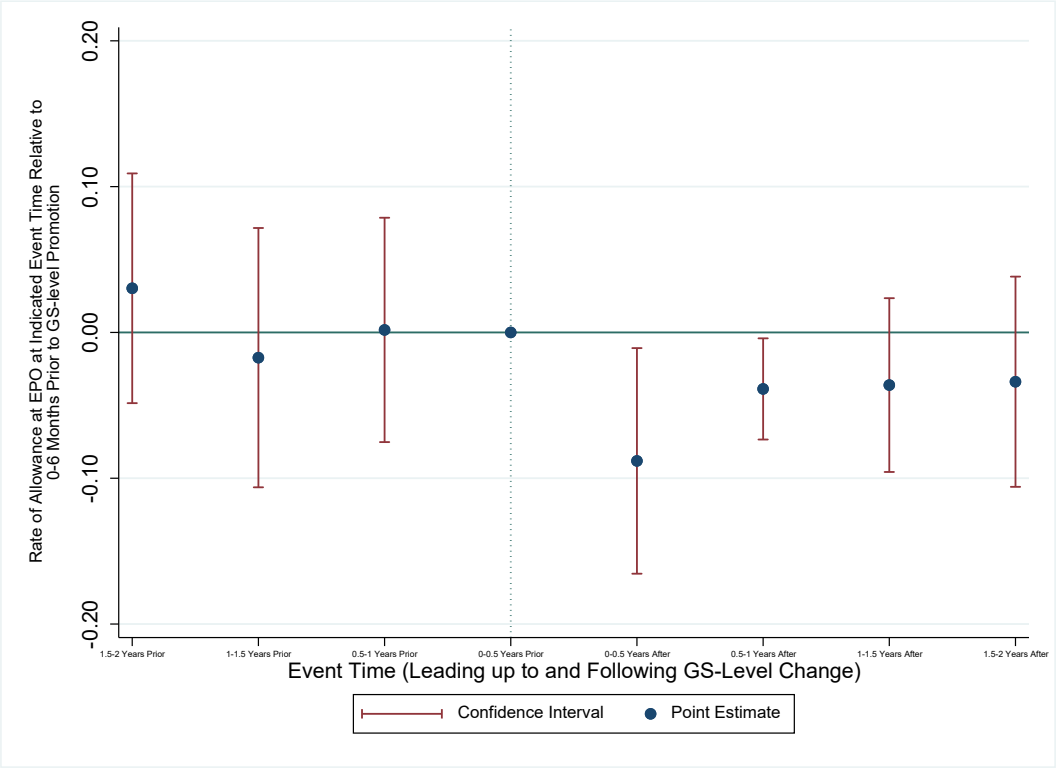


FIGURE A8. EVENT-STUDY ANALYSIS: TREND IN EPO-ALLOWANCE LIKELIHOOD IN PERIOD OF TIME LEADING UP TO AND FOLLOWING GS-LEVEL PROMOTION, SECONDARY PATENTS (1/2 YEAR INCREMENTS, 4-YEAR WINDOW)



Event-Study Analysis and Active-Ingredient Patents

Above, when estimating an event-study counterpart to Figure 2 in the text, we presented results using the active-ingredient Orange Book sample. In this section of the Online Appendix, we present related results that replicate Figure 2 from the text but using the active-ingredient sample. However, instead of breaking this into 2 panels, we present two separate figures across Figure A9 and Figure A10, one for the difference-in-difference version of the stacked event-study design and one for the simpler event-study design. In the case of both figures, we find a less striking pattern of post-promotion declines in EPO allowance relative to that estimated in the secondary-patent sample. The dynamic results are consistent with the binary post-promotion effects presented in Table 2 of the text, where we again found stronger effects in the case of the secondary sample.

FIGURE A9. EVENT-STUDY ANALYSIS, INCLUDING PROMOTED-OUT GS-14 EXAMINERS AS "CLEAN" CONTROLS (ACTIVE-INGREDIENT DRUG PATENTS)

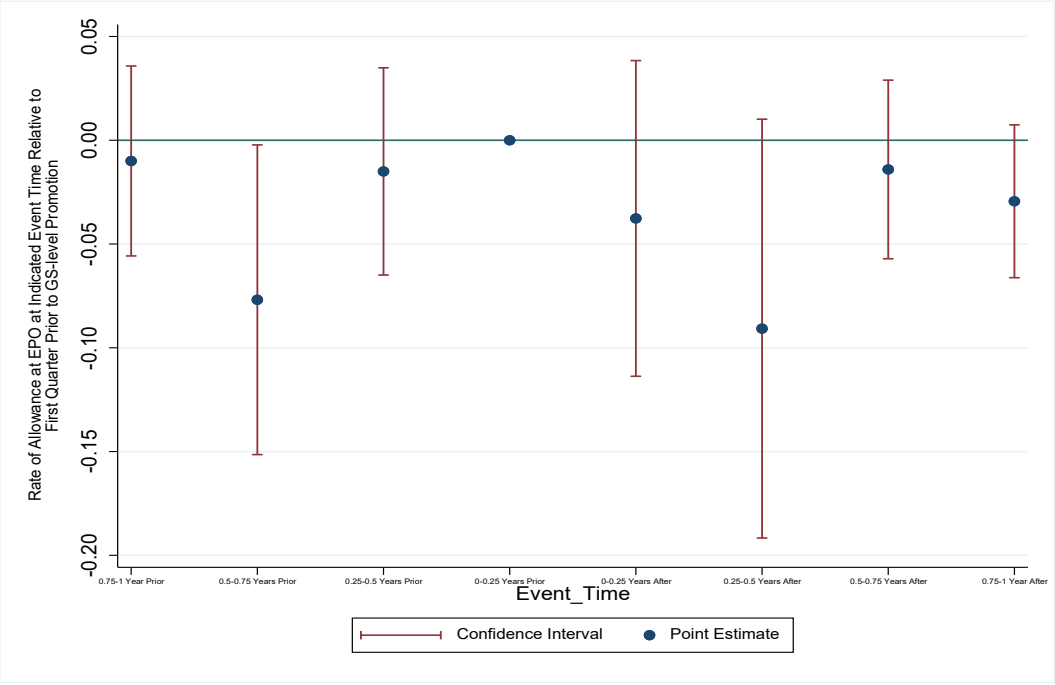
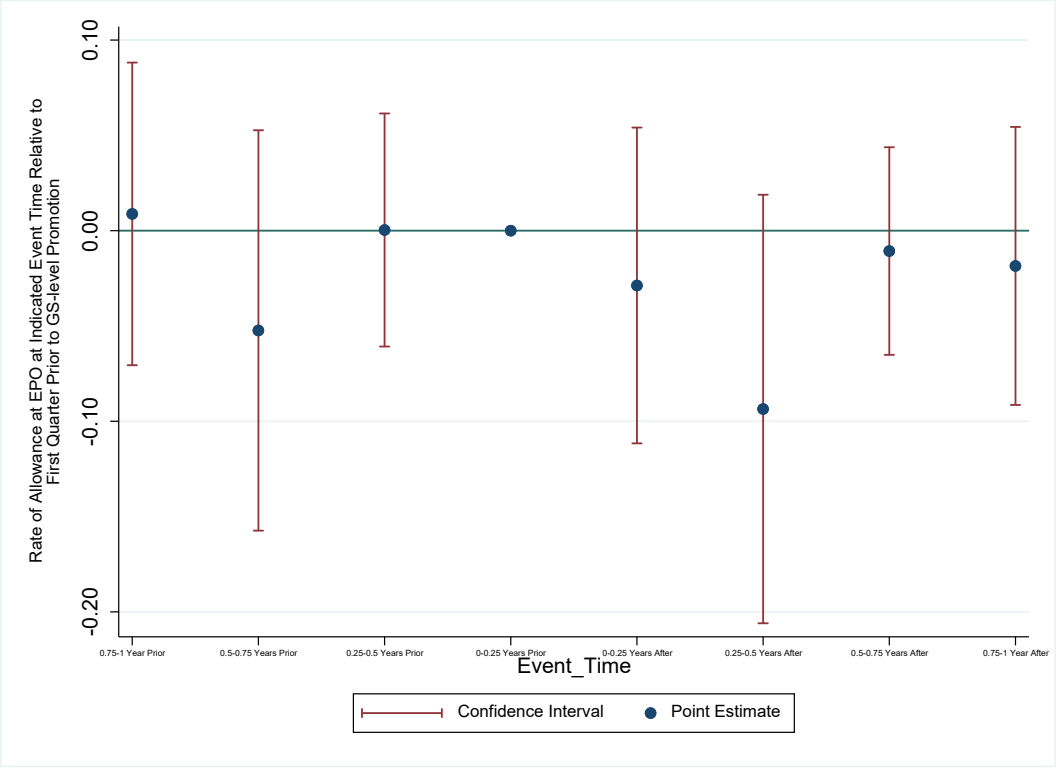


FIGURE A10. EVENT-STUDY ANALYSIS: TREND IN EPO-ALLOWANCE LIKELIHOOD IN PERIOD OF TIME LEADING UP TO AND FOLLOWING GS-LEVEL PROMOTION, ACTIVE-INGREDIENT PATENTS (QUARTER INCREMENTS, 2-YEAR WINDOW)



Litigation Analysis (Part IV of Text)

In Table A4, we present results of our investigation into the increase in overall litigation frequency we would expect to observe in connection with the occurrence of time-allocation-reducing promotions. We attempt to capture both mechanisms for such an effect discussed in Part IV of the text: (1) a mechanical effect in which time-reducing promotions will cause examiners to issue more patents on the margin, which creates a greater scope for litigation in the first place and (2) a review-quality effect in which time-reducing promotions cause the average patent to be issued by an examiner to be of more questionable validity, thereby inviting more litigation. We can capture both such effects by estimating specification (1) using litigation assertion counts as the dependent variable but using a sample of drug-patent applications, rather than issued patents. This approach is conservative in the sense that our goal is to estimate the effects of giving examiners more time on secondary applications, but we estimate this specification on primary and secondary applications (lacking such an assignment on the application level). We present results from a Poisson specification that includes the various effects and controls from specification (1). Litigation data is from Lex Machina. We limit those patent applications disposed of through 2014 to provide time to observe litigation outcomes.

