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# Evaluating the US Pharmaceutical Patent Policy*

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**Abstract**

The debate on whether COVID-19 vaccine patents are slowing down the pace of vaccination and the recovery from the crisis has brought the optimal design of pharmaceutical patent policy to the fore. In this paper we evaluate patent policy in the US pharmaceutical industry. We estimate the effect of patent length and scope on generic entry prior to the expiration of new drug patents using two quasi-experimental approaches: one based on changes in patent laws and another on the allocation of patent applications to examiners. We find that extending effective patent length increases generic entry whereas broadening protection reduces it. To assess the welfare effects of patent policy, we match these empirical results with a model of new drug development, generic entry, and patent length and scope. Optimal policy calls for shorter but broader pharmaceutical patents.

Keywords: Patent policy, pharmaceuticals, generic entry, innovation, imitation
JEL: I18, K20, L13, O34, O31

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# 1 Introduction

Patent policy aims at stimulating innovation by providing exclusive rights to innovators at the cost of reduced competition. This tradeoff between competition and innovation incentives is at the core of the mature theoretical literature on the optimal design of patent length and scope, dating back to the seminal works by Nordhaus (1969) and (1972). Empirical studies such as Sakakibara and Branstetter (2001), Moser (2005), Quian (2007), and Lerner (2009) estimate the effects of patent policy reforms on innovation.[1] We combine theory and two-quasi experimental approaches to assess the welfare effects of the US pharmaceutical patent policy. Our results indicate that the terms of pharmaceutical patents should be shorter and their scope broader. The key mechanism behind our conclusion is the positive effect of longer patent term on early generic entry: we find that one year increase in effective patent length increases generic entry before the expiration of new drug patents by roughly five percentage points.

The US pharmaceutical industry provides a well-defined setting to assess the effects of patent policy on generic entry: The Drug Price Competition and Patent Term Restoration Act of 1984 (aka the "Hatch-Waxman" Act) introduced generic drug applications with Paragraph IV (PIV) certifications. In such a PIV challenge a generic firm certifies noninfringement or invalidity of a new drug patent, allowing the U.S. Food and Drug Administration (FDA) to approve the generic application before the patent expires. Higgins and Graham (2009), Hemphill and Sampat (2011) and Branstetter et al. (2016) document a substantial increase in PIV challenges during this millennium.

We estimate how the probability of *PIV entry* (generic entry via a PIV patent challenge) is impacted by patent length and scope. We exploit two patent law reforms inducing quasi-experimental variation in the effective terms of patents depending on their prosecution time at the U.S. Patent and Trademark Office (USPTO): First, the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) of 1994 changed the statutory patent term from 17 years from the grant date to 20 years from the first filing date. TRIPS also introduced patent term adjustments (PTAs) to compensate for delays in patent prosecution, but we document that those USPTO PTAs were initially insignificant. Second, the American Inventors Protection Act (AIPA) of 1999 expanded PTAs to compensate for long delays in patent prosecution. We show how the two reforms affected

[1] Denicolò (1996) and Belleflamme and Peitz (2015, Chapter 19) synthesize the theoretical literature and Boldrin and Levine (2013), Moser (2013), Budish et al. (2016), and Sampat (2018) survey the empirical evidence.

the effective terms of patents with grant lags exceeding three years, whereas the effective terms of patents with shorter grant lags were hardly changed.

Using difference-in-differences (DiD) regressions, we find that TRIPS decreased the effective terms of patents prosecuted at least three years by 17 percent, compared to other patents. This shorter effective patent length reduced the rate of PIV entry around 8–10 percentage points. In contrast, AIPA increased the effective terms of patents with the long prosecution lags by 10 percent, which in turn increased the rate of PIV entry by seven percentage points. These results, together with supporting evidence from ordinary least squares (OLS) regressions, suggest a positive effect of longer patent duration on PIV entry.

