NBER WORKING PAPER SERIES

# INVESTING IN EX ANTE REGULATION: EVIDENCE FROM PHARMACEUTICAL PATENT EXAMINATION

Michael D. Frakes
Melissa F. Wasserman

Working Paper 27579
http://www.nber.org/papers/w27579

NATIONAL BUREAU OF ECONOMIC RESEARCH
1050 Massachusetts Avenue
Cambridge, MA 02138
July 2020

We are thankful to seminar participants at the USC Schaeffer Center Workshop, the Indiana University O'Neill Public Affairs and Public Finance Speaker Series Workshop, the NSF Future of IP Conference, the Empirical Health Law Conference, the Duke Law and Economics Colloquium, the Texas Law and Economics Workshop, and the ZIPOW IP Workshop for helpful comments. The views expressed herein are those of the authors and do not necessarily reflect the views of the National Bureau of Economic Research.

Investing in Ex Ante Regulation: Evidence from Pharmaceutical Patent Examination
Michael D. Frakes and Melissa F. Wasserman
NBER Working Paper No. 27579
July 2020
JEL No. I18,O34

## ABSTRACT

The debate surrounding escalating prescription drug prices has increasingly focused on the legitimacy of the practice of brand-name manufacturers receiving patent protection on peripheral features of the drug such as the route of administration, as opposed to just the active-ingredient itself. The key question is whether these later-obtained, secondary patents protect novel features and represent true innovation or, instead, provide little to no innovative benefit and improperly delay generic entry. In this paper, we explore how the Patent Office may improve the quality of the secondary patents issued—thereby reducing the degree of unnecessary and harmful delays of generic entry—by giving examiners more time to review patent applications. Our findings suggest that current examiner time allocations are causing patent examiners to issue low quality secondary patents on the margin. We further set forth evidence suggesting that the costs to investing in greater ex ante scrutiny of secondary pharmaceutical patent applications by the Patent Office are greatly outweighed by the benefits, which include the avoidance of downstream litigation expenses and gains to consumer and total surplus from reduced drug prices.

Michael D. Frakes
Duke University
School of Law
210 Science Drive
Box 90362
Durham, NC 27708
and NBER
Michael.frakes@law.duke.edu

Melissa F. Wasserman
University of Texas
College of Law
727 E Dean Keeton Street
Austin, TX 78705
mwasserman@law.utexas.edu

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

## I. 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 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).

The United States generally relies upon two regulatory bodies to apply these patentability standards and to screen valid from invalid patents: (1) the United States Patent and Trademark Office (Patent Office or Agency) and (2) the federal courts. The existence of these two pathways implicates a tradeoff of another variety, one that is characteristic of many areas of regulatory policy—that is, the choice between the lower per-unit costs but higher screening workload associated with ex ante regulation or the higher per-unit costs but lower screening workload associated with ex post litigation. Our overarching objective with this paper is to explore this latter tradeoff as it applies to small-molecule pharmaceutical pricing and patenting. That is, in an effort to help strike the proper balance between minimizing the harms of elevated drug pricing and spurring innovation, is it cost effective to invest in greater ex ante screening of pharmaceutical patent applications by the Patent Office rather than relying upon the courts as a backstop?

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

In confronting this question, we will assess the merits of the most straightforward means of investing in greater scrutiny at the Patent Office: increasing time allocations to patent examiners. Conceptually, the link between examination time and the legal validity of patents issued through this examination process is quite simple. 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 to them. Should these time constraints bind, examiners may be forced to allow legally invalid patents (Frakes and Wasserman 2017). In our empirical analysis, we will explore whether these constraints indeed bind and estimate the elasticity of the validity of issued pharmaceutical patents with respect to the time allocated to examiners.

In this process, we will pay particular attention to the controversial practice by brand-name drug manufacturers of seeking patent protection not just on the active-ingredient itself but on subsidiary features of the drug—e.g., on its route of administration. Considering the potential of these so-called "secondary" patents to prolong the effective patent life of drugs and delay generic entry (Amin and Kesselheim 2012) and considering the arguably more nuanced evaluation entailed in assessing the innovativeness of these secondary matters, 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.

This inquiry into the cost effectiveness of increasing time allotments to examiners has been addressed in limited form by the literature to date. Lemley (2001) famously argued that because so few patents are litigated or licensed, it is better to rely on federal litigation to make detailed validity determinations in those rare instances rather than giving examiners more time for all applications. In our prior work (Frakes and Wasserman 2017), we attempted to obtain empirical traction on the question Lemley posed by drawing on application-level data and relying upon the

fact that time allocations to examiners are a function of two simple 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. Taking advantage of an application-assignment process that is tangential to the patent-worthiness of the application, we followed application outcomes as examiners underwent time-allocation-reducing promotions. Pooling across all technologies, our prior work demonstrated that as examiners experienced such promotions, they began to grant applications at higher rates, with the marginal patents being issued exhibiting markers of weaker validity, consistent with a story in which time pressures are inducing examiners to issue invalid patents on the margin.

The present analysis will build on Frakes and Wasserman (2017) in several critical ways. First, benefiting from the receipt of new data on the precise day of each examiner's GS-level promotion, we estimate stacked event-study specifications—i.e., specifications tracking patent outcomes in periods leading up to and following promotions, generalizing over the various promotions—that are better designed to isolate the impacts of promotions themselves. We also supplement this GS-level inquiry with a new analysis of a shock to examiner time allocations that is unrelated 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 separately estimate our analysis on a set of patents—active-ingredient patents—with respect to which we predict that examination time constraints are less likely to bind and thus with respect to which we predict a weaker elasticity of validity to examination time.

Methods aside, the most critical difference between the present analysis and Frakes and Wasserman's (2017) analysis of examiner time allocations respects our present focus on pharmaceutical patents, specifically those listed in the FDA's "Orange Book" and associated with

drug products that have been deemed safe and efficacious by the FDA. Not only is this specific inquiry of special relevance to the drug-pricing debate, but our analysis also focuses on a setting that facilitates a more complete evaluation of the merits of ex ante versus ex post regulation. Frakes and Wasserman's (2017) assessment of this tradeoff was limited to a comparison of the administrative costs of one system versus the other—i.e., comparing the personnel and overhead costs associated with increasing examination time versus the litigation savings that could ensue from relieving some of the screening function from the courts. In the case of pharmaceuticals, we have the ability to go beyond a comparison of administrative costs and also consider marketplace impacts. That is, we can combine our estimates of the degree to which examination-time increases may reduce the issuance of invalid secondary patents—which in turn provides us a means of estimating the impact of time-allocation increases on acceleration in generic entry—with other critical pieces of information from the drug-pricing literature, including the degree to which generic entry depresses drug prices. Pulling these pieces together, we are able to set forth simple back-of-the-envelope calculations bearing on the welfare impacts of greater ex ante scrutiny stemming from reduced drug prices.

Using two alternative markers for the validity of issued patents and drawing on administrative data from the Patent Office, the FDA, and the OECD, our results are suggestive of a striking relationship between examination time and the likelihood that examiners issue invalid patents. For instance, among other sets of results, our stacked-event study analysis suggests that upon a given GS-level promotion, examiners experience a 10 percentage-point drop in the likelihood that the secondary pharmaceutical patents they issue are valid, only to then see this validity likelihood ultimately return to its pre-promotion level by a year following the promotion. This pattern of results is consistent with a story in which examiners possibly improve in quality with experience,

only to have these improvements interrupted by time-allotment-reducing promotions. Reinforcing a time-allocation interpretation of these findings, we do not document a promotion-effect in the case of active-ingredient patents, which we predict are less likely to be sensitive to time pressures given the more straightforward patent rules available to assess their novelty and non-obviousness. Further reinforcing a time-allocation interpretation of the estimated promotion effect, we document a jump in our validity marker upon the adoption of the 2010 reform extending all examiners an additional two hours per application review.

Extrapolating from specifications that directly estimate the relationship between the likelihood of validity of secondary Orange Book patents and a series of GS-level dummies of the associated examiners (along with a rich set of fixed effects to help isolate a promotion and time-allocation mechanism), our results imply that a 50 percent increase in examination time is associated with a 10 percentage-point decrease in the likelihood that U.S.-issued secondary Orange Book patents are invalid. Through a simple simulation exercise, we then predict that increasing time allocations by this amount over just one year of reviews will result in an aggregate acceleration of generic entry of 18.5 years among the set of small-molecule FDA-approved drugs (e.g., roughly 1 year of accelerated generic entry for each of nearly 19 different drug products). Drawing on various pieces of information from the drug-pricing and generic-entry literature, these findings imply gains to consumer surplus that vastly exceed the extra costs that we calculate are needed to finance this expansion in examination time, along with gains to total surplus and reduced litigation expenses that are each independently nearly double (or more than double) the costs of the time expansion to the Agency. All told, our results imply that it may indeed be cost effective for the Patent Office to expand time allocations for patent applications on secondary drug features.

In addition to building on the examination-time studies already mentioned, our analysis contributes to certain other strands of literature in economics and medicine. First, we build on a literature that more broadly addresses ex ante versus ex post regulation, including Shavell (1984) and Kolstad et al. (1990). Second, we contribute to an established but still growing literature focused on generic patent challenges and / or on secondary pharmaceutical patenting, including, among others, Grabowski and Vernon (1992), Scott Morton (1999), Danzon and Chao (2000), Reiffen and Ward (2005), Higgins and Graham (2009), 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]

Our paper proceeds as follows. In Part II, we provide a background on pharmaceutical patent examination. In Part III, we describe the data used in the analysis and in Part IV 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 V, we discuss the welfare implications of these results and in Part VI, we conclude.

## II. 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 early in the research phase of drug discovery and development. This

[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).

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, not all of the innovative efforts of brand-name manufacturers involve discovering new chemical entities. A substantial portion of bio-pharmaceutical innovation is more incremental in nature, with brand-name companies also focusing their drug discovery efforts on such things as specifying or changing the dosage or route of administration (e.g., capsules, gels, tablets 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.

All pharmaceutical patents—whether primary or secondary—expire twenty years from the filing of the underlying application. Their exclusory effects are arguably stronger than those of patents in markets for other goods. In most markets, potential entrants may enter while taking calculated risks that their products do not infringe any patents or that any such infringed patents are invalid. Pharmaceutical companies cannot simply enter in this manner, pursuant to the procedures set forth by the Hatch Waxman Act (HWA). With respect to a brand-name manufacturer's drug product approved by the Food and Drug Administration (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. This list is entered into what is known as the "Orange Book." Would-be manufacturers of generic drugs must engage in a specialized certification process with respect to each Orange Book-listed patent for the drug product in question if they would like to enter the market. In particular, the generic applicant must provide one of four certifications under the following paragraphs: (I) there is no patent information listed; (II) the patent has expired; (III) the date the patent will expire; or (IV)

the patent is invalid and/or not infringed by the generic applicant. In essence, generics must either wait until the brand-name patents expire or effectively challenge those patents in court.

This powerful blocking effect of Orange-Book-listed patents creates a strong incentive for brand-name pharmaceutical companies to obtain additional, secondary patents after first receiving the primary patent(s) in order to extend the effective patent life for the relevant drug.

### *B. Background on Patent Examination Process*

Before entering examination, U.S. patent applications are routed to an Art Unit, a group of eight to fifteen patent 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). [3] 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. For instance, an examiner can deny a patent on the grounds that the invention is not new or that the invention is obvious—i.e., represents only a trivial advance over the background art.

Examiners will naturally require a certain amount of time to apply these legal patentability standards. If, over the time allotted to them, examiners are unable to conduct a sufficient search of prior art and articulate a proper basis of rejection, they are legally expected to allow applications (Seymore 2013). Accordingly, if time constraints bind on examiners, this legal presumption leads to a prediction that examiners will allow some patents to issue that, in fact, lack legal validity.

[3] Lemley and Sampat (2012) and Frakes and Wasserman (2017) interviewed examiners and supervisors and confirmed that SPEs employ various randomization approaches to assigning applications.