In Column 2, we show the robustness of these findings to an alternative data source: the Stanford NPE Litigation Database. One of the advantages of this alternative database is that we may also refine our litigation assertion count to only count assertions by product-producing companies, which is more likely to capture assertions by other pharmaceutical manufacturers—e.g., generics. We present results using this assertion-by-product-company count as the dependent variable in Column 2. The pattern of results is very similar to our approach using data from Lex Machina (Column 1)

Note that the estimated coefficient from Column 1 suggests a 53% increase in litigation counts as one ascends from GS-11 to GS-14, all else equal and thus as one experiences a reduction in time allocations. This, in turn, suggests a roughly 35% decrease in litigation counts if we take matters in reverse—i.e., if we compare litigation frequency as one's time allocation increases from that given to GS-14 examiners to that given to GS-11 examiners, all else equal. This increase in time allocations between GS-14 and GS-11 reflects a roughly 50% increase. In this case, our results imply that a 50% increase in time allocations is associated with a roughly 35% decrease in litigation frequency.

REFERENCE:

Stanford NPE Litigation Database. https://npe.law.stanford.edu/. Accessed 06/18/2021.

TABLE A4. RELATIONSHIP BETWEEN LITIGATION FREQUENCY AND GRADE-LEVEL OF EXAMINER (POISSON RESULTS), AMONG SAMPLE OF DRUG-PATENT APPLICATIONS THROUGH 2014

	(1)	*(2)*
	LEX MACHINA DATA (DEPENDENT VARIABLE = NUMBER OF TIMES ASSERTED IN LITIGATION)	STANDARD NPE LITIGATION DATABASE (DEPENDENT VARIABLE = NUMBER OF TIMES ASSERTED BY PRODUCT COMPANY)
Omitted: GS-11		
GS 12	0.259 (0.185)	0.351 (0.191)
GS-13	0.375 (0.268)	0.514 (0.316)
GS-14	0.527 (0.245)	0.624 (0.299)
N	255,941	255,941

Notes: Results are from a Poisson specification analogous to that estimated in Panel A of Figure 1, though (1) using the count of the times litigated as the dependent variable and (2) using the full sample of drug patent applications. Estimated coefficients for the other variables in specification (1) are omitted for brevity purposes. Standard errors are indicated in parentheses and are clustered at the Art-Unit level.

Alternative Assignments of Active-Ingredient and Secondary Patents

In our primary approach to classifying active-ingredient and secondary patents, we follow the drug-substance classification provided directly by the FDA in the Orange Book data. By law, "drug substance" is supposed to account for patents on active ingredients. However, some of those patents listed as "drug substance" patents in the Orange Book data are likely patents on polymorphs of the active-ingredient—i.e., patents on different crystalline structures of the active ingredient. Unfortunately, we do not have readily available information identifying which of the "drug substance" patents are the truly original active ingredient patent and which are polymorphs. However, given the possibility that truly active-ingredient patents may be less time-consuming to review than patents on different crystalline forms of those ingredients, we make an attempt to separate out these two types of drug substance patents. Accordingly, we take the following approach to approximate such a classification, an approach which seems sensible based on taking several random draws of FDA drug products and an approach which likely errs on the side of over-classifying polymorphs. If a drug product has a drug-substance patent that was not among the first group of patents filed with that drug product, we will classify this as a possible polymorph and include it in the secondary grouping. Below, we show some results with this alternative classification.

We note at the outset that the results presented are robust to yet other approaches to guessing which drug substance patents may be polymorphs. For instance, in another approach, we also assign a possible polymorph if the drug substance patent is not the first issued patent associated with a drug product. This

differs slightly from the approach previously mentioned to the extent it is possible that there are several patents filed on the same day that are in the initial group and it is possible that the drug substance patent was not the one that was issued first among this group. In yet another approach, we assign a drug substance patent as being a possible polymorph if a given FDA-approved drug product has two or more drug substance patent associated with it and we assume the later issued patents are polymorphs and the first issued patent is the original active-ingredient patent. In the interests of brevity, we will not show results for all of these alternative approaches. Moreover, among the different approaches considered to draw on variation in examination time, we will just show results for the methodological approach best designed to causally identify the effects of time-reducing promotions—i.e., the stacked-event study approach.

We also note at the outset that future research would benefit from verifying the various algorithmic approaches to classifying secondary and active-ingredient patents taken in this paper through hand-coding, an exercise that would admittedly require considerable time. Nonetheless, it is encouraging that the main results presented in the paper are robust to the results presented below using the reclassification approach, which aggressively reassigns possible polymorphs. That result may also suggest that the time pressures from reviewing polymorph patents may be less pronounced than that of other types of secondary patents—e.g., formulation patents, methods of use patents, etc. (perhaps because it is easier to assess the novelty and non-obviousness of crystalline structures of active ingredients given the tools available to assess the novelty and non-obviousness of the active ingredients).

In Table A5, we present results from a counterpart to Table 2 in the text, which estimates the general impact of a time-reducing promotion on the likelihood of EPO allowance of a U.S.-issued Orange Book patent, separately for: (1) patents classified as secondary according to our main approach along with patents flagged as possible polymorphs in that they are patents identified as drug-substance patents but are not among the initial group of patent filings associated with a drug product (modified "secondary" group) and (2) patents classified as active-ingredient according to our main approach and that likewise are among the initial group of patent filings associated with a drug product (modified "primary" group).[4] As demonstrated, the results are very close to that presented in Table 2 of the text using our main secondary/primary assignments.

[4] For the reclassified primary-patent group using the 1-year event windows on either side of a promotion, we lack enough degrees of freedom to include art-unit-by-year fixed effects given the smaller reclassified group. According, for this smaller event-window specification for the primary-patent group, we include art unit and year fixed effects separately.

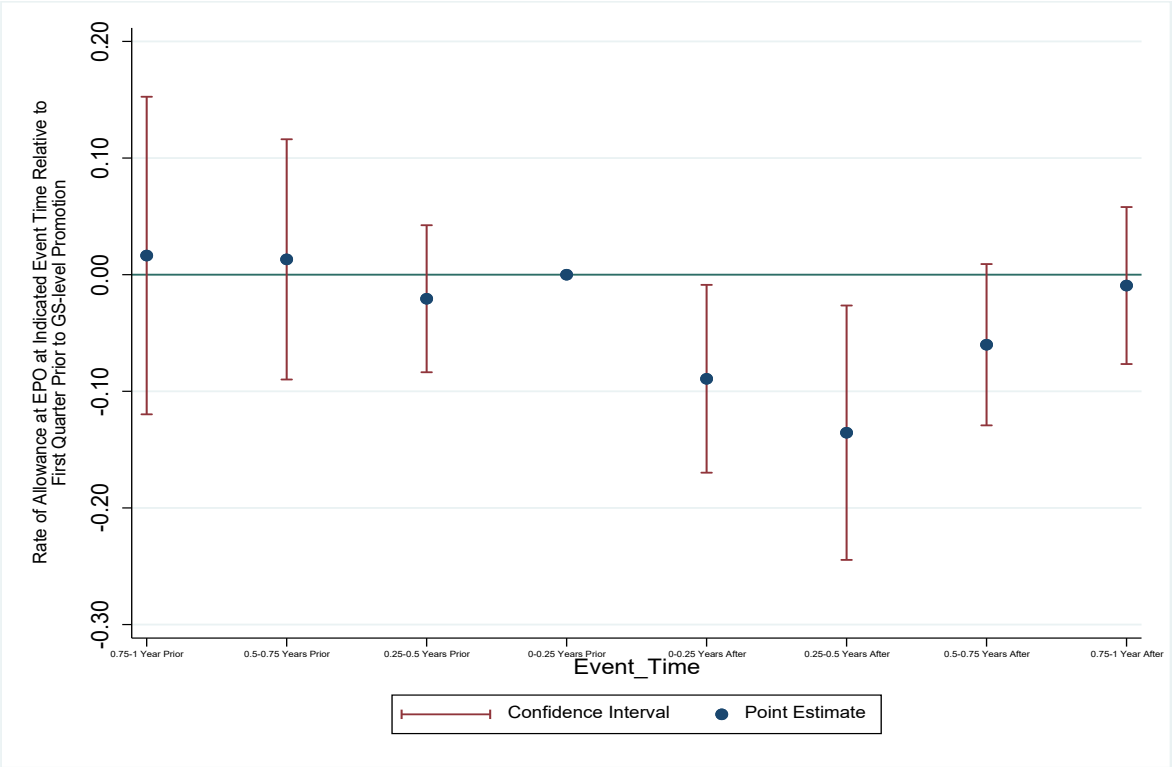
TABLE A5: RELATIONSHIP BETWEEN LIKELIHOOD OF EPO ALLOWANCE OF TWIN OF U.S.-ISSUED ORANGE BOOK PATENT AND GRADE-LEVEL PROMOTION EVENT, STACKED EVENT STUDY RESULTS, REASSIGNING POSSIBLE POLYMORPHS TO SECONDARY PATENT GROUP

	(1)	(2)	
	Secondary Patents	**Primary (Active-Ingredient) Patents**	**Difference in Promotion Effect between Secondary and Primary Patents**
Post Promotion Event	-0.083	0.000	-0.083
	(0.019)	(0.000)	(0.021)
N	1,034	81	1,115
Mean of Dependent Variable	0.86	0.95	0.87

Notes: results are from a stacked sample of secondary (Column 1) and primary (Column 2) Orange Book patents disposed of in a two-year (one on each side) event window around the reviewing examiners' promotions to GS-12, 13 and 14. The estimated specification also include the control variables indicated in specification (2). Predicted polymorph patents are included in the secondary patent group. Standard errors are reported in parentheses and are clustered at the Art-Unit level.