Using multiple measures of patent scope and OLS regressions, we also find evidence of broader patent scope reducing PIV entry. To address the endogeneity of patent scope, we develop instrumental variables (IV) for some of our scope measures by exploiting differences in the propensity of patent examiners to grant broader or more claims. The evidence from our IV regressions – though not conclusive given the lack of fully randomized examiner assignment (see Righi and Simcoe, 2019) – implies that broader patent scope decreases the PIV entry rate by about two percentage points.

To turn these data moments into policy prescriptions we build on the theory of costly imitation pioneered by Gallini (1992). Our model, while highly stylized, captures essential margins of pharmaceutical patent policy in the Hatch-Waxman era: The expiration of a new drug patent enables generic entry resulting in savings for consumers and a loss of profit for the originator firm. There is also a possibility of early generic entry via a costly PIV challenge. Patent scope affects the costs and thereby the probability of the early generic entry. Optimal patent policy must balance incentives to develop new drugs, and costs and consumer savings from generic entry.

The model allows a welfare analysis of the effects of patent length and scope only using data on generic entrants', rather than, e.g., innovating firms' or consumers', responses to policy changes. To provide policy recommendations, we only need to measure the probability of PIV entry and its elasticity with respect to effective patent length or patent scope. Based on the DiD and IV estimates, we extrapolate the elasticity of PIV entry with respect to effective length and scope to be around three and $-1$, respectively. Using these elasticity estimates, we calibrate the effects of changes in patent length and scope on innovation and consumer welfare. The results point to the optimality of shorter patent length, which should be compensated for originator firms by broadening

the scope of protection. This conclusion is at odds with some policies of balancing competition and innovation incentives in the pharmaceutical industry. For example, the Hatch-Waxman Act – as its official name suggests – simultaneously lengthened pharmaceutical patent terms and narrowed their scope by introducing the FDA patent term extension and PIV challenge mechanism.

Our empirical work is inspired by the studies on the effects of TRIPS (e.g., Abrams, 2009; Kyle and McGahan, 2012) and of commercialization lags (Budish et al., 2015) on innovation in the pharmaceutical industry. Our paper differs from these studies, e.g., in that we consider imitation as an outcome variable, the effects of AIPA, and patent policy structure. We also draw on Kuhn and Thompson (2019), Sampat and Williams (2019), Farre-Mensa et al. (2020) and Feng and Jaravel (2020) who develop similar examiner-leniency IVs as we do. Unlike these papers, we use examiner variation to estimate the impact of patent scope on non-patent outcomes. Related to our results, Gilchrist (2016), who also builds on the theory of Gallini (1992), shows how longer drug patent term encourages the entry of differentiated originator products.

Methodologically, our policy evaluation builds on the sufficient statistics approach (Chetty, 2009). We estimate the effects of changes in effective patent length and scope on generic entry, using these estimates to recover generic entry elasticities which determine the patent policy recommendations in our paper. In this respect related papers are Denicolò (2007) and Budish et al. (2016) who use estimates from earlier empirical work to construct innovation elasticities for their analyses of patent policy.

We abstract away from cumulative innovation – see Galasso and Schankerman (2015) and Sampat and Williams (2019) for the effects of the existence of patents on follow-on pharmaceutical innovation. However, characterizing the effects of patent length and scope in the classic stand-alone innovation framework at the heart of the Hatch-Waxman Act should also constitute the first step towards understanding of optimal drug patent policy when innovation is cumulative. Finally, while the sufficient statistics approach allows an evaluation of pharmaceutical patent policy without a need to collect or estimate difficult-to-obtain information on, e.g., R&D costs, and private and social value of new drugs, the precise policy prescription may be sensitive to some model details (as will be discussed at the end of Section 7). Yet, our empirical results of the effects of patent length and scope on PIV entry on their own should provide valuable information for the design of drug patent policy.

# 2 A Model

## 2.1 Assumptions

We consider a pharmaceutical market with an originator (brand) drug manufacturer (firm B) and a generic drug manufacturer (firm G). The originator firm can invest in developing a new drug, automatically protected by a patent. The generic firm can invest in challenging the new drug patent. We allow for no ex ante licensing.

