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ABSTRACT

We explore how the Patent Office may improve the quality of issued patents on "secondary" drug features by giving examiners more time to review drug-patent applications. Our findings suggest that current time allocations are causing examiners to issue low quality secondary patents on the margin. To assess the merits of expanding ex ante scrutiny of drug-patent applications at the agency, we set forth estimates of the various gains and losses associated with giving examiners more time, including reduced downstream litigation costs and added personnel expenses, along with both the static gains and dynamic innovation losses associated with earlier generic entry.

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A data appendix is available at http://www.nber.org/data-appendix/w27579

INTRODUCTION

Evidence has suggested that pharmaceutical innovation has led to substantial improvements in longevity and quality of life (Licthenberg 1996, Cutler and McClellan 2001).[1] Moreover, it is generally understood that patent protection is necessary to spur innovation in the pharmaceutical marketplace (Scherer 2006). Despite these promises of the patent system, the precise design of this system can have substantial implications for how these goals can be met in an efficient (and equitable) manner. Like other markets, the pharmaceutical arena faces a classic economic trade-off between the high prices—and consequently diminished patient/consumer access—facilitated by patent protection and the need to stimulate innovation through the granting of that protection in the first instance. The legal patentability requirements—including the novelty and non-obviousness requirements—are designed to respect this very balance (Nordhaus 1969). However, the system may fail to meet this objective if it does not provide patent examiners with the time needed to apply these patentability standards.

Conceptually, the link between examination time and the legal validity of issued patents is straightforward. Patent applications are presumed valid upon filing, in which event examiners are expected to allow applications if they are unable to find and articulate a basis to reject in the time allotted. Should these time constraints bind, examiners may be forced to allow legally invalid patents on the margin (Frakes and Wasserman 2017), which may result in periods of monopoly pricing in situations where the innovation in question was obvious or lacked novelty. In this paper, we will explore whether examiner time constraints indeed bind in the case of pharmaceutical patent applications and estimate the relationship between various markers of the validity of issued pharmaceutical patents and the time allocated to pharmaceutical patent examiners.

[1] Other studies have even demonstrated the significance of pharmaceutical innovation for labor supply outcomes. Garthwaite (2012).

Our analysis will pay particular attention to a controversial patenting practice that commentators have increasingly identified as contributing to delayed generic entry: "secondary" patenting (FTC 2019; National Academies Press 2018; Kesselheim 2016; Amin and Kesselheim 2012). By this, we refer to the practice by brand-name drug manufacturers of seeking patent protection not just on the active-ingredient itself but on subsidiary drug features—e.g., route of administration—often years after the filing of the active-ingredient patent. Considering the potential of secondary patents to prolong the effective patent life of drugs and considering the arguably more nuanced evaluation entailed in assessing the innovativeness of secondary features, it is of special, independent importance to understand how examiner time allocations are related to the underlying validity of those secondary pharmaceutical patents issued by the Patent Office.

We take two fundamental approaches to capturing variation in examination time allotments. Primarily, we build on Frakes and Wasserman (2017) and draw upon the fact that time allocations are a simple function of just two factors: (1) the technological Art Unit to which the examiner belongs and (2) her place on the General-Schedule (GS) pay scale, with a roughly 10-15 percent decrease in time allocations arising upon each GS-level promotion. Focusing on this latter source of variation, we explore whether markers indicative of patent validity weaken as the assigned examiners experience time-allocation-reducing promotions, taking advantage of a patent-application-assignment process that is tangential to the patent-worthiness of the application and taking various steps—including the estimation of stacked event-study specifications—to separate a promotion effect from the influence of factors correlated with examiner GS-levels. We further supplement this GS-level inquiry by estimating a simple event-study specification that draws on a second source of variation in time allocations—one unconnected to examiner GS levels—i.e., a 2010 reform in which examiners were allocated two additional hours across the board.

To further reinforce a time-allocation mechanism, we draw upon a prediction that examination time constraints are less likely to bind in the case of active-ingredient patents—where patentability requirements and search tools are more straightforward to apply—and thereby separately estimate our analysis on secondary drug patents and active-ingredient patents. Relatedly, we separately estimate our specification on a set of secondary patents where U.S. examiners are likely less time constrained given their potential access to information by the European Patent Office (EPO) on the novelty and non-obviousness of the application at hand.

We use two alternative markers for the validity of issued U.S. drug patents. Primarily, we use the EPO allowance of a U.S.-issued drug-patent as a validity marker, a common approach in the literature that relies on the following (i) that drug-patent applicants at the U.S. almost always file for protection at the EPO, (ii) that the U.S. and the EPO have essentially similar legal patentability standards and (iii) that patent law and innovation scholars and commentators view the EPO as the "gold standard" for examination quality (Chien 2018). Alternatively, drawing on a recent literature showing that invalid patents target federal litigation at a higher rate (Frakes and Wasserman 2019), we use litigation frequency associated with Food and Drug Administration (FDA)-approved drug patents as a validity signal.

Using these two alternative markers for the validity of issued patents and drawing on administrative data from the Patent Office, the FDA, and the Organisation for Economic Co-operation and Development (OECD), our results are suggestive of a striking relationship between examination time and the likelihood that examiners issue invalid patents. For instance, our stacked-event study analysis suggests that upon a given GS-level promotion, examiners experience a roughly 10 percentage-point drop in the near-term in the rate by which secondary pharmaceutical patents issued in the U.S. are likewise allowed at the EPO (among twin applications).

Accompanying these average EPO-allowance effects is an increase in examiner grant-rates, collectively suggesting that a time-allocation-decreasing promotion event is associated with the issuance of more patents on the margin of questionable validity. Reinforcing a time-allocation interpretation of these findings, (i) we do not document a promotion-effect in the case of active-ingredient patents, (ii) we find that the time-reducing promotion-effect is stronger when examiners do not have possible access to the relevant EPO search report on the underlying application, and (iii) we find a jump in our validity markers for secondary pharmaceutical patents upon the adoption of the 2010 reform extending all examiners an additional two hours per application review.

Even if extending examiners more time to review applications may allow the Patent Office to reduce the issuance of invalid patents, we acknowledge the argument famously set forth by Lemley (2001) that patent litigation is so rare that it may be more cost effective to rely upon the courts to execute this screening function. To address this concern, we estimate the costs and benefits of a hypothetical reform in which examiners are given a 50-percent increase in the time allocated to review secondary drug patents. We begin by comparing the added administrative costs of expanded ex ante screening at the Patent Office with the reduction in the administrative expenses associated with ex post litigation that may result from the expanded ex ante scrutiny, the latter of which we can estimate by using litigation outcomes in our time-allocation specifications. This exercise alone suggests future litigation savings will exceed the added costs to the Agency of expanding time allocations.

One of the key advantages of exploring this inquiry in the case of drug patents is that we can move beyond a mere comparison of administrative expenses of ex ante versus ex post review and can derive novel estimates of the marketplace savings from expanding the ex ante approach. As a starting point in this inquiry, our estimates of the degree to which examination-time increases

reduce the issuance of secondary patents, in turn, allows us to simulate the resulting acceleration in generic entry (considering that some of those foregone patents would have otherwise extended the effective patent lives of drug products). We can then combine these estimates with certain estimated moments from the pharmaceutical economics literature to set forth simple back-of-the-envelope calculations bearing on the welfare impacts of greater ex ante scrutiny.

Ultimately, while taking various conservative assumptions, our results suggest that increasing time allocations by 50% over just one year of reviews of secondary drug patents will result in an aggregate acceleration of generic entry of 16.9 years among the set of FDA-approved drugs. In light of certain findings from the generic-entry literature, these results imply static gains to consumer surplus and total welfare in the marketplace of existing chemical entities that vastly exceed the extra costs that we calculate are needed to finance this expansion in examination time. However, absent other reforms to patent-term lengths, the ultimate cost effectiveness of expanding time allocations at the Patent Office will depend on the extent of the welfare losses that may arise from the new molecular entities that may be foregone due to reduced prospective market sizes stemming from the accelerated generic entry.

This analysis holds important implications for the debate over elevated drug prices in the U.S. and offers empirical insight on a reform alternative to price-controls and related proposals that broadly reduce brand-name manufacturers' revenues (Sood et al. 2008). This analysis likewise builds on several academic literatures, including a literature that broadly addresses ex ante versus ex post regulation, including Shavell (1984) and Kolstad et al. (1990), along with a growing literature on generic patent challenges and / or on secondary pharmaceutical patenting, including Grabowski and Vernon (1992), Scott Morton (1999), Danzon and Chao (2000), Reiffen and Ward (2005), Panattoni (2011), Hemphill and Sampat (2012), Kapczynski et al. (2012), Berndt and

Newhouse (2012), Conti and Berndt (2014), Drake et al. (2015), Branstetter, Chatterjee and Higgins (2016), Helland and Seabury (2016), Grabowski et al. (2017).[2]

Perhaps most directly, our analysis builds on Frakes and Wasserman (2017), which similarly explored the relationship between examination time allocations and examination scrutiny, though pooling across all technologies. We build on this prior work in several critical ways. Methodologically, we employ additional tools (i) to allow us to better identity the effects of examination-time-reducing promotions, including the use of novel data on the precise timing of GS-level promotions that facilitates the estimation of event-study specifications, and (ii) to allow us to bolster a time-allocation interpretation of these promotion effects, including the exploration of a non-GS-level reform and the estimation of our specification in settings where we are less likely to predict binding time constraints (e.g., in reviewing active-ingredient patents and in situations where the EPO search report may be available). Further, this specific focus on drug patents builds on our prior work in providing us with empirical traction in expanding the welfare analysis beyond a mere comparison of administrative costs of an ante and ex post review.

Our paper proceeds as follows. In Part I, we provide a background on pharmaceutical patent examination. In Part II, we describe the data used in the analysis and in Part III we describe the various methodological approaches used to estimate the relationship between examination time and the validity of issued pharmaceutical patents and present the results of such analyses. In Part IV, we discuss the welfare implications of these results and in Part V, we conclude.

[2] More broadly, we contribute to the literature on patents in the biopharmaceutical innovation space, including, among others, Cohen et al. (2000), Jena et al. 2009, Goldman et al. (2011), Lakdawalla and Philipson (2012), Budish et al. (2015), Cockburn et al. (2016), DiMasi et al. (2016), Duggan et al. (2016), and Sampat and Williams (2019). Finally, our analysis relates to a yet even larger literature on the economics of pharmaceutical innovation and drug-pricing reform, including, among many others, Henderson and Cockburn (1996), Acemoglu and Linn (2004), Giaccotto et al. (2005), Jena and Philipson (2006), Goldman et al. (2008), Lakdawalla and Sood (2009), Duggan and Scott Morton (2010), Nicholson (2012), Garthwaite and Duggan (2012), Berndt et al. (2015), Besanko et al. (2016), Joyce and Sood (2016), Chandra and Garthwaite (2017), Bognar, et al. (2017), Lakdawalla (2018), and Dranove et al. (2020).

