A PRESCRIPTION FOR RISING DRUG PRICES: PATENT OFFICE REFORM

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The rising cost of biopharmaceuticals is of critical national concern. With a record number of Americans losing health insurance this past year, the struggle to afford prescription medicines will only intensify. The debate surrounding escalating prescription drugs prices has increasingly focused on the legitimacy of so-called secondary patents, or patents that protect peripheral features of the drug such as alternate formulations of the drug rather than an active ingredient. 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.

This Article explores 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. We find that a 50 percent increase in examination time per application over just one year at the Patent Office will result in a staggering 19 years of accelerated generic entry among the small-molecule marketplace. Our analysis also demonstrates that the benefits associated with increasing examiner time allocations far outweigh the costs of augmenting examiner review time for secondary patents. We find the case for expanding examination time to review secondary pharmaceutical patents is simply overwhelming.

INTRODUCTION

Michelle Dehetre, a mother of five, passed out at the wheel while driving her son home.[1] She was taken to the emergency room as her blood sugar dropped too low.[2] This was not an unusual occurrence for Michelle, as she cannot pay for her diabetes medication. Even with insurance, the medication costs nearly $300 a month.[3]

Pamela Holt has an incurable but treatable blood cancer.[4] The drug that will keep her cancer in remission costs more than $12,000 a year with insurance.[5] Pamela cannot afford this amount.[6]

Donnette Smith was born with a heart defect.[7] After Donnette's third heart surgery, she was told to dramatically reduce her cholesterol level.[8] Donnette's cardiologist believed a new drug could help but Donette's insurance did not cover the drug.[9] The price of the drug without insurance was $14,000 a year, an amount that is prohibitively expensive for Donnette.[10]

These stories are not uncommon. In 2019, approximately twenty percent of Americans did not fill at least one prescription due to financial considerations, while others rationed the drugs they did acquire.[11] With a record number of Americans losing health insurance in 2020, the struggle to afford prescription medicines, including vaccines or drugs developed to treat the coronavirus, will only intensify.[12]

In the United States, annual costs of prescription drugs exceed a half trillion dollars and account for nearly seventeen percent of the nation's personal health care bill.[13] Total medical expenditures are rapidly approaching twenty percent of the gross domestic product

[1]   *The Complex Web of Prescription Drug Prices, Part I: Patients Struggling with Rising Costs, Hearing before the Special Committee on Aging, United States Senate* (2019) (Statement of Michelle Dehetre) *available at* https://www.aging.senate.gov/imo/media/doc/SCA_Dehetre_3_6_19.pdf.
[2]   *Id.*
[3]   *Id.*
[4]   *The Complex Web of Prescription Drug Prices, Part I: Patients Struggling with Rising Costs, Hearing before the Special Committee on Aging, United States Senate* (2019) (Statement of Pamela Holt) *available at* https://www.aging.senate.gov/imo/media/doc/SCA_Holt_3_6_19.pdf.
[5]   *Id.*
[6]   *Id.*
[7]   *The Complex Web of Prescription Drug Prices, Part I: Patients Struggling with Rising Costs, Hearing before the Special Committee on Aging, United States Senate* (2019) (Statement of Donnette Smith) *available at* https://www.aging.senate.gov/imo/media/doc/SCA_Smith_3_6_19.pdf.*Id.*
[8]   *Id.*
[9]   *Id.*
[10]   *Id.*
[11]   Gallup-West Health National Healthcare Study, 2019, *available at* https://news.gallup.com/poll/268094/millions-lost-someone-couldn-afford-treatment.aspx.
[12]   *As Disease Sweeps The U.S., a Record 5.4 Million Americans Have Lost Health Insurance, Study Finds*, N.Y. TIMES (July 13, 2020) *available at* https://www.nytimes.com/2020/07/13/world/coronavirus-updates.html?action=click&module=Top%20Stories&pgtype=Homepage#link-4a45abca. Remdesivir, the first medicine shown to have an impact on coronavirus, is priced at over $3,100 for a course of treatment. Matthew Herper, *Gilead announces long-awaited price for Covid-19 drug remdesivir*, BIOTECH (June 29, 2020), available at https://www.statnews.com/2020/06/29/gilead-announces-remdesivir-price-covid-19/. Even before COVID-19 pandemic, approximately thirty percent of Americans who take prescription medications have seen their out-of-pocket expenses increase in 2019. Lisa L. Gill, *The Shocking Rise of Prescription Drug Prices*, CONSUMER REPORTS (Nov. 26, 2019).
[13]   NATIONAL ACADEMIES PRESS, MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE, at 11 (2018) [hereinafter NATIONAL IMPERATIVE].

in the United States, which represent the highest per capital expenditures in the world.[14] Prescription drugs are among the fastest growing segments of health care spending.[15] Given these facts, it is undeniable that the rising cost of biopharmaceuticals is a critical national concern.[16]

While arguably several factors have contributed to rising prescription drugs prices,[17] the debate on escalating costs of prescription medications has increasingly focused on the legitimacy so-called secondary pharmaceutical patents, or patents that protect peripheral features of the drug rather than its active ingredient.[18] Patents provide exclusive rights over a product for twenty years, enabling the rights holder (e.g., a brand name drug manufacturer) to charge higher than competitive prices to recoup their research and development costs.[19] After the twenty-year patent term expires, generics can enter the market, which drives down drug prices and increases access to life saving pharmaceuticals. In order to limit competition, pharmaceutical companies do not obtain a single patent on a drug product but instead a series of patents on different aspects of a drug.[20] The first patents are filed early in the research phase and typically claim the active ingredient of a drug.[21] Later in the drug discovery process, firms often attempt to acquire secondary patents on different formulations, dosages, or alternative forms of the drug's active ingredient.[22] Because patents expire twenty years from filing, these later-filed secondary patents extend the exclusivity period associated with the drug.

The legitimacy of secondary pharmaceutical patents have become such an important issue that secondary patents have been the subject of multiple reports by the National Academies and the Federal Trade Commission[23] as well as the target of Congressional reforms that seek to stem the rising costs of prescription medications.[24] At the heart of the secondary patents debate is a dispute about patent quality.[25] Critics of secondary patents

[14]   *Id.* at vii.

[15]   *Id.* at 12.

[16]   *Id.* at 1 ("The cost of biopharmaceuticals is a serious national concern with broad political implications.").

[17]   Aaron S. Kesselheim, *The High Cost of Prescription Drugs in the United States Origins and Prospects for Reform,* 316 JAMA 860–62 (2016) (discussing sources of high drug prices in the United States).

[18]   *See, e.g.*, *Id.* at 860 (2016) ("The most important factor that allows manufacturers to set high drug prices for brand-name drugs is market exclusivity . . . ."); IMAK, OVERPATENTED, OVERPRICED: HOW EXCESSIVE PHARMACEUTICAL PATENTING IS EXTENDING MONOPOLIES AND DRIVING UP DRUG PRICES (2018) (finding that twelve best selling drugs are associated with hundreds of patent applications which extend their monopolies far beyond twenty years).

[19]   *See* WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 299–300 (2003); FTC v. Actavis, Inc., 570 U.S. 136, 147 (2013) ("[Patent rights] may permit the patent owner to charge a higher-than-competitive price for the patented product.").

[20]   C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, patent challenges, and effective market life in pharmaceuticals*, 31 J. HEALTH ECON. 327 (2012) ("observers have identified the increasing acquisition of additional patents by brand-name drug makers . . . in order to delay generic competition.").

[21]   Tahir Amin & Aaron S. Kesselheim, *Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could be Extended for Decades*, 31 HEALTH AFFAIRS 2286, 2286 (2012).

[22]   *Id.* Amy Kapczynski, Chan Park, and Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, 7 PLOS ONE, 1, 4 (2012).

[23]   NATIONAL IMPERATIVE, *supra* note 13, at vii; FED. TRADE COM., REPORT ON STANDALONE SECTION 5 TO ADDRESS HIGH PHARMACEUTICAL DRUG AND BIOLOGIC PRICES, (2019); Luke M. Olson & Brett W. Wendling, *The Effect of Generic Drug Competition on Generic Drug Prices During the Hatch-Waxman 180-Day Exclusivity Period,* Working Paper No. 317 Bureau of Econ. Fed. Trade Com..(April 2013).

[24]   TERM Act of 2019, H.R. 3199; REMEDY Act, S. 1209/H.R. 3812; Second Look at Drugs Patents Act of 2019, S. 1617; Affordable Prescriptions for Patients Act of 2019; S. 1416; Orange Book Transparency Act of 2019, H.R. 1529; Biologic Patent Transparency Act, S. 659; Preserve Access to Affordable Generics and Biosimilars Act, S. 64/H.R. 2374.

[25]   Amin & Kesselhein, *supra* note 21, at 2286 ("A key question is to what extent these later-issued [secondary] patents protect valid features or methods, instead of serving as a business strategy to delay generic competition").

argue that such patents are of questionable legal validity, offering only trivial modifications over the active ingredient patent, and in many cases should not have been allowed to issue from the Patent Office in the first place.[26] Accordingly, such critics contend that secondary patents unfairly delay generics in the marketplace, keeping drug prices arbitrarily high.[27] Defenders contend that there is nothing inherently dubious about secondary patents, which are subject to the same requirements for patentability as any other patents.[28] Moreover, defenders argue that secondary patents stem from continuous research and development and offer important clinical and therapeutic benefits over the patent on the active ingredient.[29]

This Article does not wholly condemn or embrace secondary patents but instead takes a middle position. We contend that some secondary patents protect valid novel features and represent true innovation, hence warranting the extension in the exclusionary period of the brand name drug. Consider for instance, Lumigan, a drug which treats the eye disease glaucoma.[30] The original formulation of Lumigan had the side effect of severe red eye.[31] This side effect led patients to discontinue use of the drug without telling their physician, sometimes resulting in blindness.[32] Allergen, the manufacturer of Lumigan, developed a second formulation that reduced the adverse side effect and improved patient compliance.[33] The secondary patent associated with this improved formulation provided a significant clinical benefit over the primary patent and arguably warranted an extension in market exclusivity.

We also believe that other secondary patents provide little to no innovative benefit over the patent on the active ingredient and hence improperly delay generic entry. Consider for example, Buspar, a drug used to treat anxiety.[34] Bristol Myers Squib obtained a secondary patent on the metabolite of the active ingredient of Buspar on the eve of the active ingredient patent's expiration.[35] A metabolite of a compound is the modified form of the compound resulting from ingestion or metabolization.[36] Under standard patent law

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[26]   Julian W. Marrs, *Forever Green? An Examination of Pharmaceutical Patent Extensions*, 18 OR. REV. INT'L L. 81, 83-89 (2016); Aaron S. Kesselheim, *Think Globally, Prescribe Locally: How Rational Pharmaceutical Policy in the U.S. Can Improve Global Access to Essential Medicines*, 34 AM. J.L. & MED. 125, 136 (2008) ("Loose interpretation of patent law has permitted patent evergreening, where overly broad or otherwise inappropriate patents have been granted on peripheral aspects of pharmaceutical products . . . ."); Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 354 (2007) (noting that although "innovating firms have succeeded in getting [secondary] patents issued by the PTO," "[t]he industry's track record in actually winning these infringement claims . . . has been considerably worse"). Hemphill & Sampat, *supra* note 20, at 328–29.

[27]   *Id.*

[28]   GlaxoSmithKline, *GSK Public Policy Positions: Evergreening*, May 2019, at 1 https://www.gsk.com/media/2949/evergreening-policy.pdf ("Patents for improvements to existing products, in the field of pharmaceutical and other technologies are only available if they meet the requirements of patentability (i.e., that they are new, useful and involve an inventive step) as assessed by trained patent examiners."). Christopher M. Holman, Timo Minssen, and Eric M. Solovy, *Patentability Standards for Follow-On Pharmaceutical Innovation*, 37 BIOTECH. L. REPORT 131, 132 (2018); Christopher M. Holman, *In Defense of Secondary Pharmaceutical Patents: A Response to the UN's Guidelines for Pharmaceutical Patent Examination*, 50 IND. L. REV. 759 (2017); Christopher M. Holman, *Congress Should Decline Ill-Advised Legislative Proposals Aimed at Evergreening of Pharmaceutical Patent Protection*, 51 U. PAC. L. REV. 493 (2020).

[29]   *Id.*

[30]   Allergen, Inc. v. Sandoz, Inc., 796 F.3d 1293, 1298 (Fed. Cir. 2015).

[31]   *Id.*

[32]   *Id.*

[33]   *Id.* at 1298–99.

[34]   *In re Busprione Patent Litig.*, 185 F. Supp. 2d 340, 342 (S.D.N.Y. 2002).

[35]   *Id.* at 366.

[36]   A metabolite results when a compound is metabolized by the body into a modified form which continues to have its biological effects in the body.

principles, this secondary patent was invalid and should have never been issued by the Patent Office. Buspar had been marketed—and thereby ingested—long before Bristol Myers Squib applied for the secondary patent, in which event the metabolite of Buspar was in public use.[37] Moreover, patentability standards aside, the secondary patent provided no clinical benefit over the primary patent, as patients already benefited from the metabolite every time they ingested Buspar. Even though a court later found secondary patent invalid on summary judgment, its existence allowed Bristol Myers Squib to delay generic entry and hence keep the price for Buspar arbitrary high, for a significant period.[38]

Given that some secondary patents protect novel innovative inventions and others do not, we approach the drug pricing and patent practicing debate by asking how the Patent Office can more reliably sort pharmaceutical patent applications—i.e., grant patents only to those inventions that meet the patentability standards. In doing so, this Article makes two primary contributions to the literature. First, although patent quality is at the core of the secondary pharmaceutical patent debate, the existing literature on drug pricing reform largely ignores the role that can be played by the Patent Office.[39] This Article begins to rectify this deficiency by asking how the Patent Office can issue fewer invalid pharmaceutical patents, facilitating earlier generic entry and lower drug prices. Importantly, reorienting the drug pricing debate to focus on how the Patent Office can issue fewer invalid patents helps to neutralize the biggest objection to diminishing prescription medications prices: concerns that lower drug prices will stifle drug innovation.[40] Because the patentability standards are set to generally track the economic incentives to innovate, our approach, unlike more blunt proposals such as price controls or drug importation, focuses the lost profits on areas where the prospect of such profits was not needed to incentivize the creation of the drug or drug-feature (e.g., formulation) in the first instance.

How should we go about ensuring that the Patent Office issues higher quality pharmaceutical patents? A promising path forward—and one that is at the forefront of current policy discussions[41]—is to give patent examiners more time to evaluate applications

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[37]   *Id.* at 359. *See* Dan L. Burk and Mark A. Lemley, *Inherency*, 47 WM. & MARY L. REV. 371, 381 (2005) noting that the public has already obtained the benefit of a drug's metabolite by ingesting and metabolizing the drug).

[38]   *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 340, 359 (S.D.N.Y. 2002); *In re Buspirone Antitrust Litig.*, 183 F. Supp. 2d 363, 376 (S.D.N.Y. 2002).

[39]   To be sure, the role of patents themselves in the drug-pricing debate is front and center, with many noting the need for patents to stimulate innovation, while acknowledging that patents provide the foundation for elevated prices in the first place. See, e.g., F.M. Scherer, *The Political Economy of Patent Policy Reform in the United States* 6–8, 13 (Dynamics of Insts. & Mkts. in Eur., Intellectual Prop. Rights Working Paper No. 26, 2006), *available at* http://www.dime-eu.org/files/active/0/IPRWORKING-PAPER-26_Scherer.pdf. Most commentators, scholars and policymakers addressing drug pricing reform, however, often treat the patent system as a fixed constant and turn to such tools as price controls or government bargaining power. *See, e.g.*, Rachel Sachs, *Understanding the House Democrats' Drug Pricing Package*, HEALTH AFFAIRS BLOG, September 19, 2009, available at https://www.healthaffairs.org/do/10.1377/hblog20190919.459441/full/ (summarizing recent Congressional drug-pricing bills focused on government negotiating powers and controls on drug-price growth rates). Less common are studies or policy discussions that propose changes to the administration of patent system as a way to address drug prices. *But see*, Amin and Kesselheim, *supra* note 21 at 2292 (proposing a pre-patent-grant opposition mechanism and a raising of the bar for patentability standards for secondary drug features).