Again, while we find a post-promotion effect in the case of our secondary patent group (in both the main approach and this modified approach), one might be concerned that this decline in examination quality predated the promotion itself. Accordingly, to assess such concerns in the case of this modified secondary sample, we estimate a counterpart to Figure 2 in the text using this modified secondary-patent categorization. For the sake of brevity, we simply show this equivalence in findings in the case of the simpler event-study framework without using promoted-out GS-14 examiners as controls.

FIGURE A11. EVENT-STUDY ANALYSIS: TREND IN EPO-ALLOWANCE LIKELIHOOD OF TWIN OF U.S.-ISSUED SECONDARY ORANGE BOOK PATENT IN PERIOD OF TIME LEADING UP TO AND FOLLOWING GS-LEVEL PROMOTION, REASSIGNING POSSIBLE POLYMORPHS TO SECONDARY PATENT GROUP



Secondary "Secondary" Patents

Some drug products receiving approval from the FDA do not necessarily emanate from an original active ingredient patent. A brand name manufacturer may instead revisit an old ingredient and develop a new use based on a novel strength or formulation or an ingredient previously patented by another manufacturer (or simply based on an ingredient that has long been in the public domain). The original patents received by this new brand name manufacturer may indeed be categorized as a secondary patent in our database in that the patent is on a new formulation, strength and/or method of use. That manufacturer may then go on to obtain even more secondary patents in connection with this new drug product—e.g., a manufacturer may find a new use for an old ingredient and obtain a patent on it and subsequently patent an extended-release version of its drug. In an alternative approach to categorizing "secondary" patents, we exclude from this sample of secondary patents all such original patents for new drug products of this nature. In other words, we consider an alternative sample of original patents that includes (1) patents that are secondary to a previous active-ingredient patent by that manufacturer and (2) patents that are issued following an original patent obtained by a manufacturer to create a new drug product, but where that original patent is nonetheless not a patent on the original active-ingredient itself.

The essence behind this alternative approach is to view as "secondary" those patents that are truly secondary within a marketed drug. In Figure A12, we replicate Panel A of Figure 1 of the text focusing on this alternative formulation of secondary patents (ignoring Panel B of Figure 1 as our focus in this exercise is simply on an alternative set of secondary patents). As demonstrated by Figure A12, we find a nearly identical pattern in this instance.

The remainder of the secondary patent results are likewise robust to this alternative approach. In the interests of brevity, we will only show this for the case of the event-study graph analogous to Figure 2b in the text, which we demonstrate in Figure A13. As can be seen, this event-study figure is nearly identical to that presented in Figure 2b.

FIGURE A12. RELATIONSHIP BETWEEN LIKELIHOOD OF EPO ALLOWANCE OF "TWIN" OF U.S.-ISSUED ORANGE BOOK PATENT AND GRADE-LEVEL OF EXAMINER ASSIGNED TO RELEVANT U.S. PATENT, EXCLUDING SECONDARY PATENTS THAT CONSTITUTE ORIGINAL PATENTS FOR NEW DRUGS

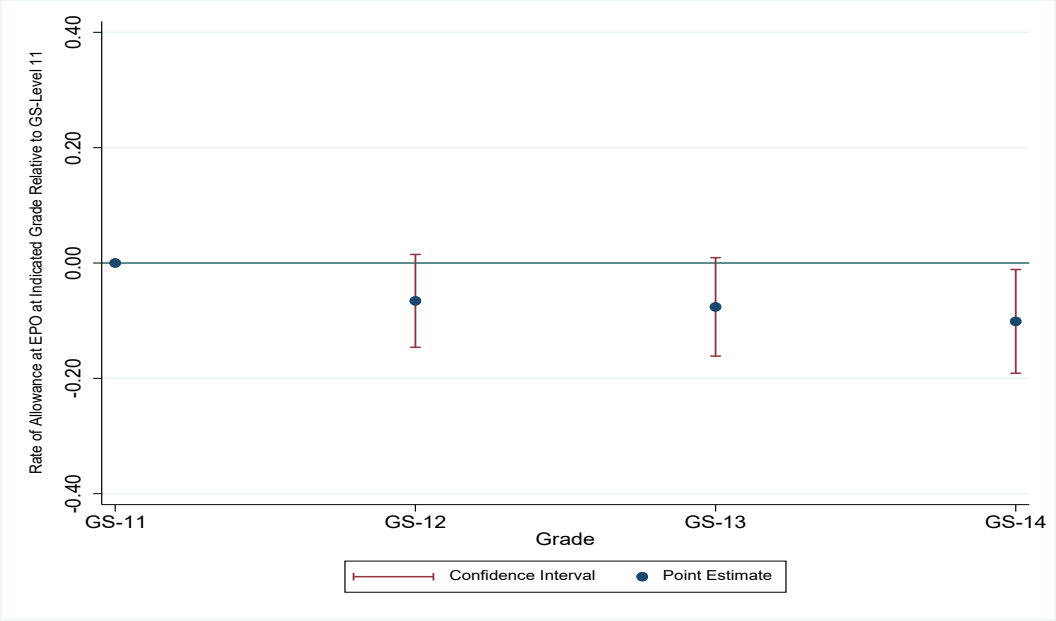
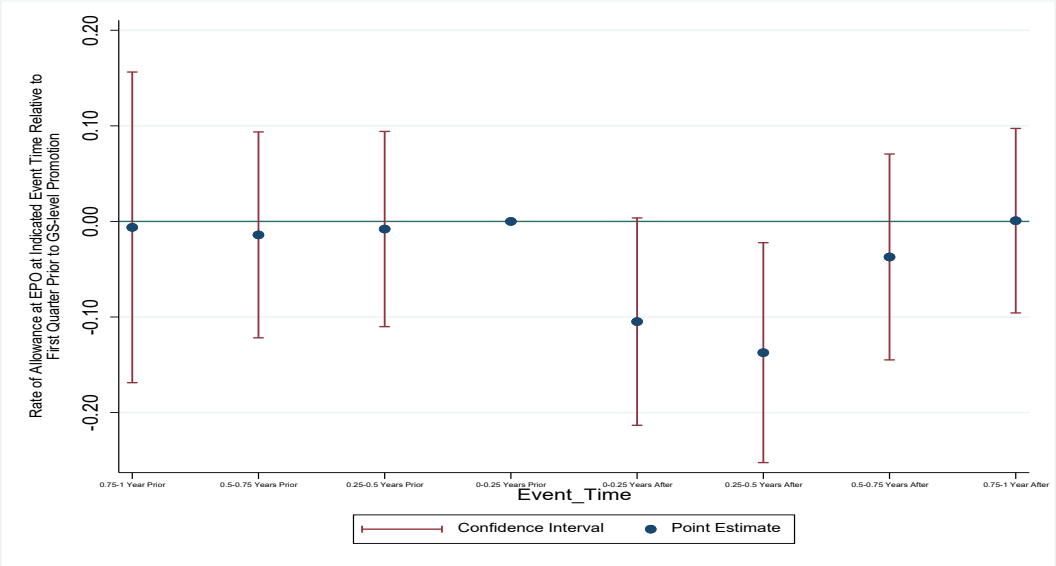


FIGURE A13. EVENT-STUDY ANALYSIS: TREND IN EPO-ALLOWANCE LIKELIHOOD OF TWIN OF U.S.-ISSUED SECONDARY ORANGE BOOK PATENT IN PERIOD OF TIME LEADING UP TO AND FOLLOWING GS-LEVEL PROMOTION, EXCLUDING SECONDARY PATENTS THAT CONSTITUTE ORIGINAL PATENTS FOR NEW DRUGS



Estimated Personnel Costs associated with 50% Increase in Examination Time

As indicated in Part IV of the text, we consider a hypothetical reform in which the Patent Office increases time allocations by 50% for each application, without sacrificing throughput, in which case, we contemplate a 50% increase in hours for each of 23,418 annual secondary pharmaceutical patent applications. To determine the costs associated with this reform, we begin in Table A6 by calculating the increase in hours this will entail broken out by examiner GS-level (Column 3), which in turn requires a breakdown of applications by GS-level per year (Column 1) and the number of hours assigned by GS-level (which is based on a weighted average of allocated examiner hours for that GS-level across the different Art Units comprising the set of pharmaceutical applications) (Column 2). In Column 4, we indicate the cost per hour to review an application broken down by GS-level. These estimates are from Frakes and Wasserman (2019), which uses federal salary scales (assuming step 5 salaries within each grade level) and uses a salary multiplier of 2.04 to determine associated benefits and overhead expenses associated with that hour of compensation. Multiplying Column 3 by Column 4 and then aggregating across GS-levels, we calculate that this 50% increase in examination time for secondary pharmaceutical applications will cost the Patent Office roughly $20 million per year.