I. BACKGROUND

A. Background on Pharmaceutical Patenting

Brand-name pharmaceutical firms typically obtain a series of patents for each drug. The first patents are usually filed in the early stages of drug discovery and development. This initial patent—often referred to as a primary patent—generally protects a potential active ingredient that forms the basis of the new drug. Of course, a substantial portion of bio-pharmaceutical innovation is more incremental in nature, with brand-name companies also focusing research efforts on such things as specifying or changing the dosage or route of administration (e.g., capsules or topicals) of already identified chemical entities. In connection with a given drug product, pharmaceutical companies almost always file patents on peripheral features of this nature, typically later in the drug development process. These patents are referred to as secondary patents.

Because patents expire twenty years from filing, these later-filed secondary patents expire after the earlier filed primary patent. Moreover, the exclusionary effects of drug patents are especially strong in the light of the procedures set forth by the Hatch Waxman Act (HWA). With respect to a brand-name manufacturer's drug product approved by the FDA, the HWA requires the brand-name manufacturer to list those patents that would be infringed if a generic version of the relevant drug product is launched before the expiration of the listed patents in what is known as the "Orange Book." In essence, pursuant to the HWA, generics desiring to enter the marketplace must either wait until the brand-name patents listed in the Orange Book expire or raise a Paragraph IV challenge, which essentially initiates a legal challenge of the brand-name patents.[3] The initiation of this legal challenge, triggers a thirty month stay in which the FDA cannot approve the generic

[3] According to paragraphfour.com, brand-name manufacturers will file suit against the entry-seeking generics roughly 85% of the time upon the filing of a Paragraph IV challenge.

while the parties litigate the patent dispute. This powerful blocking effect creates a strong incentive for brand-name pharmaceutical companies to obtain additional secondary patents to extend the effective patent life for the relevant drug, even if the secondary patent is of dubious quality.[4]

B. Background on Patent Examination Process

Incoming U.S. patent applications are routed to an Art Unit, a group of up to fifteen examiners who review applications in the same technological field. Upon arrival, the Supervisory Patent Examiner (SPE) of that Art Unit assigns the application to a specific examiner. Though not always purely random—insofar as there is some evidence of sub-specialization within Art Units—this assignment process is nonetheless tangential to the patent worthiness of the application and thus effectively random for the purposes of this patent-validity analysis (Righi and Simcoe 2017).[5] The assigned examiner will conduct a prior art search and then assess the patentability of the invention based on the criteria outlined in the Patent Act—e.g., the examiner will assess the invention for obviousness or lack of novelty. If, over the time allotted, examiners are unable to conduct a sufficient search of prior art and articulate a proper basis of rejection, they are legally expected to allow the application (Seymore 2013). Accordingly, if time constraints bind, this legal presumption leads to a prediction that examiners will allow some patents to issue that, in fact, lack legal validity.

The Patent Office allocates examination time according to two factors: (1) the technological field in which the examiner is working and (2) her position in the General Schedule (GS) pay scale. Conditional on the technology of an application, the second dimension to this time allocation

[4] For a summary of the debate regarding the quality of secondary patents see the Online Appendix.

[5] Lemley and Sampat (2012) and Frakes and Wasserman (2017) interviewed examiners and supervisors and confirmed that SPEs employ various randomization approaches to assigning applications. Feng and Jaravel (2020) provide a list of Art Units with respect to which we may have even greater confidence in the randomness of assignments insofar as these Art Units appear to assign applications based on application serial numbers. In the Online Appendix, we demonstrate that our key event-study analysis demonstrating the effects of time-reducing promotions on the quality of examination reviews is virtually identical when we limit our sample to those Art Units represented on the Feng and Jaravel list.

procedure is effectively random. The higher the pay grade of an examiner within a technology area, the fewer the number of hours the Patent Office allocates. A promotion to each subsequent pay grade is roughly equated to a ten to fifteen percent decrease in the number of allocated hours. In Table A6 of the Online Appendix, we show the average number of hours allocated to examiners across GS levels for the sample of Orange Book patents. While GS-11 examiners reviewing pharmaceutical patents are allocated nearly 25 hours on average to review each application, GS-14 examiners are allocated less than 18 hours on average to review the same application.

Our primary methodological approach in this paper will focus on exploring variations in time allocations arising from GS-level promotions, conditioning on the unit of assignment (Art-Unit-by-year cells). If time constraints bind (and we acknowledge the empirical possibility that they may not), then we predict that further tightening of such constraints through the relevant promotion events will increase the degree to which examiners issue patents that fail to meet the patentability requirements. As will be discussed below, we will take various approaches to account for potential endogeneity in GS levels and in the fact of promotion itself. To supplement our discussion of these approaches, we set forth in the first section of the Online Appendix a brief background on examiner hiring and promotion in the pharmaceutical Art Units. On a final note, in February 2010, the Patent Office increased the time allocations of all examiners by two hours. We will also consider a supplementary analysis drawing on the variation in review time afforded by this reform.

C. Examination Time and Secondary Patents

As above, should examination time constraints bind, examiners may not be in a position to fully search the prior art and articulate applicable bases of rejections. There are reasons to believe that this outcome is more likely in the case of secondary relative to primary patents. This prediction stems from an assumption that less time is needed to review primary patents for novelty

and obviousness. Primary patents are drawn to chemical structures that clearly define the invention in question and make it easier for an examiner to understand the scope of the invention and search for relevant prior art. The Patent Office has long had strong search capabilities for chemical structures. Moreover, patent law provides relatively clear rules for when a compound that is structurally similar to a known compound is novel and nonobvious.[6]

In contrast, assessing the patentability of secondary patent applications can be more time consuming. For instance, to argue the controlled release formulation of a known compound is nonobvious, the examiner will attempt to find prior art that would teach why it would be beneficial to have a controlled release formulation of the known compound, a structurally similar compound, or for the indication the compound treats, a search task that is more delicate and nuanced and that requires a broader scope of potential prior art to draw from than that required for exploring the innovativeness of a brand new compound itself. Second, conditional on the prior art collected, equally as difficult is a determination of whether the controlled release formulation of the known compound represents an inventive enough leap over the prior art to render the invention nonobvious. In contrast to the primary chemical compound patents, the rules on whether it would be "obvious" to the person of ordinary skill in the art to modify the existing prior art to achieve a modification of a known compound, such as its mode of administration, are less clearly delineated.

Arguably confirming this prediction that secondary patents will more likely face binding time constraints is evidence that the vast majority of patent invalidations during Paragraph IV litigation in federal court are for secondary, rather than primary, patents (Hemphill and Sampat 2012). The

[6] That is, a structurally similar compound may be deemed nonobvious if it has chemical properties that are unexpected of the known compound. For example, a methyl group ($-CH_3$) is a relatively inert functional group and hence adding it to a known chemical compound with anti-cancer properties will not a result in the new compound with the same anti-cancer properties being patentable.

validity benchmark that we set forth below also suggests—as a baseline—greater concern over invalidity in the case of secondary patents than primary patents.

II. Data

We draw on several primary sources of data in this investigation into the relationship between examination time allotments and the validity of patents issued through the examination process.

A. FDA Data

To begin, drawing from the FDA's Orange Book records (current and historical), we compile a list of those patents associated with drug products approved by the FDA for safety and efficacy. Critically, the Orange Book data provide an indication as to whether the patent covers the active ingredient associated with the relevant drug product or covers a secondary feature (e.g., new method of use, new route of administration, etc.).[7]

B. Patent Data

Next, for those patents listed in the FDA's Orange Book, we collect certain information about the underlying patent application from the Patent Office's Patent Application Information Retrieval ("PAIR") database, drawing on records from patent applications filed on or after March 2001 and reaching a final disposition by May 2017. Importantly, for each issued patent, we obtain information on the name of the examiner primarily charged with reviewing the underlying application and information on the Group Art Unit to which she is assigned. For each examiner in our merged PAIR/Orange Book database, we obtained information from a Freedom-of-Information-Act (FOIA) request regarding the precise timing—to the day—of each GS-level

[7] The current version of the FDA's Orange Book dataset can be found at: https://www.fda.gov/drugs/drug-approvals-and-databases/orange-book-data-files. Drug products may be de-listed over time, however, raising concerns over the ability to identify patents issued early in our PAIR database that may have been listed in the Orange Book at some point but not listed in the most recent iteration. To address this concern, we pull historical Orange Book records organized by the National Bureau of Economic Research from 1986 to the present, allowing us to identify a unique record for each patent ever listed in the Orange Book over this time period. We identify active-ingredient patents by those listed as "drug substance" patents in the Orange Book. In the Online Appendix, we discuss potential challenges associated with this assignment as it relates to patents on polymorphs of compounds and discuss results based on certain alternative assignment approaches.

promotion that the relevant examiner received over her career. The merged analytical sample contains 3,313 secondary drug patents and 791 active-ingredient patients. In our grant-rate analysis, we will rely on a larger subset of over 310,000 pharmaceutical applications from the PAIR data—whether or not culminating with an Orange Book listing—where we identify pharmaceutical applications using the technology sub-categories developed by Hall et al. (2001).

C. Patent Family Data and Patent Validity Measure

To provide a marker of the legal validity of the drug patents of interest, we follow various studies (Lei and Wright 2017, Frakes and Wasserman 2017, and Lemley and Sampat 2012) and rely on the fact that many U.S. applicants likewise file for patent protection on the underlying innovation with the European Patent Office (EPO), an office that has essentially similar patentability standards to the U.S. but that invests substantially more examination resources per application (including examination time allotments and examiner compensation) and that works in examination teams (Picard and van Pottelsberghe de la Potterie 2013; Chien 2018). With this structure in mind, if one compares a U.S.-issued patent whose "twin" is allowed at the EPO with a U.S.-issued patent whose "twin" is rejected at the EPO, the former is *more likely* to be legally valid than the latter. Accordingly, we focus on a subset of U.S.-issued patents with twin EPO applications and use the allowance outcome at the EPO as a validity benchmark.[8] For these purposes, we draw on administrative data compiled by the OECD.