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. The first such factor is ostensibly non-random in nature. Applications in more complex fields are extended more hours to review. Conditional on the technology of an application, however, the second dimension to this time allocation procedure is effectively random. The higher the pay grade of an examiner within a technology area the fewer number of hours the Patent Office extends to that examiner. A promotion to each subsequent pay grade is roughly equated to a ten to fifteen percent decrease in the number of allocated examination 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 that we will discuss below. 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). As will be discussed below, when comparing various examination outcomes across examiner GS-levels and when exploring changes upon promotion, 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 regarding time allocations, in February 2010, the Patent Office increased the time allocations of all examiners by two hours. In our analysis below, we will also consider a supplementary analysis drawing on the variation in examination 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 relevant prior art and articulate applicable bases of rejections. There are reasons to believe that this outcome is more likely in the case of secondary patents relative to primary patents. 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 limiting the time needed for an effective search of the prior art. Moreover, patent law provides relatively clear rules for when a compound that is structurally similar to a known compound is novel and nonobvious—e.g., the structurally similar compound may be deemed nonobvious if it has chemical properties that are unexpected of the known compound.[4]

In contrast, assessing the patentability of secondary patent applications—such as whether a controlled release formulation of a known compound is patentable—is arguably a more difficult, delicate, and time-consuming task. 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 an arguably 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 and hence patentable. In contrast to the primary chemical compound patents, the rules on whether it would be "obvious" to the person of ordinary

[4] 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.

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 arguably less clearly delineated.

Arguably confirming this prediction that secondary patents will face more challenging examinations at the Patent Office 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).[5] The 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.

For these reasons, our investigation into the relationship between allotted examination time and the validity of issued patents will focus on secondary pharmaceutical patents. Nonetheless, as a validation exercise, we will also separately explore the relationship between time allocations and examination outcomes in the case of primary patents, where our expectation of a lower likelihood of binding time constraints leaves us to predict a weak relationship. As discussed below, however, this primary-patent validation exercise will be limited by small sample sizes.

## III. 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. Patent Data*

To begin, we collect data on individual patent applications filed on or after March 2001 and reaching a final disposition by May 2017—i.e., excluding ongoing applications—from the Patent Office's Patent Application Information Retrieval ("PAIR") database. Though these data cover over 3.9 million utility patent applications across all technology areas, we will primarily focus

[5] We have further confirmed this hypothesis—that is, in general, it is a more difficult and time-consuming process to determine the patentability of secondary patents relative to primary patents—by interviewing current and former patent examiners that review applications on drug products (more specifically, drug products that had been listed in the Orange Book).

only on a subset of these applications that culminate in issued patents that are listed in the FDA's Orange Book. We provide further details on this FDA-approved / Orange Book subset below. In some subsidiary analyses, we will rely on a larger subset of nearly 360,000 pharmaceutical applications—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).

Importantly, for each issued patent (or application), we possess 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 PAIR database, we obtained information from a Freedom-of-Information-Act (FOIA) request regarding the precise timing—to the day—of each GS-level promotion that the relevant examiner received over her career.

*B. FDA Data*

We next collect information from the FDA's Orange Book records. To begin, the Orange Book data provide information on those patents associated with drug products approved by the FDA for safety and efficacy. Critically, the Orange Book data also 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.).[6]

*C. Patent Family Data and Patent Validity Measure*

As discussed above, our aim is to assess whether examination time pressures are causing examiners to allow patents with questionable legal validity. To provide a marker of validity to use for these purposes, we follow various recent studies (Lei and Wright 2017, Frakes and Wasserman

[6] 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.

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 is known to invest substantially more resources per application in the examination process while having essentially similar patentability standards (Picard and van Pottelsberghe de la Potterie 2013). It is also critical to note that EPO examiners work in teams, unlike in the U.S., providing a greater opportunity to catch mistakes in applying the underlying patentability standards. Accordingly, we focus on a subset of U.S.-issued patents whose underlying innovations were also the subject of patent applications at the EPO and use the allowance outcome at the EPO as a benchmark to assess what the allowance outcome at the U.S. Patent Office would have been if the U.S. examiners were given more time and resources to determine the patentability of the relevant invention. The core idea behind this approach is that if one compares a U.S.-issued patent whose "twin" application is allowed at the EPO with a U.S.-issued patent whose "twin" application is rejected at the EPO, the former is *more likely* to be legally valid than the latter.[7]

As a robustness check, we will also explore those U.S.-issued patents whose underlying innovations are part of a family of applications that are filed at both the EPO and the Japan Patent Office (JPO), yet another patent office with similar patentability standards to the U.S. and that extends more time to examiners than the U.S. Patent Office (Picard and van Pottelsberghe de la Potterie 2013). We elect to focus on the EPO for our primary approach given that examiners at the EPO both work in teams and are extended more time per application that U.S. examiners. However, including the JPO in this benchmark approach may be worthwhile considering that it provides yet another screen for us to use in flagging an innovation with questionable validity—that is, we use allowance at *both* the EPO and the JPO as an additional marker for validity.

[7] We note that our welfare analysis below will effectively take this one step further and assume that this EPO-allowance measure provides us with a marker for validity in a more absolute, binary sense, not just a marker signifying a stronger degree of validity.

Easing concerns over the non-generalizability of a subset of patents that are part of a family of applications with other world patent offices, we note that over 86% of the Orange Book patents are associated with a family of applications filed at both the EPO and the JPO. This representation is notably higher than the corresponding figure of 27% across all patents. In any event, as discussed in further detail in Part IV.G below, we will also consider and discuss an alternative approach to developing a marker for patent validity, whereby we look to the frequency by which the issued Orange Book patents are asserted in litigation, a validity marker that is not limited to patents that are part of an international family of applications.

As a baseline, we note that Orange-Book-listed patents exhibit strong validity likelihoods. Active-ingredient U.S.-issued patents that are listed in the Orange Book and that are part of a family of international applications are allowed at the EPO roughly 92% of the time. Moreover, secondary U.S.-issued patents that are listed in the Orange Book and that are part of a family of international applications are allowed at the EPO roughly 84% of the time. When using allowance at both the EPO and the JPO as the validity benchmark, these numbers become 90% and 76%, respectively. We report these summary statistics in Table I.

[Table I Here]

As a preliminary matter, these summary statistics are immediately suggestive of two things. First, they suggest that much of secondary patenting activity may indeed reflect meaningful underlying innovation—i.e., they may not all simply represent wasteful strategies by brand-name pharmaceutical companies to extend the effective patent lives of their drug products. Nonetheless, consistent with the above predictions of fewer time pressures in the case of primary patents, these summary statistics suggest that concerns over invalid patents are indeed stronger in the case of

secondary patents than active-ingredient patents. Our analysis will focus on whether a relaxation of such time constraints may improve validity markers on the margin for secondary patents.

## IV. Analysis

In this Part, we discuss the two basic approaches that we take to exploiting variation in examiner time allocations, beginning with our exploration into the effects of grade-level promotions that carry with them substantial reductions in examination time. We will present our results incrementally after laying out each separate methodological approach.

### *A. Grade-Level Promotions: Preliminary Analysis*

Recall from Part II that time allotments fall by 10-15% upon each GS-level promotion. As a preliminary approach to exploit this variation, we regress 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**). Taking advantage of effectively random assignment of applications within Art Units, we include Art-Unit-by-year fixed effects, $\boldsymbol{\partial_{kt}}$, in all specifications (Feng and Jaravel 2020). 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:

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

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 pharmaceutical patents typically enter the Patent Office with advanced degrees and thus start at GS-level 11 or 12, we focus this analysis on those examiners between GS-levels 11 and 14.[8] We exclude a dummy variable for GS-11 to

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

leave it 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 our validity marker as examiners ascend the GS scale.

The chief challenge with this approach is that other aspects of the examiner at particular points in time may be correlated with her GS-level and may also impact the quality of the examination review. In our first, motivating step in confronting this challenge, we take a control-function approach and explore the relationship between examiner GS-levels and EPO outcomes (looking within technology-by-year groups) while accounting 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**. While temporal experience will naturally correlate with grade-level changes, GS-level promotions do not occur lockstep with experience at the higher GS levels where pharmaceutical patent examiners reside—as we discuss further in the Online Appendix—facilitating a disentangling of experience and GS-level effects. Second, we include fixed effects for the hiring-year cohort of the examiner, **COHORT**. At any point in time, higher-GS examiners will have been part of earlier hiring cohorts. Frakes and Wasserman (2016) demonstrate the significance of examiner cohort effects given persistence in examiner practice styles and variations in initial hiring conditions due to changes in the examination philosophy of Agency directors. Third, we include fixed effects for the ultimate tenure (in years) of the examiner with the Patent Office, **TENURE**. For instance, one may be concerned that GS-11 examiners consist of a greater number of individuals who will leave the Patent Office for industry within several years relative to the group of GS-14 examiners who

have ostensibly stayed with the Agency over time, coupled with a concern that career examiners may differ fundamentally from those who use this position as a springboard to industry.[9]

Given an application assignment process that is tangential to patent worthiness, there is arguably little concern of bias arising from unobservable application characteristics. Nonetheless, we do control for a range of observable characteristics in the vector X, including such characteristics as small-entity-size status,[10] the total number of claims, number of dependent claims, the total (and average) length of all claims and of dependent claims, and the minimum word count per claim for all claims and for dependent claims.

As a preliminary falsification exercise, we test for covariate balance in these measures across the different GS-levels of interest for our analysis. In order to demonstrate such balance in a simple figure, we take an omnibus approach in which we plot the relationship between examiner GS-level and predicted EPO-allowance outcomes for each Orange Book patent, where these predictions are formed after regressing the incidence of the U.S.-issued Orange Book patent also being allowed at the EPO on this full set of application characteristics along with a set of Art-Unit-by-year fixed effects. This predicted EPO-allowance outcome can be seen as a collective reflection of those various application characteristics. As demonstrated by Figure I, these predicted rates of EPO allowance remain flat across examiners at different grades, suggesting a lack of variation in fundamental application characteristics across GS levels, consistent with the random-assignment assumption.

[Figure I here]

[9] In our primary results, we cluster at the unit of assignment—that is, at the Art-Unit-by-Year level. In the Online Appendix, we demonstrate that our results are robust to clustering at the Art Unit level (though we acknowledge that there are a small number of Art Units operating within the pharmaceutical space) and to two-way clustering at both the Art Unit and year level. Cameron et al. (2011).

[10] Entities defined by the PTO as "small" include individuals, nonprofit corporations, or corporations which qualify as small businesses under the Small Business Act. 37 C.F.R. § 1.27(a)(1)-(3).

While predicted EPO allowance outcomes remain flat across GS levels, actual EPO allowance outcomes for secondary patents fall monotonically as examiners ascend GS levels, as we depict in Panel A of Figure II, which presents results of the estimated GS-level coefficients from specification (1). In Table A1 of the Online Appendix, we provide the estimated coefficients for the remaining variables. The drop in validity likelihoods as GS levels rise is precipitous. 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 influence of various application characteristics and for other personnel factors—e.g., experience and hiring-year cohort—that are associated with examiner grade levels. This result provides preliminary, suggestive evidence in support 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 II here]

Above, we predicted that time constraints are less likely to bind in the case of active-ingredient patents given more straightforward tests to apply to assess novelty and nonobviousness and given more readily available search tools. We find suggestive evidence in support of this claim in Panel B of Figure II, where we document no discernable relationship between GS-levels and EPO-allowance likelihoods, with point estimates of the various GS-level indicators that are near 0 in magnitude. We emphasize, however, that we have a small number of active-ingredient patents in our relevant analytical sample (624 active-ingredient patents versus 2,678 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 three separate subsamples, where each subsample represents all Orange Book patents whose applications were disposed of in a window around each respective promotion. 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 the sub-sample (**EVENT_SAMPLE**). This alternative specification is as follows:[11]

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

We first consider a one-year window on either side of the event. This approach 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 (as discussed further in the Online Appendix). In the alternative, we consider a window of two years pre- and post-event, where we exclude patents reviewed by examiners in a post-event window who happen to receive a promotion within that two-year window (which affects those promoted 1-2 years after being promoted to GS 12 or 13).