[40]   Dhruv Khullar and Peter B. Bach, *3 Actions Congress Can Take to Reduce Drug Prices*, HARVARD BUSINESS REVIEW (2020) ("Drug companies argue . . . regulating prices would cripple research budgets, stifle innovation, and lead to fewer treatments in the future); *see also* Joseph Golec, Shantaram Hedge, & John A Vernon, *Pharmaceutical R&D Spending and Threats of Price Regulation*, 45 J. FIN & QUAN. ANAL. 239 (2010) (documenting a link between R& D spending and pharmaceutical profits).

[41]   Request for Comments on Examination Time Goals, 81 FED. REG. 73,383 (Oct. 25, 2016). Patent examiner time allocations have not been substantially modified since 1976.

and to perform this critical sorting task. Because patent applications are presumed valid upon filing, if examiners are unable to find and articulate a basis of rejection in the allotted time, they are legally expected to allow the patent.[42] Accordingly, insufficient examination time may cause examiners to allow patents that lack validity. In the case of secondary patents, this may lead to unnecessary delays in generic entry, leaving consumers with prolonged periods of elevated drug prices. Notably, there have been strong anecdotal sentiments that time constraints facing patent examiners indeed bind in practice. Recent reports commissioned by the federal government bemoan that examiners believe they are "fighting for their lives" and are "not [given] enough time to do a proper job."[43]

For our second contribution, this Article uses sophisticated empirical methodologies to both test whether giving patent examiners more time to review patent applications on peripheral drug features will actually increase the quality of issued pharmaceutical patents and to conduct a cost benefit analysis of this reform. In doing so, this Article brings much needed empirical evidence to the secondary patents debate, which has been the subject of much policy attention, but little analysis.[44] We begin this exercise by compiling a novel database on individual pharmaceutical patents—along with various outcomes associated with such patents—from information collected by the Patent Office, the Food and Drug Administration (FDA), the Organisation for Economic Co-operation and Development, the Lex Machina litigation database, and certain other sources. Using these data, we then construct various markers reflective of the legal validity associated with U.S.-issued drug patents.

To empirically investigate the link between examination time and these various markers of the legal validity, we primarily rely upon the fact that examiners incur a roughly 10-15 percent decrease in time allocations upon each promotion up the General-Schedule (GS) pay scale. Taking advantage of an application-assignment process that is effectively random, we explore whether examiners issue secondary patents of more dubious validity when they undergo promotions that leave them with substantially less time to review applications. We also employ a host of additional methodological approaches to help ensure that we are isolating the effects of time, as distinct from other factors that are correlated with examiner GS levels, including drawing on a second source of time variation that is independent of examiner's GS-level.

We find evidence that current time allotments are causing the Agency to issue invalid secondary patents and that expansions in time allotments will therefore result in the Agency issuing fewer invalid secondary patents that unnecessarily delay generic entry. More specifically, we find that a 50-percent increase in examination time is associated with a 10 percentage-point decrease in the likelihood that the Patent Office will issue invalid secondary

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[42]   Because patent applications are presumed valid, if examiners are not able to conduct a sufficient search of prior art and articulate a proper basis of rejection over these hours, they are legally expected to allow the application. *See* Sean B. Seymore, *The Presumption of Patentability*, 97 MINN. L. REV. 990, 995–96 (2013) ("An applicant enjoys a presumption of patentability, which means that at the time of filing the application is rebuttably presumed to comply with the utility, novelty, nonobviousness, and disclosure requirements of the patent statute.").

[43]   MANHATTAN STRATEGY GRP., PATENT EXAMINERS PRODUCTION EXPECTANCY GOALS RE-ASSESSMENT AND ADJUSTMENT STUDY, at D-9 (2010) (on file with author) (quoting patent examiners participating in a focus group).

[44]   Amin & Kesselheim, *supra* note 21, at 2287 ("Although secondary patenting is both common and controversial, few researchers have rigorously analyzed this practice.").

patents. Drawing on this estimate, we simulate that a 50 percent increase in examination time per application over just one year at the Patent Office will result in a staggering 19 years of accelerated generic entry among the small-molecule marketplace.

Finally, we conduct a cost benefit analysis associated with our proposed reform. We estimate that a 50 percent increase in examiner time allocations for pharmaceutical patents will only cost the Patent Office roughly $20 million per year in additional expenses but will generate marketplace and other gains that vastly exceed this amount. Consider those individuals who would still consume the drug products in question while they are under patent protection. Even though access to the marketplace for these consumers does not turn on the timing of generic entry, they may gain considerably to the extent they are able to benefit from lower drug prices. Even when taking various conservative assumptions, our results suggest that the hypothesized increase of 50% in examination time will generate an astronomical $1.4 billion in annual gains to these consumers. Another set of consumers—i.e., those like Michelle, Pamela, and Donnette above—will benefit from acquiring access to the marketplace in the first place following the resulting price reductions. We conservatively estimate an additional $34.2 million in welfare gains annually from this expanded access. Moreover, by addressing the problem of invalid secondary patents at the examination stage, society may also avoid costly downstream litigation that would have been triggered by the issuance of invalid drug patents. Our analysis implies that the court fees and attorney expenses that could be saved because of these litigation effects generate an additional $44 million in savings. Altogether, the case for expanding examination time to review secondary pharmaceutical patents is simply overwhelming.

This Article proceeds in seven parts. Part I provides a background on drug discovery and the import of patents to biopharmaceutical innovation. Part II outlines the patent examination system and our hypothesis that giving examiners more time to review secondary pharmaceutical patent applications will result in increasing the quality of these issued patents. Part III discusses our data and methodology. Part IV presents our results. Part V sets forth the various social benefits associated with augmenting the time examiners spend reviewing patent applications, such as litigation savings and increases in consumer surplus associated with earlier generic entry. Part VI sets forth the various social costs associated with increasing the time examiners have to review patent applications. Part VII concludes that because the benefits associated with increasing examiner time allocations far outweigh the costs of augmenting examiner review time for secondary patents, society should increase the resources to the Patent Office. Finally, Part VII provides some specifics as to how the Patent Office should increase examiner time allocations.

I.   DRUG DISCOVERY AND PATENTS

A. The Import of Patents to Pharmaceutical Innovation

Drug discovery and development is one of the riskiest and most expensive scientific endeavors. It is estimated that only one out of ten thousand lab-tested compounds

successfully completes human clinical trials and can be marketed in the United States.[45] The process of identifying promising lead compounds and subsequently obtaining Food and Drug Administration's (FDA) approval takes on average ten to fourteen years.[46] It is estimated that it costs 200 million to over a billion dollars to bring to market a new chemical entity—that is, a chemical compound that has not yet been approved by the FDA.[47] Of course, not all drug discovery involves new chemical entities. A substantial portion of biopharmaceutical innovation is more incremental in nature.[48] Brand pharmaceutical companies also focus their drug discovery efforts on modifying existing drug products such as changing the dosage or route of administration.[49] Such efforts are significantly less risky and costly to pursue than the development of a new chemical entity.[50]

In contrast, drug development of generics pharmaceuticals, which are copies of the brand-name drugs, is relatively cheap and fast. To gain FDA approval, generics developers do not need to conduct extensive human clinical trials like brand-name pharmaceuticals. Instead, the manufacturer of a generic pharmaceutical must submit an Abbreviated New Drug Application (ANDA) in which they must demonstrates their product is "bioequivalent" to the brand.[51] As a result, generic-drug manufacturers spend on average only $2 to 5 million on the approval process.[52] The lower development costs of generic drugs are reflected in their prices, which are typically 85% less than their brand counterparts.[53]

Once a generic drug enters the market, it dramatically reduces the sales of the brand-name drug it imitates.[54] State substitution laws typically require the pharmacists to substitute the cheaper, generic version when a physician prescribes the brand-name medication, unless the physician specified otherwise.[55] These laws facilitate generic market

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[45] 21 U.S.C. § 355(d) (2018). *See generally* DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA 465–543 (2010) (detailing the organizational politics around reviews of new drugs).

[46] *See New Drug Application (NDA)*, U.S. Food & Drug Admin., https://www.fda.gov/ Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/d efault.htm (last updated Mar. 29, 2016) (providing an overview of the approval process for new drugs); *see also* Henry G. Grabowski & John M. Vernon, *Effective Patent Life in Pharmaceuticals*, 19 INT'L J. TECH. MGMT. 98, 103–04 (2000) (describing the FDA regulatory process).

[47] *See, e.g.*, Christopher P. Adams & Van V. Brantner, *Estimating the Cost of New Drug Development: Is It Really $802 Million?*, 25 HEALTH AFF. 420, 420 (2006) (estimating a total cost of $868 million); Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL & DECISION ECON. 469, 469, 475 (2007) (estimating a total R&D cost per drug of $1.24 billion for large-molecule biopharmaceuticals); Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 180–83 (2003) (estimating a total R&D cost per drug of $802 million).

[48] U.S. Gen. Accounting Office, GAO-07-49, *New Drug Development*: *Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts* 17 (2006) (finding that New Drug Applications submitted from 1993 through 2004 approximately 60% were modifications to existing drugs).

[49] *Id.*

[50] *Id.* at 28 (noting that "drugs which have a very similar chemical formulation to drugs already on the market . . . are less risky to develop because the safety and efficacy of the drugs on which they are based have already been studied.").

[51] *See* 21 U.S.C. § 355(j) (2006) (laying out the abbreviated FDA application process for generic drugs).

[52] Big Generic Pharma, ECONOMIST, July 30, 2005, at 58.

[53] FEDERAL TRADE COMMISSION, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS (2010) at 8.

[54] CONG. BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 16 (2006); *see* Richard G. Frank & Erica Seiguer, *Generic Drug Competition in the U.S.*, *in* BUSINESS BRIEFING: PHARMATECH 56, 56–58 (2003), *available at* http://www.touchbriefings. com/download.cfm?fileID=493 (contending that generic manufacturers have seen significant gains in market share vis-à-vis brand-name manufacturers because of lower pricing).

[55] ALISON MASSON & ROBERT L. STEINER, GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES: ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS, 1 (1985) ("As of mid-1984 all states have laws allowing pharmacists some choice in selecting which brand of drug to dispense in filling a prescription that names a specific brand. The stated purpose of these drug

penetration; a generic version of the drug routinely captures 90% of the market within a few months of launch.[56] Given these market realities, it is unsurprising that brand name pharmaceutical firms regularly report that patent protection, which keeps generics off the market for some time period, is critical to their efforts to bring new drugs to market.[57] In fact, drug development is routinely acknowledged as an area where patents are vital to promoting innovation.[58]

B. Primary and Secondary Patents

Brand pharmaceutical firms typically obtain a series of patents associated with an approved drug.[59] The first patents associated with a drug are typically filed early in the research phase—i.e., before human clinical trials commence.[60] This initial patent often protects a potential active ingredient that forms the basis of the new drug.[61] Patents on the active ingredient of a drug product are referred to as primary patents.[62] A primary patent is often the strongest means of protecting a newly invented drug.[63]

In addition, pharmaceutical companies almost always file patents on peripheral features of the drug, typically later in the drug development process.[64] These patents are referred to as secondary patents and have narrower protection than primary patents. One such example of a secondary patent is a formulation patent, which typically claim the combination of an active drug ingredient with various inactive ingredients that allow for the delivery of the active ingredient.[65] Some types of formulations relate to the mode of the administration, such as capsules, gels, tablets, or topical formulations.[66] Other formulation patents may allow for sustained release or increase the shelf-life or stability of the drug.[67] Another example of a secondary patent is a method-of-use patent.[68] A method-of-use patent

product selection (DPS) laws is to lower the prices consumers pay for prescription drugs through substitution of lower-price version of the drug for the higher-priced brands typically prescribed by physicians.").

[56]   FEDERAL TRADE COMMISSION, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS (2010) at 8.

[57]   For a concise summary of this evidence, *see* Scherer, supra note 39 at 6-8, 12. *See also* Henry G. Grabowski & John M. Vernon, *Effective Patent Life in Pharmaceuticals*, 19 INT'L J. TECH. MGMT. 98, 109–17 (2000); Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 MANAGERIAL & DECISION ECON. 491, 492 (2007).

[58]   *See also* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1676–77 (2003) (using pharmaceutical development as an example of where the patent system is essential for promoting innovation).

[59]   Hemphill & Sampat, *supra* note 20, at 327 ("observers have identified the increasing acquisition of additional patents by brand-name drug makers [for a single drug product] . . . ."); Amin & Kessleheim, *supra* note 21, at 2286 (brand name pharmaceutical companies often "additional patents beyond the original patents that protect the drug's underlying active ingredient and disease targets.").

[60]   Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 539 (2009) ("Pharmaceutical patents are typically filed when drugs are in early preclinical research . . . ."); Harold C. Wegner & Stephen B. Maebius, *The Global Biotech Patent Application*, *in* BIOTECHNOLOGY LAW: BIOTECHNOLOGY PATENTS & BUSINESS STRATEGIES IN THE NEW MILLENNIUM 87, 129–30 (2001).

[61]   Amin & Kessleheim, *supra* note 21, at 2286.

[62]   *Id.*

[63]   Anyone who makes, uses, or sells a product in which the molecule is present infringes the primary patent. 35 U.S.C. § 271 (2018).

[64]   Amin & Kessleheim, *supra* note 21, at 2286.

[65]   JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 48 (3rd ed. 2015).

[66]   *Id.*

[67]   GlaxoSmithKline, *GSK Public Policy Positions: Evergreening*, May 2019, at 2 https://www.gsk.com/media/2949/evergreening-policy.pdf ("Patents cannot give exclusive rights for things that are already known or obvious. Therefore, patents for modifications of existing products, sometimes referred to as 'secondary patents', are necessarily narrower in scope than what has gone before.").

[68]   THOMAS, *supra* note 65, at 54.

claims a method of using the drug for medical treatment, such as a method for treating cancer by administration an effective amount of drug A.[69] A third example of secondary patent includes patents on different crystalline structures or polymorphs of the active ingredient.[70] A pharmaceutical compound in a solid state may exist either in a crystalline structure, which has orderly molecular relationship with an identifiable state, or an amorphous state, which lacks molecular ordering.[71] The different arrangements of crystalline structure are termed polymorphs.[72] The crystalline structure of a drug may affect its biologic activity and its ability to be manufactured.[73]

It is undeniable that brand-name firms have an incentive to extend the exclusivity of their first patent by filing and obtaining secondary patents. Because patents expire twenty years from filings, the primary patent expires before later filed secondary patents.[74] Further, it is critical to note that the exclusory effect of patents is notably stronger in pharmaceutical markets than in markets for other goods. That is, if a company invents a new printer, it can sell that printer on the market and take a calculated risk that its product does not infringe any patents or that any such infringed patents are invalid. Not so in the pharmaceutical market.

The Hatch Waxman Act, which governs competition between brand and generic pharmaceutical companies,[75] links FDA approval of generics to the patent rights associated with brand drugs. Brand name pharmaceuticals are required to list patents that would be infringed if a generic is launched before the expiration of these patents in what is known as the Orange Book.[76] 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.[77] 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.[78]

Paragraph (I) and (II) certifications do not affect FDA's ability to approve the generic drug.[79] If the generic applicant makes a Paragraph (III) certification, however, FDA may not

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[69]   *Id.* In situations where an inventor discovers a new therapeutic use for a known active ingredient—situations in which the active ingredient may already be patented—method-of-use patents are the typical way in which patent protection is sought. In this scenario, the "pioneering" or first patent filed associated with a drug product is a secondary patent, not a primary patent.