Easing generalizability concerns, we note that over 86% of the Orange Book patents are associated with a family of applications filed at the EPO. This representation is notably higher than the corresponding figure of 27% across all patents. In any event, as discussed in further detail

[8] That is, we use EPO allowance for its validity signaling value, and, given the signal associated with this metric, we are able to theorize that EPO allowance will fall in connection with reductions in time allocations. We acknowledge, of course, that there be some noise associated with this benchmark. After all, there may be residual differences in patentability standards and the EPO may also make some degree of erroneous decisions. Nonetheless, consistent with expectations, we do find that the US allows / EPO rejects scenario motivating the benchmarking approach is roughly 3.4 times more likely to occur than the alternative scenario in which the U.S. Patent Office rejects and the EPO allows.

below, we will also consider and discuss an alternative validity marker that is not limited to patents that are part of an international family of applications, whereby we look to the frequency by which the issued Orange Book patents are asserted in litigation.[9]

As a baseline, we note that Orange-Book-listed patents exhibit strong validity likelihoods. Active-ingredient Orange Book patents that also seek EPO protection are allowed at the EPO roughly 93% of the time. The corresponding amount in the case of secondary patents is 84%. We report these summary statistics in Table 1.

TABLE 1: SUMMARY STATISTICS

	(1)	(2)
	Secondary Patents	**Primary (Active-Ingredient) Patents**
Allowance at EPO	0.84	0.93
	(0.36)	(0.26)
N (EPO Allowance)	2,786	750
Number of times asserted in litigation, among Orange Book patents issued pre-2015	1.79	1.42
	(3.65)	(3.92)
Incidence of any litigation assertion among Orange Book patents issued pre-2015	0.39	0.28
	(0.49)	(0.45)
N (litigation sample)	2,579	713

Standard errors in parentheses. EPO allowance measures are from a subset of data on Orange Book patents whose underlying innovations are part of a family of international applications at the U.S. Patent Office and the EPO. Litigation assertion data is based on Orange Book patents issued prior to 2015.

[9] 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. We address this possibility by estimating the same specifications explored below but using as the dependent variable the incidence of the relevant U.S.-issued patent being associated with an EPO twin. As demonstrated in the Online Appendix, we find no evidence to suggest that examination time is related to the incidence of a U.S.-issued drug patent being associated with an EPO twin.

As a preliminary matter, these summary statistics suggest that much of secondary patenting activity may indeed reflect meaningful underlying innovation, as opposed to predominantly reflecting wasteful strategies by brand-name firms to extend effective patent lives. Nonetheless, these summary statistics suggest that concerns over invalid patents are indeed stronger in the case of secondary patents than active-ingredient patents, consistent with the prediction that examination time constraints are more likely to bind in the case of secondary patents.

III. Analysis

A. Grade-Level Promotions: Preliminary Analysis

In this Part, we explore the relationship between the time allocated to an examiner and the quality of their drug-patent reviews, as reflected by the validity markers associated with the patents they issue. To capture variation in examination time, we primarily draw upon the roughly 10-15% reduction in time allotments associated with grade-level promotions.

We begin this inquiry by regressing our primary marker of validity (*VALID*)—i.e., allowance of the U.S. patent's twin application at the EPO—on a series of dummy variables indicating the GS level of the assigned examiner (**GS**). We include Art-Unit-by-year fixed effects, $\boldsymbol{\partial_{kt}}$ (Feng and Jaravel 2020), such that we compare validity outcomes across examiners of different GS levels within given Art-Unit-by-time groups. More specifically, we estimate the following specification, focusing on the sub-sample of U.S.-issued patents that are listed in the Orange Book and that are part of a family of applications at both the U.S. Patent Office and the EPO:

$$(1) \qquad VALID_{aikt} = \alpha + \boldsymbol{\partial_{kt}} + \boldsymbol{\beta_1}\mathbf{GS_{it}} + \boldsymbol{\beta_2}\mathbf{EXPER_{it}} + \boldsymbol{\beta_3}\mathbf{COHORT}_i + \boldsymbol{\beta_4}\mathbf{TENURE}_i + \boldsymbol{\beta_5}\mathbf{X}_{aikt} + \varepsilon_{aikt}$$

where *i* denotes the individual examiner, *a* the individual patent, *k* the relevant Art Unit, and *t* the year of patent issuance. Given that examiners reviewing drug patents typically enter the Patent

Office with advanced degrees and thus start at least at GS-level 11, we focus this analysis on those examiners between GS-levels 11 and 14,[10] leaving GS-11 as the reference group. If time constraints are binding on examiners and thus crowd out their ability to apply the patentability requirements, one would predict a decrease in validity as examiners ascend the GS scale.

Given an application assignment process that is tangential to patent worthiness and given the inclusion of fixed effects at the level of assignment, there is little concern over bias arising from unobservable application characteristics. To nonetheless appease residual concerns, we conduct a falsification exercise whereby we test for covariate balance in these application characteristics across the different GS-levels. In order to demonstrate this balance in a simple figure, we take an omnibus approach and plot the relationship between the examiner GS-level and predicted EPO-allowance outcomes, where these predictions are formed after regressing the incidence of the relevant patent also being allowed at the EPO on a set of application characteristics, **X**, along with a set of Art-Unit-by-year fixed effects. Included in **X** is an indicator for "small-entity" status, along with various measures capturing the number and length of claims (dependent and independent). Encouragingly, as demonstrated by Figure A1 of the Online Appendix, these predicted rates of EPO allowance remain flat across examiners at different grades.

In the Online Appendix, we further demonstrate that the results presented below are nearly unchanged when including the application controls, **X**, in specification (1). We reserve this exercise as a robustness check given that the various claims measures are not available for the full set of Orange Book patents (i.e., not available for the full set of sample years). We include the entity-size variable in all specifications, however, given the full availability of this control.

[10] We do not include GS-15 examiners as examiners generally stop examining full-time at this point and become SPEs of Art Units.

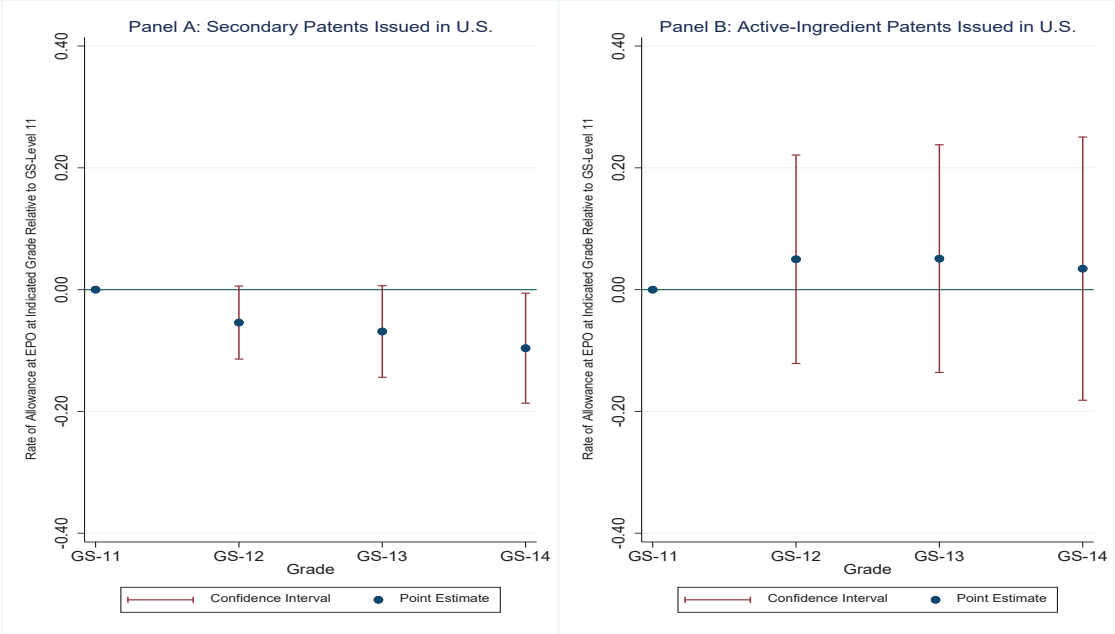
While application-quality confounders are addressed through the assignment process, the chief challenge in estimating specification (1) is that other examiner characteristics at the relevant points in time may be correlated with her GS-level and may also impact the quality of the examination review. With this preliminary exercise, we take a control-function approach and account for the potentially confounding influence of several examiner-related factors that are predicted to correlate with GS-levels, drawing on those factors identified by Lemley and Sampat (2012) and Frakes and Wasserman (2017). First we include fixed effects for examiner experience (in years), **EXPER**, taking advantage of the fact that GS-level promotions do not occur lockstep with experience at the higher GS levels where pharmaceutical patent examiners reside. Second, we include fixed effects for the hiring-year cohort of the examiner, **COHORT**, to address potential concerns posed by persistence in examiner practice styles along with variations in initial hiring / training conditions due to changes in the examination philosophy of Agency directors (Frakes and Wasserman 2016). Third, we include fixed effects for the ultimate tenure (in years) of the examiner with the Patent Office, **TENURE**, to address concerns that career examiners may differ fundamentally from those who use this position as a springboard to industry.[11]

In Panel A of Figure 1, we plot the estimated GS-level coefficients from specification (1) (in Table A1 of the Online Appendix, we present estimates for all coefficients). We document a precipitous and monotonic decline in validity likelihoods as examiners ascend GS levels. EPO-allowance likelihoods are roughly 10 percentage-points (or 13 percent relative to the mean) lower for GS-14 examiners relative to GS-11 examiners, after accounting for the included controls. This

[11] In this specification and in the subsequent specifications, we cluster the standard errors at the Art Unit level given that there may correlations in unobservable determinants of examination quality over time within assignment groups. The results are nearly identical when we instead cluster at the Art-Unit-by-year level or by the Art Unit and year levels separately Cameron et al. (2011).

result provides preliminary evidence suggestive of the contention that examination time constraints may be binding and may be leading to the issuance of more invalid patents on the margin.

FIGURE 1. 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



Notes: results in Panel A are from a sample of 2,446 secondary Orange Book patents issued in the U.S. and part of a family of applications at both the U.S. Patent Office and the European Patent Office. Results in Panel B are from a sample of 600 active-ingredient Orange Book patents issued in the U.S. and likewise part of an international family of applications. The plotted coefficients represent the coefficients of the GS-level indicator variables from specification (1). Estimated coefficients for the other variables are provided in Table A1 of the Online Appendix. 95% confidence intervals are indicated by the vertical bars. Standard errors are clustered at the Art-Unit level.

Above, we predicted that time constraints are less likely to bind in the case of active-ingredient patents given more straightforward tests to apply in assessing novelty and nonobviousness and given more readily available search tools. We find suggestive evidence in support of this claim in Panel B of Figure 1, where we fail to find evidence demonstrating a decline in examination quality—as reflected by EPO-allowance likelihoods—as examiners experience time-allocation-reducing promotions. We emphasize, however, that we have a small number of active-ingredient

patents in our relevant analytical sample (600 active-ingredient patents versus 2,446 secondary patents), leaving us with a meaningful degree of imprecision in the findings in Panel B.