Note that specification (2) continues to control for experience, cohort and tenure effects, just as specification (1) does. However, by generalizing around an event that strikes examiners at times when they are at a range of different 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

[11] 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. Accordingly, for these specifications, we cluster the standard errors both at the level of assignment (Art-Unit-by-year) and at the patent-number level. The results are nearly identical when we only cluster at the patent-number level.

itself—rather than personnel characteristics that are generally correlated with promotions—relative to specification (1).

We present results from specification (2) in Table II. When using a 1-year window on either side of a promotion and when focusing on secondary patents, we find that an average GS-level promotion is associated with an 8.7 percentage-point decline (or nearly 10 percent relative to the mean) in our EPO validity marker. This effect is smaller in magnitude—i.e., a 5.3 percentage-point decline—when using a two-year window on either side of the event. Explaining the notably larger decline when using the shorter window, our analysis below estimates a dynamic variant of this event study approach and documents a sharp initial decline in EPO allowance after the promotion followed by a retreat to pre-promotion validity levels, a pattern that we discuss further below.

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. We estimate near-zero point estimates for the event indicator variable when estimating specification (2) on the sample of primary (active-ingredient) Orange Book patents, with standard errors of the estimated event coefficient of 2-2.6 percentage points. These results are generally suggestive of a lack of binding time constraints on examiners reviewing primary pharmaceutical patents.

[Table II here]

### *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 and following a promotion event, as in the following specification:

(3)
$$VALID_{aikt} = \alpha + \boldsymbol{\partial_{kt}} + \boldsymbol{\beta_1} \sum_{q=-4}^{4} E_q + \boldsymbol{\beta_2 EXPER_{it}} + \boldsymbol{\beta_3 COHORT}_i + \boldsymbol{\beta_4 TENURE}_i + \boldsymbol{\beta_5 X}_{aikt} + \boldsymbol{\beta_6 EVENT\_SAMPLE}_{aikt} + [\boldsymbol{\gamma_i}] + \varepsilon_{aikt}$$

where $E_q$ represents the various event lead and lag indicator variables. 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 above and given that this dynamic specification is rather taxing for the small active-ingredient sample.[12]

At the outset of this exercise, we demonstrate covariate balance within the event window by plotting predicted EPO allowance outcomes for each secondary Orange Book patent—calculated as above—across the various event dummy variables. As demonstrated by Figure III, we observe a flat trend in predicted validity rates across the entire event window, suggesting little concern over selection in application characteristics across this window.

[Figure III here]

Arguably the chief advantage of this dynamic specification is the falsification exercise that it affords in assessing trends in validity outcomes leading up to promotions. Evidence of negative pre-trends would otherwise challenge a causal interpretation of the above findings. For instance, hypothetically, perhaps examiners trend downwards in the quality of their reviews as they gain experience with the Patent Office. Even though specification (1) includes experience fixed effects and even though experience and promotions do not transpire lockstep, one may nonetheless be concerned with collinearity in these measures and with an insufficient separation in their estimation in specification (1). Relatedly, one may also be concerned with endogeneity in the fact of promotion itself and with the possibility that trends in outcomes may affect who gets promoted.

[12] 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.

Arguably, this latter possibility is of 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.

Mediating against both such concerns, we observe a relatively flat trend in EPO-allowance likelihoods in the time leading up to the promotion, as demonstrated by Figure IV. We then observe a substantial drop in EPO-allowance outcomes subsequent to the promotion itself—an over 10 percentage-point drop in the likelihood that the U.S.-issued secondary patents are also allowed at the EPO. This drop persists over a 2-quarter period, 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.[13] In the Online Appendix, we demonstrate the robustness of the drop in EPO allowance rates upon GS-level changes to alternative event windows.

[Figure IV here]

[13] To complement this analysis, we consider also the estimated experience effects from specification (1)—the estimated experience effects accompanying the estimated GS-level effects from Figure II. 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. At the very least, we can statistically rule out a meaningful decline in validity outcomes as examiners gain experience in years. As such, the separate experience and GS-level effects from specification (1) are also suggestive of a story in which examiners perhaps improve over time only to be met with setbacks arising from time-allocation-reducing promotions.

Overall, these event study results support the contention that there is a drop in validity outcomes for secondary pharmaceutical patents that arises *upon* examiner promotions, appeasing concerns over both reverse causality and over the influence of factors correlated with GS-levels.

*D. Exploring Alternative Mechanisms behind Promotion Effects*

Of course, even if the observed reduction in validity outcomes are indeed caused by the GS-level promotions, one may still be concerned that a non-time-allocation mechanism may underlie such results. That is, 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 behavioral response by examiners to being promoted may hypothetically explain our results.

For instance, one may be concerned with a possible story in which as examiners rise in the ranks, they are given less supervision over their work and may thus more easily shirk, which may lead to the issuance of more invalid patents and explain the GS-level pattern depicted in Figure II. Mediating against such a story 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 discussed in greater detail in the Online Appendix—even though Figure II depicts a monotonic decline in examination quality upon each promotion, not just the GS-14 promotion. Even if, hypothetically, the structural aspects of examiner supervision happen to change for the other promotions, a supervision explanation of this nature is arguably incomplete as such structural changes in supervision would be static after the promotion, which would be inconsistent with dynamic pattern depicted in Figure IV. As discussed above, however, that pattern is consistent with a story in which improvements in quality over experience are met with interruptions in time allocations upon promotions.

Nonetheless, we do acknowledge that one plausible non-time-allocation-related explanation behind the dynamic pattern depicted in Figure IV may be that examiners celebrate their promotions with a transitory period of increased shirking—marked by lower quality reviews—only to return to their previous behavior after this "celebratory" period.[14] We take two 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 relative to primary pharmaceutical patents. The fact that the results do not materialize in the case of active-ingredient patents thus arguably lends additional support to a time-allocation mechanism. We continue to caution, however, that small sample sizes for primary Orange Book patents limit our ability to make this claim with precision. Consider the approach with arguably the greatest statistical power for these purposes—i.e., the binary event-study results presented in Table II. Even though we find meaningful effects for secondary patents that are distinguishable from zero and near-zero point estimates that are not distinguishable from zero for the active-ingredient patents, this approach still cannot rule out statistically that the promotion effect for secondary patents is greater than (in an absolute sense) the promotion effect for primary patents, with a p-value of 0.2 in testing for such differential effect sizes.[15]

Nonetheless, even if in any single approach we cannot rule out same promotion-effect sizes between secondary and primary patents, we do consistently document evidence of large effects in the secondary sample and no evidence of effects in the primary sample (with smaller or near-zero

[14] A counterpart to this story may be one in which supervisors transitorily and informally—as opposed to systematically—lighten their scrutiny of examiners for some period of time following supervisee promotions.
[15] The most straight-forward way to test for a differential promotion effect size is to include all Orange Book patents in the sample and test the interaction between the event indicator variable and an indicator for being an active-ingredient patent.

point estimates) across all of our various approaches—from specifications (1), (2) and (3) to the estimation of the 2010-reform analysis that we will discuss momentarily. This consistent pattern arguably lends support to a broader inference that GS-level promotions affect outcomes in the case of secondary and not primary patents, which, in turn, lends support to a time-allocation interpretation of these findings. We note that this primary-versus-secondary discussion complements the analysis in Frakes and Wasserman (2017) which predicted a stronger likelihood of time pressures in making obviousness rejections than in the case of lack-of-novelty rejections and thereafter found evidence consistent with these projections, supporting a time-allocation story.

To further mediate between a time-allocation mechanism and a temporary-shirking mechanism, we next turn to our second fundamental approach to exploiting variation in examination time and draw on a source of variation that is not specific to examiner GS levels.

*E. 2010 Examination-Time Reform*

Over the course of our sample, the Patent Office enacted a reform—effective in February, 2010—extending all examiners (regardless of grade level or technology) an additional two hours of review per application.[16] Accordingly, as an additional empirical exercise, we consider a simple event-study analysis where we track the likelihood that twin applications of U.S.-issued Orange Book patents are also allowed at the EPO in the period of time before and after the effective date of this two-hour extension (basing this analysis on the timing of issuance of the U.S. patents).

This approach is not without important caveats. Lacking a control group, our modest aim here is to simply conduct a validation exercise in which we attempt to detect a jump in EPO allowance outcomes upon this one-time increase in time allotments, rather than to nail down with precision the steady-state improvement in quality that arises from this time expansion. Since we are drawing

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

on time-series variation only and since EPO allowances outcomes will be changing over time for other reasons, we are inclined not to embrace a comparison window that is too wide. Nonetheless, considering an already small sample of Orange Book patents, we cannot consider an observation window that is too small. To balance these concerns, we elect to look for a change in outcomes in a window characterized by two years prior to and subsequent to the two-hour reform in February, 2010. This approach entails focusing on only roughly 20% of our original Orange Book sample.

In Table III, we demonstrate results from a specification similar to that of speciation (1) but focusing on this more limited sample and including an indicator for the 2010 reform.[17] As demonstrated by Column 1, we find a statistically-significant post-reform increase of 9.1 percentage points—or roughly 11 percent relative to the mean—in the likelihood that the twin application of a secondary U.S.-issued Orange Book Patent is also allowed at the EPO. As demonstrated by Column 2, we document no such increase in the case of active-ingredient Orange Book patents, with a near-zero point estimate of the reform coefficient.[18]

[Table III here]

In Figure V, we take a dynamic approach to this event-study analysis, where we replace the reform dummy with a series of event-time indicator variables in order to track these EPO-allowance outcomes period-by-period leading up to and following the February 2010 reform, again within this 4-year window (using half-year groups as the incremental observation period). Given our aim to use this approach as a robustness check on the findings from Table III, we focus only on the sample of secondary Orange Book patents. Figure V plots the estimated coefficients of the event-time indicator variables, with the indicator for the period immediately prior to the reform

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

[18] We acknowledge, of course, that with a standard deviation of 4.3 percentage points, we cannot rule out that a meaningful increase in this validity marker for the active-ingredient patents is possible.

excluded to serve as the reference group. Encouragingly, we find no evidence that the post-reform increase in validity suggested by Table III materialized prior to the reform, instead finding a jump at the moment of the reform. Given the small sample size entailed by looking at the window around 2010 and given the relatively taxing dynamic specification, our estimates in Figure V are somewhat imprecise. Though the point estimate of the first post-reform event indicator suggests a strong jump in EPO allowance outcomes, this estimate is not statistically distinguishable from zero. The second post-reform event indicator, however (signifying the 6-12 month period following the reform) is statistically distinguishable from zero.

[Figure V here]

Finally, in Figure VI, we demonstrate that these results are not due to differences in fundamental patent characteristics across the event window. For these purposes, we follow the approaches set forth above and plot a corresponding time trend in *predicted* EPO allowance rates (based on the observable covariates). Consistent with the similar falsification tests conducted above, we find stability in predicted EPO allowance outcomes across this time window.

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

[Figure VI here]

### *F. Robustness Checks*

In the Online Appendix, we also present results from various robustness checks. First, we demonstrate that our results persist when using the allowance at both the EPO and the JPO as an indication of the validity of the U.S.-issued patent. Second, we estimate specifications that include

a set of examiner fixed effects, $\gamma_i$. This inclusion complements the event-study approach from Figure IV in further isolating the act of promotion itself and in accounting for the influence of unobservable factors inherently correlated with GS-level. One challenge with an examiner-fixed effects approach is that our sample of Orange Book patents is a selective sample of all pharmaceutical patents, with many examiners only reviewing a handful of Orange Book patents over their careers, in which case we would be arguably identifying the effects of interest off only a subset of our examiners. For this reason, we leave this exercise as a robustness check only. Nonetheless, as we discuss in the Online Appendix, our results are robust to the inclusion of examiner fixed effects, which is perhaps not surprising given the steps taken in the above approaches—e.g., estimating a stacked event study around a generalized promotion event.

*G. Alternative Validity Marker: Litigation Rates*

We next discuss the robustness of our 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 as they are given less time to review applications, 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 will attract litigation at a higher rate than valid patents. Frakes and Wasserman (2019) discuss this prediction as a general matter across the patent system and find strong empirical support for this claim. We begin here by noting that the theoretical support for this claim is particularly strong in the pharmaceutical context.