[70]   *Id.* at 50.

[71]   *Id.*

[72]   *Id.*

[73]   *See* HOWARD C. ANSEL ET AL., PHARMACEUTICAL DOSAGE FORMS AND DRUG DELIVERY SYSTEMS (10th ed. 2013).

[74]   35 U.S.C. 154.

[75]   Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, §101, 98 Stat. 1585, 1585–92 (1984). The statue's goal are two-fold: to incentive drug innovation through the protection of patent rights of brand-name drug manufacturers while facilitating earlier generic entry to ensure the access of these medicines at reasonable prices. *See* H.R. Rep. No. 98-857, pt. 1, at 14–15 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647.

[76]   More specifically, FDA regulations require brand name pharmaceutical to list patents that claim the active ingredients, drugs products, or method-of-use patents that would be infringed if a generic is launched in the Orange Book. 21 C.F.R. 314.53.

[77]   21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

[78]   There is a narrow exception to this certification process. With respect to patents that claim a method of using a drug, the generic applicant may file a "section viii" statement when seeking approval only for a use that is not claimed in the listed patnet. 21 U.S.C. § 355(j)(2)(A)(vii).

[79]   *Id.* at § 355(j)(5)(b)(i).

approve the generic version of the drug until the patent at issue has expired.[80] A Paragraph (IV) certification triggers the Hatch Waxman's specialized patent dispute procedures, which often results in litigation.[81] The generic applicant must give notice of its intent to market the drug and the Paragraph (IV) certification to the patentee and brand-name manufacturer.[82] The patent holder then has forty-five days to sue the generic applicant.[83] If the brand-name manufacturer sues, the FDA cannot approve the generic for up to thirty months while the parties litigate the patent dispute—even if the patent listed in the Orange Book is likely invalid.[84] This blocking effect of Orange Book listed patents creates a strong incentive for brand-name pharmaceutical companies to obtain additional, secondary patents even if they are of low quality.[85] Finally, as an incentive for a generic to enter the market, Hatch-Waxman also provides 180 days of marketing exclusivity to the first generic to make a Paragraph (IV) certification.[86]

The average number of patents per drug has been steadily rising since Hatch-Waxman was enacted in 1984.[87] Pharmaceutical companies obtain more secondary patents for more profitable drugs.[88] On average, a secondary patent adds 6 to 7 years of patent life to an approved drug.[89] Consider for example, Lipitor, which is one of the bestselling pharmaceuticals of all time.[90] Pfizer listed six patents in the Orange Book for Lipitor.[91] The primary patent on the active ingredient for Lipitor, U.S. Patent No. 4,681,893, was filed in 1986.[92] Subsequently Pfizer obtained a series of secondary patents, including U.S. Patent No. 7,902,206 which claimed novel polymorphs of the active ingredient of Lipitor. The '206 Patent expired six years after the primary patent and helped generate a staggering $125 billion dollars in Lipitor sales for Pfizer.[93]

The key question is whether these secondary, later-issued patents protect valid novel features and represent true innovation, hence warranting the extension in the exclusionary period of the brand-name drug or its slightly modified version.[94] Or instead, do these secondary patents provide little to no innovative benefit over the patent on the active ingredient and hence improperly delay generic entry? As the examples outlined in the Introduction suggests, some secondary patents likely protect novel, genuine follow-on innovation whereas others are likely invalid and offer no innovative advance over the

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80   *Id.* at § 355(j)(2)(B)(i)-(iv).

81   Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.SD. 399, 407 (2012).

82   21 U.S.C. § 355(j)(5)(b)(ii).

83   *Id.*

84   21 U.S.C. § 355(i)(5)(b)(iii).

85   Amin & Kesselheim, *supra* note 21, at 2286 ("Pharmaceutical manufacturers therefore have an incentive to extend market exclusivity for their products as long as possible.").

86   21 U.S.C. § 355(j)(5)(b)(iv).

87   Hemphill & Sampat, *supra* note 20, at 619–20.

88   Kapczynski, et al., *supra* note 22, at 5.

89   *Id.* tbl3 at 7.

90   Linda A. Johnson, *Lipitor beat tough odds on way to top*, HOUSTON CHRONICLE (Dec. 28, 2011).

91   *Pfizer Inc. v. Apotex Inc.*, 44 F. Supp. 2d 758, 761 (N.D. Ill. 2010). Linda A. Johnson, *Lipitor beat tough odds on way to top*, HOUSTON CHRONICLE (Dec. 28, 2011).

92   Runjhun Randon, Nitin Tandon & Rajesh Kumar Thepar, *Patenting of Polymorphs*, 7 PHARM. PAT. ANAL. 59, 60 (2018).

93   *Id.* Linda A. Johnson, *Lipitor beat tough odds on way to top*, HOUSTON CHRONICLE (Dec. 28, 2011).

94   *See supra* notes 30-38 and accompanying text. Admittedly, in the product hopping example even if the secondary patent is valid, we may have antitrust concerns. See Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167 (2017).

primary patent.[95] As a result, this Article proceeds by asking how the Patent Office can more effectively screen the valid from invalid secondary patents. More specifically, this Article asks if we give patent examiners more time to review patent applications, are they more likely to allow higher quality secondary pharmaceutical patents?

II.   PATENT EXAMINATION

Every patent application filed with the Patent Office contains a specification, which describes the invention, and a set of claims that defines the metes and bounds of the legal rights the applicant is seeking.[96] Before it enters examination, an application is 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 randomly assigns the application to a specific examiner.[97]

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. An examiner can deny a patent on the grounds that the claimed invention does not involve statutory subject matter,[98] that the invention is not useful,[99] that the application fails to satisfy the disclosure requirements,[100] that the invention is not new,[101] or that the invention is obvious—i.e., represents only a trivial advance over the background art.[102] In reality, this rejection and acceptance process is somewhat iterative in nature, often entailing some back and forth between the examiner and applicant.[103] Though these details are not critical for the discussion to follow, we provide further background on this process in the Online Appendix (in addition to further information on the random assignment process).

A. Examination-Time Allocations

On average, a U.S. patent examiner spends only twenty hours reviewing an application associated with a drug,[104] including reading the application, searching for prior art, comparing the prior art with the application, writing a rejection, responding to the patent applicant's arguments, and often conducting an interview with the applicant's attorney. If, over these hours, examiners are unable to conduct a sufficient search of prior art and

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[95]   For an excellent summary of clinical benefits flowing from valid secondary patents, *see* Holman, *supra* note 28.
[96]   35 U.S.C. § 112.
[97]   A recent paper by Cesare Righi and Timothy Simcoe documents evidence of examiner specialization within technology-group assignments, as well as specialization within technology subgroups. Cesar Righi & Timothy Simcoe, *Patent Examiner Specialization*, 48 RES. POL'Y 137, 141 (2019). However, Righi and Simcoe's analysis finds "little evidence" suggesting that applications are assigned to examiners based on the impor4tance or claims breadth of the applications or on their patent worthiness. *Id.* at 147.
[98]   35 U.S.C. § 101.
[99]   *Id.*
[100]   35 U.S.C. § 112.
[101]   35 U.S.C. § 102.
[102]   35 U.S.C. § 103.
[103]   *See* Phillips v. AWH Corp., 415 F.3d 1303, 1317 (Fed. Cir. 2005) (en banc) (calling patent prosecution "an ongoing negotiation between the PTO and the applicant" over the scope of the invention).
[104]   Michael D. Frakes & Melissa F. Wasserman, *Irrational Ignorance at the Patent Office*, 72 VAND. L. REV. 975 (2019); Online Appendix tbl.A2.   The Online Appendix is *available at* http://vanderbiltlawreview.org//lawreview/2019/04/online-appendix-to-irrational-ignorance-at-the-patent-office/. [hereinafter, *Irrational Ignorance*]

articulate a proper basis of rejection, they are legally expected to allow applications.[105] In light of this legal presumption of validity, one might predict that a further tightening of time constraints will only cut the underlying search and evaluation period shorter and cause examiners to error even further on the side of allowing additional patents on the margin that might have otherwise been rejected if given sufficient time.[106]

The Patent Office sets expectations regarding the amount of time examiners should spend on applications.[107] The number of hours allocated for review depends on both the technological field in which the examiner is working and on her position in the general schedule (GS) pay scale.[108] A patent examiner in a more complex field is provided more hours to review an application than an examiner of the same grade who is working in a less complex field.[109] The higher the pay grade of an examiner within a technology area the fewer number of hours the Patent Office extends to that examiner.[110] A promotion to each subsequent pay grade is roughly equated to a ten percent decrease in the number of allocated examination hours.[111] As discussed below, examiners in the pharmaceutical Art Units predominantly start at GS-11. At the beginning of our sample period, GS-11 examiners reviewing drug patents applications were allocated 23.2 hours. This amount decreased to 21.0 hours for GS-12 examiners, 17.5 for GS-13 examiners, and 15.6 for GS-14 examiners.[112]

Finally, in February 2010, the Patent Office increased the time allocations of all examiners by two hours.[113] In the empirical analysis below, we will primarily explore the effects of examination time on examination quality by drawing on variations in time allotments that come with changes in examiner GS-levels. However, drawing on variation in time allotments stemming from the 2010 reform will provide a useful robustness check on these primary results. In particular, this latter reform analysis will allow us to overcome hypothetical concerns that the GS-level results derive from factors other than time that also change upon GS-level promotions, taking advantage of the fact that this latter source of variation is not at all related to GS-levels.

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[105]   *See* Seymore, *supra* note 42, at 995–96 ("An applicant enjoys a presumption of patentability, which means that at the time of filing the application is rebuttably presumed to comply with the utility, novelty, nonobviousness, and disclosure requirements of the patent statute.").

[106]   That is, the legal landscape leads to a simple prediction that time constraints will produce a bias towards granting, as opposed to producing symmetrical noise in the examination process. We discuss the reasonableness of this prediction further in the Online Appendix. In other words, given this underlying legal structure, insufficient examination time is expected to lead produce one-sided, rather than two-sided errors.

[107]   These time allotments have largely remained unchanged since 1976 (discussed further in the Online Appendix).

[108]   U.S. DEP'T COMM., OFFICE OF INSPECTOR GEN., USPTO SHOULD REASSESS HOW EXAMINER GOALS, PERFORMANCE APPRAISAL PLANS, AND THE AWARD SYSTEM STIMULATE AND REWARD EXAMINER PRODUCTION 7 n.6 (2004), https://www.americanbar.org/content/dam/aba/migrated/intelprop/109legis/CommerceDept_IGReportonPTO.authcheckdam.pdf [https://perma.cc/G94G-62T4] ("Expectancy goals vary among examiners and are based on the individual examiner's grade level and the complexity of the technology under review.").

[109]   Andy Faile, Deputy Comm'r for Patent Operations, Examination Time and the Production System, Presentation at the Santa Clara-Duke Quality Conference (Sept. 9, 2016), http://1x937u16qcra1vnejt2hj4jl-wpengine.netdna-ssl.com/wp-content/uploads/FaileExamination-Time-and-the-Production-System.pptx [https://perma.cc/4S3N-GKDB].

[110]   *Id.*

[111]   *See* U.S. PATENT & TRADEMARK OFFICE, HOW THE USPTO DETERMINES PRODUCTION FOR USPTO PATENT EXAMINERS at 1 (on file with author).

[112]   Further details regarding the patent examiner promotion process can be found in the Online Appendix.

[113]   USPTO JOINT LABOR AND MANAGEMENT COUNT SYSTEM TASK FORCE, OVERVIEW OF COUNT SYSTEM INITIATIVES AND CHANGES at 7 (U.S. Patent & Trademark Office PowerPoint, Mar. 8, 2010), *available at* http://www.uspto.gov/sites/default/files/patents/init_events/Count_System_changes-Overview_3-8-2010.ppt.

B. Hypothesis

When given sufficient time, we assume examiners will conduct their examination practices in line with proper patentability standards. However, tightening of time constraints—e.g., that arising through GS-level promotions—may force examiners of this otherwise competent disposition to decrease the degree to which they search prior art, decrease their ability to extend meaningful rejections and thus increase the propensity by which they grant patents of questionable validity. Concomitantly, patent examiners of otherwise competent disposition facing binding time constraints that are relaxed—e.g., such as the 2010 policy change at the Patent Office that gave all examiners an additional two hours to review an application—may increase the degree to which they search prior art, increase their ability to extend meaningful rejections and thus decrease the propensity by which they grant invalid patents. Assuming an otherwise competent examination process, patent examiners, regardless of whether they are facing binding time constraints, will deny the clearly invalid patent or grant the clearly valid patent. Time pressures are most likely to manifest in the review of patent applications with respect to which it is more difficult to determine whether the claimed invention meets the patentability standards.

There are reasons to believe that the examination of secondary patents is more likely to be affected by binding time constraints than the examination of primary patents. In other words, on average it is more difficult and time consuming to determine whether the modification of a known chemical compound—i.e., such as controlled release formulation of a known compound—is patentable than to determine whether a chemical compound is patentable. Why? To begin, 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.[114] The Patent Office has long had strong search capabilities for chemical structures limiting the time needed for an effective search of the prior art.[115] Moreover, patent law provides relatively clear rules for when a compound that is structurally similar to a known compound is patentable, which also reduces the time necessary to determine if the active ingredient is novel and nonobvious—i.e., represents more than a trivial advancement over the prior art.[116] For example, a compound that is structurally similar to a known compound may be patentable—more specifically may be deemed not obvious—if the compound has chemical properties that are unexpected of the known compound.[117]

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[114]   JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 106–07 (2008) (noting that boundaries of patents that claim chemicals are relatively clear).

[115]   JAYCE GARNETT AND VERONICA CALDERHEAD, CHEMISTRY in MANUAL OF ONLINE SEARCH STRATEGIES 151-52 (C.J. Armstrong & J.A. Large eds., 2 ed. 2018) (discussing chemical abstracts and scientific and technical information network comprehensive database for searching chemical structures); U.S. Patent & Trademark Office, Commercial Data Bases Available at USPTO, *available at* https://www.uspto.gov/learning-and-resources/support-centers/scientific-and-technical-information-center-stic/commercial (noting the commercial data bases available at the USPTO including scientific and technical information network and chemical abstracts).

[116]   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. Richard C. Levin, et al. *Appropriating the Returns from industrial Research and Development*, in BROOKINGS PAPERS ON ECONOMIC ACTIVITY 798 (1987) (noting the uniqueness of chemical structure makes it easier to demonstrate patentability relative to other inventions).

[117]   In re Papesch, 315 F.2d 381, 381 (C.C.P.A. 1963).

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. To begin, the search for the relevant prior art can be more challenging.[118] Ideally, 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 it treats.[119] Second, equally as difficult and nuanced 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 skill in the art to modify the existing prior art to achieve a modification of a known compound, such as its mode of administration, is arguably less clearly delineated.[120] We have 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).[121]

Beyond the difficulties associated with reviewing secondary relative to primary patents, there is a second although closely related reason to believe that binding time constraints are more likely to affect the review of secondary relative to primary patents. As noted above, assuming a competent examination process, binding time constraints are more likely to affect the marginally issued patent. Examiners, regardless of time pressure, will grant the clearly valid patents and reject the clearly invalid patents. There is growing empirical evidence that an issued secondary patent, on average, is of a more marginal quality than is an issued primary patent, on average. Secondary patents that are litigated to finality, for instance, are far more likely to be invalidated than primary patents that are litigated to finality.[122] As discussed below, our own quality indicator suggests that primary patents are of stronger validity than secondary patents.[123]

In summary, we predict that binding time constraints are more likely to manifest during the review of secondary relative to primary patent applications and hence increasing examination time will likely have a greater effect on the quality of issued secondary relative to primary patents.