B. Stacked Event-Study Specification

Of course, one of the strains to estimating specification (1) comes in estimating three separate GS-level indicators. To attain greater power, we also estimate a specification that attempts to explore the average change in our validity marker arising from a GS-level promotion as a general matter. For these purposes, we create and then stack a series of separate subsamples, where each subsample represents all Orange Book patents whose applications were disposed of by the relevant promoted examiner in a window around each respective promotion in the sample (one-year on either side of the promotion).[12] We then estimate a specification essentially identical to equation (1) but where our main regressor is an indicator for the application being disposed of after the relevant promotion within the relevant sub-sample and where we include a set of fixed effects indicating whether the focal promotion is one to GS-12, GS-13 or GS-14 (**PROMOTION_TYPE**). This alternative specification is as follows:[13]

$$VALID_{aikt} = \alpha + \boldsymbol{\partial_{kt}} + \beta_1 POST - PROMOTION_{it} + \boldsymbol{\beta_2 EXPER_{it}} + \boldsymbol{\beta_3 COHORT_i} + \boldsymbol{\beta_4 TENURE_i} + \boldsymbol{\beta_5 X}_{aikt} + \boldsymbol{\beta_6 PROMOTION\_TYPE}_{it} + \varepsilon_{aikt} \quad (2)$$

Specification (2) continues to control for experience, cohort and tenure effects. However, by generalizing around an event that strikes examiners at times when they are at a range of different

[12] This window length ensures balance in that, at the GS levels of interest for our analysis, examiners universally spend at least a year at each grade before promotion. In the Online Appendix, we show results from a longer four-year window (2 on each side).

[13] Since we are stacking sub-samples around promotion events, some patents are included more than once in the ultimate estimation—e.g., in the post-period for the GS-12 promotion event and in the pre-period for the GS-13 promotion event. Nonetheless, clustering at the Art Unit still allows us to account for correlation within given patents over the analytical sample as a result of this stacked structure and the results are identical if we also cluster at the patent-number level.

cohorts, experience levels and tenures with the Patent Office, this event-study specification by its very design arguably better isolates the effect of the promotion itself.

TABLE 2: RELATIONSHIP BETWEEN LIKELIHOOD OF EPO ALLOWANCE OF TWIN OF U.S.-ISSUED ORANGE BOOK PATENT AND GRADE-LEVEL PROMOTION EVENT, STACKED EVENT STUDY RESULTS

	(1)	(2)	
	Secondary Patents	**Primary (Active-Ingredient) Patents**	**Difference in Promotion Effect between Secondary and Primary Patents**
Post Promotion Event	-0.097	-0.023	-0.074
	(0.021)	(0.016)	(0.022)
N	948	162	1,110
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.

We present results from specification (2) in Table 2. When focusing on secondary patents, we find that an average GS-level promotion is associated with a 9.7 percentage-point decline (or nearly 11 percent relative to the mean) in our EPO validity marker. Encouragingly, this approach does leave us with somewhat better precision in estimating the impacts of GS-level promotions in the case of active-ingredient patents, with a standard error of roughly 1.6 percentage points. This binary-event framework also facilitates a straightforward test of whether the time-allocation effect is stronger in the secondary-relative-to-the-primary context (which we effectuate by stacking these separate samples, fully interacting the specification by secondary-patent status, and then reporting the coefficient of the interaction between this secondary-patent indicator and the post-promotion

indicator). As demonstrated by column three of this table, we find relatively precise estimates of a negative difference between the secondary and primary effects, suggestive of a story in which time constraints are indeed more likely to bind and compromise examination quality in the review of secondary relative to primary patents.

C. Dynamic Event-Study Analysis

We next take a more dynamic approach to this stacked-event study analysis, where instead of simply treating the event in a binary manner, we track validity outcomes in quarters leading up to and following a promotion event. In the process, we also account for general time effects by assigning to each promotion event a set of control examiners that do not experience a promotion over the event window, using promoted-out GS-14 examiners for such purposes.[14] In this manner, we estimate a stacked difference-in-difference specification (with "clean" controls) in the spirit of Deshpande and Li (2019) and Cengiz et al. (2019). This approach generalizes the analysis over event time such that we can effectively view all promotion events as occurring contemporaneously, thereby avoiding certain concerns associated with difference-in-difference frameworks that draw on staggered events over calendar time (Goodman-Bacon 2019). More specifically, we build on the pre-and-post-promotion window from Table 2 and estimate the following specification:[15]

[14] In our primary approach, we select as controls those promoted-out GS-14 examiners who have been at GS-14 less than four years (though greater than one-year), in order to appease non-comparability concerns. The results we present, however, are virtually identical if we do not include this restriction and include all promoted-out GS-14 examiners as controls.

[15] Frakes and Wasserman's (2017) related investigation into the effects of examination-time-allotments on grant rates across all technologies did not estimate an event-study specification of this nature. The data used in this previous study indicated promotions at the year level, unlike the data in the present study which identifies promotions down to the specific day, facilitating the ability to trace outcomes in quarter periods leading up to and following promotions.

(3)
$$VALID_{aikte} = \alpha + \boldsymbol{\partial_{kt}} + \boldsymbol{\beta_1} TREATMENT_{ie} + \boldsymbol{\beta_2} \sum_{q=-4}^{4} E_{qe} + \boldsymbol{\beta_3} \sum_{q=-4}^{4} E_{qe}\, X\, TREATMENT_{ie} + \boldsymbol{\beta_4 EXPER_{it}} + \boldsymbol{\beta_5 COHORT_i} + \boldsymbol{\beta_6 TENURE_i} + \boldsymbol{\beta_7 X_{aikt}} + \boldsymbol{\beta_8 EVENT_e} + \boldsymbol{\delta_m} + \varepsilon_{aikte}$$

where E represents the various event lead and lag indicator variables, e represents the relevant promotion event, and q represents the relevant event quarter. $TREATMENT_{ie}$ indicates whether the focal Orange Book patent was reviewed by the treated examiner experiencing the promotion within the focal event window or one of the control / promoted-out GS-14 examiners associated with the focal promotion event.

For this dynamic exercise, we focus only on the case of secondary patents given that our objective with this analysis is to check the robustness of the binary stacked-event-study results from Table 2.[16] Within each subsample in the stack—i.e., within each promotion event—this approach assigns both the treated and controls examiners dummy variables representing the respective event quarter and then interacts this series of event-quarter dummies with an indicator for the treatment group.[17] The coefficients of interest are captured by the estimated coefficients of these interaction terms, allowing us to observe how validity outcomes for the promoted examiners evolve in the time leading up to and following promotion, while using the control

[16] Nonetheless we present dynamic event-study results for the active-ingredient sample in the Online Appendix and continue to find no robust evidence indicative of a GS-level impact on the validity of issued active-ingredient patents that is nearly as strong as that of secondary patents.

[17] The underlying specification also includes the constitutive treatment indicator, along with the various controls included in Table 2—e.g., experience-in-years fixed effects, tenure-in-years fixed effects, small-entity indicator and Art-Unit-by-year fixed effects. In addition to accounting for year effects, this specification allows for seasonal effects by including a set of month fixed effects, $\boldsymbol{\delta_m}$. We fully interact these various controls with an indicator for the treatment group to allow for differential such effects by treatment status. We also include a set of fixed effects representing each promotion event (i.e., each subsample within the stack). This way, we look within a given subsample and ask how promotion-effect dynamics are differentiated from corresponding control dynamics. Since this approach uses control examiners to create a non-treated counterfactual over the event-time path, the inclusion of calendar-time effects in the specification is arguably superfluous. Consistent with this point, the results are virtually identical when calendar-time effects are dropped from the specification. Finally, we cluster the standard errors at the event level and at the Art-Unit level to account for correlation in unobservables within events and within Art Units across the various events represented in this stacked approach.

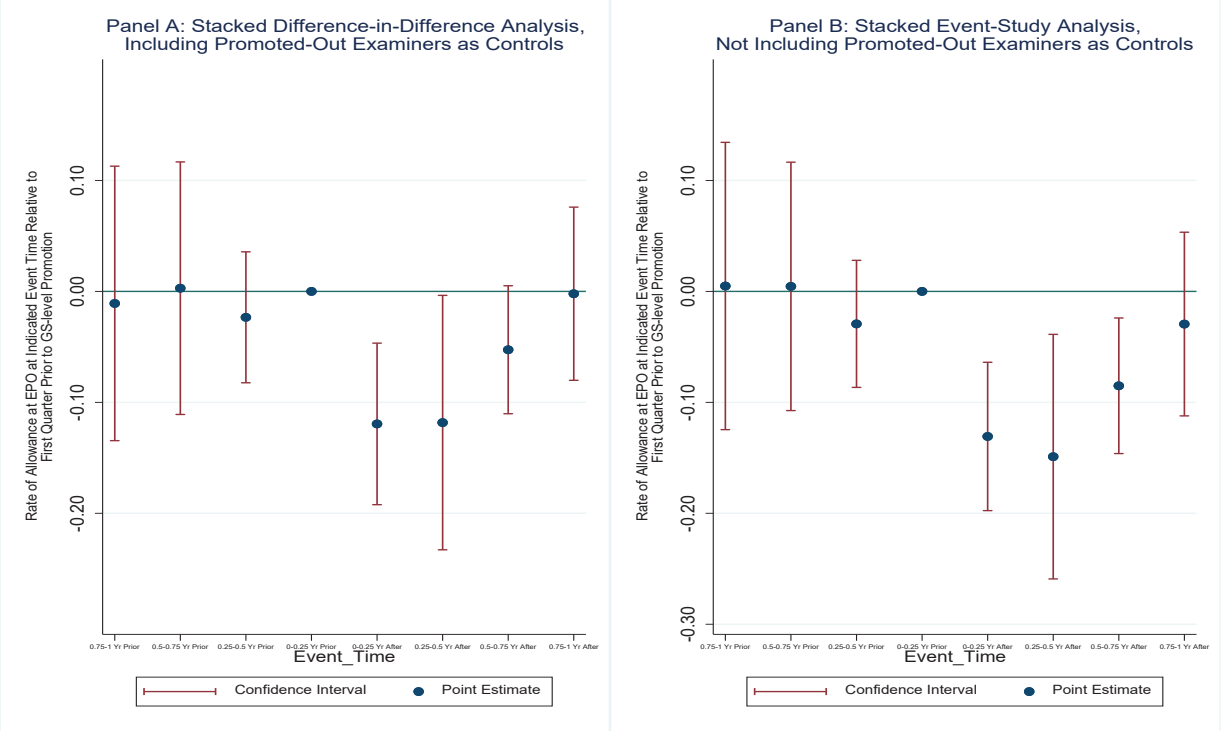
examiners to create an event-path counterfactual that is unaffected by the treatment and thus using the control examiners to further separate these promotion dynamics from general time effects.[18]

We note at the outset that the results from this exercise are virtually identical when we estimate a similar stacked-event design that simply extends Table 2 to incorporate event dynamics but that does not use promoted-out GS-14 examiners as controls. In Panels A and B of Figure 2, we demonstrate this comparison between a stacked difference-in-difference design and a simpler stacked design that just tracks the treated / promoted examiners in event time before and after their promotions. The nearly identical nature of the results across these approaches is perhaps not surprising given that the benefits one obtains from using promoted-out examiners as controls to separate calendar effects from event-time effects is already somewhat provided by the fact the events themselves strike over a range of calendar times and by the fact that a simpler event-study design that just differences within the treated examiners also centers the analysis in event time.