Table A6. Estimated Personnel Costs associated with 50% Increase in Aggregate (and Per-Application) Examination Time

	(1)	(2)	(3)	(4)	(5)
GS-level	**Number of Annual Dispositions by Examiners**	**Mean Number of Hours Assigned**	**Total Additional Hours After 50% Increase in Hours per Application**	**Examiner Cost per Hour (Salary, Benefits, and Other Costs)**	**Extra Costs when Doubling Examination Hours**
GS-11	1268	24.6	15,597	$57.58	$898,047
GS-12	3125	22.7	35,469	$68.99	$2,447,006
GS-13	5690	19.4	55,193	$82.05	$4,528,586
GS-14	13334	17.8	118,672	$96.96	$11,506,495
Total	23,418	19.2	224,931	$87.46	$19,672,465

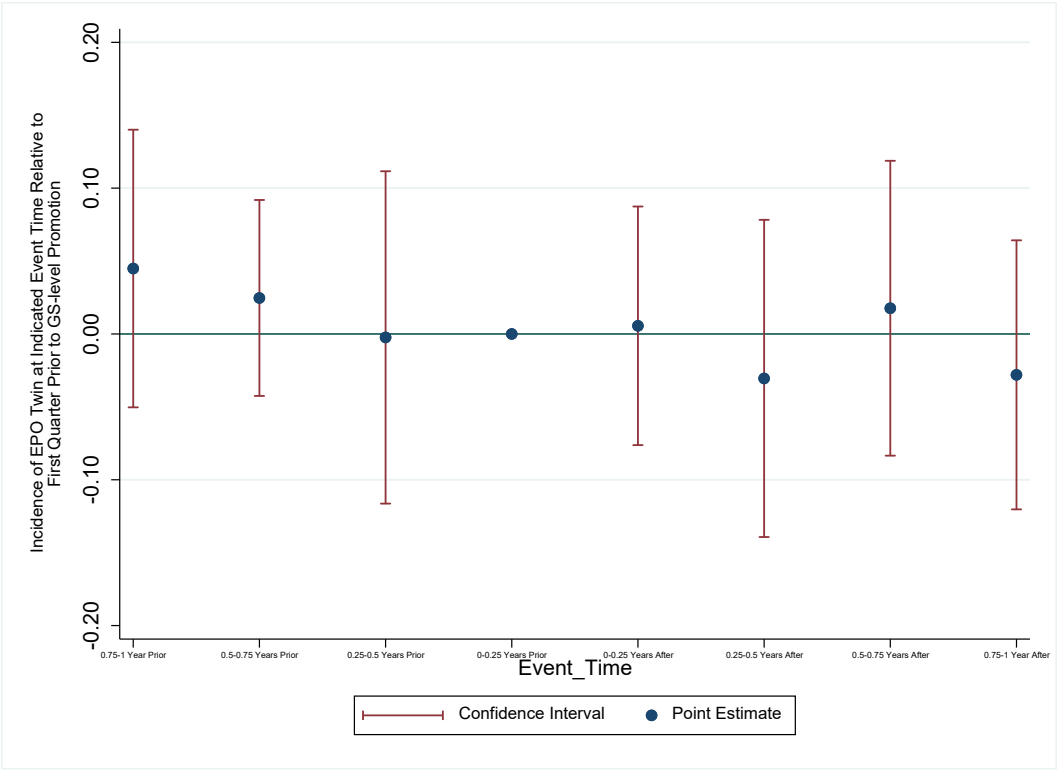
The mean number of hours per grade is calculated using the PAIR sample after assigning hour allotments to each application in the PAIR database based on the associated technology group and examiner grade level.

Reference: Frakes, Michael, and Melissa Wasserman. 2019. "Irrational Ignorance at the Patent Office," Vanderbilt Law Review 72(3): 975-1030.

Effect of Examination Time Constraints on the Likelihood that Innovators with U.S.-Issued Drug Patents also File with the EPO

As stated in the text, one may be concerned that our EPO-twin analysis will under-estimate the full negative impacts of examination time constraints on the validity of issued patents to the extent that the holders of weak U.S. patents may have decided not to file with the EPO due to such validity concerns and the likelihood of EPO rejection. To address this concern, we turn to our specification that is perhaps best suited to causally explore the impact of examination-time-reducing promotions—the event-study specification—and use as the dependent variable the incidence of an EPO twin among the sample of secondary-drug patents associated with FDA-approved drug products. We present the results of this exercise in Figure A14. As demonstrated, there appears to be no relationship between the likelihood that a secondary drug patent is associated with an EPO-twin filing and the occurrence of an examination-time-reducing promotion.

FIGURE A14. EVENT-STUDY ANALYSIS: TREND IN INCIDENCE OF EPO-TWIN ASSOCIATED WITH U.S.-ISSUED SECONDARY ORANGE BOOK PATENT IN PERIOD OF TIME LEADING UP TO AND FOLLOWING GS-LEVEL PROMOTION



Relationship between Examiner Scrutiny and Promotion Speed

We now explore the relationship between an examiner's average examination quality—as measured by our key validity metric—and their promotion outcomes. It is difficult to study the quality determinants of the incidence of a promotion as examiners may depart the Patent Office prior to promotions, where quality may be related to departure for outside activities. Given this concern, we instead focus on those examiners that ascend all the way to GS-level 14 and we explore the time it takes them to rise from GS-11 to GS-14. We regress the log of that duration (Winsorizing the top and bottom 1%) on the examiner's mean rate of EPO allowance among the patents that they issue. Alternatively, we adjust the examiner's mean validity metrics by a range of inherent examiner characteristics (e.g., hiring year cohort, ultimately tenure with the Patent Office) and examiner characteristics at the time of the focal application (e.g., GS-level, experience, disposition year and Art Unit). For this alternative approach, we focus on the sample of patents with EPO twins and regress the incidence of EPO allowance on these various factors, predict the residuals from this regression and then form examiner means of these residuals. At the examiner-level, we then regress the log of the aggregate GS-11-to-GS-14 promotion time for the examiner on these alternative mean validity metrics, weighting this regression by the examiner's associated number of reviews of EPO-twin patents. We also normalize the mean validity metric by its standard deviation so that we can interpret the results as the relationship between a 1-standard-deviation increase in the rate by which an examiner's average issued patent is allowed by the EPO and the log-point change in the time it takes the examiner to ascend from GS-11 to GS-14. Finally, we conduct this exercise on all examiners (Columns 1 and 2) and on examiners that have ever reviewed a pharmaceutical patent (Columns 3 and 4).

As demonstrated by Columns 1 and 3 of Table A7, when we focus on the overall average rate of EPO allowance for the examiner, we either find a near-zero relationship with promotion speed (all examiners) or a positive relation (drug patent examiners). Both of these are inconsistent with a story in which promotions appear to be driven by high-quality examinations, where quality is measured in the sense it is treated in this investigation—i.e., by the targeting of patent awards to those applications that meet the legal patentability requirements. This finding, in turn, lends further confidence a time-allocation interpretation of Figure 2. As demonstrated by Columns 2 and 4, this conclusion is robust to the use of a mean EPO-allowance score that is first adjusted for a range of time-varying and time-invariant examiner characteristics. While we omit the following check for the sake of brevity, we note that we find nearly identical results when we perform yet another modification to the adjusted mean EPO-rate calculation where we employ an empirical Bayesian approach that shrinks noisier estimates towards the mean, following Kane and Staiger (2008).

Additional references

Kane, Thomas J., and Douglas O. Staiger. 2008. "Estimating Teacher Impacts on Student

Achievement: An Experimental Evaluation," NBER Working Paper No. 14607.

Table A7. Estimated Relationship between an Examiner's Duration of Ascension from GS-Level 11 to GS-Level 14 (Logged) and the Examiners' EPO Allowance Rate among the Patents that they Issue

	(1)	**(2)**	**(3)**	**(4)**
	All Examiners		Examiners Reviewing Pharmaceutical Patents	
Mean EPO-Allowance Rate (Normalized by 1 Standard Deviation)	0.002	-	0.035	-
	(0.004)		(0.014)	
Adjusted Mean EPO-Allowance Rate (Normalized by 1 Standard Deviation)	-	-0.004	-	0.011
		(0.004)		(0.014)
N	4,206	4,206	506	506

Notes: Adjusted examiner EPO-allowance rates in the specifications estimated in Columns 2 and 4 are formed by taking examiner means of the residuals of a regression (using the sample of issued patents associated with EPO twins) of the incidence of EPO allowance on a series of time-variant (e.g., examiner experience effects, examiner GS-level effects and disposition year effects) and time-invariant (e.g., examiner hiring-year cohort effects, examiner tenure effects) characteristics. Regressions are at the examiner level and are weighted by the number of EPO-twin-associated patents reviewed by the focal examiner.

Mechanism Analysis: Are Promotion Effects Weaker when the EPO Moves First?

To further mediate between a time-allocation interpretation of the GS-level promotion effects demonstrated by Figure 2 of the paper and possible non-time-allocation explanations for such effects, we exploit certain differences in the timing between when the EPO and the U.S. Patent Office conducts their analyses. When the EPO moves first, U.S. examiners may have access to the EPO-generated search reports providing information on the prior art relevant to the focal innovation. While our own data does not contain reliable information on when U.S. examiners reviewed EPO search reports, we at least have information—among those applications with EPO twins—regarding whether the EPO applications were filed prior to the U.S. applications. Accordingly, we separately estimate our GS-promotion-effects models on a subset of secondary Orange-Book patents where the U.S. Patent Office moved first and on a subset of secondary Orange-Book patents where the EPO moved first. To the extent that we find weaker effects when the EPO moved first, this may lend even further confidence to a time-allocation interpretation of the results presented in the text to the extent that this exercise allows us to exploit variation in access to information that may, in turn, allow us to exploit variation in time pressures.