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[118]   Telephone Interview with Patent Exam'r No. 1, U.S. Patent & Trademark Office (March 3, 2020); Telephone Interview with Patent Exam'r No.2, U.S. Patent & Trademark Office (May 20, 2020); Telephone Interview with Patent Exam'r No. 3, U.S. Patent & Trademark Office (May 23, 2020).

[119]   Telephone Interview with Patent Exam'r No. 1, U.S. Patent & Trademark Office (March 3, 2020).

[120]   Telephone Interview with Patent Exam'r No. 1, U.S. Patent & Trademark Office (March 3, 2020); Telephone Interview with Patent Exam'r No.2, U.S. Patent & Trademark Office (May 20, 2020); Telephone Interview with Patent Exam'r No. 3, U.S. Patent & Trademark Office (May 23, 2020).

[121]   Telephone Interview with Patent Exam'r No. 1, U.S. Patent & Trademark Office (March 3, 2020); Telephone Interview with Patent Exam'r No.2, U.S. Patent & Trademark Office (May 20, 2020); Telephone Interview with Patent Exam'r No. 3, U.S. Patent & Trademark Office (May 23, 2020).

[122]   Hemphill & Sampat, *supra* note 20, at 328 ("Later issued, later expiring patents tend to be weaker, in the sense that a court is less likely to conclude that they are valid and infringed by a competing generic product.").

[123]   *See infra* Part IV.

III.   Data

We draw on several sources of data in this investigation into the relationship between the amount of time allocated to examiners who review secondary and active-ingredient pharmaceutical patents listed in the Orange Book and the validity of said patents.

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 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 the National Bureau of Economic Research (NBER).[124]

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 the examiner is assigned.[125] For each examiner in our PAIR database, we obtained information from a Freedom-of-Information-Act (FOIA) Request regarding the precise time—to the day—of each GS-level promotion that the relevant examiner received over their 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.).[126]

C. Patent Family Data and 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

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[124]   [Hall, B. H., A. Jaffe, and M. Trajtenberg. 2001. "The NBER Patent Citations Data File: Lessons, Insights and Methodological Tools," NBER Working Paper 8498.]. Specifically, to identify drug patents, we use the Patent class field in the PAIR data and merge in a Patent-class / technology-category cross-walk developed by the NBER.

[125] We treat the individual who did the majority of work on the application as the examiner charged with reviewing that application—the nonsignatory examiner, when both a nonsignatory and an examiner with signatory authority are associated with an application, or the signatory examiner, when only one examiner is associated with an application.

[126]   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.

validity for these purposes, we follow our earlier work[127] and that of others[128] and focus on a subset of U.S.-issued patents whose underlying innovations were also the subject of patent applications at the European Patent Office (EPO), a patent office with essentially similar patentability standards to that of the U.S. We then 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. In other words, we treat a U.S. issued Orange Book patent as valid if its "twin" application is allowed at the EPO.[129]

Underlying this approach is the view that the EPO is often thought of as the "gold standard" in patent quality.[130] The EPO invests substantially more resources per application in the examination process than the U.S. Patent Office.[131] EPO examiners also work in teams, unlike in the U.S., providing a greater opportunity to catch mistakes in applying the underlying patentability standards.[132] Furthermore, there is some evidence that the EPO may be able to attract and retain higher quality employees relative to the U.S. Patent Office. EPO examiners, for example, are paid nearly twice as much as their American counterparts and tend to view their job as prestigious, often spending the duration of the careers at the agency.[133] In contrast, the U.S. Patent Office has been plagued with high attrition, as U.S. examiners often advance professionally by leaving the agency.[134]

While this benchmarking analysis rests on the idea that the patentability standards between the U.S. and Europe are highly similar, it does not necessarily require that they be exactly the same. Our aim is primarily to use the EPO outcome to provide a *signal* of validity and then to test whether variation in examination time—which, in our primary approach will come from observing GS-level promotions—are associated with differences in this validity signal. Slight differences in standards between the U.S. and Europe may add some noise to

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[127]   Michael D. Frakes & Melissa F. Wasserman, *Is the Time Allocated to Review Patent Applications Inducing Examiners To Grant Invalid Patents?: Evidence from Micro-Level Application Data*, 99 REV. ECON. & STAT. 550, 560 (2017).

[128]   Zhen Lei & Brian D. Wright, *Why Weak Patents? Testing the Examiner Ignorance Hypothesis*, 148 J. PUB. ECON. 43, 44 (2017); Mark A. Lemley & Bhaven Sampat, *Examiner Characteristics and Patent Office outcomes*, 95 REV. ECON. & STAT. 817, 823 (2012).

[129]   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. In the proceeding analysis, we actually take this point one step further and assume that the U.S.-issued patent is actually "valid" if it is allowed at the EPO and "invalid" if it is rejected at the EPO, as opposed to simply being more likely to be valid if allowed at the EPO and more likely to be invalid if rejected at the EPO. This assumption will allow for greater tractability in deriving welfare implications from our findings—i.e., it will allow us to more concretely identify the number of invalid secondary pharmaceutical patents that could be avoided by giving examiners a specified increase in time to review patents.

[130]   Colleen Chien, *Comparative Patent Quality*, 50 ARIZ. ST. L.J. 71, 74 (2018) ("[T]he European Patent Office ("EPO"), whose covered GDP is comparable to the USPTO's and which in recent years has come to be viewed by many as the 'gold standard' in patent quality . . .).

[131]   Pierre M. Picard & Bruno van Pottelsberghe de la Potterie, *Patent Office Governance and Patent System Quality*, 104 J. PUB. ECON. 14, 16–17 (2013) (presenting "stylized facts on differences between the U.S. Patent and Trademark Office (USPTO), the European Patent Office (EPO), and the Japan Patent Office (JPO)").

[132]   European Patent Office, Examination procedure, *available at* https://jobs.epo.org/content/Examination/?locale=en_GB.

[133]   Pierre M. Picard & Bruno van Pottelsberghe de la Potterie, *Patent Office Governance and Patent System Quality*, 104 J. PUB. ECON. 14, 17 (2013) (presenting "stylized facts on differences between the U.S. Patent and Trademark Office (USPTO), the European Patent Office (EPO), and the Japan Patent Office (JPO)").

[134]   *Id*.

this endeavor, but do not in any way impose bias in our estimated relationship between time allocations and validity.[135]

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.[136] We elect to focus on an EPO benchmark as our primary approach given that examiners there both work in teams and are extended more time per application than 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.

We acknowledge that not all U.S. patentees whose patents are listed in the Orange Book also file for protection at the EPO (and the JPO), implicating concerns that our results may not generalize to all Orange Book patents. Appeasing these concerns, however, we note that over 86% of the Orange Book patents are indeed associated with a family of applications filed at both the EPO and the JPO (as compared with a corresponding figure of 27% in the case of all patents listed in the PAIR data across all technologies).

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.

These summary statistics immediately suggest 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. After all, the vast majority of secondary patents exhibit a market suggestive of legal validity. 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. As our ultimate welfare analysis will demonstrate, these patents have

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[135]   That is, some degree of the rejections at the EPO that we observe for "twin" applications of U.S.-issued patents might not necessarily reflect inadequate examination at the U.S. We acknowledge that some of this might instead reflect different substantive standards across the patent systems. Any effect of this nature, however, would be expected to play out the same way for applications reviewed by GS-11, GS-12, GS-13 and GS-14 examiners. Nonetheless, theories of the impacts of time constraints on quality leave us to predict that GS-level promotions that tighten examination time constraints will impact the quality of review. Given this theoretical foundation, if we observe different EPO outcomes across these different GS-levels, that effect should target the examination-quality features of this EPO benchmarking metric—i.e., the validity signal—and net out any noise that might stem from slight differences in patentability standards.

[136]   It is generally thought that JPO's quality of issued patents fall in between those of EPO and U.S. PTO. *Id.* at 15.

such substantial marketplace impacts that even improving matters on the margin will lead to considerable social gains.

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

As discussed above, examination time is a simple function of two elements: (1) the technology associated with the application and (2) the General-Schedule level of the assigned examiner, where each GS-level promotion is associated with a roughly 10-15% reduction in examination time. Since applications are not randomly assigned across technologies but are randomly assigned within technologies across GS-levels, our basic strategy is to exploit variations along this GS-level dimension. We take several fundamental sub-approaches in this regard.

To begin, we look within technology-by-year groups—that is, the level at which applications are assigned—and compare validity outcomes across examiner GS levels, using EPO outcomes to proxy for patent validity (as discussed above).[137] The idea is that within assignment group, the GS-14 examiners are given considerably less time than the GS-11 examiners but are nonetheless not assigned applications of different levels of patent worthiness due to the (effectively) random assignment process. If time constraints are crowding out the ability to apply the patentability requirements, one might therefore predict that the GS-14 examiners will be more likely to issue invalid patents relative to the GS-11 examiners. We will test for evidence of this outcome.

The chief challenge with this approach is that, while random assignment alleviates concerns over differences in application characteristics across examiners, other aspects of the examiner herself may be correlated with her GS-level and may also impact the quality of the examination review. In our first, motivating step to confront this challenge, we take a control-function approach and explore the relationship between examiner GS-levels and EPO outcomes while accounting for the potentially confounding influence of the following examiner-related factors that our prior work[138] predicted may correlate with GS-levels: (1) the experience in years of the examiner (since GS-level promotions do not occur perfectly lockstep with experience, it becomes possible to disentangle an experience and GS-level effect), (2) the hiring-year cohort of the examiner (at any point in time, higher GS-level examiners will have been part of earlier hiring cohorts, and our previous work has demonstrated the significance of examiner cohort effects in explaining levels of examiner scrutiny)[139], and (3) the ultimate tenure of the examiner with the Patent Office (e.g., one may be concerned that the GS-11 examiners consist of a greater number of individuals who will

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[137] By technology, we are referring to the specific Art Unit within the Patent Office.
[138] Frakes & Wasserman, *supra* note 127 at 560.
[139] Michael D. Frakes & Melissa F. Wasserman, *Patent Office Cohorts*, 65 DUKE L.J. 1601, 1602, 1605 (2016).

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, a consideration that is concerning given the possibility that examination quality may differ between career examiners and those using this position as a springboard to industry).

To effectuate this approach, will consider 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 and will then regress whether the relevant patent is also allowed at the EPO—our primary validity metric—on a series of indicator variables capturing the various GS-levels. Given that examiners reviewing pharmaceutical patents typically enter the Patent Office with advanced degrees and thus start at the Patent Office at GS-level 11 or 12, we focus this regression analysis on those examiners between GS-levels 11 and 14. We exclude a dummy variable for GS-11 to leave it as the reference group, in which event the coefficients for the GS-12, 13 and 14 dummies can be interpreted as the likelihood of EPO-allowance for the indicated GS-level relative to that of GS-11.

Of course, we do not simply intend to present average differences in validity outcomes across GS-levels. Our goal is to explore the link between examination time and validity outcomes while using GS-level promotions to leave us with variation in examination time. To better isolate the time-allocation aspect of this GS-level variation, it is important to control for the influence of factors that may be correlated with examiner GS-levels and that likewise may impact patent validity. Accordingly, this regression controls for a range of other factors, including (i) a series of fixed effects to capture different examiner experience groups, hiring-year cohorts and examiner tenure groups, to address the concerns raised earlier in this Subpart, (ii) technology-by-year fixed effects, such that we allow for completely fixed differences in EPO outcomes across different technology-by-year cells and thereby ensure that we are comparing outcomes across GS-levels within the same unit of application assignment, and (iii) a range of observable application characteristics, including such characteristics as small-entity-size status, [140] 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.[141]

Given an application assignment process that is tangential to patent worthiness, there is arguably little concern of bias arising from unobservable application characteristics. Nonetheless, as just discussed, we control for a range of available characteristics. In the Online Appendix, we demonstrate that these fundamental application characteristics are balanced across the examiners at different GS-levels in our sample, confirming the contention that applications are effectively randomly assigned to examiners within Art Units.

In Panel A of Figure I, we present estimated GS-level coefficients from this regression, focusing specifically on the sub-sample of secondary patents sample (Table A1 of the Online Appendix provides the estimated coefficients for the remaining variables included in the

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[140]   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).

[141]   Primarily, we estimate linear probability models, though the results are nearly unchanged when estimate logit specifications. We cluster the standard errors at the level of assignment to account for correlation in unobservables within assignment groups.

regression underlying Figure I). We find a precipitous monotonic drop in EPO allowance outcomes as examiners ascend GS levels, suggesting that as examiners experience GS level promotions—i.e., have less time to review patent applications—they issue lower quality patents. 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 and examiner characteristics.[142]   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 I. 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
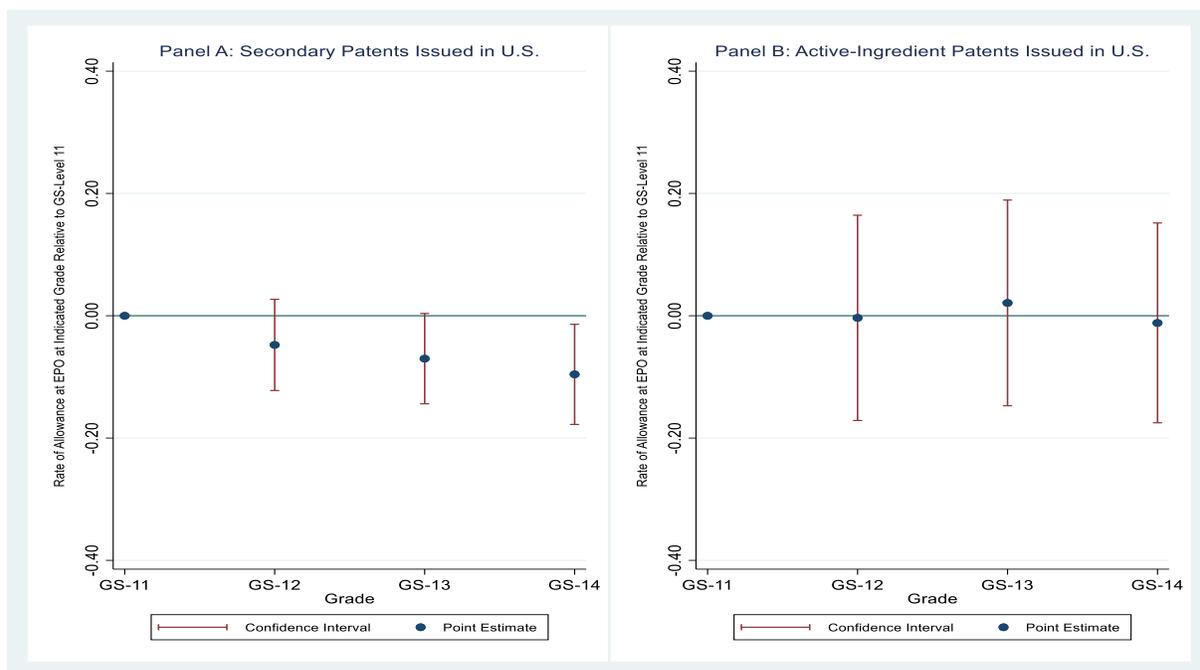
Notes: results in Panel A are from a sample of 2,678 secondary Orange Book patents issued in the U.S. and part of a family of applications at both the U.S. Patent Office and the European Patent Office. Results in Panel B are from a sample of 624 active-ingredient Orange Book patents issued in the U.S. and likewise part of an international family of applications. The plotted coefficients represent the coefficients of the GS-level indicator variables from the regression specification described in this Subpart. Estimated coefficients for the other variables included in this regression 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.

Above, we predicted the time constraints are less likely to bind in the case of active-ingredient patents. We find suggestive evidence in support of this claim in Panel B of Figure

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[142]   While the point estimates of the various GS levels suggest that this decline transpires monotonically, our sample size is not big enough to allow us to state with statistical significance that each individual step is lower than the previous step. Nonetheless, we do not necessarily ask the reader to draw such a specific inference. The key inference that we wish to draw from this figure is that there is a general negative relationship between GS-levels and EPO outcomes. Supporting this general inference, we find with greater than 95% statistical confidence that the EPO allowance rate at GS-14 is below that of the corresponding rate at GS-11.