The chief advantage of this dynamic specification—whether estimated as a difference-in-difference framework or a simpler event-study framework—is the falsification exercise that it affords in assuring that the drop in validity associated with GS-level promotions did not predate the promotion. Relatedly, one may also be concerned with the possibility that trends in outcomes may affect who gets promoted. This latter possibility is of perhaps minor concern at the outset in that one would tend to expect that this would bias *against* the negative relationship that we find—that is, one would expect that if anything, examiners would tend to be promoted after an increase in observed validity, not a decline. Nonetheless, observing trends prior to the promotion events will provide us with a rationality check in this regard and provide greater confidence in interpreting the effects arising from promotion rather than from factors leading to promotion.

[18] In the Online Appendix, we ease concerns over selection in application characteristics across this event window by demonstrating that *predicted* EPO allowance outcomes for each secondary Orange Book patent—calculated as above—stay flat across the event window.

FIGURE 2. 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



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 each promotion event. For each event, Panel A includes a set of promoted-out GS-14 examiners (among those who have been at GS-14 at least one year and no more than 4 years) as controls (N = 61,652). The plotted coefficients represent the estimated coefficients of the interactions between the treatment indicator and the event-time indicators from specification (3). Panel B only includes the stacked sample of patents in the event window for the treated examiners and excludes promoted-out GS-14 controls. The plotted coefficients represent the estimated coefficients of the event-time indicators from a specification analogous to that in specification (2) but that includes quarter-event bins rather than a simple post-promotion dummy. 95% confidence intervals are indicated by the vertical bars.

Mediating against these concerns, we observe a relatively flat trend in EPO-allowance likelihoods in the time leading up to the promotion. We then observe a substantial drop in EPO-allowance outcomes *upon* the promotion itself. This drop persists over several quarters, after which we see the EPO-allowance outcome creep back up to where it had been. These findings are perhaps suggestive of a tendency of examiners, if anything, to improve in quality over time, only to have such improvements met with an interruption that leads to a decline in quality at the moment

of the GS-level promotion, a moment that is characterized by a roughly 10-15% reduction in the amount of time allocated to review applications.[19]

D. Exploring Alternative Mechanisms behind Promotion Effects

Even though a reduction in examination time is a key, or *the* key, institutional feature that changes at the moment of a GS-level promotion—at least as it relates to the application of the patentability requirements—we acknowledge the possibility that some other examiner response to promotion may explain our results. For instance, one may be concerned with a possible story in which as examiners rise in the ranks, they receive less supervision and thus more easily shirk. Mediating against this concern is the fact that the nature of examiner supervision only changes upon one of these promotions—i.e., the move to GS-14, as we discuss in greater detail in the Online Appendix—even though Figure 1 depicts a monotonic decline in examination quality upon each promotion. Perhaps of greater possibility is a story in which examiners maintain heightened scrutiny prior to promotions in order to bolster the case for the promotions, only to lighten this scrutiny after the promotion—e.g., as a temporary celebration. We take several approaches throughout this paper to confront this and related concerns in an attempt to bolster support for a time-allocation interpretation of the negative effects demonstrated by our above results.

One of these approaches we have already touched upon. First, recall our prediction that time constraints are more likely to bind and thus contribute to the issuance of invalid patents in the case of secondary pharmaceutical patents than primary patents. Column 3 of Table 2 presented evidence consistent with these expectations. To the extent this prediction stems from a story

[19] In the Online Appendix, we demonstrate the robustness of the drop in EPO allowance rates upon GS-level changes to alternative event windows. To complement this analysis, we consider also the estimated experience effects from specification (1). We plot these experience coefficients in the Online Appendix. Though the confidence intervals are large, the point estimates suggest a pattern of increasing examination quality—i.e., increasing likelihoods of issuing valid patents—as examiners gain experience in years. As such, despite this noise in the experience estimates, the separate experience and GS-level effects from specification (1) are also suggestive of a story in which examiners possibly improve over time only to be met with setbacks arising from time-allocation-reducing promotions.

regarding examination time constraints, this differential pattern thus lends support to a time-allocation interpretation of the promotion results.

Second, to address the temporary-shirking possibility, we further explore the determinants of promotion outcomes in the Online Appendix. Much academic and other commentary on the Patent Office has suggested that various personnel policies—including its bonus structure—prioritizes examination quantity over quality (Schuett 2013; GAO 2016; Langinier and Marcoul 2018). Supporting the view that PTO personnel policies place a heavy emphasis on quantity, our prior work (Frakes and Wasserman 2020) has demonstrated examiners' strong commitments to hitting their examination quotas. Ultimately, to the extent that promotions are more heavily driven by quantity attainments relative to quality, the less one may be concerned that the pattern depicted in Figure 2 reflects examiners maintaining elevated quality rates prior to promotions and relaxing them thereafter (and the more one may generally view Figure 2 in causal terms). As demonstrated by the Online Appendix, we find little relationship between an examiner's mean EPO-allowance rate among the patents that they issue and the speed by which they rise in the ranks within the Patent Office, lending further support to the suggestion that the patterns estimated above are reflective of the large changes in time allocations associated with these events and not to the examination-quality implications of the promotion process.[20]

Third, we take advantage of the timing differences between U.S. Patent Office and EPO applications. When EPO examiners have acted first, U.S. examiners may have access to the prior-art search reports generated by the EPO, information which may ease the workload of time-constrained U.S. examiners (Wada 2016). As such, one would predict weaker effects of examination-time reducing promotions on EPO allowance in situations where such reports might

[20] This inquiry is broadly related to recent research investigating the link between promotions and skills (Benson et al. 2019).

be available. In the Online Appendix, we consider this question and find evidence suggestive of weaker GS-level promotion impacts when the EPO process predates the U.S. process.

Finally, to further evidence a time-allocation mechanism, we consider yet another exercise in the Online Appendix whereby we exploit a source of variation in examination time that is not specific to examiner GS levels. In particular, we explore outcomes following a February, 2010 reform extending all examiners (regardless of grade level or technology) an additional two hours of review per application.[21] We find evidence of an increase in EPO allowance of a secondary U.S.-issued Orange Book Patent following this reform, with no evidence of a pre-trend along with no evidence of a reform effect altogether on examination quality in the case of active-ingredient patents. This pattern of results is consistent with the promotion-based analysis above.

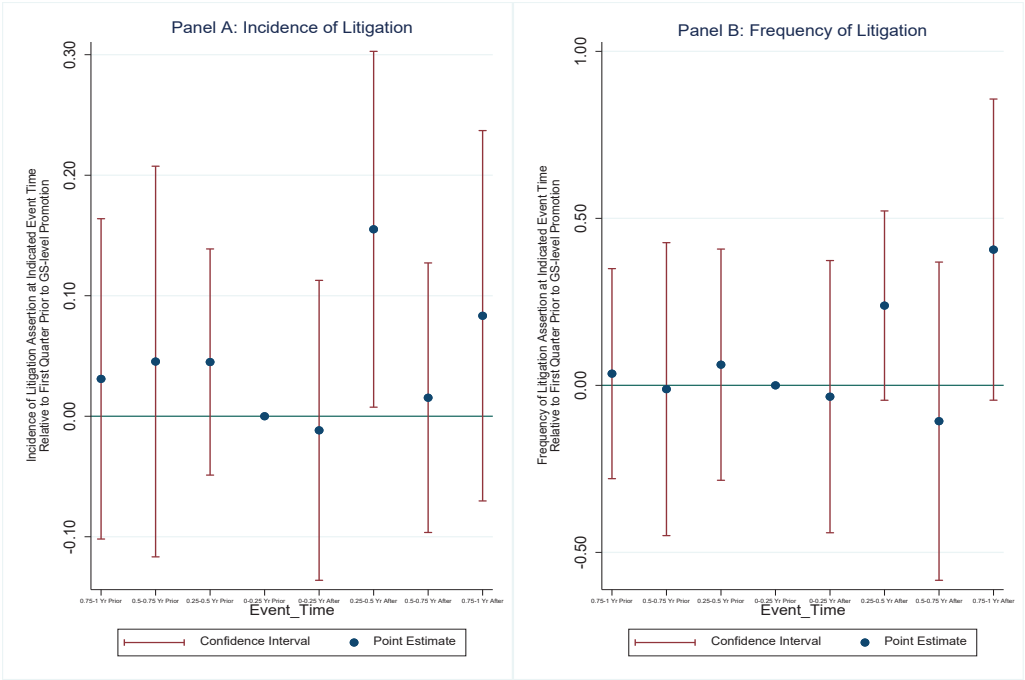
E. Alternative Validity Marker: Litigation Rates

We next discuss the robustness of the above findings to the use of an alternative marker signifying questionable validity for Orange Book patents. If examiners issue a greater number of invalid secondary pharmaceutical patents, one might also predict that the frequency by which an average issued patent is asserted in litigation will rise. At root here is a prediction that invalid patents attract litigation at higher rates than valid patents, a prediction with respect to which prior scholarship has provided empirical support (Frakes and Wasserman 2019). Of course, one of the challenges in using litigation frequency for a given patent as a signal of validity for that patent is that non-infringement / infringement is also often at issue in a typical suit in addition to patent validity. Given the noise imposed by infringement as a potential legal issue, we relegate this exercise as a secondary counterpart to the primary EPO-benchmarking exercise.[22]

[21] Otherwise, the time-allotment schedule remained entirely fixed over the sample period.
[22] A related challenge is posed by the fact that other factors, such as the economic value of the focal patent, are also important determinants of litigation frequency, adding further noise to the validity signal.