To see why, consider the discussion from Section II.B. New generics may only enter prior to the expiration of the brand-name manufacturer's relevant patent(s) if they challenge the brand-name patent(s) through a paragraph (IV) certification, essentially inviting the brand-name firm to sue the generic. In other words, litigation in the pharmaceutical context is often effectively initiated by

challengers to the patent—i.e., by parties who will often be inclined to challenge patent validity. If the brand-name manufacturer holds an invalid patent, the potential generic entrant may naturally be more likely to bring forth a Paragraph (IV) certification. This may be especially true given the six-month exclusivity bounty awarded to the first generic to make a Paragraph (IV) challenge.

With this in mind, we also estimate specification (1) using the number of times in which the relevant Orange Book patent is litigated as the dependent variable—i.e., as an alternative validity marker. We present the results of this analysis in Table IV, showing results both for Ordinary Least Squares and negative binomial specifications (presenting incidence rate ratios in the latter context). One challenge with this analysis is presented by the passage of the America Invents Act (AIA), which occurred in the middle of our sample period and which modified the rules regarding joinder of multiple defendants in single lawsuits, with the result being a nearly 100% increase in litigation counts per patent following September, 2011. The chief concern is really one of interpretation in that the AIA greatly altered the significance of litigation counts as an outcome. For these reasons, we take two approaches. First, we only inquire as to whether the relevant Orange-Book patent was litigated after September, 2011, no matter when it issued at the Patent Office. Second, we simply focus only on those patents that were issued after September, 2011. We find that the litigation results generally parallel those of the EPO-benchmarking analysis—though in opposite sign given that higher litigation signifies weaker validity. That is, we find an increase in the rate by which a given patent is litigated as GS-levels rise.[19]

In the Online Appendix, we estimate a dynamic event-study counterpart to Figure IV but using post-AIA litigation counts as the dependent variable. The point estimates of this figure suggest

[19] In the Online Appendix, we also show results where we use the whole sample and use total litigation counts as the outcome variable—whether or not before or after the AIA—acknowledging the interpretation challenges just discussed. We continue to find a monotonic increase in the point estimates of the GS-level coefficients, though the magnitude of the effects are smaller and the coefficients are not distinguishable from 0.

that examiners issue patents over time with litigation rates that tend to fall, suggesting an improvement in quality with experience. However, when examiners undergo an examination-time-reducing promotion, we observe a large increase in litigation rates, suggesting a negative shock in the quality of their reviews and a disruption of this general quality improvement process.[20]

[Table IV here]

*H. Marginal versus Average Effects*

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. This average effect could be due to a situation in which an examiner issues the same number of patents regardless of her time allocation, but where increases in time pressures constrain her ability to narrow the claims of some of those patents, with the effect being that time pressures cause a greater portion of those patents to be invalid. Alternatively, the observed decline in average validity may be due to a situation in which the time pressures inhibit her ability to find bases to reject some applications that she otherwise would have rejected altogether if she had more time. This latter scenario could account for the above findings to the extent that the issuance of an additional set of invalid patents on the margin could lower the average likelihood of validity among the full set of issued patents.

Arguably, whether this decline in average quality is driven by insufficient claim narrowing among a consistent set of patents or insufficient rejecting among the set of applications is of no consequence in the aggregate. Either mechanism could account for the issuance of some amount of patents that lack legal validity. Nonetheless, in this sub-section, we attempt to shed light on this mechanism question and ascertain if at least some of the effects derived above arise from a situation in which examiners are issuing a greater number of invalid patents on the margin.

[20] We do not conduct a corresponding analysis based on the 2010 reform considering that the AIA was passed in this window and would confound the necessary time-series analysis.

To explore this possibility, we follow the approach of Frakes and Wasserman (2017) and test whether the allowance rate of pharmaceutical patent applications increases as examiners ascend the GS-level scale. For these purposes, we need data at the level of the individual application, as distinct from the individual issued patent. We do have this data for all pharmaceutical applications—not necessarily the select subset of those that are likely to wind up being listed in the Orange Book. One advantage of working with this broader application sample 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.

In Figure VII, we present results from a counterpart to specification (1) that instead uses the full pharmaceutical patent application sample and that uses the incidence of the application being allowed as the dependent variable. We find a strong increase in the rate of allowance—and thus the number of patents issued—as examiners experience grade-level promotions, consistent with the results we found across all technologies in Frakes and Wasserman (2017). These findings, in conjunction with the above findings, are consistent with a story in which, as examiners receive less time to review, they allow an additional set of invalid patents on the margin that lower the average likelihood of validity among issued patents.

[Figure VII here]

## V. Welfare Analysis

The above analysis suggests that as examiners are allocated more time to review applications for secondary pharmaceutical patents, they are substantially less likely to issue invalid patents. Though such allocations will require additional governmental expenditures, this outcome is likely to produce various benefits, including a reduction in future litigation expenses and earlier generic entry, the latter of which may generate increases in both consumer and total surplus through

reduced drug prices. Though these benefits are hard to quantify with precision—especially the latter benefits—this section will offer simple back-of-the-envelope calculations that draw from the above estimates to shed light on whether the benefits of extending patent examiners more time to review pharmaceutical patent applications will outweigh the additional costs involved.

*A. Costs*

We begin by estimating the costs associated with an expansion in examiner time allotments. To do so, it is first necessary to make a couple of assumptions regarding the nature of the expansion envisioned. 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 being deemed safe and efficacious by the FDA and ultimately being listed in the Orange Book. Accordingly, we envision and will evaluate a reform in which the Patent Office increases time allocations for all pharmaceutical patent applications, not just those that culminate in an Orange Book listing. We do assume, however, that the Patent Office will be able to distinguish between an active-ingredient and a secondary patent application. Accordingly, we assume that the Patent Office will increase the amount of time extended to examiners on all incoming secondary patent applications. We estimate that this represents an increase in time allocations for roughly 23,418 secondary applications per year.[21]

Second, we assume a reform in which the Patent Office increases examination time by 50% to all examiners. The key reason behind choosing the 50-percent amount stems from our GS-level analysis. GS-11 examiners are given roughly 50-percent 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.

[21] 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.

Finally, we assume that the Patent Office will enact this 50-percent expansion in time allocations while not sacrificing aggregate application throughput—that is, while not reducing the number of reviews that it performs. Accordingly, we assume that the Patent Office will increase by 50 percent the aggregate number of hours that it spends reviewing these 23,418 secondary patents per year, a feat that it will accomplish via an assumed hiring of additional examiners.

In the Online Appendix, we calculate the amount of additional expenses required to enact this hypothesized reform. For these purposes, we consider the distribution of pharmaceutical patent applications that we observe across Art Units and GS-levels and then consider the amount of hours allocated to each examiner across this distribution. Based on this distribution and based on the hours-allotment schedule across GS-levels and Art Units, we project that this reform will require the funding of an additional 224,931 hours of review annually. Next, we use information on current salaries, benefits and other personnel expenses across GS-levels to estimate that funding these additional hours will cost the Patent Office roughly $20 million per year.

*B Benefits*

*Litigation Savings*

As discussed in Part IV.G, an increase in examination time may be expected to, and does appear to, lead to a decrease in federal litigation. In some sense, this effect is intuitive in that our current system relies on two sectors of government to screen out invalid patents: the administrative agency (the Patent Office) and the courts. If we increase the role of the former in screening out invalid patents, it may leave less of a role in this regard for the courts. In this sub-section, we will attempt to estimate the court fees, attorney fees and other litigation expenses that may be saved through increased examination scrutiny.

Our calculation will be conservative in that we will only assess the litigation expenses associated with secondary patents listed in the Orange Book, even though we are contemplating the extra costs of increasing time for all secondary pharmaceutical applications. Our analysis will proceed in three steps: (1) assessing the number of patent-lawsuit pairs that are expected to result from those secondary Orange Book patents that issue annually, (2) drawing on the results from Part IV.G and the calculations from (1) to estimate the number of secondary pharmaceutical patent-lawsuit-pairs that will be avoided by increasing examiner time allocations by 50% and (3) drawing on estimates of costs per patent-lawsuit pairs to calculate the overall litigation savings.

To begin, we estimate that the annual issuance of secondary Orange Book patents will be associated with roughly 686 federal lawsuit-patent pairs. This number is derived from the fact that, recently, there were an average of 411 secondary patents issued each year that culminate in an Orange Book listing[22] and that these patents are litigated on average 1.67 times.[23]

It is important to acknowledge that a portion of these lawsuits will also experience contemporaneous challenges before the Patent Trial and Appeal Board (PTAB). PTAB challenges provide a pathway for third parties to challenge the validity of issued patents at the Agency via proceedings that share a host of features that mimic certain characteristics of a civil trial (Wasserman 2013). 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. In the case of the Orange Book secondary pharmaceutical patents that are challenged in lawsuits in Article III courts,

[22] These counts were slightly smaller in the last few years of the sample (between 315 and 360 per year); however, that is to be expected, as it takes time post issuance before the relevant drugs will receive FDA approval. Accordingly, in light of this censoring issue, we focus on the number of secondary patents per year issued in 2013-2014 to estimate a more steady-state depiction of the prevailing number of annual secondary patent issuances that culminate in an Orange Book listing.

[23] To arrive at this value, we average over those secondary Orange Book patents issued by the Patent Office between 2012 and 2014—that is, past the implementation of the AIA. We stop in 2014 to allow time for the drugs associated with the issued patents to go through the FDA approval process. Our conclusions with this analysis, however, hold true if we average over the full post-AIA period (where the patents in our sample are litigated on average 1.25 times). We note that this is a nearly 100-times higher litigation rate than the typical issued patent. 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.

we find that only 18 percent of such patents are also challenged at PTAB. For the purposes of calculating litigation savings associated with increasing examination time, we make a conservative analytical choice and focus on the savings associated only with these 82 percent of cases that are challenged in Article III courts only—i.e., 563 lawsuit-patent pairs.

We then assess how many of these 563 lawsuit-patent pairs can be avoided by increasing time allotments by 50%. For these purposes, we draw on the estimated GS-14 coefficient from Part IV.G. This estimate is useful for this exercise considering that a policy that gives GS-14 examiners the amount of time allotted to GS-11 examiners—holding everything else fixed–would amount to a 50% increase in examination time. The incidence rate ratio from the negative binomial regressions from Table IV suggests that as examiners ascend from GS-11 to GS-14, the secondary Orange Book patents that they issue are litigated at a 137-percent higher rate (relative to their GS-11 litigation rate). If we think of this progression in reverse—as examiners move backwards from GS-14 to GS-11—this incidence-rate ratio result suggests that the secondary Orange Book patents issued by examiners are litigated at a roughly 58 percent lower rate relative to their GS-14 litigation rate. Accordingly, our results imply a 58-percent reduction in litigation frequency as examination time is increased by 50 percent. With roughly 563 lawsuit-patent pairs stemming from each year's issuance of secondary Orange Book patents, this examination time increase is thus projected to reduce the amount of lawsuit-patent pairs by roughly 326.

Frakes and Wasserman (2019) estimate that a given patent lawsuit is associated with a present discounted value of litigation expenses of $386,836.9, after accounting for the fact that the average litigation expense occurs 5.2 years after patent issuance and thereby discounting these future expenses at a conservative 7% discount rate.[24] We then adjust this amount for the fact that

[24] Importantly, our estimate of the litigation expenses associated with patent cases comes from a prior analysis of ours that is not limited to pharmaceutical patents. If we were to attempt to narrow the focus of the calculations underlying our prior work to the pharmaceutical patent space,

pharmaceutical patent lawsuits generally involve 2.87 patents. Accordingly, we estimate that the expected litigation expenses associated with a lawsuit-patent pair are $134,876.1. With 326 lawsuit-patent pairs avoided through our hypothetical reform, we estimate litigation savings of $44 million dollars.

All told, even when taking several conservative assumptions, we find that the estimated administrative savings arising from lower levels of federal litigation will more than double the added personnel expenses entailed with increasing examination time allotments for secondary patents by 50%. The case for expanding such allotments becomes even stronger when we consider the benefits beyond reduced litigation expenses—primarily, those benefits resulting from the earlier entry of generic competitors and the resulting reductions in drug prices that will come with that entry. We turn now to a discussion of these benefits.