I, 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. These results suggest that, on average, there is no link between examination time and the quality of issued primary patents. 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. In other words, while the point estimates suggest no difference in outcomes across GS-levels—consistent with our theoretical expectations—we cannot statistically rule out a meaningful such relationship.

B. Stacked Event-Study Analysis

Of course, one of the strains to estimating the regression underlying Figure I—and thus one factor contributing to the imprecision just discussed—is the estimation of three separate GS-level coefficients. To attain greater statistical power, we also estimate a regression specification that attempts to estimate a single parameter that captures the average change in our validity marker arising from a GS-level promotion as a general matter. In other words, we estimate the average change in our validity marker that occurs after a promotion across each of the three key promotions (GS-11 to GS-12, GS12 to GS-13 and GS-13 to GS-14).

For these purposes, we create three separate sub-samples where each subsample represents all Orange Book patents whose applications were disposed of in a window around each respective promotion. We then stack these sub-samples on top of one another and estimate a regression specification essentially identical to that underlying Figure I but where our main regressor is no longer the set of GS-level indicator variables but is instead a single indicator variable for the application being disposed of in the post-promotion period of the relevant sub-sample. By stacking these sub-samples, we can estimate an average promotion effect across the three different promotion events.[143]

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. In other words, examiners in the post-promotion period of any one promotion window (e.g., the GS-11 to GS-12 window) will not experience a subsequent promotion during that designated post-promotion period (e.g., will not experience a GS-13 promotion during the post-promotion period of the GS-11 to GS-12 promotion window). In the alternative, we consider a window of two years pre- and post-event. This approach raises the possibility that an examiner will be in the post-promotion period of one window while experiencing a promotion to the next level. To avoid this scenario, we exclude patents reviewed by examiners in a post-event window who happen to receive a promotion within that two-year window.

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[143]   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, we cluster the standard errors both at the level of assignment and at the patent-number level to account for correlation in unobservables within assignment groups and within individual patents. In this specification, we also include fixed effects indicated the relevant promotion sub-sample, such that we allow for fixed differences in validity outcomes among each promotion window sub-sample.

In this stacked event-study approach, we continue to control for experience, cohort and tenure effects, just as we did in Figure I. 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 itself—rather than personnel characteristics that are generally correlated with promotions—relative to the specification estimated in Figure I

We present results from this event-study analysis in Table I. 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. In other words, we find that a GS-level promotion as a general matter is strongly associated with a decline in the validity of issued patents and thus in examination quality. 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. Both estimates are statistically significant at the 1% level. 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.

TABLE I: 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 included in the specification underlying Figure I. 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%.

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 this event-study specification 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.

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 before-after manner, we track validity outcomes in quarters leading up and following a promotion event. For these purposes, we simply modify the specification estimated in the stacked-event study approach such that our key regressor(s) is no longer the single indicator variable for being in the post-promotion period but is represented by a series of event-time indicators—i.e., indicator variables for the various quarters prior to the promotion and the various quarters following the promotion, leaving out the quarter prior to the promotion to serve as the reference period. For this exercise, we focus only on the case of secondary patents given that our objective with this analysis is to check the robustness of the binary stacked-event-study results from Table I (as discussed further below) and given that this dynamic specification is rather taxing for the small active-ingredient sample.[144] At the outset of this exercise, as we did with the analysis underlying Figure I, we confirm in the Online Appendix that the fundamental characteristics of the applications are balanced across these various event-time groups.

While we already know from Table I that EPO allowance rates fall after promotion events, this dynamic approach will allow us to explore how EPO allowance rates evolve more incrementally within the 1-year window on either side of the promotion. Arguably the chief advantage of being able to observe these incremental developments is the falsification exercise that it affords in assessing trends in validity outcomes leading up to promotions. If EPO allowance rates were already trending down *prior* to the promotion date, such an outcome would be inconsistent with a story in which the examination-time-reducing promotions *cause* examiners to issue patents with weaker validity on average. For instance, hypothetically, perhaps examiners trend downwards in the quality of their reviews as they gain experience with the Patent Office. Even though the regression from Figure I 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 Figure I. The ability to explore dynamic trends in outcomes within these generalized event windows will allow us to address this concern.

Relatedly, exploring these dynamics will allow us to address concerns over possible endogeneity in the fact of promotion itself—that is, to address the possibility that trends in validity outcomes may affect who gets promoted, a possibility that would complicate our ability to interpret the results as reflecting how promotions *cause* changes in examination

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[144] 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.

quality. Arguably, this possibility is of minor concern at the outset in that one would tend to expect that—if such endogeneity would exist at all—it would likely bias *against* the negative relationship that we find. After all, one would expect that if anything, examiners would tend to be promoted after an increase in observed validity, not a decline. Nonetheless, the ability to test for trends prior to the promotion events—and to confirm that the declines in our validity marker materialize after the promotion—will provide us with confidence in interpreting the effects as arising from the promotion rather than from factors leading to promotion.

Mediating against both concerns raised in the preceding two paragraphs, we observe a relatively flat trend in EPO-allowance likelihoods in the time leading up to the promotion, as demonstrated by Figure II. Consistent with a causal effect of the promotion itself, the drop in the average validity of issued patents implied by Table I does not occur until the promotion occurs. At that time, we observe a substantial drop in EPO-allowance outcomes—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 following the promotion, 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.[145]

The implication of such a story would be that, absent the tightening of time constraints, the improvement in quality with experience would have simply continued onwards, leaving experienced examiners with even higher average rates of validity among the patents they issue. In other words, the fact that average validity rates go back to their pre-promotion level after two quarters does not suggest that time constraints lead to temporarily negative effects. Rather, the harms to examination quality caused by time constraints *continuously* work against the gains that may arise from examiners gaining more experience—i.e., the harms are systematic in nature. That interpretation is consistent with our results presented in Panel A of Figure I, where, after controlling for the effects of experience and other factors on examination quality, we see a systematic negative relationship between examiner GS levels and the average validity of issued Orange Book patents. Our goal in this analysis is to determine the causal effects of examination time on examination quality; we do so knowing that other factors will also impact quality—e.g., experience. Just because other factors may also improve examination quality does not take away from the value to policymakers of knowing that giving examiners more time will generate additional gains.

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[145]   To complement this analysis, we consider also the estimated experience effects accompanying the estimated GS-level effects from Figure I. 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 the regression specification underlying Figure I 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. In the Online Appendix, we also demonstrate the robustness of the drop in EPO allowance rates upon GS-level changes to alternative event windows.

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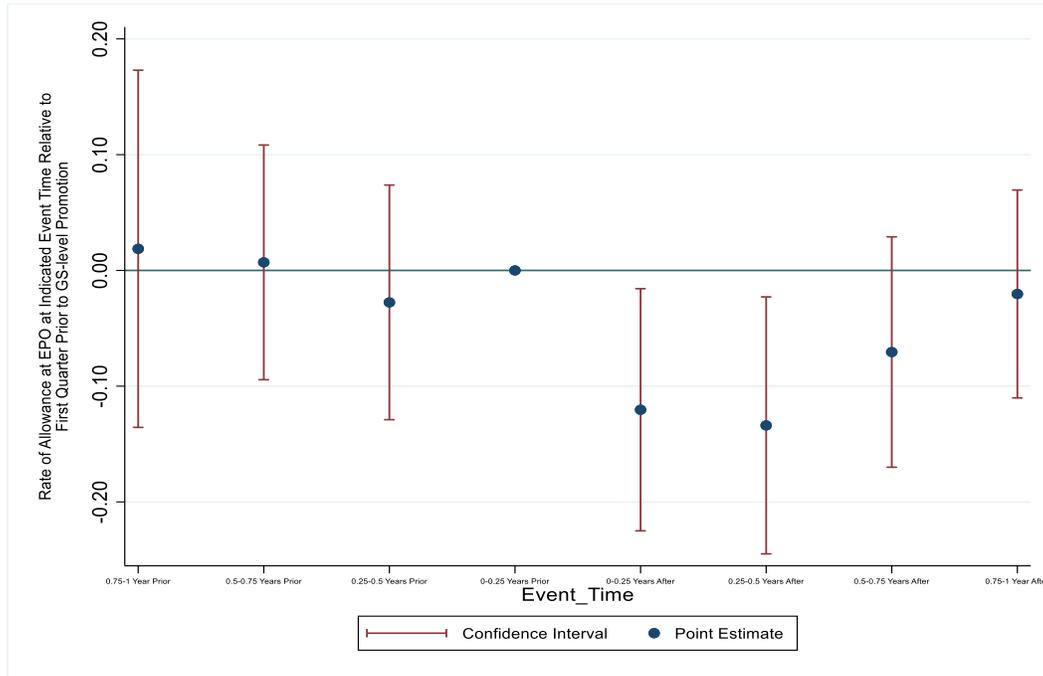
Notes: results are from a stacked sample of secondary Orange Book patents disposed of in a two-year (one on each side) event window around the reviewing examiners' promotions to GS-12, 13 and 14 (N=1069). The plotted coefficients represent the estimated coefficients of the event-time indicators from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

D. *Exploring Alternative Mechanisms behind Promotion Effects*

The analysis in Subpart C bolsters the conclusion that the GS-level results depicted in Figure I represent true 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 effects. 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 I. Any such explanation is incomplete given that only the GS-14 promotion carries with it a formal change in supervision—upon this GS-14 promotion, examiners are given full authority to sign off on their office actions without supervisory oversight.[146] If our

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[146]   Frakes & Wasserman, *supra* note 127 at 552.

only promotion under investigation were the GS-14 promotion, this institutional feature would give us greater pause. However, as demonstrated by the monotonic pattern in Figure I (at least based on the point estimates), our results are not specific only to the move to GS-14, appeasing such concerns. 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 given that this hypothesized change in oversight would remain true throughout the whole post-promotion period despite the fact that we observe validity outcomes dropping after a promotion but thereafter improving within a year. That dynamic pattern is arguably more consistent with the story discussed above whereby examiners improve with experience only to have those improvements met with setbacks due to the altered time-allocations upon promotions.

Nonetheless, we do acknowledge that one plausible non-time-allocation-related explanation behind the dynamic pattern depicted in Figure II 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.[147] 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 our results consistently hold for secondary patents while they do not materialize in the case of active-ingredient patents—consistent with what one might predict based on a theory of time pressures but arguably not consistent with what one might expect from non-time-related, alternative stories—lends critical support to a time-allocation mechanism.[148]

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.

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[147]   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.

[148]   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 I. 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 (which we derive from a specification in which we 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). Nonetheless, even if in any single approach we cannot rule out with statistical confidence that the promotion effect for secondary patents equals that for 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 point estimates) across all of our various approaches—from the various specifications estimated above to the estimation of the 2010-reform analysis that we will discuss momentarily. Even if this is hard to formalize, 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.

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.[149] 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. With this exercise, we are simply following validity outcomes over time—i.e., before and after the reform. Of course, EPO allowances outcomes will be changing over time for other reasons beyond this reform. This consideration leaves us inclined not to embrace a before and after comparison window that is too wide. For instance, considering that there may be other time-varying factors that we cannot observe and that may impact examination quality, it may be imprudent to draw strong inferences on whether the 2010 reform may have led to higher EPO allowance rates by observing the prevailing EPO allowance rates in, for instance, 2014. Other factors may also have changed by that point. If we were able to take advantage of a control group of patents that were not subject to the two-hour-rule change, we would be less concerned in this regard and could take advantage of this hypothetical control group to estimate and net-out the influence of general time trends (subject to certain assumptions in that hypothetical case). Lacking this ability, our goal here is more modest—i.e., to simply detect a *jump* up 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. If we are able to detect such a jump in 2010, it will lend confidence to the validity of the primary results set forth above with our GS-level analysis.

Of course, in order to detect any such jump following February 2010, we cannot consider a window of observation that is too small. Our sample of Orange Book patents is already limited in size as it is. If we only look over a tight window before and after the two-hour reform, this would leave very little observations—and thus little statistical power—by which to event detect a jump in validity outcomes in the first place. To balance these concerns over selecting an observation window that is too short with one that is too long, we elect to look for a change in outcomes in a window characterized by two years prior and two years subsequent to the two-hour reform in February, 2010. This approach entails focusing on only 20% of our original Orange Book sample.

In Table II, we demonstrate results from a regression specification similar to that underlying Figure I but focusing on this more limited sample and including an indicator for the 2010 reform.[150] 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

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

[150]   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.

allowed at the EPO. In other words, we document an improvement in examination quality in connection with an expansion in the amount of time given to examiners, an effect consistent with the GS-level analysis set forth above. Moreover, 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, further consistent with the results of the GS-level analysis.[151]

TABLE II. 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 included in the regression underlying Figure I 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%.

In Figure III, we take a more dynamic approach to this event-study analysis, where we track these EPO-allowance outcomes period-by-period leading up to the February 2010 reform and following the reform, again within this 4-year window around the reform (using half-year groups as the incremental observation period). For these purposes, we estimate the same regression specification discussed in the preceding paragraph, but include a series of event-time indicator variables rather than a simple post-reform indicator variable. Figure III plots the estimated coefficients of these event-time indicator variables, with the indicator for the period immediately prior to the reform excluded to serve as the reference group. The value of this exercise is in demonstrating that this increase in validity outcomes occurred at the time of the reform itself, as opposed to pre-dating the reform (any such anticipation effect would undermine a causal interpretation of these findings). Encouragingly, we document no such pre-trend. Instead, the estimated point estimates of the event-time indicator variables demonstrate a jump at the moment of the reform. Given that we are using this dynamic approach to test the robustness of the findings from Table II, we demonstrate this dynamic trend only for the case of secondary Orange Book patents.

One important caveat with this dynamic event-study analysis is that we are focusing on an especially small sample size given our use of only a four-year window of Orange Book patents, leaving us with little precision to draw strong inferences on the period-by-period movements in EPO allowance outcomes. Though the point estimate of the first post-reform event indicator suggests a strong jump in EPO allowance outcomes, this estimate is not statistically distinguishable from zero. The second post-reform event indicator, however (signifying the 6-12 month period following the reform) is statistically distinguishable from zero. In any event, the key rationale for this dynamic approach was to observe whether we found evidence

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[151] 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.

indicative of an upward trend in EPO allowance outcomes that pre-dated reform; and, subject to the caveat of large standard errors with our pre-reform indicators, we find no such evidence of a pre-trend. In terms of drawing an inference that validity outcomes increased following the reform, the simple approach taken in Table II (with just one post-reform indicator variables) arguably provides us with the most statistical power for such inferential purposes; and when taking that more straight-forward approach, we can indeed say with statistical confidence that EPO allowance outcomes for secondary patents increase following the reform.