Some of these simplifying assumptions reflect industry practices. For example, the Hatch-Waxman Act contains mandatory disclosure requirements which eliminates the originators' possibilities to use secrecy, forcing them to rely on patents (see, e.g., Tang, 2013). There is also little evidence of generic entry via licensing prior to PIV challenges. On the contrary, our data, as also, the results e.g., in Higgins and Graham (2009), Hemphill and Sampat (2011) and Branstetter et al. (2016), show that PIV challenges occur frequently. (We return to this ex-ante licensing issue at the end of Section 7.) However, although the Hatch-Waxman Act awards the first generic entrant via a PIV challenge a 180-day exclusivity period during which no further generic entry is allowed, there may in practice be many generic entrants. Allowing many generic challengers would complicate the model without changing its empirical implications.[2]

The success $Y_f : \{0,1\} \to \{0,1\}$, $f = B, G$, of the firm $f$'s investment has a Bernoulli distribution with parameter $p_f \in [0,1]$. Time $t \in [0,\infty)$ is continuous but, for brevity, we assume that the firms act sequentially at $t = 0$ by directly choosing the their success probabilities $p_f$. (Alternatively, we may think that the firms choose an investment from a collection of projects indexed by $p_f$.) The associated investment cost functions $C_f : [0,1] \to [0,\infty)$ are twice continuously differentiable with the standard properties $\partial C_f/\partial p_f > 0$ and $\partial^2 C_f/\partial p_f^2 > 0$ for $p_f > 0$, and $C_f(0) = \partial C_f(0)/\partial p_f = 0$. The cost functions are sufficiently convex to satisfy second-order conditions.

We consider two patent policy variables, length (term) $T \in [0,\infty)$ and scope (breadth) $b \in [0,\infty)$. (To simplify the proofs, we only allow $b$ and $T$ to take arbitrarily large but finite values.) As is

[2]With one generic challenger, we need not to differentiate between successful non-infringement and invalidity challenges. A generic firm has a stronger incentive to file an infringement challenge since the challenged patent is still valid and enforceable against other generic firms. The prior work (see, e.g., Gallini, 1992; Wright, 1999; Maurer and Scotchmer, 2002) suggest that allowing multiple entrants via non-infringement challenges would not qualitatively change the results. If generic entry occurs via invalidation rather than non-infringement, however, then a waiting game among generics might arise (Henry and Ponce, 2011). But in our context the 180-day exclusivity period dilutes the generics' incentives to wait.

common in the theoretical literature (see Budish et al., 2015, for an exception), we assume that a marketing authorization and a patent are granted to a new drug simultaneously upon the investment success realization $y_B = 1$ at $t = 0$, from which patent length is counted. Hence, $T$ reflects *effective patent length*.

Following Gallini (1992), we assume that if a new drug patent expires at $t = T$, then $\partial C_G(p_G, b)/\partial b > 0$ for $t < T$ and $b = 0$, with $C_G(p_G, 0) = 0 \ \forall p_G$, for $t \geq T$. (Maurer and Scotchmer, 2002, argue for this modeling of patent scope.). In words, a broader patent makes early generic entry more difficult whereas the patent expiration makes generic entry costless. For example, sometimes pharmaceutical patents can relatively cheaply be designed around by replacing one component with a slightly different one that serves the same function, but if patent claims are broader or interpreted more broadly by the courts, designing around becomes more difficult (Tang, 2013; Voet, 2016). There are also other costs of generic entry specific to the scope of new drug patents (e.g., costs of the FDA approval process and associated litigation). In *Allergan, Inc v. Exela Pharmasci, Inc*, for example, the Federal Circuit found Exela's design-around formulation sufficiently different to avoid infringement of Allergan's patent, but the same difference prompted the FDA to request Exela to perform expensive bioequivalence studies (Voet, 2016). Higgins and Graham (2009) report the average cost of a PIV challenge to be $5 million. While the assumption of costless post-patent entry is made for simplicity, the Hatch-Waxman Act greatly reduced the costs and lags of generic entry after patent expiration (see, e.g., Tang, 2013).