*Accelerated Generic Entry*

By granting examiners additional time, the Patent Office may afford itself a greater opportunity to reject invalid secondary pharmaceutical patent applications. To the extent one such application would otherwise culminate in the last-expiring patent for a drug product, the rejection of the invalid 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.[25]

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.

[25] 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 arguably 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.

To estimate the acceleration of generic entry arising from the Patent Office issuing fewer invalid secondary patents, we begin by considering our results from Panel A of Figure II. In light of the 50% increase in time allocations implicit in giving GS-14 examiners the amount of time given to GS-11 examiners (after accounting for experience, cohort, year and other effects), our analysis in Figure II suggests that a 50% increase in time allocations is associated with a roughly 10 percentage-point reduction in the likelihood that an average secondary Orange Book patent is invalid. If one thinks of this effect in the aggregate over the full set of secondary patents issued, the increase in examination time can be expected to reduce some aggregate number of invalid patents issued by the Patent Office, where this number of fewer invalid patents issued equals 10% of the number of secondary patents generally issued per year. Some—though not all—of this aggregate amount of invalid secondary patents that are foregone through increased examination scrutiny could have otherwise been the last expiring patent associated with a drug product. In the case of those drug products where this is true, an increase in examination scrutiny will have accelerated generic entry for that drug.

To calculate just how large of an acceleration effect this represents for our sample, we randomly drop 10 percent of the secondary patents from the Orange Book sample and then determine the resulting reduction in the expiration date of the last patent in the chain of patents associated with each drug product in this sample. After doing this 100 times and considering the average reduction of this nature across each drug product, we estimate that the assumed 50% increase in time allocations will accelerate the expiration of the last patent of a given drug product by 82 days. Considering that roughly 164 drug products are approved each year, our results imply that a 50-percent increase in examination time for secondary patents in a given year will result in

13,448 days of earlier generic entry across the small-molecule pharmaceutical marketplace. This represents nearly 37 years of accelerated generic entry in the aggregate across this market.[26]

We acknowledge, of course, that some of those patents that are estimated to be invalidated through our assumed 50% increase in examination time would have otherwise been invalidated anyway in federal court via a Paragraph IV challenge. Accordingly, the net effect of a 50% annual increase in time allocations will be something short of an aggregate 37-year acceleration in generic entry. Paragraph IV challenges, however, would not be expected to *fully* accelerate generic entry for invalidly issued secondary patents—i.e., federal litigation is not an immediate and all-capturing backstop to the scrutiny applied by the Patent Office. After all, some patents may not even be challenged in the first place. And, for those that are challenged, there can be considerable delay between drug approval and a final court decision on the validity of the patent, during which time generics will still be unable to enter. Moreover, Paragraph IV challenges of secondary patents settle 37% of the time (Hemphill and Sampat 2012), where much of these settlements operate to maintain the delayed entry (Drake et al. 2014). With all sides of this issue in mind and taking an arguably conservative approach, we assume that roughly half of the acceleration in generic entry that could come from more substantive review at the Patent Office would have occurred any way due to federal litigation.[27] Even in this case, a 50-percent increase in examination time allotments annually for secondary patent applications will be associated with an aggregate acceleration in generic entry of nearly 18.5 years.

*Consumer and Total Surplus Gains*

[26] For instance, one could imagine 37 different drug products each having one year earlier generic entry. To be clear, this result is just based on an assumed one-year increase in examination time for secondary patents by 50 percent. If the Patent Office were to repeat this expansion every year for 10 years (and if all else stays the same), the net result would be an aggregate acceleration of generic entry across the marketplace of 370 years.

[27] Bear in mind of course that if the Patent Office were not to avoid these invalid patents through increased time allotments and if the courts would invalidate some of them instead, the outcome would be especially costly given the costs of litigation. This was the point of the litigation savings discussion above.

Recall that the Patent Office would need to incur roughly $20 million in additional expenses in order to enact the reform in question. While we demonstrated above that the savings from reduced litigation expenses alone would more than double these costs, let us assume for the moment—for the purposes of demonstration—that there are no litigation savings from expanding time allocations and the only savings would derive from earlier generic entry. This 18.5-year aggregate estimate of generic entry acceleration suggests that as long as the social benefits from a given drug product experiencing one-year earlier of generic entry surpasses $1.08 million, the benefits from this investment in added examination time will outweigh the costs.

Lower drug prices resulting from generic entry have the potential to (1) increase consumer surplus for those consumers who would have otherwise purchased even without generic entry and (2) increase overall surplus given the possibility of increased drug sales following generic entry. We assess each of the possible gains for a given FDA-approved drug product and, in turn, assess whether they meet this $1.08 million threshold. At the outset, we of course acknowledge that the relevance of this first possible gain depends on whether the relevant policymaker places independent weight on consumer surplus.

To facilitate an informal back-of-the-envelope calculation of these gains to consumer and total surplus, we set forth in Figure VIII a very elementary monopoly pricing scenario for a hypothetical drug (assuming a flat marginal cost curve and linear demand curve for the sake of simplicity). While still under patent protection, a brand-name manufacturer will produce until the point at which marginal revenue equals marginal costs, $Q_m$, and will set a corresponding price of $P_m$. Generic entry after patent expiration will push the market to a price and quantity of $P_c$ and $Q_c$.[28]

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

As stated above, we aim to provide a back-of-the-envelope calculation of the increase in consumer surplus for those that would have purchased anyway under monopoly pricing—that is, the area represented by rectangle *A*—along with the increase in total surplus—that is, the area represented by triangle *D*.

[Figure VIII here]

Let us begin with a calculation of the consumer-surplus gains represented by rectangle *A*. Since the area of *A* is essentially linked one for one with the height of $P_c$ relative to $P_m$, it can be readily observed that the area of rectangle *A* as a percentage of revenue ($C + A$) is equal to the percent price reduction resulting from generic entry, in which event *A* 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 in health economics and medicine. For instance, a recent report by the IMS Institute for Healthcare Informatics (2016) found that generics that entered the pharmaceutical marketplace between 2002 and 2014 reduced the price of drugs by 51 percent in the first year and 57 percent in the second year following loss of exclusivity (LOE), with notably higher reductions in the case of oral medications and notably higher reductions in more recent years. To be conservative, let us take the low end of the range identified by the IMS report and assume that prices will fall by 50 percent following generic entry. For the revenue estimate necessary to complete this calculation, we turn to a recent study by Ernie Berndt, Rena Conti and Stephen Murphy (2017), who report that the average revenue received by brand-name companies per drug product (based on 2016 data from the Quintiles IMS National Sales Perspective Data) is roughly $153.1 million.[29]

[29] This value itself is likely an underestimate of those revenues received during the patent exclusivity period as this averages over brand-name revenue received while the brand may still be competing with generics.

Together, these estimates suggest that the average gain in consumer surplus arising from one year of earlier generic entry for a given drug product—for those consumers who would have purchased the brand-name drug anyway—is roughly $77 million. This amount far exceeds the $1.08 million per year that we estimate it would cost in added examination scrutiny to accelerate generic entry by one year for a given drug product.[30]

Finally, we explore whether the reduction in deadweight loss (annualized) associated with a given drug product's generic entry is enough to surpass the roughly $1.08 million in additional Patent Office expenses needed to allow a 1-year acceleration in generic entry for a given drug product. 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). Averaging over the six molecules losing exclusivity discussed in 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—and assume that the analysis in Aitken et al. (2018) is representative of a typical small-molecule drug—to help provide a rough calculation of the reduction in deadweight losses that might arise from generic entry.[31]

For the reduced deadweight losses to surpass this $1.08 million cost-effectiveness threshold, the area of triangle *D* would have to be at least 1.4 percent of the area of rectangle *A*, in light of the estimated area of $77 million for rectangle *A*. Considering the possibility of a 4.6-percent increase in quantity implied by Aiken et al. (2018), one can view the base of triangle *D* as being

[30] As noted above, we estimated that a 50 percent increase in time allocations would result in 18.5 years of accelerated generic entry. Assuming 18.5 different drug products are each associated with one year of earlier generic entry, we estimate the annual aggregate consumer surplus gain associated with increased time allocations to be roughly $1.4 billion dollars.

[31] We also ignore any reduction in advertising expenses that may come from generic entry, but that would perhaps only strengthen the conclusion we reach anyway.

4.6 percent of the base of rectangle *A*. As such, it is indeed likely that the area of *D* is at least as large as 1.4 percent of the area of *A* and thus likely that the gains from reduced deadweight losses surpass the additional personnel expenses associated with the hypothesized reform.[32]

To be clear, even if the various assumptions underlying these simple consumer and total surplus calculations do not hold, the litigation savings alone more than account for the costs involved in increasing examiner time allotments.

## VI. 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 find no evidence that this is the case for active-ingredient patents, where we predict that time constraints are less likely to bind in the first place given the relatively more straightforward means of evaluating the novelty and non-obviousness of the chemical compounds themselves.

These findings shed light on pharmaceutical price reductions that may come from a reform—i.e., providing examiners with greater resources to assess the novelty and nonobviousness of pharmaceutical inventions—that inherently respects the balance between the harms of high drug prices and the benefits of spurred innovation through the promise of monopoly rents. That is, while producers may profit less from the accelerated generic entry that results from a reform of this nature, those lost profits will be focused on areas where the prospect of such profits were not needed to incentivize the creation of the idea at issue. In this sense, reforms to the administration of the Patent Office stand in contrast with more blunt approach such as price controls, unless such controls are specifically tailored to track the innovativeness of the relevant drugs.

[32] This can readily be shown graphically if one assumes that the demand curve is linear. Assume that the quantity sold under monopoly is at a level of Y. We are assuming that the quantity post generic entry will increase to 1.046Y, in which case the triangle's base will be 0.046Y. Assume the height of the rectangular region A is X. This will also be the height of the relevant triangle, in which case the area of rectangle A is XY and the area of the triangle is 0.046XY/2 or 0.023XY. In this case the area of the triangle D is 2.3 percent of the area of rectangle A.

We acknowledge that our analysis is inherently assuming that the legal patentability standards of novelty and nonobviousness (and other matters such as patent term lengths) are capable of achieving a favorable tradeoff between static monopoly costs and dynamic innovation incentives, with our analysis simply focusing on whether examiners should be given more time to apply these standards. In any event, even if such standards (or term lengths) are not optimally set and even if manufacturers may face insufficient incentives to innovate, it need not be the case that the second best response in such situations would be to continue with a lightened review at the Patent Office and allow brand-name manufacturers to receive additional monopoly protection based on obvious or non-novel ideas.

## REFERENCES


Acemoglu, Daron, and Joshua Linn. 2004. "Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry," *Quarterly Journal of Economics* 119(3):1049-1090.

Amin, Tahir, and Aaron S. Kesselheim. 2012. "Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could be Extended for Decades," *Health Affairs* 31 (10): 2286-2294.

Berndt, Ernst R., and Joseph P. Newhouse. 2012. "Pricing and Reimbursement in US Pharmaceutical Markets." in The Oxford Handbook of the Economics of the Biopharmaceutical Industry, edited by Patricia M. Danzon and Sean Nicholson, 201–65. NewYork: Oxford University Press.

Berndt, Ernst R., Deanna Nass, Michael Kleinrock, and Murray Aitken. 2015. "Decline inEconomic Returns from New Drugs Raises Questions about Sustaining Innovations," *Health Affairs* 34 (2): 245–52.

Berndt, ER, RM Conti, and SJ Murphy. 2017. "The Landscape of US Generic Prescription Drug Markets, 2004–2016," NBER Working Paper No. w23640.

Besanko, David, David Dranove, and Craigh Garthwaite. 2016. "Insurance and the High Prices of Pharmaceuticals," NBER Working Paper 22353.

Bognar, Katalin, John Romley, Jay Bae, James Murray, Jacquelyn Chou and Darius N. Lakdawalla. 2017. "The Role of Imperfect Surrogate Endpoint Information in Drug Approval and Reimbursement Decisions," *Journal of Health Economics* 51: 1-12.

Branstetter, Lee, Chirantan Chatterjee, and Matthew Higgins. 2016. "Regulation and welfare: evidence from paragraph IV generic entry in the pharmaceutical industry," *RAND Journal of Economics* 47(4): 857-890.