FIGURE III. 2010 TIME-ALLOCATION REFORM EVENT STUDY
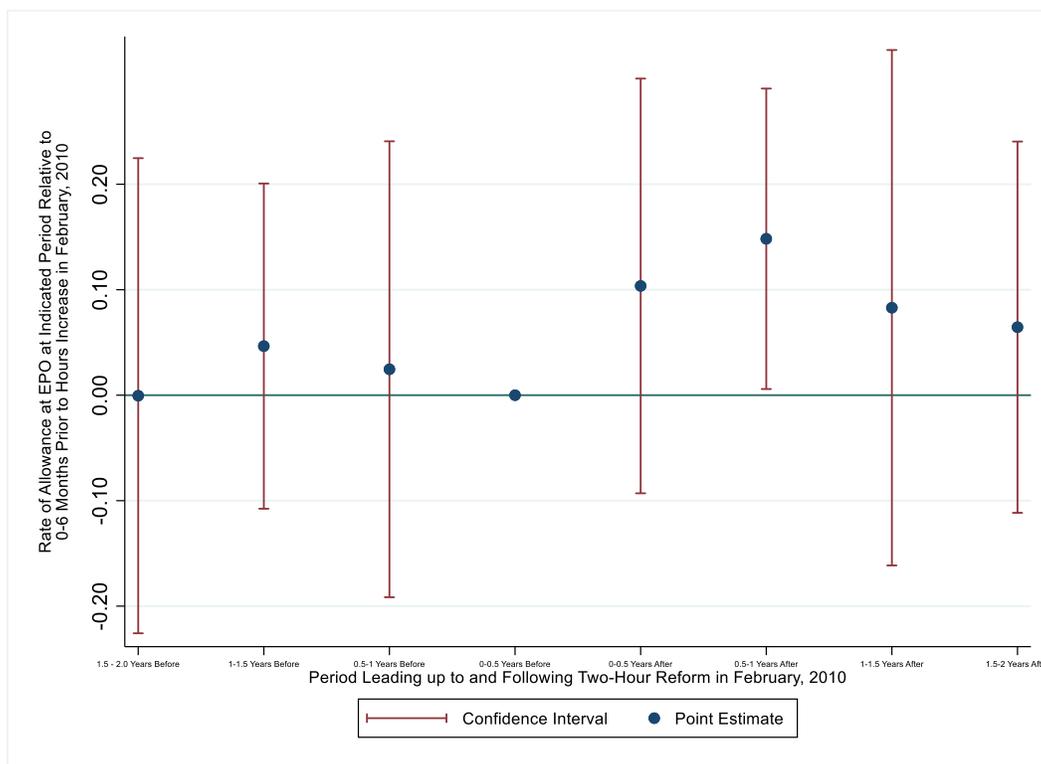
Notes: results are from a sample of secondary Orange Book patents disposed of in a four year (two on each side) event window around the February 2010 reform extending all examiners two additional hours to review applications. Specifications include the control variables from the specification underlying Figure I 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.

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.

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, which allow us to account for inherently different levels of quality across each examiner. In this specification, we estimate the effects of GS-level promotions by always exploring changes in outcomes within individual examiners as they individually experience those promotions, an approach that complements the event-study approach from Figure II in better 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.

H. 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. In a recent article of ours,[152] we 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 I.B. Again, the pharmaceutical industry is not like other industries where new firms can simply enter a market under the risk of facing a potential patent infringement lawsuit. In the case of pharmaceuticals, 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.[153] In other words, litigation in the pharmaceutical context is effectively initiated by challengers to the patent—i.e., by parties who will often be inclined to challenge the validity of the relevant patent. 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.[154]

Altogether, if the Patent Office issues more invalid Orange Book patents, there may be reason to believe that litigation rates will increase. With this in mind, we re-estimate the specification underlying Figure I 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 III, estimating negative binomial

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[152]   *Id.*
[153]   21 U.S.C. § 355(i)(5)(b)(iii).
[154]   21 U.S.C. § 355(j)(5)(b)(iv).

specifications (presenting incidence rate ratios).[155]   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,[156] with the result being a nearly 100% increase in litigation counts per patent following September, 2011 (as observed in our data). The chief concern is really one of interpretation in that the AIA's joinder changes 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.[157] In Part V, we flesh out the magnitude of this result in greater depth.

In the Online Appendix, we estimate a dynamic event-study counterpart to Figure II but using post-AIA litigation counts as the dependent variable. The point estimates of this figure suggest 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.[158]

TABLE III. RELATIONSHIP BETWEEN LITIGATION FREQUENCY AND GRADE-LEVEL OF EXAMINER ASSIGNED TO RELEVANT SECONDARY ORANGE BOOK PATENT, NEGATIVE BINOMIAL RESULTS (REPORTED AS INCIDENCE RATE RATIOS)

	(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)
Omitted: GS-11		
GS 12	1.379 (0.326)	1.010 (0.294)
GS-13	1.709* (0.486)	1.372 (0.467)
GS-14	2.027** (0.586)	2.374*** (0.756)
N	3,126	1,810

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

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[155]   As demonstrated by the Online Appendix, the results are robust to the estimation of Ordinary Least Squares specifications.
[156]   35 U.S.C. § 299.

[157] 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.
[158] 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.

V. Welfare Analysis: Savings Associated with Decreasing the Issuance of Invalid Secondary Patents

The above analysis provides evidence that as U.S. patent examiners are allocated more time to review secondary pharmaceutical applications, they are substantially less likely to issue invalid patents. Nonetheless, it is not immediately clear that patent examiners should be given more time. While the increase in quality of issued secondary pharmaceutical patents will produce various social benefits, including a reduction in future litigation expenses and earlier generic entry, augmenting examiner time allocations will require additional governmental expenditures. But, will these benefits outweigh the costs?

Perhaps most famously, Mark Lemley has argued against increasing the resources to the Patent Office.[159] More specifically, Lemley has argued that because so few patents are litigated or licensed (i.e., valuable), it is better to rely on federal litigation to make detailed validity determinations in those rare instances rather than increasing examination time and resources for the review of all applications.[160] Lemley supported his thesis with certain back-of-the-envelope calculations.[161] In prior work we pointed out that although some of the numbers in Lemley's cost-benefit analysis reflect hard data, the dearth of empirical evidence available at the time forced him to guess the value of several key parameters.[162] In our previous work, we utilized new data and sophisticated empirical techniques to estimate values of these parameters.[163] Our estimates demonstrated that the savings associated with the Patent Office issuing fewer invalid patents as a result of extending examiners greater review time outweigh the costs in doing so. As a result, we concluded the opposite of Lemley: society would be better off investing more resources into the Agency to improve patent quality than relying on ex post litigation to weed out invalid patents.[164]

From a conceptual standpoint, the case for increasing time allocations for secondary pharmaceutical patent applications, especially those that will be listed in the Orange Book upon issuance, is substantially stronger than the case for increasing resources to review all patent applications at the Patent Office. Orange Book listed patents are vastly more valuable than the average patent issued by the Patent Office, meaning mistakes in issuance of the former are significantly more costly to society than mistakes in issuance of the latter. Moreover, unlike most patent applications, the commercial value of Orange Book listed patents is known early on—often at the patent application stage. Given these economic realities, increasing the review resources for secondary pharmaceutical patent applications seems like low hanging fruit.

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[159]   Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. U. L. Rev. 1495, 1497 (2001).
[160]   *Id.* ("Because so few patents are ever asserted against a competitor, it is much cheaper for society to make detailed validity determinations in those few cases than to invest additional resources examining patents that will never be heard from again.").
[161]   *Id.* at 1508–10.
[162]   *Irrational Ignorance*, *supra* note 104 at 1022–24.
[163]   *Id.* at 1022.
[164]   *Id.* at 1020–22.

Despite the power of this conceptual observation, it is ultimately an empirical question as to whether increasing the Patent Office resources is in fact more cost effective than continuing to rely upon litigation to weed out improvidently granted secondary pharmaceutical patents. As a result, the remainder of this Article turns to conducting this cost-benefit analysis.

The cost-benefit investigation set forth in this Article builds off our prior investigation into the relative benefits of ex-ante Agency review versus ex-post litigation[165] in several critical ways. Some of our extensions of this prior work are methodological in nature, facilitating a more convincing identification of the effects of examination time on outcomes. For instance, our analysis in Part IV employed various novel tools, including (i) the use of updated data on the precise date of GS-level promotions, facilitating the novel estimation of the event study designs set forth above, (ii) the ability to test our model among a group of patents where we predict time pressures are and are not expected to bind (in this case, secondary versus primary patents) and (iii) the exploration into the 2010-reform analysis. The most critical extension of our analysis, however, is in regards to our specific focus on Orange Book patents.

Critically, focusing on pharmaceutical patents enables us to broaden the scope of benefits that we can calculate and thus incorporate in the fundamental cost-benefit exercise that animated Professor Lemley's and our prior work. Our previous investigation into the benefits of investing in greater screening at the Patent Office relative to the courts predominantly focused on the litigations savings that would arise from a richer screening function at the Agency level.[166] These savings are outlined in Supbart A. At the same time, we have long thought that the biggest social gains associated with reducing the issuance of invalid patents would likely come from avoiding the marketplace harms that derive from extending unnecessary patent protection—e.g., the elevated prices and hampered consumer access that can result from the monopoly power facilitated by patent rights.[167] Unfortunately, we lacked the ability to estimate those gains across most technological fields. Nonetheless, in the pharmaceutical context we do have that potential.[168] And in this Article, we take up that challenge in Supbart B.

We will begin this cost-benefit investigation by assessing the various social benefits that may arise form an expansion in time allocations at the Patent Office. Before turning to this benefits analysis, we must choose a particular incremental increase in examination time to evaluate. We have elected to estimate the benefits and costs associated with a 50-percent increase in the number of hours given to examiners to review secondary pharmaceutical patents. We choose a 50-percent increase primarily because GS-11 examiners are given roughly 50-percent more time to review applications relative to GS-14 examiners, providing

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[165]   *Irrational Ignorance*, *supra* note 104.
[166]   *See id.* at 989–1006.
[167]   *Id.* at 1013-1016. We acknowledge that the marketplace harms to stem from the Patent Office issuing invalid patents may go beyond these classic harms stemming from the monopoly protection facilitated by patent rights. For instance, invalid patents can be utilized to opportunistically extract licensing fees from innovators. Robin Feldman & Nicholson W. Price II, *Patent Trolling Why Bio & Pharmaceuticals Are at Risk,* 17 STAN. TECH. L. REV. 773, 779–86 (2014). They may also inhibit the ability of startups to obtain venture capital. *See* FED. TRADE COMM'N, *supra* note **Error! Bookmark not defined.**, at 8 ("The threat of being sued for infringement by an incumbent [patent holder]—even on a meritless claim—may 'scare . . . away' venture capital financing." (quoting public comment of Joshua Lerner, Professor, Harvard Business School)).
[168]   *Id.*

us with a straightforward way to build off the estimates set forth in Figure I and predict the outcomes associated with a time-allocation expansion of this magnitude.[169] Importantly, we do not advocate that a 50-percent increase in examiner time allocation is optimal among possible expansion sizes. It may be that a doubling of time allotments is even more cost effective relative to a 50-percent increase. Nevertheless, determining the optimal increase in examiner time allocations is beyond the scope of the Article and hence we leave this question for future work. We will also assume that the Patent Office will enact this 50-percent expansion in time allocations while not sacrificing aggregate application throughput. This assumption is discussed in more detail in Part VI.

A. Litigation Savings

We begin this cost-benefit exercise by setting forth the litigation savings that may ensue from this envisioned reform. As discussed in Part IV.H, invalid pharmaceutical patents attract litigation at higher rates than validly issued pharmaceutical patents. As examiners are extended more time, the average patent that they issue is less likely to be invalid, which will in turn lead to a reduction in litigation.[170]

To estimate the aggregate litigation savings that may ensue from an annual expansion of 50% in examination time allotments, we will proceed in three parts: (1) estimate the number of secondary pharmaceutical patent-lawsuit pairs that are expected to result from those Orange Book patents that issue annually; (2) estimate the number of secondary pharmaceutical patent-lawsuit pairs that will be avoided upon a 50-percent increase in examiner time allocations; and (3) draw on estimates of costs per patent-lawsuit pairs to estimate how much aggregate litigation savings is derived by these avoided lawsuits.[171]

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[172] and these patents are litigated on average 1.67 times.[173]

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[169]   Again, very few pharmaceutical patent examiners are hired at GS-7, GS-9 and GS-11; if this were not the case, we could include these lower grade levels in our empirical analysis and provide us with more confidence in being able to predict outcomes from a more expansive increase in time allocations.

[170]   Increased time allocations may also reduce litigation through another mechanism. In the Online Appendix, we demonstrate that increased examination time is also associated with a reduction in the number of pharmaceutical patents granted. Even if examination time has no effect on the average validity of patents that are issued, this grant-effect lone will also mechanically lead to a reduction in litigation. After all, with fewer patents in existence, there is simply less scope for litigation in the first place. Our estimated litigation savings will not capture this latter mechanism and will instead focus on savings stemming from the effects of time allocations on the validity of average-issued patents. This is just one, among many, reasons why our estimates are conservative and stacked against the conclusion we ultimately reach.

[171]   Since we are presently in the post-America-Invents-Act (AIA) era, we will also focus our estimates on post-AIA litigation frequency.

[172]   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.

[173]   To arrive at this time, 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 this average 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

The next question is how many of these 686 lawsuit-patent pairs can be avoided by a 50% increase in examination time allotments? For these purposes, let us turn to our litigation analysis from the Part IV.H compare the rate of litigation for issued secondary Orange Book patents for examiners at GS-11 relative to GS-14 (controlling for a range of other examiner and application characteristics). As examiners move from GS-11 to GS-14, they experience a 33.3-percent reduction in the amount of time allocated to them, relative to the time they had at GS-11. If we think about this in reverse—as examiners move backwards from GS-14 to GS-11—this entails a 50-percent increase in the amount of time allocated to examiners, relative to the time they had at GS-14. The reported incidence rate ratios (IRR) from Table III suggest 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).[174] If we think of this progression in reverse—as examiners move backwards from GS-14 to GS-11—these IRR results suggest 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 686 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 398.

Our next step in this analysis is to determine how much savings in litigation expenses can derive from observing 398 fewer lawsuit-patent pairs per year. Before doing so, however, it is important to acknowledge 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.[175] In the case of the secondary Orange Book patents that are challenged in lawsuits in Article III courts, our PTAB and litigation data suggest 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 are going to make a conservative analytical choice and focus on the savings associated only with these 82 percent of patents facing challenges in Article III courts only. In other words, we will only calculate the litigation savings associated with a reduction of 326 (not 398) lawsuit-patent pairs per year.[176]

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.

[174]   This estimate is based on the estimated 2.347 incidence-rate ratio from the Negative Binomial regression reported in the Online Appendix (focusing the analysis on the post-AIA period), which suggests that the litigation rate for GS-14 examiners is 237% of the litigation rate of that for GS-11 examiners, which implies a 137 percent *higher* litigation rate.

[175] Melissa F. Wasserman, *The Changing Guard of Patent Law:* Chevron *Deference for the PTO*, 54 WM. & MARY L. REV. 1959, 1981–88 (2013). Perhaps most saliently, the Patent Act requires these new administrative hearings to take place through an adversarial, court-like hearing in which parties are entitled to oral arguments and discovery. *Id.*

[176]   We make this choice considering that Article III courts will frequently stay their proceeding until the contemporaneous PTAB challenge is resolved, a development that will naturally lead to lower litigation expenses associated with the Article III challenge.   Our decision to focus on patents that are only challenged in Article III courts will likely cause us to meaningfully underestimate the full degree of administrative costs associated with the forgone legal challenges for two fundamental reasons. First, PTAB challenges themselves are trial-like proceedings that carry with them substantial legal expenses. The American Intellectual Property Law Association (AIPLA) reports the median cost of post-grant proceedings before the Patent Office to each side is $200,000 through the end of motion practice, $250,000 through the PTAB hearing, and $350,000 through appeal, AM. INTELLECTUAL PROP. LAW ASS'N, 2017 REPORT OF THE ECONOMIC SURVEY 43 (2017), expenses that may turn out to be even higher in the case of pharmaceutical PTAB challenges. If we were to include PTAB-related legal costs, the estimated legal

In previous work, we estimated that a given patent lawsuit is associated with $549,949.30 in expected litigation expenses.[177] Because these litigation savings will be incurred in the future, the final step of our calculation will adjust the litigation savings to account for their present value. Accounting for the fact that the average litigation expense occurs 5.2 years after patent issuance[178] and utilizing a discount rate suggested by the Office of Management and Budget of 3% and 7%, we estimate that this $549,949.30 in expected litigation expenses per case equals in $471,594.9 and $386,836.9 in present value terms, respectively.[179] To be conservative, we will focus on the lower of these two estimates.[180]

Lastly, we need to adjust for the fact that patent lawsuits generally involve more than one patent. In the case of pharmaceutical patents, typical lawsuits involve 2.87 patents. Accordingly, to determine the expected litigation expenses associated with a lawsuit-patent pair, we divide $386,836.9 by 2.87, arriving at $134,876.1. With 326 lawsuit-patent pairs avoided, we estimate aggregate litigation savings of $44 million dollars.