In Figures A15 and A16, we revisit Figure 2b from the text (using the simpler event-study framework for the purposes of brevity and ease) but separate this analysis into when the EPO does not move first (Figure A15) and when the EPO moves first (Figure A16).[5] As demonstrated, the pattern of point estimates suggest a substantially more pronounced promotion effect in situations where the EPO does not move first relative to when it does move first. The pattern of point estimates for the EPO-priority sub-sample actually suggests that time-allocation changes upon promotions may not be associated with changes in examination-review quality, in which case time constraints may not be binding in situations where examiners potentially have access to information from EPO search reports. Nonetheless, it is important to acknowledge that the confidence intervals are quite large in the EPO-priority sample given its small sample size.

[5] There are some situations where the EPO and the US applications are filed on the same day. We group these situations into the group where the EPO does not move first (or, as titled in the figures, when the U.S. moves first). The results are robust to alternative treatments of these tied applications.

FIGURE A15. EPO-ALLOWANCE EVENT-STUDY ANALYSIS, US IS FIRST-MOVER

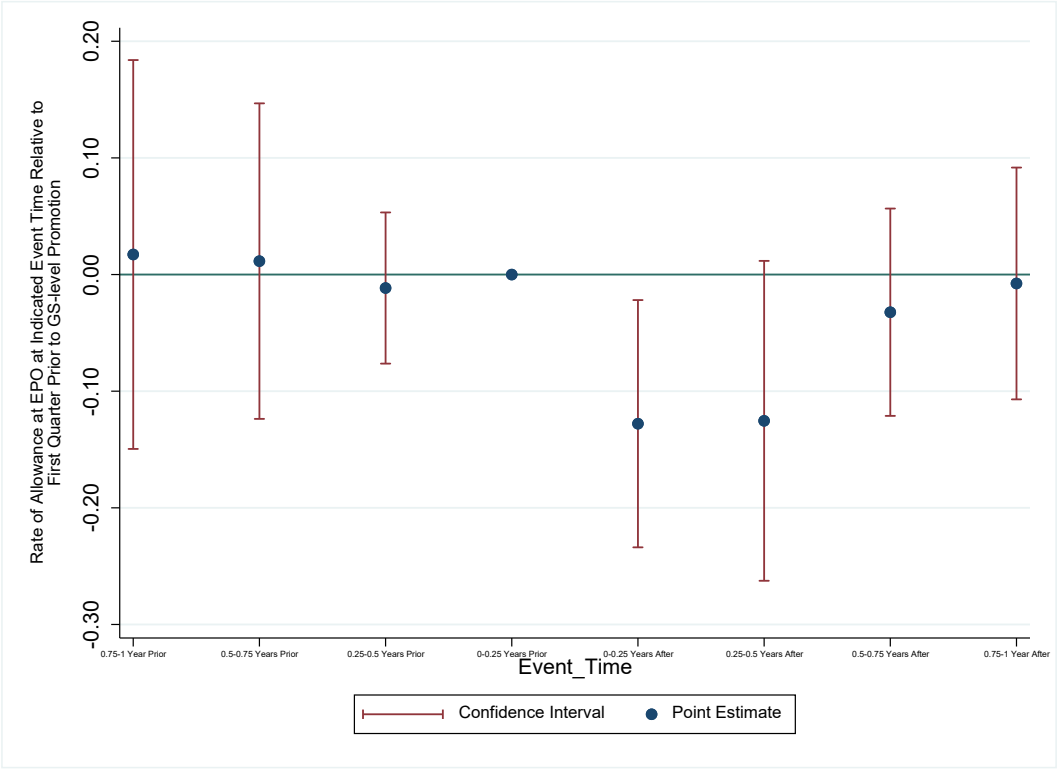


FIGURE A16. EPO-ALLOWANCE EVENT-STUDY ANALYSIS, EPO IS FIRST-MOVER

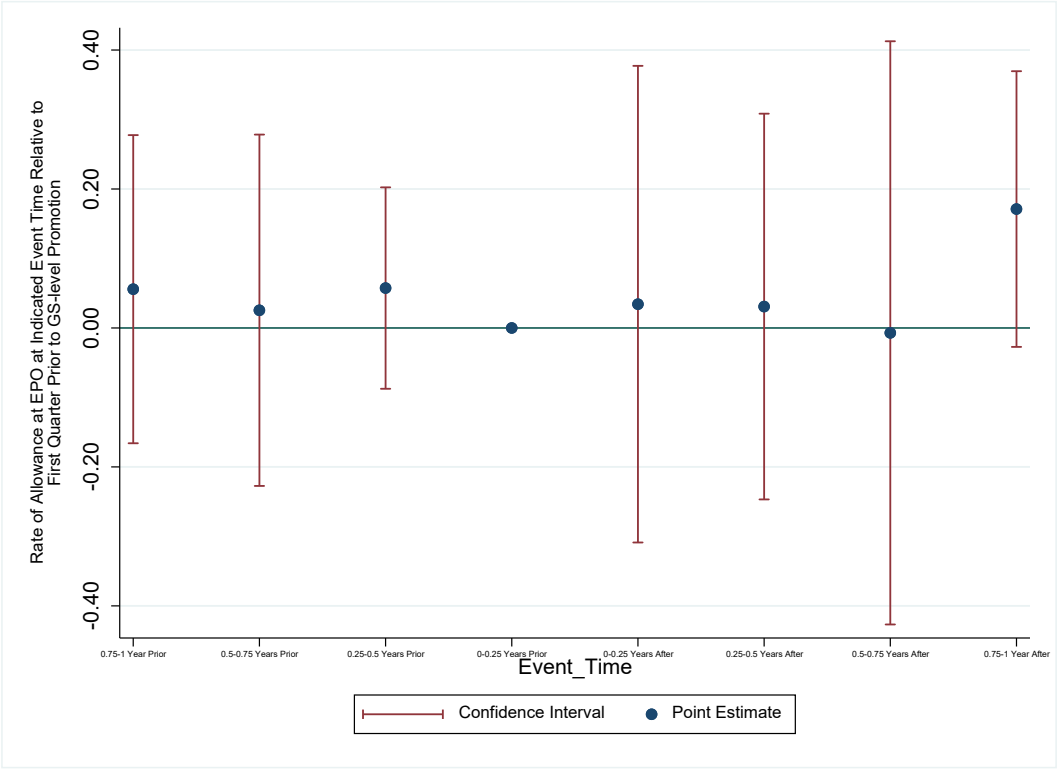


TABLE A8: RELATIONSHIP BETWEEN LIKELIHOOD OF EPO ALLOWANCE OF TWIN OF U.S.-ISSUED ORANGE BOOK PATENT AND GRADE-LEVEL PROMOTION EVENT, STACKED EVENT STUDY RESULTS, SEPARATELY BY U.S. OR EPO MOVING FIRST

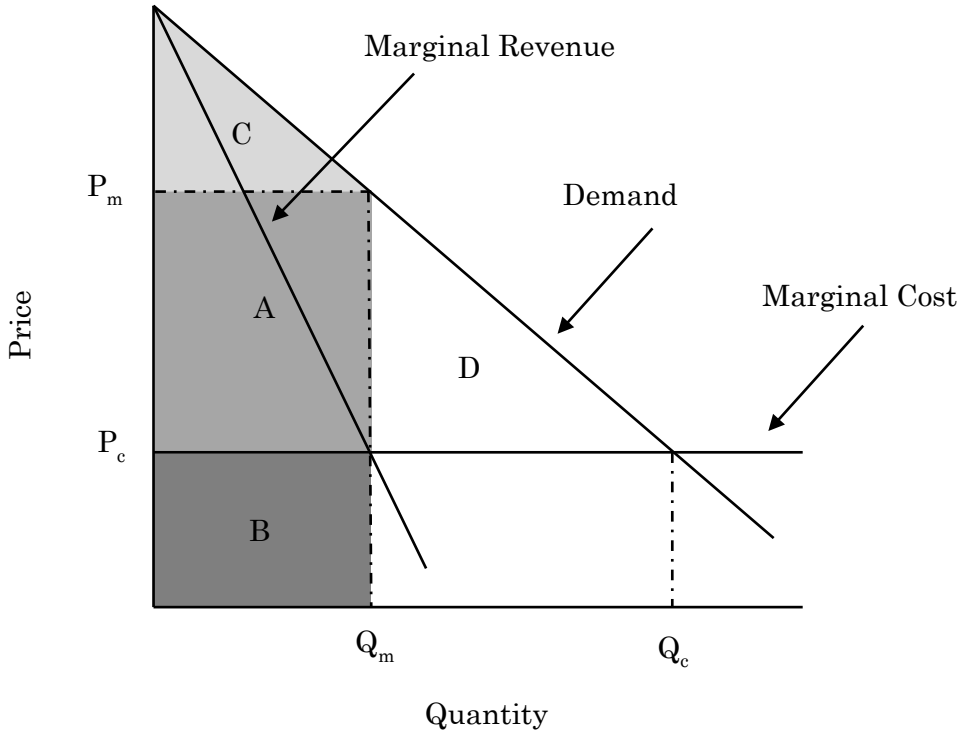
	(1)	(2)
	US Moves First	**EPO Moves First**
Post Promotion Event	-0.081	-0.049
	(0.039)	(0.036)
N	689	216

Notes: results are from a stacked sample of secondary Orange Book patents disposed of in a two-year (one on each side) event window around the reviewing examiners' promotions to GS-12, 13 and 14. The estimated specification also include the control variables indicated in specification (2). Standard errors are reported in parentheses and are clustered at the Art-Unit level.