Nonetheless, we note that the conceptual support for litigation as a validity marker is perhaps stronger in the pharmaceutical context relative to other technologies. Due to the nature of the Paragraph IV challenge process, litigation in the pharmaceutical setting is effectively initiated by the non-patent-holders, as opposed to patent holders initiating suit for infringement purposes. Moreover, the patent challenges initiated by the generics are primarily focused on validity rather than non-infringement (Grabowski et al. 2017), given that non-infringement arguments threaten the generics' claims for bio-equivalence.

FIGURE 3. EVENT-STUDY ANALYSIS: TREND IN LITIGATION RATES OF SECONDARY DRUG PATENTS IN PERIOD OF TIME LEADING UP TO AND FOLLOWING GS-LEVEL PROMOTION



Notes: results are from a specification analogous to that underlying Panel A of Figure 2. In Panel A, we estimate a linear probability model where the dependent variable is the incidence of any litigation assertion. In Panel B, we estimate a Poisson specification where the dependent variables is the number of times asserted in litigation. The sample is limited to patents issued prior to 2015. 95% confidence intervals are indicated by the vertical bars.

With this in mind, in Panel A of Figure 3, we use the sample of secondary Orange Book patents and estimate an event-study difference-in-difference counterpart to Panel A of Figure 2 but using the incidence of litigation assertion as the dependent variable.[23] In Panel B of Figure 3, we do the same but use the number of times asserted in litigation as the dependent variable.[24] Albeit with less precision (and albeit with a slight lag), we find that the litigation results generally accord with those of the EPO-benchmarking analysis—though in opposite sign given that higher litigation signifies weaker validity.

H. Grant-Rate Analysis

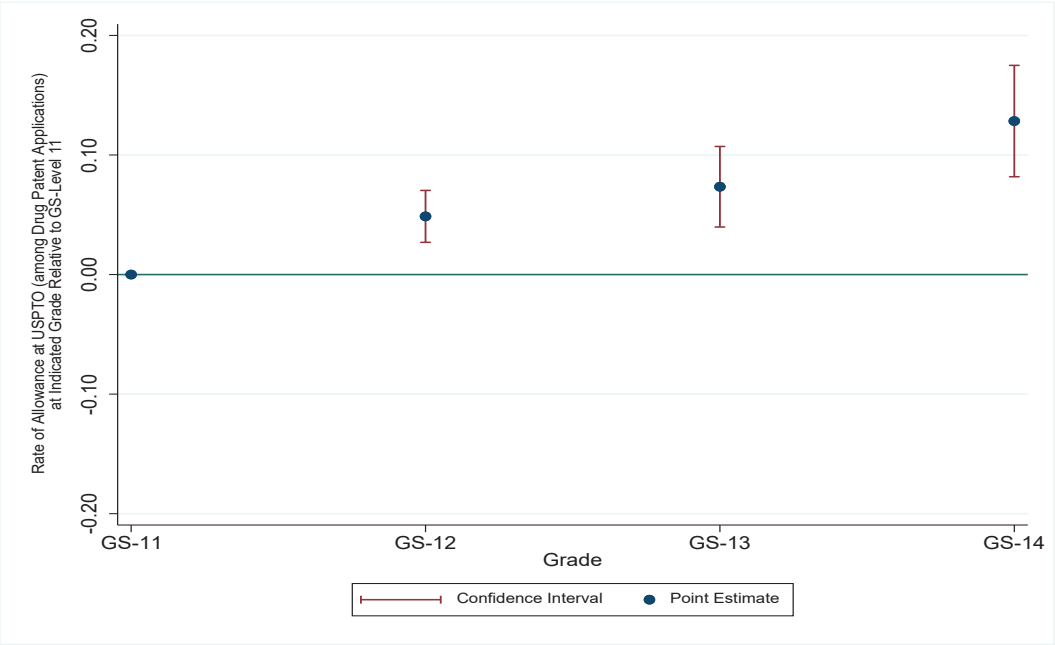
The above analysis implies that as examiners are given less time to review secondary patents, the average patent that they issue is less likely to be valid. In this section, we provide additional evidence suggesting that this average effect is consistent with examiners issuing more patents on the margin with questionable validity as they are allocated less time to review patents. This effect, in turn, is reasonable considering the legal presumption of validity of incoming applications and considering that time pressures inhibit an examiner's ability to find bases to reject some applications that she otherwise would have rejected altogether if she had more time.

For the purposes of this additional analysis, we build on the average examination-quality findings implied by the above EPO-allowance results and estimate a specification analogous to that underlying Figure 1, but where we use the full sample of pharmaceutical patent applications with the Patent Office and where our dependent variable is an indicator for whether the application

[23] We focus on the sample of patents issued in 2014 and before in order to provide post-issuance time to track litigation outcomes, though the results are robust to simply estimating this specification on the remaining sample years. Litigation data is from the Lex Machina database.
[24] We estimate a Poisson specification to produce this figure, though the results are virtually the same when we estimate an Ordinary Least Squares specification.

is allowed.[25] We present results from this analysis in Figure 4. We find a strong increase in the rate of allowance—and thus the number of patents issued—as examiners experience grade-level promotions. This finding is consistent with a story in which time constraints cause examiners to issue invalid patents on the margin. In the Online Appendix, we estimate stacked-event-study specifications using grant outcomes analogous to Figure 2, demonstrating strong increases in grant-rates at the moment of a generalized promotion event.

FIGURE 4. RELATIONSHIP BETWEEN LIKELIHOOD OF ALLOWANCE AT THE U.S. PATENT OFFICE OF PHARMACEUTICAL PATENT APPLICATIONS AND GRADE-LEVEL OF ASSIGNED EXAMINER



Notes: results are from a sample of 310,286 patent applications identified as drug applications by the NBER technology sub-categories. Results are from a counterpart to specification (1) that uses this sample and that uses the incidence of allowance of the application as the dependent variable, while also including examiner-by-Art-Unit fixed effects (and using year effects separately). Only the estimated coefficients of the GS-level dummies are presented. 95% confidence intervals are indicated by the vertical bars. Standard errors are clustered at the Art-Unit level.

[25] One advantage of working with this broader application sample—as opposed to the sample of issued patents listed in the Orange Book—is that each examiner reviews a meaningful number of pharmaceutical patents over their careers facilitating a straight-forward estimation of an examiner fixed effects approach. Since examiners sometimes switch Art Units, we include examiner-by-Art-Unit fixed effects, though the results are virtually identical when including these effects separately and when including examiner-by-Art-Unit-by-year fixed effects.

IV. Discussion; Welfare Analysis

The above analysis suggests that as examiners are allocated more time to review secondary drug-patent applications, they are notably less likely to issue invalid patents. Though such a reform will require additional governmental expenditures, this outcome may produce various benefits, including a reduction in future litigation expenses and potential net-benefits stemming from earlier generic entry. This section will provide estimates of the costs associated with time-allocation increases and associated litigation savings. Though full estimates of the net costs/benefits associated with accelerated generic entry will depend on certain parameters from the relevant pharmaceutical economics literature—with respect to which findings are mixed—this Part will set forth certain back-of-the-envelope calculations and generally attempt to set the stage for future research that may more completely flesh out the ultimate welfare implications. In Table A20 of the Online Appendix, for each category of costs of benefits explored in this welfare analysis, we briefly identify the key parameter inputs into the analysis and summarize the ultimate findings.

A. Costs

To estimate the costs associated with an expansion in examiner time allotments, we begin by making a few assumptions. First, we acknowledge that it is difficult at the time of the application itself for the Patent Office to know which applications will wind up ultimately being listed in the Orange Book. Accordingly, we envision a reform in which the Patent Office increases time allocations for all secondary drug-patent applications, of which there are roughly 23,418 per year.[26] Second, we assume a reform in which the Patent Office increases examination time by 50%. GS-

[26] In recent years, the Patent Office has on average received roughly 28,000 applications per year with an NBER sub-category classification for "drugs." Given the ratio of secondary patents to active-ingredient patients of 4.7:1 in the Orange Book data and assuming that active-ingredient patents are allowed at a roughly 8 percentage-point higher rate than secondary patents (an assumption based on the EPO allowance differential between active-ingredient and secondary patents listed in the Orange Book), we assume that there are roughly 23,418 secondary pharmaceutical applications per year at the Patent Office.

11 examiners are given roughly 50% more time to review applications relative to GS-14 examiners, providing us with a straightforward way to build off the estimates set forth above and predict the outcomes associated with a time-allocation expansion of this magnitude. Finally, we assume that the Patent Office will enact this 50% expansion in time allocations while not sacrificing aggregate application throughput. Accordingly, we assume that the Patent Office will increase by 50% the aggregate number of hours that it spends reviewing these 23,418 secondary patents per year. Throughout, we will estimate the costs and benefits of this hypothetical reform on an annualized basis.

In the Online Appendix, we calculate the amount of additional expenses required to enact this hypothesized reform. For these purposes, we consider various sources of information, including the distribution of drug patent applications that we observe across Art Units and GS-levels, the amount of hours allocated to each examiner across this distribution, and information on current salaries, benefits and other personnel expenses across GS-levels. All together, we estimate that funding these additional hours will cost the Patent Office roughly $20 million per year.

B. Benefits

B. 1. Litigation Savings

Increasing examiner time allocations may reduce downstream litigation expenses through two mechanisms. First, with a reduction in patent issuances—as implied by Figure 4 above—there will ostensibly be fewer patents upon which one may sue in the first place. Second, with an increase in the likelihood of validity of the average patent issued—as implied by Figures 2 and 3 above—we may observe less downstream litigation insofar as improving this screening function

at the agency level may leave less of a role for this function for the courts. In this subpart, we estimate the aggregate administrative expenses that may be saved as a result.

To begin this exercise, we estimate that those secondary Orange Book patents that are issued in a given year will ultimately lead to roughly 686 federal lawsuit-patent pairs.[27] A portion of these lawsuits—roughly 18 percent—will also experience contemporaneous challenges before the Patent Trial and Appeal Board (PTAB), which provides an administrative pathway for third parties to challenge the validity of issued patents. Federal litigation expenses in these instances of overlap may be lower as the federal action is often stayed pending the outcome of the PTAB challenge. We make a conservative analytical choice and focus on the savings associated only with those 82 percent of cases that are challenged in federal courts only—i.e., 563 lawsuit-patent pairs.