B. Generic Entry, Drug Prices and Consumer and Social Welfare

As discussed in Part I, secondary patents can extend the effective patent life of a drug by delaying generic entry on that drug product until the expiration of that secondary patent (or an even later secondary patent associated with that drug product). 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 invalid secondary patents 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. Because generic entry is associated with rapid market penetration and substantial price reductions, earlier generic entry could result in substantial consumer and total social welfare savings.

In this Subpart, we begin to sketch such welfare gains. We perform this calculation in three parts. First, using results from Part IV, we simulate the degree to which a 50-percent increase in examination time at the Patent Office will facilitate earlier generic entry. Second,

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savings that we will estimate below would be even larger. Second, with respect to those 18 percent of patents that are challenged in both federal court and at PTAB, even if the Article III courts stay the proceedings, there will still be some litigation expenses associated with the limited Article III proceedings that do transpire. But ignoring these expenses, we are further taking a conservative approach to deriving the litigation savings stemming from increasing examiner time allocations.

[177]   *Irrational Ignorance*, *supra* note 166, at 1000–02.
[178]   *Id.* at 1002.
[179]   For an in depth discussion of the selection of discount rates please *see Irrational Ignorance*, *supra* note 166, at 1002–03.
[180]   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, 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 than the $386,836.9 value just discussed. Nonetheless, to be conservative, we will use this likely lower estimate derived from our prior work on patent litigation expenses across all technologies.

we combine this estimate with those from the health economics and medicine literatures to approximate the consumer surplus gains associated with a reduction in drug prices for consumers that would have bought the drug even at its higher patented price. Third, we combine the estimate of earlier generic entry with those from the health economics and medicine literatures to estimate the social welfare gains associated with more patients deciding to purchase the drug after the price reduction, or what is referred to by as economists as the reduction in deadweight loss.

1. *Generic Entry Acceleration.*

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 I. 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 I 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 patents associated with certain drug products. 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 through this simulation exercise that the assumed 50% increase in time allocations will accelerate the expiration of the last patent of an average drug product by 82 days.[181] 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.[182]

We acknowledge, of course, that even absent reform of examiner time allocations, generics may enter prior to patent expiration if they succeed in a Paragraph IV challenge of the brand-name manufacturer's patent(s). Accordingly, the net effect of a 50-percent annual increase

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[181] In doing so, we account for the Patent-Term Extension received by the primary patent pursuant to the terms of Hatch-Waxman Act to compensate for the reduction in effective patent life resulting from the time involved in regulatory approval. 35 U.S.C. §156

[182] 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.

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. 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,[183] where much of these settlements operate to maintain the delayed entry.[184] 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.   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.

Of course, theoretically, just because generics can enter after the loss of patent protection for the brand-name drugs does necessarily not mean that they will and does not necessarily mean that patients and physicians will select the lower-price generics. The evidence, however, does suggest substantial rampant generic penetration in the small-molecule drug marketplace after the loss of exclusivity (LOE) by the brand-name drug, aided by state substitution laws requiring or permitting pharmacists to substitute for generics. Based on a recent report by the IMS Institute for Healthcare Informatics, generics represent 90 percent of dispensed prescriptions.[185] Based on the results of a rich literature in health economics and medicine, the resulting declines in prevailing drug prices from this robust competition are substantial. For instance, the IMS report just referenced 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 LOE, with notably higher reductions in the case of oral medications and higher reductions in more recent years (e.g., 90 percent reduced generic pricing within 2.5 years of LOE in recent years for oral medications).[186]

The substantially lower drug prices resulting from the projected accelerated generic entry have the potential to lead to two types of gains: (1) increases in consumer surplus and (2) decreases in deadweight-losses / increases in overall social welfare.

2. *Consumer Surplus Gains*

Consumer surplus represents the aggregate degree to which those consumers who purchase the given drug product value that product above the price they pay for that product. If prices fall, consumer surplus may be expected to rise for two reasons. First, for those consumers who would have purchased the product under the older, higher prices, they will continue to purchase after the price reduction, but will ostensibly garner greater surplus given the lower prices they will pay to obtain the drugs that they value. Consumer surplus

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[183]   Hemphill & Sampat, *supra* note 20, at 327.

[184]   Keith Drake, Martha Starr & Thomas G. McGuire, *Do "Reverse Payment" Settlements of Brand-Generic Patent Disputes in the Pharmaceutical Industry Constitute an Anticompetitive Pay for Delay?*

[185]   IMS INSTITUTE FOR HEALTHCARE INFORMATICS, PRICE DECLINES AFTER BRANDED MEDICINES LOSE EXCLUSIVITY IN THE U.S. (2016)

[186]   *Id.*

may also go up if more patients decide to purchase the drug after the price reduction. For the purposes of this Subpart, we will calculate the first type of consumer surplus gains, reserving the second type for our discussion of the reduction in deadweight losses that may arise from lower drug prices.[187]

To aid in a back-of-the-envelope calculation of these gains to consumer surplus, we depict in Figure IV a simple monopoly pricing scenario for a hypothetical drug.[188] 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. As stated above, we aim to calculate the increase in consumer surplus resulting from the reduced price (from P_m to P_c) for those that would have purchased anyway under monopoly pricing. This increase equals Q_m X $(P_m - P_c)$ or the area represented by rectangle A. It can be readily observed from this figure that the area of rectangle A as a percentage of the revenue received by the brand-name manufacturer during monopoly pricing (Q_m X P_m) is equal to the percent price reduction resulting from generic entry. Accordingly, the area of rectangle A equals the average percent price reduction upon generic entry times an average brand-name manufacturer's revenues during monopoly pricing. For the first such parameter, we assume that prices will fall by 50%, taking a conservative approach and using the lower end of the estimated price reductions upon generic reported in the IMS publication referenced above. For the latter parameter, we turn to a recent study by Ernie Berndt, Rena Conti and Stephen Murphy, who report that the average revenue received by brand-name companies per drug product is roughly $153.1 million.[189] 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.

As noted above, we estimated that a 50 percent increase in time allocations over just one year of reviews at the Patent Office would result in 19 years of accelerated generic entry in the small-molecule drug marketplace. Assuming 19 different drug products are each

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[187]   Whether we view this increase in consumer surplus in and of itself as a benefit depends on the objectives of the relevant policymakers. Some, after all, may contend that the increase in consumer surplus resulting from a reduction in price for those consumers who would have purchased anyway merely results from a one-for-one transfer from producers, in which event the net societal benefit is zero. However, when it comes to antitrust / competition law and policy, it is perhaps uncontroversial that policymakers indeed place independent weight on consumer surplus and well-being. HERBERT HOVENKAMP, THE ANTITRUST ENTERPRISE: PRINCIPLE AND EXECUTION (2005) ("[The] only articulated goal of the antitrust laws is to benefit consumers"). There is little reason to think that a specific focus on drug pricing and competition in the pharmaceutical industry is any different. Much of the lay commentary regarding drug pricing focuses on the implications for consumers; moreover, much of the economics literature on drug pricing also gives considerable independent attention to consumer surplus. See, e.g., Rexford Santerre and John Vernon, Assessing Consumer Gains from a Drug Price Control Policy in the U.S., 73 S. ECON. J. 233 (2006).

[188]   A formal estimation of consumer surplus for a given small-molecule drug product is beyond the scope of this paper as such an exercise would warrant an entire paper or series of papers. See Lee Branstetter, Chirantan Chatterjee & Matthew J. Higgins, Regulation and welfare: evidence from paragraph IV generic entry in the pharmaceutical industry, 47 RAND. J. ECON. 857 (2016). As a result, we take an informed but back-of-the-envelope approach to calculating consumer surplus.

[189]   Ernst R. Berndt, Rena M. Conti, & Stephen J. Murphy, The Landscape of US Generic Prescription Drug Markets, 2004–2016, NBER Working Paper No. w23640 (2017). 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.

associated with one year of earlier generic entry, we estimate the consumer surplus gain associated with increased time allocations to be $1.4 billion dollars.

FIGURE IV. IMPACT OF GENERIC ENTRY ON PRICES AND OUTPUT
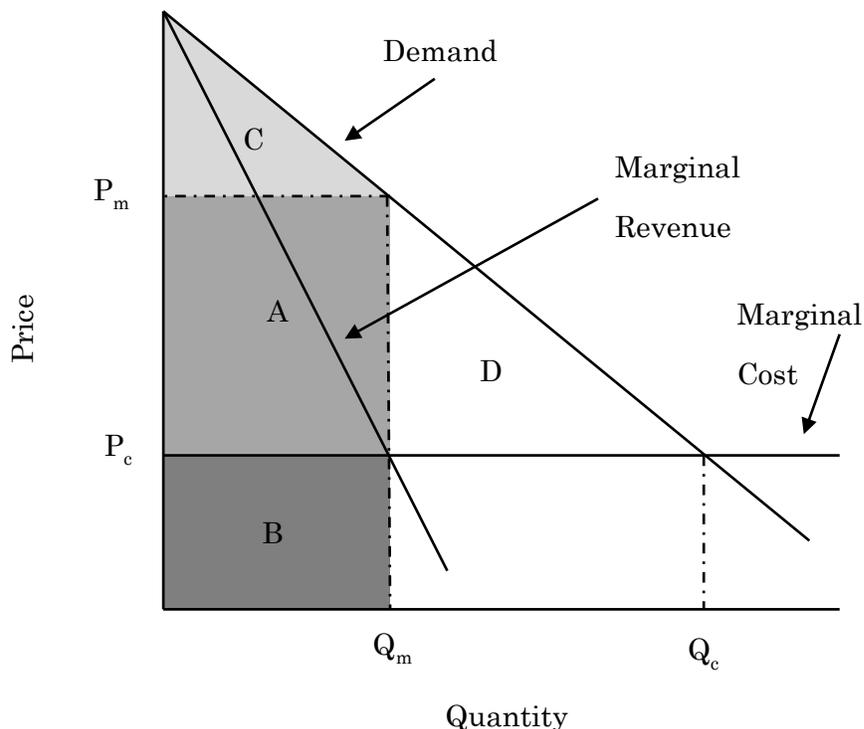
3. Social Welfare Gains / Reduction in Dead-weight Losses

Standard economic theory suggests that the price reductions resulting from generic entry will increase social welfare to the extent that they bring new customers into the market that would have otherwise been priced out. That gain in social welfare is represented by triangle D in Figure IV, representing the surplus (difference between the value of the goods consumed and the cost to produce them) associated with those new customers. In this Subpart, we will estimate this social welfare gain in the case of an average small-molecule drug product. We make certain simplifying assumptions for the purposes of tractability in this exercise, including an assumed linear demand curve and flat marginal cost curve.

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.[190]   Averaging over the six molecules losing exclusivity discussed in recent research by Aitken and colleagues suggests that generic entry is associated with a 4.6 percent increase in quantity of the affected drug product.[191]   We draw on this amount—and assume that the Aitken et al. analysis 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.[192]

Since the quantity sold under monopoly is assumed to be at a level Q_m, the Aitken et al. estimate suggests that the increase in the quantity sold post-generic-entry—i.e., the base of the triangle D—will be $0.046Q_m$. As can be readily discerned from Figure IV, the height of both rectangle A and triangle D equals the price reduction from generic entry, $P_m - P_c$. Accordingly, the area of triangle D is one half its base times its height or $\frac{1}{2} \times 0.046Q_m \times (P_m - P_c)$. The area of rectangle A is, as above, $Q_m \times (P_m - P_c)$. Accordingly, the area of triangle D is $\frac{1}{2} \times 0.046$ of the area of rectangle A—i.e., the deadweight loss triangle is 2.3 percent of the estimated gains in consumer surplus derived in Subpart (2) above, or approximately $1.8 million. Again, we estimate that a 50 percent increase in time allocations over 1 year of reviews at the Patent Office would result in 19 years of accelerated generic entry. Assuming 19 different drug products are each associated with one year of earlier generic entry, we estimate the reduction in deadweight loss associated with increased time allocations to be $34.2 million dollars.

VI. Welfare Analysis: Costs Associated with Increasing Examination Time at the Patent Office

The previous Part calculated the potential savings associated with increasing examiner time allocations by 50 percent. Of course, in order to determine whether society would be better off devoting more resources to the Patent Office to increase the quality of examination of secondary pharmaceutical patents, we must also know the costs associated with a reform of this nature. This Part turns to this task.

As noted above, we assume that the Patent Office will enact this 50-percent expansion in time allocations while not sacrificing aggregate application processing. That is, we assume the Patent Office could increase its operating budget to maintain its examination capacity while concomitantly providing examiners with additional time per application. We believe this assumption is a good one for several reasons. First, the Patent Office is under tremendous pressure to decrease its large backlog of patent applications and hence would not want an increase in time per application to mean fewer applications processed.[193] Second,

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[190]   L. Aitken, Ernst R. Berndt, Barry Bosworth, Iain M. Cockburn, Richard G. Frank, Michael Kleinrock, and Bradley Shapiro, *Regulation of Prescription Drug Competition and Market Responses: Patterns in Prices and Sales Following Loss of Exclusivity*, *in* Measuring and Modeling Health Care Costs 243–271 (Ana Aizcorbe, Colin Baker, Ernst R. Berndt & David M. Cutler, eds. 2018).

[191]   *Id.*

[192]   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.

[193]   *Top Management Challenges Facing the Department of Commerce in FY 2013: Hearing Before the H. Comm. On Appropriations Subcomm. On Commerce, Justice, Science, and Related Agencies*, 113th Cong. 2 (2013) (statement of Todd Zinser, Inspector Gen. of the U.S. Dep't of Commerce) (noting that addressing patent backlog is one of the top challenges facing the Department of Commerce); U.S. Patent & Trademark Office, Performance and Accountability Report for Fiscal Year 2008, at 33 (2008), http://www.uspto.gov/about/stratplan/ar/USPTOFY2008PAR.pdf [https://perma.cc/8U8P-3NXH] (noting the Patent Office's "biggest challenge is to address the growth of pendency and the backlog of patent applications waiting to be

the Patent Office, which is funded almost entirely through user fees, has fee-setting authority which enables the Agency to increase its budget without having to lobby Congress for additional funds.[194] In other words, the Patent Office has the means to increase its budget to meet these goals. As a result, we assume that the costs associated with this reform will primarily be the personnel expenses (and accompanying overhead) associated with hiring and paying additional examiners to account for the aggregate 50-percent increase in examination hours called for by the reform.

In the Online Appendix, we calculate the amount of such additional expenses required to be able to enact this reform for the 23,418 secondary patent applications submitted annually to the Patent Office.[195] Based on the distribution of pharmaceutical applications across Art Units and GS-levels and based on the hours-allotment schedule across these groups, 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 (and associated overhead) across GS-levels to estimate that funding these additional hours will cost the Patent Office roughly $20 million per year.[196]

VII. SUMMARY OF WELFARE ANALYSIS & REFORM PROPOSALS

This Part summarizes our welfare analysis from Parts V and VI and compares the potential savings and costs associated with increasing examiner time allocations by 50-percent for secondary pharmaceutical patents. This Part then concludes by providing some specifics as to how the Patent Office should go about increasing review time.