After the realizations $y_f \in \{0, 1\}$ of $Y_f$, $f = B, G$, the firms compete in the market. The net cash flow from selling a drug is given by $\widetilde{\pi}_N \in [0, \infty)$, in which subscript $N \in \{0, 1, 2\}$ denotes the number of competing drugs in the market. The pharmaceutical market will exist only if $y_B = 1$; otherwise $N = 0$ and $\widetilde{\pi}_0 = 0$. Conditional on $y_B = 1$, our assumptions imply that $N = 1$ only if $t < T$ and $y_G = 0$; otherwise $N = 2$. As usually, $\widetilde{\pi}_1 > 2\widetilde{\pi}_2$. (The assumption of equal net cash flows upon entry can be relaxed at the cost of complicating the notation.)

Somewhat as in Wright (1999), the shape of $C_G(p_G, b)$ turns out to be a determinant of our patent policy evaluation. We introduce the following definitions:

$$\epsilon_p(p_G) := p_G \frac{\partial^2 C_G/\partial p_G^2}{\partial C_G/\partial p_G}, \tag{1}$$

and

$$\epsilon_b(p_G) := p_G \frac{\partial^2 C_G/(\partial b \partial p_G)}{\partial C_G/\partial b}. \tag{2}$$

The elasticity of the marginal cost of patent challenging, $\epsilon_p(p_G)$, provides a measure of the convexity of the generic firm's cost function. To avoid the need to check out additional corners, we assume that $\epsilon_p(p_G) > 0 \; \forall p_G$. (The additional restrictions here are mild, since our other assumptions imply that $\epsilon_p(p_G) > 0$ at least for $p_G \in (0,1)$.) In turn, $\epsilon_b(p_G)$ is the elasticity of the impact of patent scope on patent challenging costs. Since $\partial C_G/\partial b > 0$, the sign of $\epsilon_b(p_G)$ is given by the sign of $\partial^2 C_G/(\partial p_G \partial b)$. We assume that $\partial^2 C_G/(\partial b \partial p_G) > 0$.

**Assumption 1.** $\epsilon_b(p_G) > 0$.

According to Assumption 1, the effect of patent scope on patent challenging costs is the stronger the easier is patent challenging. Besides shortening the analysis considerably, making this simplification has four justifications: First, as shown in online Appendix 1, effects of patent scope in the case $\epsilon_b \leq 0$ are counterintuitive. For example, if $\epsilon_b < 0$, an increase in patent scope making patent challenging more expensive has a *positive* impact on the probability of a successful patent challenge. Second, our results concerning patent length do not depend on Assumption 1 (see online Appendix 1). Third, our empirical results of the negative effect of broader patent scope on PIV entry provide support for Assumption 1. Fourth, this assumption is often implicitly done in the previous literature modelling imitation costs as a function of patent scope.

We consider the following two-stage game: In the first stage the originator firm first chooses $p_B(b,T) \in [0,1]$. In the second stage, after observing $y_B$, the generic firm chooses $p_G(y_B,b,T) \in [0,1]$. The outcome $y_G$ of that investment is realized. The firms collect their payoffs depending on the realizations of $Y_f$, $f = B,G$, and patent length $T$. Denote the firm $f$'s expected profit by $\Pi_f$. A subgame perfect equilibrium of this game is a pair $(p_B^*, p_G^*(y_B(p_B)))$ such that for $y_B(p_B) \in \{0,1\}$, $p_G^*(y_B(p_B)) = \arg\max_{p_G \in [0,1]} \Pi_G(p_G, y_B(p_B))$ and $p_B^* = \arg\max_{p_B \in [0,1]} \Pi_B(p_B, p_G^*(y_B(p_B)))$. In what follows, we present the main arguments leading to our results, relegating to Appendix 1 their technical proofs.

## 2.2 Equilibrium Analysis

Consider the second stage of the game after the realization of $Y_B$. Clearly, if $y_B(p_B) = 0$, the drug market fails to arise, and $p_G^* = 0$. We therefore focus on determining the part of the equilibrium where the market exists, $(p_B^*, p_G^*(y_B(p_B) = 1))$, and suppress the argument $y_B(p_B)$ for brevity.