We then assess what share of these 563 lawsuit-patent pairs can be avoided by increasing time allotments by 50%. For these purposes, we estimate a specification analogous to equation (1), but that uses the number of times asserted in litigation as the dependent variable and that uses the underlying sample of applications as the sample frame. Estimating over the application sample will allow us to capture both mechanisms identified above—i.e., (1) reduced patent grants, which mechanically reduces litigation and (2) improved validity of the average issued patent (note, the litigation analysis from Part III was designed to just speak to this second mechanism).[28] As we estimate in the Online Appendix, a 50% increase in time allotments is associated with a roughly 35% decrease in litigation frequency through these combined mechanisms. Drawing on this

[27] This 686 number is derived from the fact that (i) recently, there were an average of 411 secondary patents issued each year that culminate in an Orange Book listing (for these purposes, we focus on those secondary patents issued in 2013-2014 to account for censoring issues in that it takes time for an issued patent to be associated with an FDA approval and thus enter the Orange Book) and (ii) these patents are litigated on average 1.67 times (we arrive at this number by likewise looking at data from 2013-2014 to account for litigation-related temporal censoring). Note that this does not necessarily entail 686 lawsuits in their entirety as suits will often adjudicate more than 1 patent. Accordingly, we keep track of "lawsuit-patent pairs" and will later in our analysis consider the average number of patents per case in determining the costs associated with such pairs.

[28] Our estimate of the share of litigation that can be avoided through time allocation increases is arguably conservative insofar as it is drawn off the full application sample that includes both primary and secondary patent applications, despite a stronger time-elasticity in the secondary sample of interest.

estimate, the hypothesized increase in examination time of 50% over one year of reviews is projected to reduce the amount of lawsuit-patent pairs by roughly 195 patent-lawsuit pairs.

Frakes and Wasserman (2019) estimate that a given patent-lawsuit pair is associated with $234,761 in administrative expenses,[29] or roughly $165,131.6 per patent-lawsuit pair in present value terms (using a 7% discount rate). With 195 lawsuit-patent pairs avoided through our hypothetical reform, we estimate total litigation savings of $32.2 million dollars stemming from one year of a 50% increase in time allocations (with a 95% confidence interval for this estimate ranging from $4.3 to $46.5 million, when considering the 95% confidence interval for the key input into this estimate—i.e., the estimated 35% decrease in litigation).[30] All told, we find that the administrative savings from lower levels of litigation will, in expectation, surpass the added personnel expenses entailed with increasing examination time allotments.

To the extent policymakers wish to return invalid drug patents to the public domain, this analysis suggest that it is likely to be more cost effective to do so by expanding agency-level review on the margin. An additional benefit of the ex ante approach is that it may allow for an acceleration in this return to the public domain, which, in turn, may allow for an acceleration in generic entry. We turn now to a consideration of the possible benefits and costs that may ensue as a result.

B. 2. Accelerated Generic Entry

[29] Importantly, the patent-lawsuit expense estimate from Frakes and Wasserman (2019) is not limited to pharmaceutical patents. If we were to attempt to narrow the focus of the calculations underlying this prior work to the pharmaceutical patent space, there is reason to believe that these expected costs would be even larger. One of the key inputs into our calculation was information on litigation expenses from the AIPLA, which reported expenses by different amounts-at-stake categories (e.g., less than $1 million, $1-$10 million and so on). We then drew on data on patent damages from the Lex Machina litigation database to estimate the distribution of cases across these amounts at stake to aid in our estimation of expected litigation costs per case. Given the size of the pharmaceutical marketplace and the significance of patents to this marketplace, it is likely that the average amount at stake in a pharmaceutical patent case is larger than that in a non-pharmaceutical patent case, in which event one might expect that the litigation expenses in the pharmaceutical patent context would be even larger.

[30] When discounting throughout, we conservatively consider the higher of the two alternative discount rates (7%) followed by the Office of Information and Regulatory Affairs (OIRA). In the Online Appendix, we show the robustness of these findings to an alternative data source: the Stanford NPE Litigation Database.

To the extent a secondary drug patent would otherwise culminate in the last-expiring patent for a drug product, the rejection of that secondary patent made possible by an increase in time-allocations may lead to a reduction in the effective patent life of the drug product and a corresponding acceleration of generic entry.[31] To estimate the degree of this acceleration, we begin by considering the patent-allowance results from Figure 4, which suggest that a 50% increase in time allocations is associated with a roughly 12.8 percentage-point reduction in the likelihood that a drug patent is issued.[32] While this estimate was derived from a sample of all drug patent applications and while the EPO-allowance results suggest that this allowance effect would likely be even larger in the case of secondary drug patent applications, we will nonetheless conservatively assume that this hypothetical reform targeted at secondary applications will result in a 12.8 percentage-point reduced likelihood that a secondary drug-patent-application is issued. Some—though not all—of those foregone secondary patents could have otherwise been the last expiring patent associated with a drug product.

To calculate how much acceleration in patent expiration this generates, we use the Orange Book data from the FDA on the expiration dates of those patents associated with each drug product and then randomly drop 12.8% of the secondary Orange Book patents (focusing on those rejected at the EPO—i.e., with questionable validity). We then determine the resulting reduction in the

[31] Secondary patents may also delay generic entry under a second, more nuanced mechanism. Imagine a situation in which a brand name manufacturer receives approval on a drug product with the FDA and lists two patents for that drug product in the Orange Book—one for the active ingredient and one for the route of administration for that ingredient. Next, imagine that, after having marketed the original drug for some number of years and before the patent term is up for those two patents, the brand-name manufacturer receives a new secondary patent and receives FDA approval of a *new* drug product—e.g., one with the same active ingredient but using under a different route of administration than that taken by the original drug product. While generics may enter under the original drug product once those original two patents expire, the generics may be prevented from entering the market for the new drug product with the new route of administration. To the extent that brand-name manufacturers are successful in encouraging physicians and patients to use the new drug product, the end result of this "product-hopping" strategy will be to keep generics out of the market until the expiration of this latest secondary patent. Our empirical analysis below is conservative in that we will not attempt to calculate the degree to which product-hopping strategies that build off secondary patents may delay generic entry. Instead we will simply explore the extent to which secondary patents may extend the effective patent life and delay generic entry for a *given* drug product.

[32] Note that the 0.128 figure is near in size to the 0.10 figure implied by Panel A of Figure 1. That is, we find that an increase in time allocations of 50% is associated with a 12.8 percentage-point reduction in the likelihood of patent issuance and a 10% reduction in the likelihood that an average issued patent is invalid. Together, this supports a suggestion that those patents foregone through increased time allocations are of questionable legal validity, a result that is intuitive given the legal presumption of validity.

expiration date of the last patent in the chain of patents associated with each drug product. After doing this 100 times and considering the average reduction across each drug product, we estimate that the assumed reform will accelerate the expiration of the last patent of an average drug product by 162 days.

Of course, some of those patents that are estimated to be invalidated through our hypothesized reform would have otherwise been invalidated anyway in federal court. Litigation, however, would not be expected to fully catch invalidly issued secondary patents. After all, among other considerations, upwards of 50% of Paragraph IV challenges may settle (Hemphill and Sampat 2013), where much of these settlements operate to maintain delayed entry (Drake et al. 2014; FTC 2017). To determine the share of accelerated entry stemming from a time-allocation reform that would have otherwise occurred anyway via litigation, we reconsider the above simulation exercise but use an "effective" patent expiration benchmark that equals the earlier of: (i) the date of expiration of the last-expiring patent for a drug product or (ii) the date of first generic entry associated with that drug product (which may arise prior to the date of patent expiration due to litigation challenges).[33] Incorporating litigation-induced generic entry in this manner, we find that 68% of the acceleration in patent expiration that might arise through eliminating secondary patents at the Patent Office would have occurred anyway via litigation.

Altogether, this analysis suggests that increasing time allocations by 50% for secondary drug patents will lead to 51.8 days (32% of 162 days) of acceleration of patent expiration for an average drug product. Considering that the FDA has recently approved, on average, roughly 119 new drugs per year, this 51.8-day estimate implies that the hypothesized one-year 50% increase in time allocations for secondary drug-patent applications will lead to an aggregate of roughly 16.9 years

[33] Additional details on this simulation exercise are provided in the Online Appendix. Data on the dates of generic entry are from the Drugs@FDA database.

of accelerated generic entry across the marketplace (with a 95% confidence interval of between 10.9 and 22.8 years based on the 95% confidence interval of the key input into this estimation—i.e., the 12.8% effect on grant rates).

B.2.a. Static Gains Associated with Accelerated Generic Entry

For those markets experiencing earlier generic entry as a result of this hypothesized reform, such 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 total 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 of the Online Appendix an elementary monopoly pricing scenario for a hypothetical drug. As this simple scenario demonstrates, this first outcome—the increased consumer surplus among those would have purchased under monopoly pricing—equals the average percent price reduction upon generic entry times an average brand-name manufacturer's revenues during monopoly pricing.

The price-reduction parameter has been the subject of substantial research. A recent report by the IMS Institute for Healthcare Informatics (2016) found that generics that entered the marketplace between 2002 and 2014 reduced the price of drugs by 51 percent in the first year alone, with notably higher reductions in the case of oral medications and in more recent calendar years. To be conservative, we assume that prices will fall by 50 percent following generic entry. For the relevant revenue estimate, ideally, we do not necessarily want the annual revenue of an average drug, but instead the average annual amount among those drugs that are likely to be affected by the hypothesized reform—i.e., drugs that use secondary patents to extend effective patent terms. Hemphill and Sampat (2012) present evidence to suggest that drugs of this patent-term-extending nature are on the upper end of the sales distribution. To proceed, we use the

average annual amount among the sample explored in Hemphill and Sampat (2012)—i.e., $748 million. In the Online Appendix we offer a greater discussion surrounding this issue and present alternative estimates of consumer surplus gains—even if overly conservative—that draw on information bearing on average revenues among all drugs (finding gains slightly greater than half of the amount implied by the Hemphill and Sampat revenue figure).

Together, these estimates suggest that the average gain in consumer surplus arising from one year of earlier generic entry for an average drug—for those consumers who would have purchased the brand-name drug anyway—is roughly $374 million. In light of our above estimate of 16.9 years of accelerated generic entry across the marketplace, we estimate the annual aggregate consumer surplus gain associated with a hypothesized 1-year increase of 50% in time allocations to be roughly $6.32 billion dollars.