Static Welfare Analysis: Elementary Monopoly Pricing Model

As stated in the text, focusing on the markets for the affected drug products (i.e., focusing on the static gains associated with the affected products and ignoring any dynamic losses associated with future innovation effects), accelerated generic entry is likely to result in: (1) increased consumer surplus for those consumers who would have otherwise purchased the relevant drug even without generic entry and (2) increased overall surplus given the possibility of increased access following generic entry. To facilitate an informal back-of-the-envelope calculation of these gains, we set forth in Figure A17 a very elementary monopoly pricing scenario for a hypothetical drug (assuming a flat marginal cost curve and linear demand curve for the sake of simplicity). While still under patent protection, a brand-name firm will produce until the point at which marginal revenue equals marginal costs, Q_m, and will set a corresponding price of P_m. Generic entry after patent expiration will push the market to a price and quantity of P_c and Q_c.[6] The increased surplus for those consumers who would have purchased anyway under monopoly pricing is captured by rectangle *A* the increased total surplus by triangle D.

FIGURE A17. IMPACT OF GENERIC ENTRY ON PRICES AND OUTPUT



[6] This essentially assumes that generics will have penetrated the market and drawn patients (and physicians) from purchasing the brand-named drugs. To be sure, aiding in this process are state substitution laws requiring (or permitting) pharmacists to substitute generics for brand-named drugs when filling prescriptions. In practice, the evidence indeed suggests rampant generic penetration on average. Based on a recent report by the IMS Institute for Healthcare Informatics (2016), generics represent 90 percent of dispensed prescriptions.

To calculate the reduced deadweight losses associated with such accelerated generic entry, assume that the quantity sold under monopoly is at a level of Y. Considering the possibility of a 4.6-percent increase in quantity implied by Aiken et al. (2018), the quantity post generic entry will increase to 1.046Y. In this case, the base of the triangle D will be 0.046Y. Assume the height of the rectangular region A is X. This will also be the height of the relevant triangle, in which case the area of rectangle A is XY and the area of the triangle is 0.046XY/2 or 0.023XY. In this case the area of the triangle D is 2.3 percent of the area of rectangle A.

Estimated Costs of Obtaining Secondary Drug Patent

For the purposes of this exercise, we will draw on data from the 2019 *Report of the Economic Survey* issued by the American Intellectual Property Law Association, which provides mean estimates of the law firm charges associated with, among other things, obtaining patents for their clients, broken down coarsely by technology category. In Table A9, we draw on various components of these mean charges to estimate the cost of obtaining a secondary drug patent. We note that we will draw on information from the AIPLA's category of "biotechnology/chemical" patents for such purposes.

TABLE A9: ESTIMATED COSTS OF OBTAINING AND MAINTAINING SECONDARY DRUG PATENT

Legal costs associated with:	
Preparation and filing	$11,339
Amendments and arguments	$6,407
Board hearings	$183
Post-allowance activity in preparation of issuance	$876
Paying and processing maintenance fees (Present Value)	$413
PTO fees total (Present Value)	$8,033
Total	$27,251

Estimates are from the 2019 *Report of the Economic Survey* from the American Intellectual Property Law Association, available at https://www.aipla.org/home/news-publications/economic-survey. Costs associated with amendments and arguments are equal to the amount reported by the AIPLA multiplied by 1.7 to account for the fact that the pharmaceutical applications in our data have on average 2.74 office actions per application file number (meaning that applicants are asked to amend roughly 1.74 times on average beyond the first office action on the merits). Costs associated with board hearings are calculated by multiplying the AIPLA reported amount by 3.4% to reflect the rate by which appeal briefs are filed for the pharmaceutical files in our sample. PTO fees are calculated as follows: (1) basic filing fee of $320, (2) $96 expected fee for independent claims in excess of 3 (using claims data for this sample over last 7 years), (3) $330 expected fee for 3.3 claims in excess of 20 (using recent claims data), (4) $700 search fee, (5) $800 examination fee, (6) $1200 issuance fee, (7) $1295 in expected 4-year maintenance fees, based on an assumed 84.9 maintenance rate from Frakes and Wasserman (2013) and discounting to the present at 7 percent, (8) $1383 in expected 8-year maintenance fees, based on an assumed 63.2 maintenance rate from Frakes and Wasserman (2013) and discounting to the present at 7 percent, and (9) $2160 in expected RCE fees considering an estimated 0.34 RCEs per application file in the pharmaceutical application sample of PAIR.

Reference:

Frakes, Michael, and Melissa Wasserman. “Does Agency Funding Affect Decisionmaking?: An Empirical Assessment of the PTO’s Granting Patterns,” Vanderbilt Law Review 67 (2013).

Distribution of Orange Book Patents (That are Part of EPO Patent Families) Across Technology Centers and Art Units

Table A10 presents the distribution of the patents in our analytical sample (Orange Book patents part of EPO twin-*application* families) across Patent Office Technology Centers. As demonstrated, roughly 90% of the sample if reviewed by Art Units in Technology Center 1600. In Table A11, we breach down this 1600 Technology Center into is various Workgroups. Each such Workgroup itself is comprised of upwards of 10 different Art Units.

TABLE A10: DISTRIBUTION OF ORANGE BOOK PATENTS ACROSS TECHNOLOGY CENTERS

Technology Center	Number of Patents	%
1600	3,186	90
1700	18	0.5
2100	1	0.0
2600	11	0.3
2800	10	0.3
3600	7	0.2
3700	299	8.5
4100	1	0.0

TABLE A11: DISTRIBUTION OF ORANGE BOOK PATENTS ACROSS TECHNOLOGY CENTER 1600

Technology Workgroup	Number of Patents	%
1610	1,326	41.6
1620	1,484	46.6
1630	35	1.1
1640	74	2.3
1650	159	5.0
1670	108	3.4

Additional Details on Accelerated Patent Expiration Simulation

To determine the degree to which the 12.8 percentage-point grant-rate reduction following a 50% time allocation increase will accelerate patent expiration, we run a simulation exercise wherein in each simulation we randomly drop 12.8% of the secondary Orange Book patents, focusing on those with questionable validity as flagged by non-EPO-allowance (since our EPO analysis suggests that those marginal patents that may no longer be allowed due to time allocation increases are those likely to be of questionable validity). For each drug product, we then calculate the degree of acceleration, if any, these dropped secondary patents have on patent expiration.

One challenge arises in a situation in which the patent(s) dropped in a simulation constitute all of the patents associated with that drug product (after all, some drug products do not have active-ingredient patents). In this case, we follow Kapczynski et al. (2012) and assume that these drug products will at least get the five years of exclusivity provided by the FDA approval itself.

For this simulation exercise, we focus on relatively more recent drug products, limiting our sample of drug products to those with an expiration date of the first patent in the drug product of at least 2015. This allows us to be consistent with the scope of our analysis from Part III where we analyze patents issued in 2001 and beyond. The results are not sensitive to this precise year cutoff, however. For instance, if we use a cut-off of 2020, the predicted accelerate degree differs by only two days.

Overall, through this simulation exercise, we predict that the 12.8 percentage-point grant-rate reduction following the hypothesized time allocation reform will accelerate the expiration of the effective patent life of an average drug product by 162 days.

Matters are slightly more challenging in our attempts to determine the percent of this acceleration in patent expiration that would have occurred anyway via litigation. How do we figure out this percentage? In short, we incorporate information on first generic entry—even if before expiration of the last patent for the drug product—into this simulation (this early generic entry would be due to litigation). Imagine a drug product whose last expiring patent is set to expire in 2020 and whose second-to-last expiring patent is set to expire in 2016. But assume generics entered in 2018 after successful legal challenges. And assume that one of those secondary patents that would have not be allowed if examiners were given more time is the one set to expire in 2020. Without this litigation, the time-allocation reform would have accelerated patent expiration and thus generic entry by 4 years. However, 2 of those years would have been accelerated anyway via litigation.

There is a challenge here, however, in operationalizing this approach. With our main simulation exercise, we are able to focus on patents issued in the 2010s, many of which are associated with drug products whose last-expiring patents will not expire until notably into the future. If we use all of those recent patents/drug-products in a modified simulation exercise that adjusts for observed generic entry prior to patent expiration, we will be heavily discounting the role of litigation to induce generic entry as we will not have given litigation a chance yet. For instance, if we use a drug product whose last-expiring patent that is not set to expire until 2030, we can

simulate that dropping its last secondary patent will lead to X days/years of acceleration of patent expiration. But, for this particular drug product, it is too premature to empirically ask how much of that acceleration would have happened anyway as a result of litigation. Why? Because we do not yet know what litigation will do between now and 2030.

As such, in this modified approach that incorporates early generic entry into the simulation exercise, we focus on those drug products with a last-expiring patent with an expiration date of 2021 and prior. That is, we only focus on drug products with respect to which we have let litigation play its course in possibly accelerating patent expiration. The challenge is that we will also still need to rely on somewhat recent patents, as above. As such, we take a subset of drug products whose first-expiring patents expires at least after 2015 and whose last-expiring patent expires at least by 2021. This is indeed a particular group of drugs that may look different from other drug products. They are recent but the extensions coming from secondary patents are limited given that we are stopping things in 2021. That being said, we can still use this sub-sample to determine what percentage of the patent-expiration acceleration implied by dropping secondary patents (presumably through better examination) within this sub-sample would have transpired anyway through litigation-induced generic entry. Doing so, we estimate that 68% of the simulated acceleration in patent expiration (among this subsample of drug products) that would arise from our hypothesized time-allocation reform would have occurred anyway via litigation.