Budish, Eric H., Benjamin H. Roin, and Heide Williams. 2015. "Do Firms Underinvest in Long Term Research? Evidence from Cancer Clinical Trials." *American Economic Review* 105 (7): 2044–85

Cameron, A. Colin, Jonah G. Gelbach, and Douglas L. Miller. 2011. "Robust Inference with Multi-Way Clustering." *Journal Business and Economic Statistics* 29(2): 238-249.

Chandra, Amitabh, and Craig Garthwaite. 2017. "The Economics of Indication-Based Drug Pricing," *New England Journal of Medicine* 377: 103-106.

Cockburn, Iain, Jean Lanjouw, and Mark Schankerman. 2016. "Patents and the Global Diffusion of New Drugs," *American Economic Review* 106(1): 136-64.

Cohen, Wesley M., Richard R. Nelson, and Joseph P. Walsh. 2000. "Protecting Their Intellectual Property Rights: Appropriability Conditions and Why U.S. Manufacturing Firms Patent or Not." NBER Working Paper No. 7552.

Conti, RM, and ER Berndt. 2014. "Specialty Drug Prices and Utilization after Loss of US Patent Exclusivity, 2001–2007." NBER Working Paper No. 20016.

Danzon, Patricia, and Li-Wei Chao. 2000. "Does Regulation Drive Out Competition in Pharmaceutical Markets?," *Journal of Law and Economics* 43(2): 311-357.

de Ree, Joppe, and Rob Alessie, "Life Satisfaction and Age: Dealing with Underidentification in Age-Period-Cohort Models," *Social Science and Medicine*, 73 (2011), 177–82.

DiMasi, Joseph A., Henry G. Grabowski, and Ronald W. Hansen. 2016. "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs." *Journal of Health Economics* 47: 20–33.

Drake, Keith M., Martha A. Starr, and Thomas McGuire. 2014. "Do `Reverse Payment' Settlements of Brand-Generic Patent Disputes in the Pharmaceutical Industry Constitute an Anticompetitive Pay for Delay?," NBER Working Paper 20292.

Dranove, David, Craig Garthwaite, and Manuel Hermosilla. 2020. "Expected Profits and the Scientific Novelty of Innovation," NBER Working Paper w27093

Duggan, Mark, and Fiona Scott Morton. 2010. "The Effect of Medicare Part D on Pharmaceutical Prices and Utilization." *American Economic Review*, 100 (1): 590-607.

Feng, Joshua, and Xavier Jarevel. 2020. "Crafting Intellectual Property Rights," *American Economic Journal: Applied Economics* 12(1): 140-81.

Frakes, Michael, and Melissa Wasserman. 2016. "Patent Office Cohorts," *Duke Law Journal* 65: 1601-1655.

Frakes, Michael, and Melissa Wasserman. 2017. "Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents?: Evidence from Micro-Level Application Data", *Review of Economics and Statistics* 99(3): 550-563.

Frakes, Michael, and Melissa Wasserman. 2019. "Do Patent Law Suits Target Invalid Patents?," in SELECTION AND DECISION IN JUDICIAL PROCESS AROUND THE WORLD: EMPIRICAL INQUIRIES, ed. Yun-chien Chang, Cambridge University Press.

Garthwaite, Craig. 2012. "The Economic Benefits of Pharmaceutical Innovations: The Case of Cox-2 Inhibitors," *American Economic Journal: Applied Economics* 4(3): 116-37.

Duggan, Mark, and Craig Garthwaite. 2012. "Empirical Evidence on the Value of Pharmaceuticals," in The [Oxford] Handbook of the Economics of the Biopharmaceutical Industry: Oxford University Press: Oxford: 463-492.

Duggan, Mark, Craig Garthwaite, and Aparajita Goval. 2016. "The Market Impacts of Product Patents in Developing Countries," *American Economic Review* 106(1): 99-135

Giaccotto, Carmelo, Rexford Santerre and John Vernon. 2005. "Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry," *Journal of Law and Economics* 48(1): 195-214.

Goldman, Dana P., Darious N. Lakdawalla, Jessie D. Malkin, John Romley, and Thomas Philipson. 2011. "The Benefits from Giving Makers of Conventional 'Small Molecule' Drugs Longer Exclusivity Over Clinical Trial Data." *Health Affairs* 30 (1): 84–90

Grabowski, Henry, Carlos Brain, Anna Taub, and Rahul Guha, 2017. "Pharmaceutical Patent Challenges: Company Strategies and Litigation Outcomes," *American Journal of Health Economics* 3(1): 33-59.

Grabowski, Henry, and John Vernon. 1992. Brand Loyalty, Entry and Price Competition in Pharmaceuticals after the 1984 Drug Act," Journal of Law and Economics 35(2): 331-350.

Helland, Eric, and Seth Seabury. 2016. "Are Settlements in Patent Litigation Collusive? Evidence from Paragraph IV Challenges," NBER Working Paper 22194.

Hall, B. H., A. Jaffe, and M. Trajtenberg. 2001. "The NBER Patent Citations Data File: Lessons, Insights and Methodological Tools," NBER Working Paper 8498.

Hemphill, C. Scott, and Bhaven N. Sampat. 2012. "Evergreening, patent challenges, and effective market life in pharmaceuticals," *Journal of Health Economics* 31: 327-339.

Henderson, Rebecca, and Iain Cockburn. 1996. "Scale, Scope and Spillovers: The Determinants of Research Productivity in Drug Discovery," *RAND Journal of Economics* 28: 32–59.

Higgins, Matthew J., and Stuart J. H. Graham. 2009. "Balancing Innovation and Access: Patent Challenges Tip the Scale." *Science* 326 (5951): 370–71.

IMS Institute for Healthcare Informatics. 2016. Price Declines after Branded Medicines Lose Exclusivity in the U.S.

Jena AB, Calfee J, Mansley E, Philipson TJ. 2009. "Me-too innovation in pharmaceutical markets," *Forum for Health Economics & Policy* 12(1).

Joyce, Geoffrey F., and Neeraj Sood. 2016."Why Medicare Price Negotiation is the Wrong Prescription for Rising Drug Spending." *Journal of Policy Analysis and Management* 35(4): 956-963.

Kapczynski, Amy, Chan Park, and Bhaven N. Sampat. 2012. "Hydrates and Solvates and Salts (oh my!): Secondary Patents in Pharmaceuticals" *PloS ONE*, 12 December.

Kolstad, C. D., Ulen, T. S., and Johnson, G. V. 1990. “Ex Post Liability for Harm vs. Ex Ante Safety Regulation: Substitutes or Complements?” *American Economic Review*, 80(4): 888–901.

Lakdawalla, Darius. 2018. “The Economics of the Pharmaceutical Industry,” *Journal of Economic Literature* 56(2): 397-449.

Lakdawalla, Darius, and Tomas Philipson. 2012. “Does Intellectual Property Restrict Output? An Analysis of Pharmaceutical Markets,” *Journal of Law and Economics* 55(1): 151-187.

Lakdawalla, Darius and Neeraj Sood. 2009. "Innovation and the Welfare Effects of Public Drug Insurance." *Journal of Public Economics* 93(3-4): 541-548.

Nicholson, Sean, 2012, “Financing Research and Development,” in The Oxford Handbook of the Economics of the Biopharmaceutical Industry, edited by Patricia M. Danzon and Sean Nicholson. Oxford University Press.

Philipson Tomas, and Anupam B Jena. 2005. “Who benefits from new medical technologies? Estimates of consumer and producer surpluses from the new HIV/AIDS drugs,” *Forum for Health Economics and Policy, Forum: Biomedical Research and the Economy*, Article 3.

Lei, Zhen, and Brian D. Wright. 2017. “Why Weak Patents? Testing the Examiner Ignorance Hypothesis,” *Journal of Public Economics* 148: 43-56.

Lemley, Mark A.. 2001. “Rational Ignorance at the Patent Office,” *Northwestern University Law Review:* 1495–1532.

Lemley, Mark A. and Bhaven Sampat. 2012. “Examiner Characteristics and Patent Office Outcomes,” *The Review of Economics and Statistics* 94(3): 817–827.

Lichtenberg, Frank R. 1996. “Do (More and Better) Drugs Keep People Out of Hospitals?” *American Economic Review*, 86(2): 384–88.

Nordhaus, William, Invention, Growth, and Welfare (Cambridge, MA: MIT Press, 1969).

Panattoni, Laura E. 2011. “The Effect of Paragraph IV Decisions and Generic Entry BeforePatent Expiration on Brand Pharmaceutical Firms.” *Journal of Health Economics* 30(1): 126–45

Picard, Pierre M., and Bruno van Pottelsberghe de la Potterie. 2013. “Patent Office Governance and Patent System Quality,” *Journal of Public Economics* 104(14).

Reiffen, David, and Michael Ward. 2005. “Generic Drug Industry Dynamics,” *Review of Economics and Statistics* 87(1): 37-49.

Righi, Cesare, and Timothy Simcoe, “Patent Examiner Specialization,” mimeo (2017).

Sampat, Bhaven, and Kenneth Shadlen. 2017. “Secondary pharmaceutical patenting: A global perspective,” *Research Policy* 46(3): 693-707.

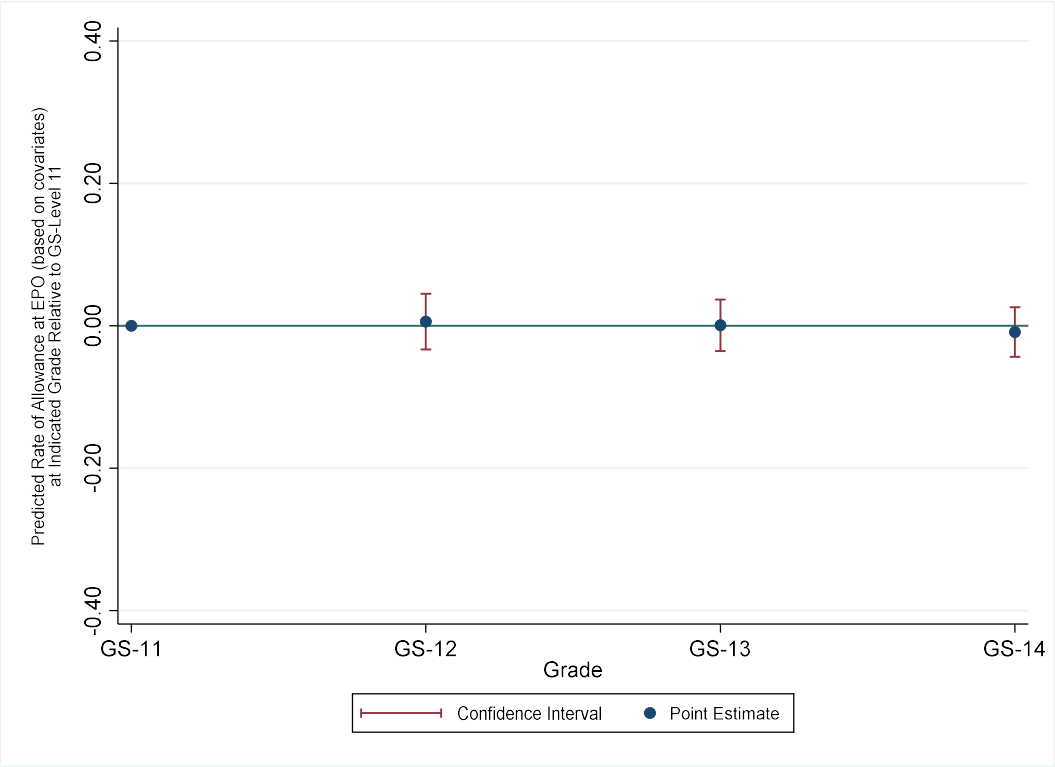
Sampat, Bhaven, and Heidi Williams. 2019. “How Do Patents Affect Follow-on Innovation? Evidence from the Human Genome,” *American Economic Review* 109(1): 203-36.

F.M. Scherer, 2006. “The Political Economy of Patent Policy Reform in the United States” (Dynamics of Insts. & Mkts. in Eur., Intellectual Prop. Rights Working Paper No. 26, 2006),

Scott Morton, Fiona M. 1999. “Entry Decisions in the Generic Pharmaceutical Industry,” *RAND Journal of Economics* 30(3): 421-440.