Of course, these gains from accelerated patent expiration will not be realized until roughly 14 years in the future considering the length of time between the issuance of a secondary patent and its expected patent expiration. As such, our estimate should discount these future gains over this time horizon. However, the $6.32 billion estimate did not itself reflect a growth rate for the $748 million revenue-per-drug input into its calculation. Thus, we proceed by using a discount rate that nets the expected brand-name revenue growth rate from our baseline 7% discount rate (itself inspired by the larger of the two rates employed by the Office of Information and Regulatory Affairs). For this revenue growth-rate estimate, we use the 3.5% growth rate in drug spending found in IQVIA (2021).[34] Altogether, this analysis implies a present discounted value of the consumer surplus gains of $3.9 billion. When incorporating the 95% confidence interval surrounding the key input into this analysis—i.e., the estimated 12.8% reduction in grant rates

[34] This amount is consistent with various alternative sources. For instance, Rome et al. (2021) find a 5.4% two-year growth-rate—or roughly 2.7% annualized rate—in net brand prices (prior to generic entry).

associated with a 50% increase in time allocations—our findings suggest a corresponding confidence interval for this consumer surplus savings of between $2.53 and $5.28 billion.

We next consider the reduction in static deadweight losses. While earlier scholarship suggested little change in quantity due to generic entry—perhaps due to the presence of third party payers and / or the reduction in advertising that arises in connection with brand-name loss-of-exclusivity—scholarship drawing on more recent experiences with generic entry suggests a modest increase in quantity following loss of exclusivity (Aitken et al. 2018). Exploring responses for six example molecules, Aitken et al. (2018) suggests that generic entry is associated with a 4.6 percent increase in quantity of the affected drug product. We draw on this amount to help provide a rough calculation of the relevant reduction in deadweight losses.[35] In the elementary monopoly pricing model set forth in the Online Appendix, we demonstrate that the reduced deadweight losses associated with 1 year of accelerated generic entry for an average drug product can be estimated as ½ of the 4.6 percent amount from Aitken et al. (2018) times the estimated consumer surplus amount from above. When discounting this amount to the present (at 7%) and aggregating over the marketplace, we find that a 50% increase in time allocations for secondary drug patents is associated with an annual reduced deadweight loss of roughly $89.8 million (with a 95% confidence interval of $58.1 – 121.5 million when considering the confidence interval for the effect of the time allocation reform on the rate of issuance of drug patents).

B.2.b. Brand-Name Firm Response: Reduction in New Molecular Entity Innovation

In addition to the static welfare gains just estimated, this hypothetical reform may also impact welfare by affecting the decisions of brand-name manufacturers moving forward. In particular,

[35] We also ignore any reduction in advertising expenses that may come from generic entry.

the resulting acceleration in generic entry may chill future efforts to produce new drugs. This outcome may be particularly possible given concerns over sub-optimal patent-term lengths (Budish et al. 2015) and given the chance that firms may use the rents from invalid secondary patenting to subsidize valid innovation efforts that are otherwise insufficiently incentivized.[36]

The literature has produced mixed findings regarding the extent and nature of innovation that may be discouraged due to decreased potential returns of drug producers. Certain studies find greater-than-unity elasticities of new-molecular-entity approvals with respect to potential market size (Acemoglu and Linn 2004; Blume-Kohout and Sood 2013; Myers and Pauly 2019). Others estimate more modest relationships. For instance, Dubois et al. (2015) estimate an elasticity of 0.25 (see also, Civian and Maloney 2009 and Rake 2017). Yet other studies also distinguish between the nature of those new drugs that may be incentivized by an increase in market size—i.e., do the marginal drugs represent the product of valuable "breakthrough" research or less valuable or even costly "me-too" imitation (Gallini 1992)? Using the introduction of Medicare Part D to capture an expansion in market size, Dranove et al. (2020) find evidence suggesting that the strongest innovation responses to this change in demand come from clinical trials that represent less scientific novelty. Similarly, Gilchrist (2016) cannot distinguish from zero the relationship between an incumbent patent holder's length of exclusionary period and the number of subsequent entrants that receive priority review with the FDA (a metric suggesting higher social value).

It is beyond the scope of this paper to resolve these uncertainties in the literature. As such, we do not settle on particular estimates of the welfare offsets that may arise through market-sized-

[36] Dynamic innovation response of this nature are, of course, not unique to patent-based drug-pricing reforms. However, a time-allocation approach to reducing drug prices relative to other proposals such as price controls may have a unique bearing on the price-innovation tradeoff to the extent that certain drug classes are more likely to be affected by the hypothesized reform to the extent such classes are more likely to make use of secondary applications. Research has shown that the share of secondary patents is highest in certain therapeutic groups such as anti-ulcer, anti-depressant, pulmonary hypertension agents, broncho-dilators, and hormones and lowest in other therapeutic groups such as anti-viral and anti-neoplastics (Abud et al. 2015). Of course, this variation speaks to the proportion of primary and secondary patents within a therapeutic group. In an absolute sense, Abud et al.'s analysis demonstrates substantial use of secondary patenting across the board.

induced reductions in innovation efforts, leaving this as an exercise for further research. That being said, we do note that should the true NME-market-size elasticity be on the larger end of that found in this literature and should laws bearing on patent term lengths remain unchanged, it may indeed be the case that the dynamic welfare losses stemming from innovation responses to the hypothesized time-allocation reform surpass the various savings estimated above.

Consider, for instance, the elasticity of 1.7 estimated recently by Myers and Pauly (2019). Given a mean effective market life of 12.2 years (Hemphill and Sampat 2013) and given the mean 51.8-day acceleration effect estimated above, the hypothesized time-allocation increase may lead to as high as a 1.2% loss in a given drug product's potential market size. Myers and Pauly's estimate, in turn, suggests that this may result in the affected manufacturer being 2% less likely to bring a new molecular entity (NME) to the market. Considering that roughly 53 NMEs are approached each year, Myers and Pauly's estimates suggest as much as 1.1 fewer NMEs may be brought to the market as a result of the hypothesized one-year time allocation increase. If the NME-market-size elasticity falls on the lower end of that found in the literature (0.25), our analysis would imply that 0.15 fewer NMEs would result from the hypothesized reform.

While the existing literature has not left us a clear sense of the social welfare of the marginal NME that may be offset as a result of a change in market size, we can at least set forth a range at which these unknown innovation-related welfare losses may begin to outweigh the gains discussed elsewhere in this Part IV. For the sake of demonstration, let us just consider the $3.9 billion in static consumer surplus gains estimated above and assume that policymakers place independent normative weight on this measure. With these gains in mind and using the 1.1 foregone-NME figure that is based on the Myers and Pauly elasticity, our analysis suggests that if the present discounted value of the welfare associated with the marginal NME is as large as $3.5 billion (net

of associated R&D expenses), then these dynamic innovation losses may be large enough to outweigh the afore-estimated consumer surplus gains. If instead we use an NME-market-size elasticity of 0.25, the present discounted value of the welfare associated with the marginal NME (net of associated R&D expenses) would have to be as large as $26 billion before the welfare losses stemming from this dynamic innovation effect would outweigh the static consumer surplus gains stemming from the earlier generic entry.

B.2.c. Brand-Name Firm Response: Reduced Patented Efforts

Accompanying these dynamic innovation losses are likely to be corresponding administrative savings. After all, reduced innovation efforts will also come with reduced administrative efforts to pursue associated patent protection. This observation is perhaps just a simple extension of the note above regarding the need to net out R&D expenses when estimating innovation losses. We nonetheless set forth this additional sub-Part insofar as the administrative savings may extend beyond those associated with foregone valid innovation efforts. That is, the analysis from Part III might further suggest that brand-name manufacturers will be deterred from expending as much administrative efforts moving forward in attaining invalid patents on secondary drug features.[37]

Future research is needed to fully quantify the elasticity of patenting efforts to likely patenting success rates. That being said, to provide a sense of the savings that could be in order through this mechanism, let us attempt to analogize this patenting elasticity to the NME-market size elasticity discussed above. In estimating the 1.1 foregone NMEs above, we assumed a greater-than-unity elasticity in new NMEs to market size. If, perhaps conservatively, we assume an elasticity of 1 in

[37] After all, taking this to a hypothetical extreme, if the Patent Office perfectly screens valid from invalid patents, manufacturers may rationally avoid all attempts to receive patents on non-innovative and non-novel features. While our results in Part III do not suggest that a 50% increase in time allocations would generate a perfect screen, they suggest a substantial improvement in screening potential and thus a potentially strong deterrent effect. After all, in the face of roughly 16% of the EPO-twin applications facing a rejection at the EPO (Table 1), our results suggest that a 50% increase in examination time may reduce the rate of EPO-rejections among twins by roughly 10 percentage-points (Figure 1A).

the rate by which manufacturers attempt to receive drug patents with respect to their likelihood of succeeding in such efforts, what might this imply in terms of reduced patenting efforts?

Returning to the above findings, we estimate that a 50% increase in time allocations will decrease the success rate of receiving patent protection by 12.8 percentage-points, though our analysis further finds that close to 2/3 of this effect would be achieved via post-allowance litigation anyway. Putting this all together, if we assume an elasticity of 1 in the patenting rate to the expected patenting success rate, this suggests that manufacturers may reduce their rate of seeking secondary drug patents by 4 percentage points, which suggests as much as 937 fewer applications per year. In light of the estimated $27,251 that it costs (as we derive in the Online Appendix) to prepare, file, prosecute and maintain a given secondary drug patent, these estimates suggest that the hypothetical 50% examination-time reform may lead to as much as $25.5 million per year in administrative savings from foregone attempts to interact with the Patent Office.

Accordingly, while future research is again needed to understand how patenting activity responds to patenting success rates, this exercise demonstrates that a degree of responsiveness on this patenting front that is comparable to the way in which firms respond in their underlying innovation activities may lead to another large set of administrative savings stemming from a time-allocation reform. In particular, this analysis suggests that such a reform may also generate savings in legal and other administrative expenses associated with interacting with the Patent Office that are nearly as large as the savings that may ensue from reduced downstream litigation expenses.

V. Conclusion

Our results suggest that time constraints facing U.S. patent examiners may be presently leading to the issuance of invalid secondary pharmaceutical patents that delay generic entry. We acknowledge, however, that these results do not immediately support the merits of increasing time

allocations at the Patent Office. After all, among other considerations, time allocations will naturally entail greater expenditures and the federal courts nonetheless provide a backstop that may catch and correct the harms stemming from invalidly issued drug patents. In Part IV of this paper, we set forth a structure by which one might evaluate the welfare consequences of a reform that increased time allocations to review secondary drug patents. For those aspects of this exercise that we can estimate—e.g., the costs associated with expanding review, the downstream litigation expenses that may be saved as a result, and the static welfare gains that may arise from accelerated generic entry—our various back-of-the-envelope findings suggest that the gains from expanding ex ante review greatly outweigh the costs. However, a full accounting of the welfare gains that may ensue from such an investment remain an important task for future research given the need to better understand the welfare implications of the dynamic innovation responses that may result from the accelerated-generic-entry-induced reductions in market sizes.

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