We then apply this percentage to our full (recent) drug-patent sample—including those that won't expire until well into the future—in order to appropriately shave down the 162-day acceleration figure implied by our naïve simulation exercise. Doing so, we predict that our hypothesized reform will lead to 51.8 days of accelerated generic entry for an average drug product even with litigation as a backdrop.

Note that the percentage found through this modified simulation exercise is roughly in accord with what we might have guessed by considering that as much as 52% of Paragraph IV challenges settle (Hemphill and Sampat 2013) and considering that these settlements predominantly reflect a compromise between the parties on the date of generic entry (FDA 2017).

Additional references:

Hemphill, Scott, and Bhaven Sampat. 2013. "Drug Patents at the Supreme Court," *Science* 339: 1386-1387.

FDA. 2017. "Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003," available at FY2017 MMA Report - Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (ftc.gov).

Event-Study Results on 2004+ Sample

The PAIR data, the OECD Triadic Patent Family data and the examiner personnel data received via FOIA that we draw on for our analysis begin in 2001. The Orange Book data does not begin flagging drug substance patents until 2004. However, for Orange Book patents issued between 2001 and 2004, such patents will usually show up in 2004-plus issues of the Orange Book and will identify themselves as "drug substance" (or not) at that time. As such, we can nonetheless assign those patents issued between 2001 and 2003 to a drug-substance status.

In any event, in this section, we also demonstrate that the results are virtually identical when we draw on a sample limited to patents issued in 2004 and beyond. To see this, consider the following graph (Figure A18) which is analogous to Figure 2b in the text but focused on this limited time-frame. Also consider Table A12, which is analogous to Table 2 of the text and which shows these event-study results as a simpler before-after parameter.

FIGURE A18. EVENT-STUDY ANALYSIS: TREND IN EPO-ALLOWANCE LIKELIHOOD OF TWIN OF U.S.-ISSUED SECONDARY ORANGE BOOK PATENT IN PERIOD OF TIME LEADING UP TO AND FOLLOWING GS-LEVEL PROMOTION, 2004-PLUS

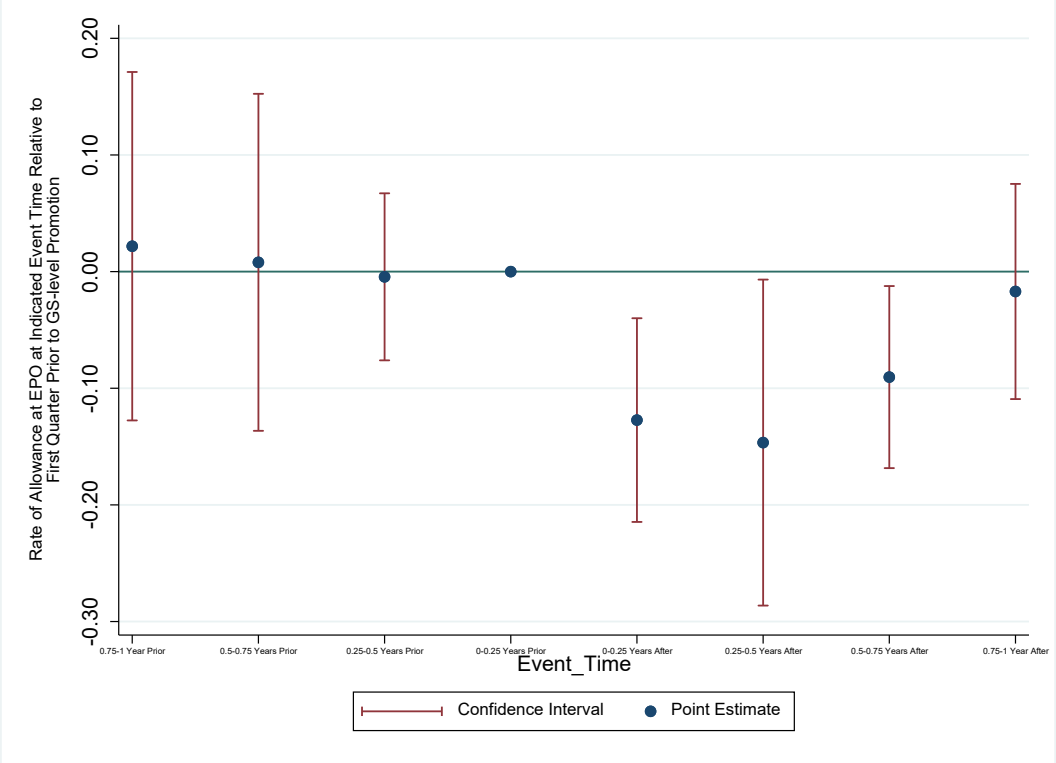


TABLE A12: RELATIONSHIP BETWEEN LIKELIHOOD OF EPO ALLOWANCE OF TWIN OF U.S.-ISSUED ORANGE BOOK PATENT AND GRADE-LEVEL PROMOTION EVENT, STACKED EVENT STUDY RESULTS, 2004-PLUS

	(1)	(2)	
	Secondary Patents	**Primary (Active-Ingredient) Patents**	**Difference in Promotion Effect between Secondary and Primary Patents**
Post Promotion Event	-0.105	-0.023	-0.082
	(0.027)	(0.028)	(0.036)
N	790	126	916
Mean of Dependent Variable	0.86	0.96	0.87

Notes: results are from a stacked sample of secondary (Column 1) and primary (Column 2) Orange Book patents disposed of in a two-year (one on each side) event window around the reviewing examiners' promotions to GS-12, 13 and 14. The estimated specification also include the control variables indicated in specification (2). Standard errors are reported in parentheses and are clustered at the Art-Unit level.

Additional Information on Revenue Estimates from Part IV

Needed for our estimates of the consumer surplus gains that may arise from accelerated generic entry (which, in turn, arises from the hypothesized increase in time allocations) is an estimate of the annual revenue generated by a brand-name manufacturer for a given drug in the time period prior to generic entry. As stated in the text, ideally, we would collect this average revenue amount among those drugs whose effective patent lives are expected to be accelerated by the hypothesized time-allocation reform—i.e., those drug products with secondary patents (with weak validity) that prolong the effective patents lives of drugs. Hemphill and Sampat's (2012) findings suggest that drugs of this nature have perhaps notably higher sales than average. Ultimately, we leave it for future research to precisely estimate the revenues associated with those drugs that meet a sample criteria of this nature. Nonetheless, to proceed for the purposes of the back-of-the-envelope calculations needed for Part IV of the paper, we turn instead to more general sources of information on the average revenues generated per drug.

Two possible sources are Hemphill and Sampat (2012) and Rome et al. (2021), both of which report revenue estimates for drug products that are not yet facing generic competition, as desired for our purposes. Hemphill and Sampat use a sample of new molecular entities that were first subjected to competition from a therapeutically equivalent generic product between 2001 and 2010. Among this sample, they find an average annual revenue amount of $748 million, with quintile cutpoints of $55 million, $144 million, $397 million and $1.1 billion. Rome et al. (2021) draw on data from a sample of brand-name drugs that are not yet facing generic competition, that have at least 1000 units sold per quarter and that have continuous data on prices over a two-year period. Using this sample, they find median annual revenues per drug in 2017 of $401 million, with an inter-quartile range of $120 million - $888 million. Though they do not report average revenues, the distribution of revenues reported in Rome et al. is larger than that found in Hemphill and Sampat. This may, in part, be due to the timing insofar as Hemphill and Sampat's figures are reported in 2010 dollars.

To make the conservative choice between these two studies, we draw on Hemphill and Sampat's figure for the purposes of the numbers set forth in Part IV. To be sure, Hemphill and Sampat's sample may not be representative of an average drug approved by the FDA and may be a higher-sales sample than a truly representative sample. Nonetheless, as above, our ideal sample for this revenue figure anyway is likely to be drawn from the higher sales end of the distribution.[7] Accordingly, we assume that the sample drawn from in Hemphill and Sampat and in Rome et al. aligns with those drugs that are likely to respond to our hypothesized reform anyway—i.e., again drugs with patent term lengths that are extended through secondary patents. As above, we leave it for future research to more precisely verify such an assumption.

All of this being said, we end by taking an even more conservative approach that attempts to draw on a revenue amount reflective of the average drug, not necessarily those drugs most likely to be affected by a time-allocation reform. This approach is actually rather straightforward. Return to our estimate in Part IV that the average drug will experience 51.8 days of acceleration in its effective patent life (accounting for the acceleration that would come anyway via litigation). Considering an effective market life of 12.2 years (Hemphill and Sampat 2012), this represents an average degree of acceleration of roughly 1.2% of a drug's expected market life. In other words, brand-name firms will expect a 1.2% hit in their expected returns. Of course, this doesn't mean that consumers will reap all of that 1.2%. After all, we are continuing to assume only a 50% price reduction upon generic entry. Together, in annualized terms, this suggests an increase in aggregate consumer surplus of an amount equal to 0.6% (1/2 of 1.2%) of the

[7] This point itself is supported by another aspect of Hemphill and Sampat's own analysis. Within their sample, they observe a strong relationship between sales and the effective patent length of the drug, where longer effective patent lengths generally result from later-expiring secondary patents.

industry's annual revenue. Considering the annual industry revenues in the United States of roughly $540 billion (IQVIA 2021)[8], this represents an aggregate increase in consumer surplus of $3.24 billion. If we discount this to the present using the discount rate set forth in Part IV, we calculate a present discounted value of $2 billion.