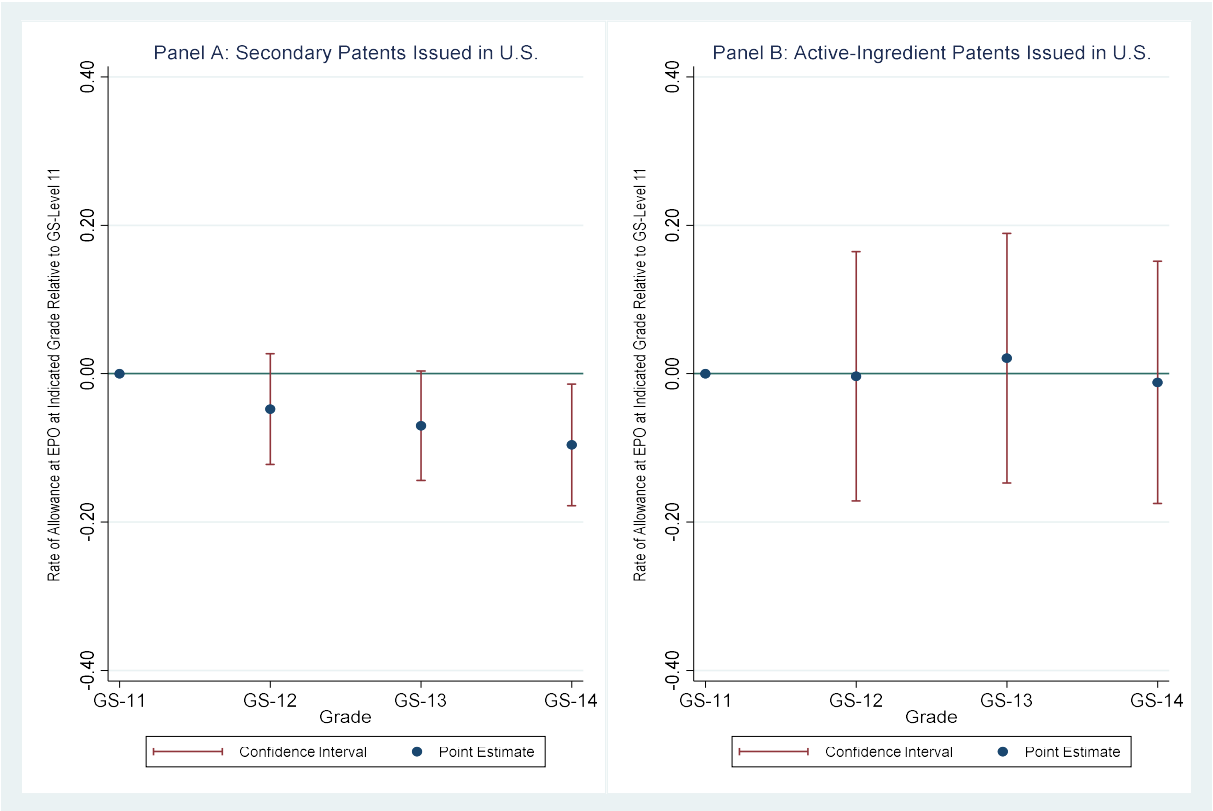
Shavell, Steven. 1984. “Liability for Harm Versus Regulation of Safety.” Journal of Legal Studies 13(2): 357-74.

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



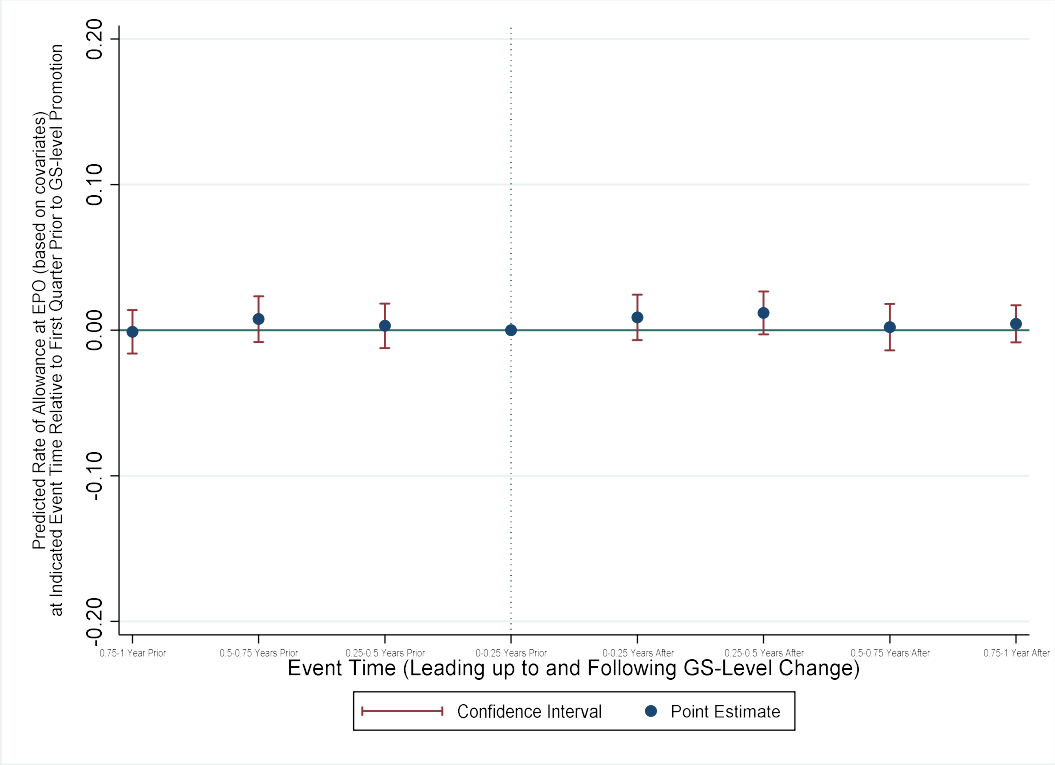

Notes: results are from a sample of 3,322 Orange Book patents (secondary and primary) issued in the U.S. and part of a family of applications at both the U.S. Patent Office and the European Patent Office. For each such patent, we form a predicted likelihood of allowance at the EPO based on a regression of the incidence of EPO allowance on the full set of covariates and on Art-Unit-by-year fixed effects. We then regress this predicted measure on the set of GS-level dummies and plot the resulting coefficients.

FIGURE II. 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



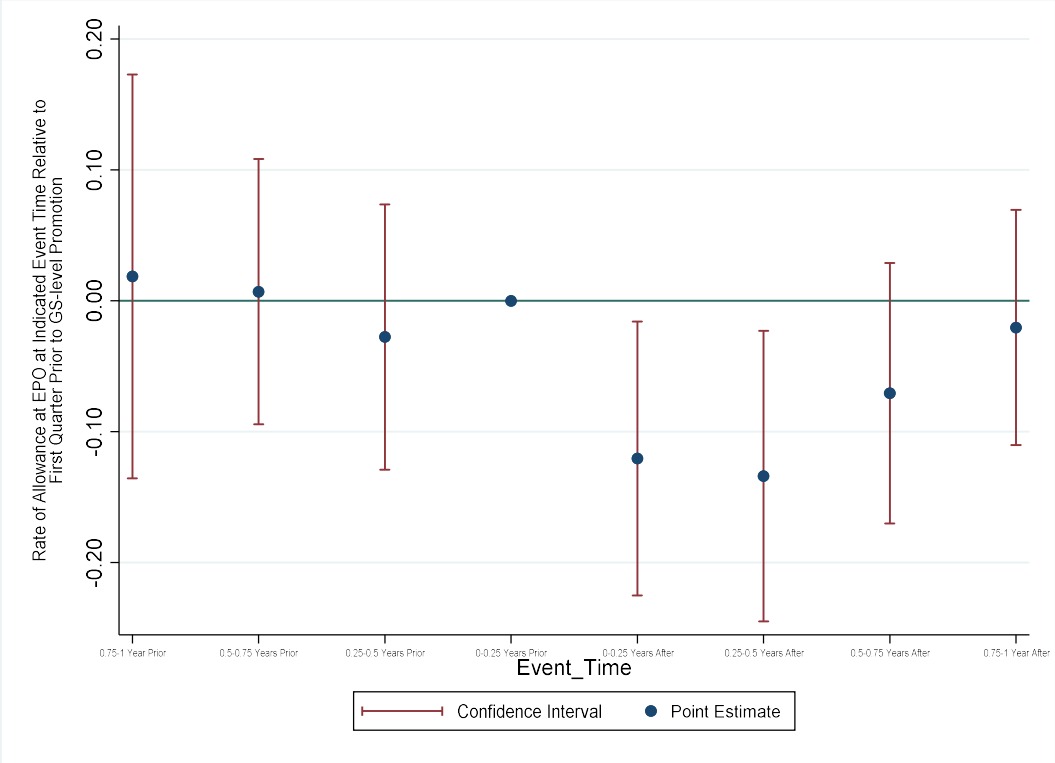

Notes: results in Panel A are from a sample of 2,678 secondary Orange Book patents issued in the U.S. and part of a family of applications at both the U.S. Patent Office and the European Patent Office. Results in Panel B are from a sample of 624 active-ingredient Orange Book patents issued in the U.S. 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-by-year level.

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



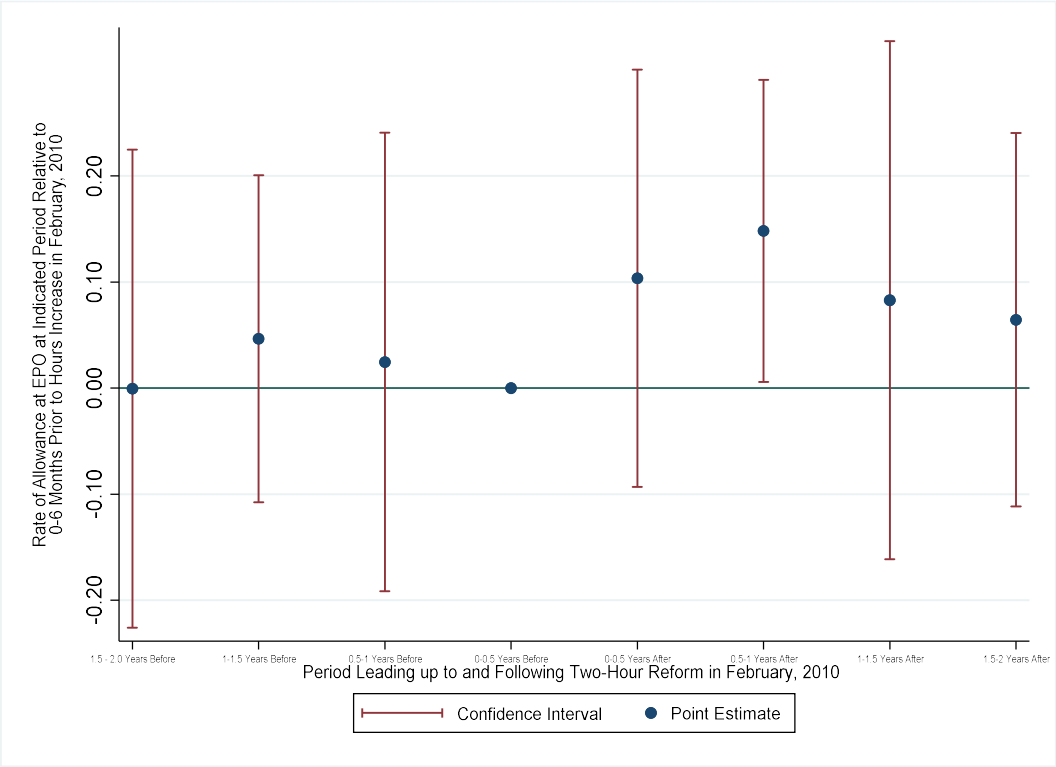

Notes: predicted EPO allowance outcomes are calculated as in Figure I. Figure III then plots the trend in these predicted outcomes over a generalized event window centered around GS-level promotions (in quarter increments).