A. The Patent Office Should Increase Time Allocations: Benefits Far Outweigh Costs

To summarize our empirical analysis, we estimate that a 50-percent increase in examination time is expected to cost the Patent Office roughly $20 million annually in increased personnel expenses. We also estimate three separate gains / savings. First, we estimate federal litigation savings of $44 million dollars. Notably, the litigation savings alone is enough to justify the extension of more examination time to examiners in reviewing secondary pharmaceutical patents. Second, we estimate that a 50-percent increase in time allocations for just one year of reviews at the Patent Office will result in roughly 19

examined"); *Inspector General's Top Management Challenges Facing the USPTO*, U.S. PAT. & TRADEMARK OFF., https://web.archive.org/web/20121010172423/http://www.uspto.gov/about/stratplan/ar/2011/oai_01.html (last visited Apr. 3, 2019) [https://perma.cc/J9F7-GMKW] (noting the management challenge of reducing the patent application backlog); *see also* Jon W. Dudas, *Message from the Under Secretary of Commerce for Intellectual Property and Director of USPTO: Fighting Piracy and Counterfeiting by Protecting Intellectual Property Rights*, U.S. PAT. & TRADEMARK OFF. (Nov. 2, 2005), https://web.archive.org/web/20130425173504/http://www.uspto.gov/about/stratplan/ar/ 2005/02_message_director.jsp [https://perma.cc/DPY4-XWNU] (noting that the "volume and complexity of patent applications continues to outpace current capacity to examine them" and the PTO has "backlog of historic proportions").

[194]   35 U.S.C. § 41 (2016); Final Rule Setting and Adjusting Patent Fees, 78 Fed. Reg. 4,212, 4,224 tbl.4 (Jan. 18, 2013) (to be codified at 37 C.F.R. §§ 1, 41, 42); Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 10101, 104 Stat. 1388 (establishing that the Patent Office is funded almost entirely through user fees). For a more detailed discussion of how the Patent Office budget is set, see. e.g., Michael D. Frakes & Melissa F. Wasserman, *Does Agency Funding Affect Decisionmaking?: An Empirical Assessment of the PTO's Granting Patterns,* 66 VAND. L. REV. 67, 76–77 (2013).

[195]   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 our estimation that active-ingredient patents are allowed at a roughly 8 percentage-point higher rate than secondary patents (this assumption is based on the EPO allowance differential between active-ingredient and secondary patents listed in the Orange Book) we calculate that there are roughly 23,418 secondary pharmaceutical applications per year at the Patent Office.

[196] We provide further details on these calculations in the Online Appendix.

accelerated years of generic entry in the small-molecule marketplace, which is associated with a $1.4 billion consumer surplus gain for those consumers who would still purchase the brand-name under patent protection. When including these consumer surplus savings, the case for reform becomes overwhelming. Finally, we estimate a reduction in deadweight losses that arise from the resulting reduction in drug prices of $34.2 million dollars.

Notably, each of the three categories of benefits *alone* is enough to justify the costs associated with increasing examination time for secondary pharmaceutical patent applications. Combining these three categories of benefits result in a staggering $1.5 billion dollars in savings that swamps the estimated costs of $20 million. This is true even in light of a number of very conservative assumptions we have made alone the way.[197] As a result, we easily conclude that society would be better off spending more resources at the Patent Office to increase the examination time afforded secondary pharmaceutical patent applications.

B. Reform Proposals

This Part has so far concluded that the benefits associated with increasing the time examiners evaluate patent applications far outweigh the costs. As a result, we advocate that the Patent Office should augment time allocations. This Article now turns to examining the specifics as to how the Agency should go about increasing review time.

1. Reform Specifics

To begin, how the Agency should go about increasing examiner time allocations will depend on the objectives of the Patent Office. Given that the mission of the Patent Office is to provide timely and highly quality review of patent applications,[198] it is reasonable to assume that the Agency will attempt to maximize the aggregate degree of quality among the patents that they issue subject to the constraint that they process a certain number of applications. Considering the quality-versus-quantity tradeoff implicit in this optimization problem, one possible solution may entail the Patent Office setting time allotments for an examiner where the examiner's time constraints are just about to bind and where she is just on the verge of having inadequate time to fully apply the patentability standards.[199]

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[197] For instance, we evaluate a reform that will enact this examination time increase for all secondary pharmaceutical applications at the Patent Office (a practice assumption since that the Patent Office may not always know if a given patent application, if issued, will ultimately being listed in the Orange Book), even though most of the benefits that we calculate will derive from the avoidance of issuing invalid patents among the small subset of those applications that culminate in a listing in the FDA's Orange Book. Various social gains are likely to ensue from eliminating invalid patent issuances that result from some of the remaining pharmaceutical patent applications. For instance, critically, we do not calculate gains arising from giving examiners more time to review large-molecule drugs (or biologics) even though we are likely including much of this in our costs calculations. As discussed above, we also do not calculate litigation savings stemming from a reduction in the number of overall pharmaceutical patents granted due to examination time increases, instead focusing our litigation savings analysis on gains stemming from higher validity likelihoods among those patents issued.

[198] U.S. PATENT & TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT, FISCAL YEAR 2019, at 3 (2019) (noting the Patent Office's "mission is to foster innovation . . . by delivering high-quality and timely examination of patent . . . applications").

[199] This is not necessarily the only solution to this problem. Depending on the shape of the value function that the Patent Office places on quality and depending on the degree of the application-volume constraint, the Patent Office may find it optimal to live with some degree of a tradeoff between quality and throughput, leaving examiners with some strained ability to assess the patentability standards. This Article has demonstrated that this is the approach that the Patent Office has taken in practice. At the same time, this Article has also demonstrated that it is sub-optimal, that examination time should be increased and that

The analysis from Parts IV-VI has suggested that it would be cost-effective to increase time allocations and that examiner time constraints are indeed binding to the sacrifice of examination quality—i.e., that examiners are currently not receiving the time they need to conduct a rigorous prior art search and evaluate the patentability of secondary pharmaceutical patents. But to meet the solution suggested in the preceding paragraph—where time allocations are set where an examiner's time constraints are just on the verge of binding—should the increases in time allocations that this Article proposes be uniform across examiners? Figure I presented above suggests that the answer is no. The declining levels of quality as examiners undergo each iterative GS-level promotion suggests that these time constraints become even more binding—with even greater quality tradeoffs—as examiners undergo each time-reducing promotion event. This would suggest that to reach the solution where examiners' time constraints are just binding, this reform should entail giving GS-14 examiners a larger increase in examination time relative to the increase given to GS-11 examiners. By proposing to give greater increases to higher GS-level examiners, this proposal stands in contrast with the approach taken in the 2010 reform, wherein the Agency gave all examiners an additional two hours to review each application.

In essence, this reform involves both giving examiners more time and rescaling the degree to which time allotments go down with promotion. To be clear, we are not suggesting that the Agency's practice of decreasing time allotments upon promotion is an inadvisable one.[200] On the contrary, the solution suggestion above—whereby time allocations are set at the point where they are just on the verge of binding—would suggest that examination time should be reduced as examiners become more efficient with their time. Our results however—particularly, Figure I—suggest that the Patent Office is simply being too aggressive with the way it is currently scaling time allotments upon promotion.

In deciding how to overhaul a time allocation system, the Patent Office may also wish to think about how frequently to update its allocations over an examiner's career. Our results depicted Figure II suggest a precipitous drop in quality upon a GS-level promotion followed by a recovery in quality due potentially to improvements with experience over the ensuing year. As a result, the Patent Office may also be able to capture some quality gains by easing patent examiners into their new time allocations rather than having the new time allocations immediately and abruptly going into effect.

Finally, in deciding how to implement expansions in time allocations to address the problem of invalid secondary pharmaceutical patents, the Patent Office may wish to consider which applications specifically to focus upon. As discussed already, the welfare analysis above was conducted assuming that time allocations would be increased for all secondary patent applications. Nevertheless, the Patent Office could adopt an even more conservative approach by targeting only those secondary pharmaceutical patents that are likely to be

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examination time-constraints should become less binding. To be sure, we have not proven that examination time should necessarily be increased all the way to the point where examiners' time constraints are just on the verge of binding and where we are just on the verge of trading off quality and throughput. Nonetheless, the points that we may in the remainder of this Subpart hold whether or not the solution is precisely at this just-binding point or someplace short of it. What is most important is that the Patent Office will be mindful of trading off quality with throughput and however it needs to increase time allocations in the present to strike this balance will likely differ across examiners at different GS levels considering that they are presently operating at different degrees of binding time constraints (as demonstrated by Figure I).

[200]   *See supra* Section I.A.

listed in the Orange Book for increased time allocations. If the Patent Office were able to effectively target applications of this nature, it could enact a reform that costs considerably less than the $20 million annually that we estimated above without sacrificing the benefits, since the benefits we have calculated above are focused on eliminated invalid Orange Book patents. Our interviews with patent examiners suggest that examiners often know whether secondary pharmaceutical patent is associated with an approved drug product, greatly enhancing the likelihood the secondary patent application, if issued, being listed in the Orange Book.[201] To aid in the patent examiner determination of whether a secondary patent, if issued, would likely be listed in the Orange Book, the Patent Office could even request information from the FDA on the molecular structure of all drugs that have been approved, submitted for approval, or under clinical trials. A statutory provision in the Food and Drug Cosmetic Act directs the FDA to respond to the Patent Office requests "to furnish full and complete information with respect to such questions relating to drugs as the Director may submit concerning any patent application."[202] Although the Patent Office has yet to rely upon this provision, theoretically it could be utilized to aid in determining which secondary pharmaceutical patents should receive more time for review.[203] Alternatively, the Patent Office could ask for patent applicants to certify whether they believe the patent application in question if issued would be listed in the Orange Book.

2. Reform Proposal: Concluding Thoughts

Importantly, we note that our proposals to decrease drug pricing by increasing the quality of secondary pharmaceutical patents issued by the Patent Office are modest. They do not require Congressional action or major restructuring of the drug pricing system, as other proposals to diminish prescription drug prices often do.[204] In addition, at least in comparison to a subset of proposals to decrease drug prices, increasing patent examiner time allocations more carefully strikes the balance between the harms associated with high prices facilitated by patent protection and the need to stimulate innovation through the granting of that protection in the first instance.

Admittedly producers will profit less from the accelerated generic entry that results from our reform. Less profits for brand name pharmaceutical companies may reduce the incentives to innovate and develop new prescription medications. Notably, however, the lost profits that will result from our proposal will be focused on areas where the prospect of such profits were not needed to incentivize the creation of the new drug in the first instance. That is, if a chemical compound is not new then a patent was not needed to induce its creation.[205] At the same time, because our proposals allows for valid secondary patents to extend the exclusivity

[201]   More specifically, patent examiners suggest this information is often discovered during prior art search.

[202]   21 U.S.C. § 372(d) (2018); Jonathan J. Darrow, *Pharmaceutical Gatekeepers*, 47 IND. L. REV. 363, 403 (2014) ("The stated purpose of the § 372(d), as described in the accompanying 1962 Senate Report, was unambiguously to reduce the number of patents issued on therapeutically questionable drugs . . .").

[203]   *See* Jonathan J. Darrow, *Pharmaceutical Gatekeepers*, 47 IND. L. REV. 363, 401–403 (2014) (noting the Patent Office lack of reliance upon § 372(d)); Dmitry Karshtedt, *The More Things Change: Improvement Patents, Drug Modifications, and the FDA*, 104 IOWA L. REV. 1129, 1143 (2019) (same).

[204]   Philip Rocco et al., *How Much Does Congress Care About Drug Prices? Less than it Should*, HEALTH AFF. BLOG (Jan. 13, 2016) (commenting that the majority of drug pricing reform proposals would require congressional action despite a decline in congressional attention to prescription drug spending over the past decade); *see also* Kevin Outterson & Aaron S. Kesselheim, *How Medicare Could Get Better Prices on Prescription Drugs*, 28 HEALTH AFF. w832, w833 (2009) (listing common drug pricing reform proposals, all of which require Congressional action).

[205]   35 U.S.C. § 102.

period of a drug, it rewards pharmaceutical companies for additional innovation. In this sense, reforms to the administration of the Patent Office stand in contrast with more blunt approach such as price controls, the latter which are not typically tailored to track the innovativeness of the relevant drugs.[206]

Of course, the above analysis assumes that patentability standards and patent laws more generally are set to optimally encourage innovation in the pharmaceutical industry.[207] To the extent they are not, then the patent laws should be adjusted to better balance the incentives to innovate with the costs associated with monopoly pricing.[208] Importantly, we do not believe the current system is the second-best alternative. That is, even if the patentability standards are too restrictive to enable pharmaceutical manufacturers to recoup the costs associated with drug development, the solution should not to allow invalid secondary patents to issued based on the GS-level of the examiner the application happens to be randomly assigned. Instead, the patentability standards should be adjusted, and the Patent Office should do their best to ensure that patents issue for only those inventions that meet the requirements of patentability. Along this vein, we also acknowledge that increasing examiner time allocations will not solve all pharmaceutical pricing concerns and additional changes to the system may be necessary.[209] Nevertheless, our proposal to increase examiner review time is likely a far more realistic pathway forward for combating rising drug prices than the majority of proposals to diminish the costs of prescription medicines, which entail sweeping changes to the structure of drug pricing.[210]

CONCLUSION

There is little doubt that rising prescription drug prices is a pressing national issue. There is growing concern that pharmaceutical patent practices are unfairly extending the exclusionary period of drug products, resulting in arbitrarily high prescription drug prices. At the heart of this debate is the legitimacy of secondary pharmaceutical patents or patents on peripheral features of a drug. Rather than take a position that all secondary pharmaceutical patents should be embraced or condemned, this Article contends that some secondary patents protect valid novel features that represent true innovation while others

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[206]   Thomas A. Abbott & John A. Vernon, *The cost of U.S. pharmaceutical price regulation: a financial simulation model of R&D decisions*, 28 MANAGERIAL & DECISION ECON. 293 (2017) .

[207]   Not surprisingly, the patentability standards reflect a careful balance between encouraging innovation and avoiding drains on consumer welfare. In order for an invention to be patent eligible it must be both new and represent a nontrivial advancement over current scientific understanding. 35 U.S.C. § 103 (2013). If an invention was obvious to the person of ordinary skill in the art or was already in the public domain, the invention would have likely arisen without the patent incentive. In contrast, an invention that represents a significant advancement in the art may not have arisen but for the patent inducement.

[208]   *See, e.g.,* Roin, *supra* note 60, at 503 (arguing that novelty and nonobviousness standard do not account for the costs of commercializing a drug that may already be in the public domain and hence unpatentable); Sapna Kumar, *Patents, Pharma, and the Pandemic, available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3636456&download=yes (noting several amendments to the Patent Act would enable greater access to pharmaceuticals including adding a limited working requirement and streamlined request for compulsory licenses); Mark A. Lemley, *Expecting the Unexpected*, 92 NOTRE D. L. REV. 1369, 1394 (2017).

[209]   Our proposal, for instance, would not address the business strategy of purchasing all the manufacturers of older drugs and then dramatically increasing the price of that drug. Andrew Pollack, *Drug Goes from $13.50 a Tablet to $750, Overnight*, NY TIMES, Sept. 20, 2015, *available at* https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html. Our proposal would also not address price increases that stem from supply shortages.

[210]   Philip Rocco et al., *How Much Does Congress Care About Drug Prices? Less than it Should*, HEALTH AFF. BLOG (Jan. 13, 2016) (noting the decline in congressional attention to prescription drug spending over the past decade).

offer little to no innovative benefit and hence improperly delay generic entry. As a result, this Article examines whether increasing examiner time allocations for secondary pharmaceutical patents will result in the Patent Office issuing higher quality pharmaceutical patents.

After finding evidence that giving examiners additional review time will result in an increase in the quality of issued patents, this Article conducts a cost-benefit analysis associated with augmenting examiner time allocations. We find that the savings associated of increasing examiner time allocations of more than $1.5 billion dollars overwhelmingly outweigh the $20 million dollars in costs associated with augment examination review time. Thus, this Article strongly advocates for the Patent Office to increase the time it gives patent examiners to review secondary pharmaceutical patents.