In other words, if we take a conservative approach that tries to consider overall average revenues and not necessarily the average revenues for those drugs that use invalid secondary patents to extend patent length, then we still estimate considerable savings—albeit at roughly half the size—to consumer surplus.

Additional reference: Rome, Benjamin, et al. 2021. "Correlation between Change in Brand-Name Drug Prices and Patient Out-of-Pocket Costs," *JAMA Network Open* 4(5).

[8] For this figure, we consider the amounts spent by all payers (including government and private insurance and out-of-pocket costs), rather than the reported amounts based on list prices.

Event-Study Analysis Focusing on Art-Units with Purely Random Assignment

Feng and Jaravel (2020) offer a list of Art Units where examiner assignments are based on application serial numbers—i.e., Art Units where we have even greater confidence in the assignment process being tangential to the patent worthiness of the applications. In a final exercise, we revisit our key event-study figure—Figure 2a of the text—but limited to those Art Units appearing on this Feng and Jaravel list. We present results in Figure A19. As demonstrated, the pattern of coefficients is nearly identical to that reported in Figure 2a.

FIGURE A19. EVENT-STUDY ANALYSIS: TREND IN EPO-ALLOWANCE LIKELIHOOD OF TWIN OF U.S.-ISSUED SECONDARY ORANGE BOOK PATENT IN QUARTERS LEADING UP TO AND FOLLOWING GS-LEVEL PROMOTION, LIMITED TO THOSE ART UNITS WITH ASSIGNMENTS BASED ON APPLICATION SERIAL NUMBERS

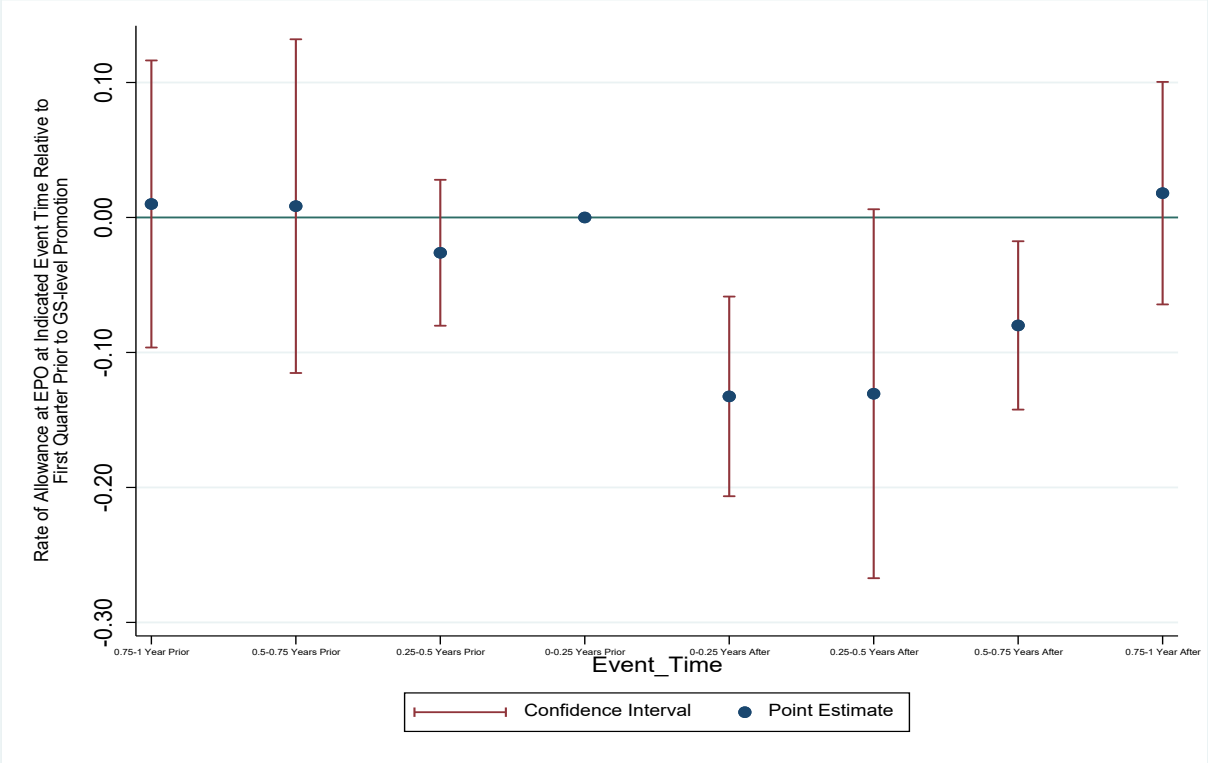


TABLE A20. SUMMARY OF INPUTS INTO WELFARE ANALYSIS IN PART IV AND SUMMARY OF ASSOCIATED FINDINGS (ORGANIZED BY COSTS AND BENEFITS EXPECTED TO ACCRUE FROM HYPOTHESIZED 50% INCREASE IN EXAMINATION TIME ALLOCATED TO SECONDARY DRUG PATENT APPLICATIONS)

COSTS	INPUTS	SUMMARY OF FINDINGS	BENEFITS	INPUTS	SUMMARY OF FINDINGS
Additional Personnel Expenses	1. Distribution of drug-patent examination reviews across GS-levels 2. Hours assignments across GS-levels for drug-patent applications 3. Salary and benefits across GS levels (from Frakes and Wasserman 2019) 4. Overhead, etc. cost multiplier (from Frakes and Wasserman 2019)	Estimate roughly $20 million in additional personnel expenses	Reduced Litigation	1. Number of lawsuit-patent pairs for Orange Book patents per year 2. Percentage of federal lawsuits that have overlapping PTAB proceedings 3. Estimated relationship between 50% increase in examination time (as inferred from GS-14 coefficient in specification 1) and number of times asserted in litigation using drug-patent application sample (Table A4 of Online Appendix) 4. Expenses per patent-lawsuit pair (from Frakes and Wasserman 2019) 5. Assumed 7% discount rate	Estimated mean litigation savings of $32.2 million. 95% confidence interval (based on confidence interval for input 3): $4.3-$46.5 million.
Dynamic Innovation Losses: Lost Consumer and Total Surplus Associated with New Molecular Entities Forgone as a Result of Brand-name Revenue Losses	1. Elasticity of new molecular entities (NMEs) with respect to expected drug market size (alternative elasticities to be drawn from Myers and Pauly 2019 and related studies) 2. Estimated reduction in expected drug market size implied by acceleration in generic entry for average drug product (51.8 days) scaled by average effective market life of drug (12.2 years) (see simulation exercise discussed in Online Appendix). 3. Present discounted value of welfare associated with marginal NME expected to be foregone as a result of reduction in expected market size, net of associated R&D expenses (unknown)	Using Myers and Pauly elasticity, estimate roughly 1.1 foregone NMEs. Using 0.25 elasticity from Dubois et al., estimate roughly 0.15 foregone NMEs. Future work needed to estimate welfare associated with marginal NME.	Consumer Surplus Gains and Total Surplus Gains From Accelerated Generic Entry for those Drug Products Receiving Additional Examination Time	1. Estimated relationship between 50% increase in examination time (as inferred from GS-14 coefficient in specification 1) and grant rate using drug-patent application sample (Figure 4) 2. Simulation of acceleration in drug-product patent expiration through random dropping of secondary patents using information from Input 1 (using FDA drug-product data, including data on early-generic entry) 3. Annual revenue-per-drug estimate (from Hemphill and Sampat 2012) 4. Estimated drug-price reductions upon generic entry (from IMS Institute for Healthcare Informatics 2016)	Estimated mean gains in consumer surplus of $3.9 billion. 95% confidence interval (based on confidence interval for input 1): $2.53 - $5.28 billion. Estimated mean gains in total surplus of $89.8 million. 95% confidence interval (based on confidence interval for input 1): $58.1 - $121.5 million.

		5. Estimated brand-name revenue growth rate (from Rome et al. 2021) 6. Assumed 7% discount rate (from OIRA) 7. FOR TOTAL SURPLUS GAINS: estimated quantity increases following generic entry (from Aitken et al. 2018)	
	Dynamic Administrative Gains: Deterred Patenting-Related Expenses	1. Number of patents associated with NMEs foregone as a result of brand-name revenue losses. 2. Administrative costs associated with patenting activity referenced in input 1. 3. Number of invalid secondary patent applications deterred as a result of reduced likelihood of succeeding in receiving patent on invalid secondary drug features, based on elasticity of patenting behavior with respect to expected success rate (unknown) 4. Administrative costs associated with patent activity referenced in input 3, including attorney costs in receiving patents and responding to office actions and range of Patent Office fees (see Online Appendix). 5. Estimated relationship between 50% increase in examination time (as inferred from GS-14 coefficient in specification 1) and grant rate using drug-patent application sample (Figure 4) 6. Estimate of share of generic-entry acceleration that would have occurred anyway via litigation, used to scale down value from input 5 to determine effective reduction in likelihood of succeeding with efforts at patenting invalid secondary drug features	For purposes of demonstration, paper assumes elasticity of 1 of patenting activity with respect to expected success rate. Estimate roughly $25 million in administrative savings associated with deterred attempts at patenting invalid secondary drug features.