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



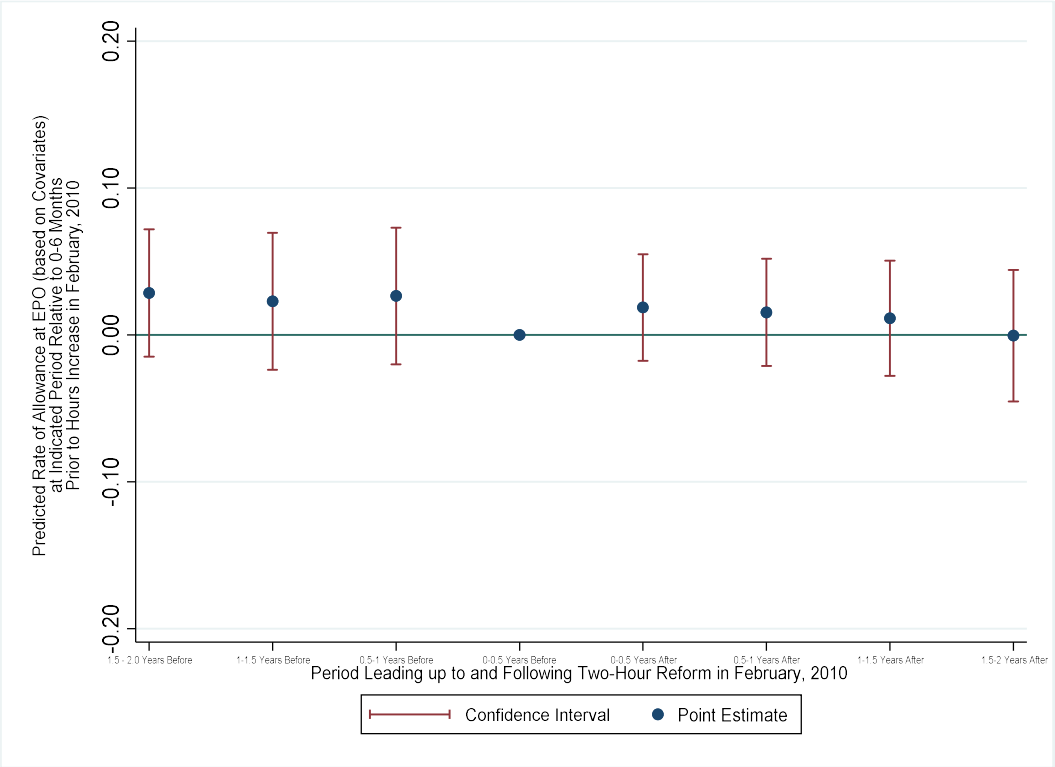

Notes: results are from a stacked sample of secondary Orange Book patents disposed of in a two-year (one on each side) event window around the reviewing examiners' promotions to GS-12, 13 and 14 (N=1069). The plotted coefficients represent the estimated coefficients of the event-time indicators from specification (3).

FIGURE V. 2010 TIME-ALLOCATION REFORM EVENT STUDY



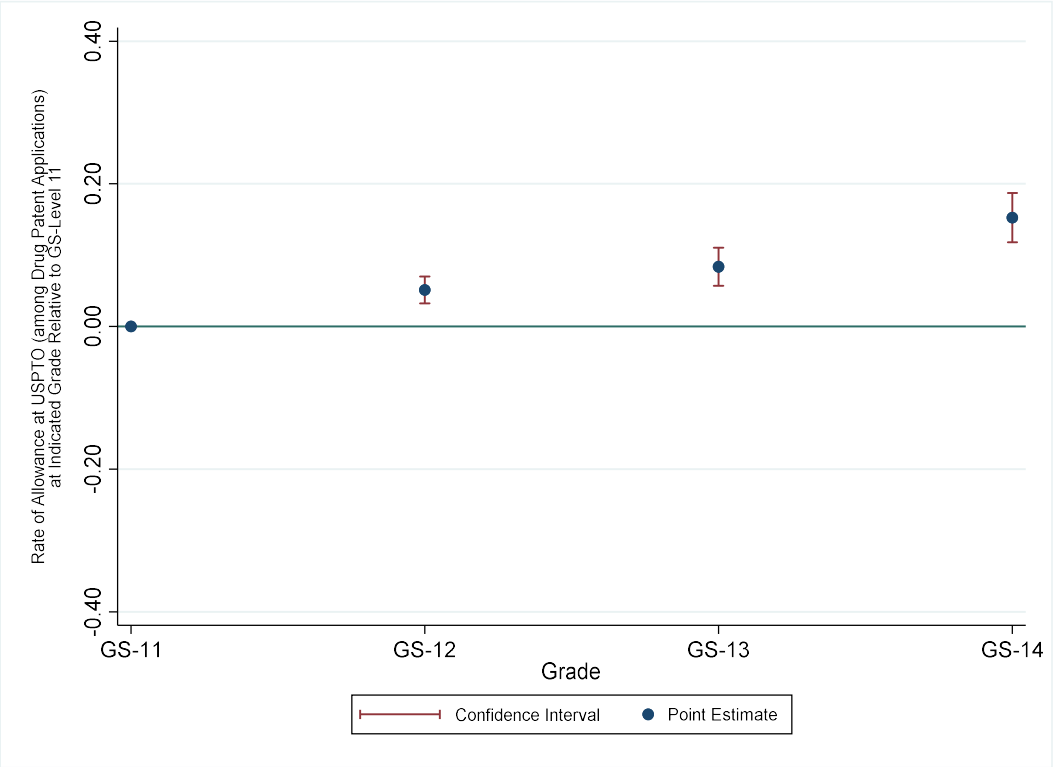

Notes: results are from a sample of secondary Orange Book patents disposed of in a four year (two on each side) event window around the February 2010 reform extending all examiners two additional hours to review applications. Specifications include the control variables indicated in specification (1)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

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




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

FIGURE VII. RELATIONSHIP BETWEEN LIKELIHOOD OF ALLOWANCE AT THE U.S. PATENT OFFICE OF PHARMACEUTICAL PATENT APPLICATIONS AND GRADE-LEVEL OF ASSIGNED EXAMINER, WITH EXAMINER FIXED EFFECTS




Notes: results are from a sample of 310,531 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 fixed effects (and using Art Unit and 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.

FIGURE VIII. IMPACT OF GENERIC ENTRY ON PRICES AND OUTPUT

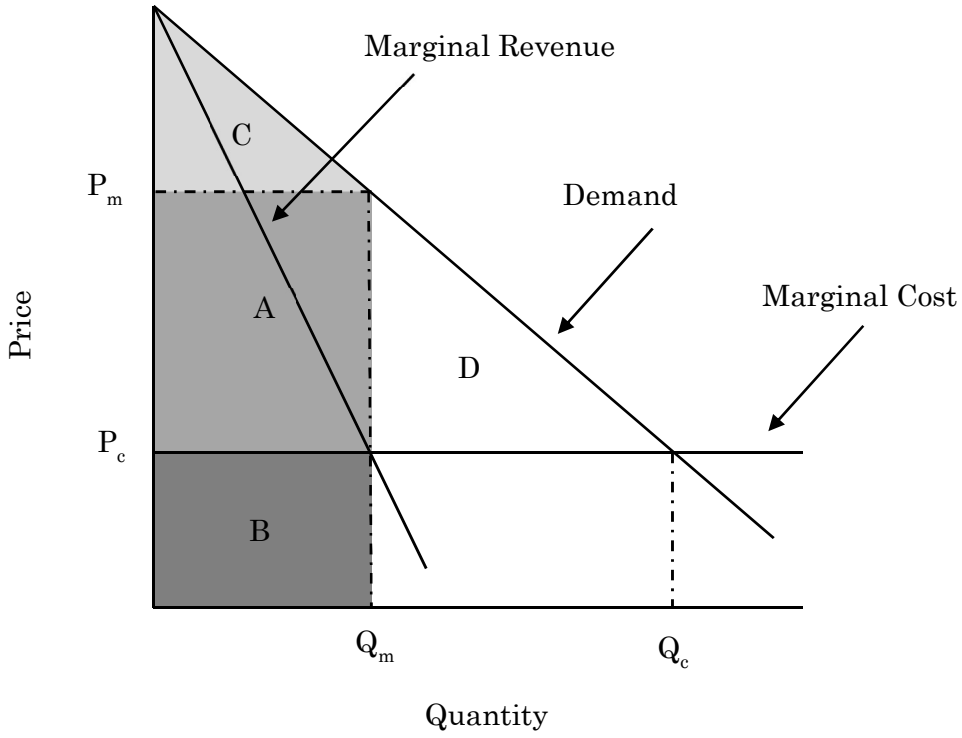


TABLE I: SUMMARY STATISTICS

| | (1) | (2) |
|---|---|---|
| | **Secondary Patents** | **Primary (Active-Ingredient) Patents** |
| Allowance at EPO | 0.84<br>(0.36) | 0.92<br>(0.27) |
| N (EPO Allowance) | 2,678 | 624 |
| Number of times asserted in litigation (post American Invents Act, issued over whole sample) | 1.10<br>(2.81) | 0.81<br>(2.87) |
| N (litigation, issued over whole sample) | 3177 | 661 |
| Number of times asserted in litigation (issued post AIA) | 1.26<br>(3.07) | 0.77<br>(3.31) |
| N (litigation, issued post AIA) | 1,883 | 276 |

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.

TABLE II: 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** |
| **Panel A. Window: One Year Pre- and Post-Event** | | |
| Post Promotion Event | -0.087*** | -0.019 |
| | (0.025) | (0.020) |
| N | 1,069 | 192 |
| **Panel B. Window: Two Years Pre- and Post-Event, Excluding Patents Issued by Examiners Promoted Again During Post-Event Window of any Event Sub-Sample** | | |
| Post Promotion Event | -0.053*** | 0.001 |
| | (0.019) | (0.026) |
| N | 1,821 | 329 |
| Mean of Dependent Variable | 0.84 | 0.92 |

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 (Panel A) or a four-year (two on each side) event window (Panel B) 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-by-year level and at the patent number level. * significant at 10%; ** significant at 5%; *** significant at 1%.

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

| | *(1)* | *(2)* |
|---|---|---|
| | SECONDARY PATENTS | ACTIVE INGREDIENT PATENTS |
| Post Hours Reform | 0.091** | -0.009 |
| | (0.039) | (0.043) |
| Number of Observations | 545 | 196 |

Notes: results are from a sample of secondary (Column 1) and primary (Column 2) Orange Book patents disposed of in a four year (two on each side) event window around the February 2010 reform extending all examiners two additional hours to review applications. Specifications include the control variables indicated in specification (1) in addition to GS-level fixed effects. Standard errors are reported in parentheses and are clustered at the Art-Unit-by-year level. * significant at 10%; ** significant at 5%; *** significant at 1%.

TABLE IV. RELATIONSHIP BETWEEN LITIGATION FREQUENCY AND GRADE-LEVEL OF EXAMINER ASSIGNED TO RELEVANT SECONDARY ORANGE BOOK PATENT

| | *(1)* | *(2)* |
|---|---|---|
| | NUMBER OF TIMES ASSERTED POST-AIA (SECONDARY PATENTS ISSUED FROM 2000-2016) | NUMBER OF TIMES ASSERTED POST-AIA (SECONDARY PATENTS ISSUED FROM 2012-2016) |
| **Panel A: Ordinary Least Squares Results** | | |
| Omitted: GS-11 | | |
| GS 12 | 0.277 | 0.043 |
| | (0.216) | (0.331) |
| GS-13 | 0.594** | 0.508 |
| | (0.255) | (0.416) |
| GS-14 | 0.737** | 1.08*** |
| | (0.299) | (0.385) |
| | 3,126 | 1,810 |
| **Panel B: Negative Binomial Results (Reported as Incidence Rate Ratios)** | | |
| Omitted: GS-11 | | |
| GS 12 | 1.379 | 1.010 |
| | (0.326) | (0.294) |
| GS-13 | 1.709* | 1.372 |
| | (0.486) | (0.467) |
| GS-14 | 2.027** | 2.374*** |
| | (0.586) | (0.756) |
| **N** | 3,126 | 1,810 |

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