Given $y_B(p_B) = 1$ the generic firm's problem can be expressed as

$$\max_{p_G \in [0,1]} \Pi_G = p_G \int_0^\infty e^{-rt} \widetilde{\pi}_2 dt + (1 - p_G) \int_T^\infty e^{-rt} \widetilde{\pi}_2 dt - C_G(p_G, b), \tag{3}$$

in which $r \in (0, \infty)$ denotes the firms' common discount rate. The first integral on the right-hand side of equation (3) captures the generic firm's profits if, with probability $p_G$, it successfully challenges the new drug patent. The second integral captures the profits if, with probability $1 - p_G$, the challenge fails and the generic entry is postponed until the patent expiration.[3] The last term captures the costs of patent challenging.

Using $\pi_2 := \widetilde{\pi}_2 / r$ we can write the first-order condition for the problem (3) as

$$\left(1 - e^{-rT}\right) \pi_2 - \frac{\partial C_G(p_G^*, b)}{\partial p_G} = 0. \tag{4}$$

Equation (4) identifies for each patent policy $(b, T) \in [0, \infty)^2$ a unique probability that a new drug patent is successfully challenged by a generic entrant. We may hence consider a new drug patent "probabilistic" (Lemley and Shapiro, 2005), with the endogenous strength of $1 - p_G^*(b, T)$. As shown by equation (4) the mapping $p_G^*(b, T)$ is qualitatively invariant to many model details. On the other hand, modifications to the model that quantitatively affect $p_G^*(b, T)$ should be reflected to our empirical estimation results.[4] Proposition 1 establishes the main properties of the mapping $p_G^*(b, T)$.

[3] As Tang (2013, p.1083) writes "...the generic manufacturer can decide to push market entry before the patent expires by filing a PIV challenge...Even if it loses the PIV challenge, it can still market its drug immediately after the patent expires..."

[4] Even equation (4) in itself is fairly resilient to some changes in model details. For example, assuming that a generic entrant's profit flow is smaller when $t \geq T$ than when $t < T$ makes both a PIV challenge and waiting for patent expiration less lucrative, and these effects tend to cancel out each other: Consider, e.g., free entry after patent expiration which drives profits to zero. Then the generic's problem $\max_{p_G \in [0,1]} \Pi_G = p_G \int_0^T e^{-rt} \widetilde{\pi}_2 dt - C_G(p_G, b)$ leads to the same first-order condition (4).

**Proposition 1:** *Increasing patent length or narrowing patent scope increases the probability of PIV entry.*

Proposition 1 confirms the standard results arising from the models of patent policy with costly imitation like ours: A longer patent duration makes waiting for patent expiration less attractive and hence stimulates early generic entry, whereas broader patent scope discourages patent challenging by increasing its costs

In the first stage the originator firm chooses $p_B$. The value of an approved new drug to its manufacturer is given by

$$V^P(T, p_G^*(b,T)) = \int_0^T e^{-rt}\left[\left(1 - p_G^*\left(b,T\right)\right)\widetilde{\pi}_1 + p_G^*\left(b,T\right)\widetilde{\pi}_2\right]dt + \int_T^\infty e^{-rt}\widetilde{\pi}_2 dt, \tag{5}$$

in which $p_G^*\left(b,T\right)$ is determined by equation (4). The first term on the right-hand side of equation (5) depicts the originator's profits when its new drug patent is in force. The originator firm will retain market exclusivity if the generic's patent challenge fails (the first term in the square brackets) but will encounter competition if the patent challenge succeeds (the second term in the square-brackets). The second term expresses the originator's profits after the patent expiration.

The originator firm's problem is given by

$$\max_{p_B \in [0,1]} \Pi_B = p_B V^P(T, p_G^*(b,T)) - C_B(p_B),$$

in which $V^P(T, p_G^*(b,T))$ is given by equation (5) and the last term captures the costs of developing a new drug. The first-order condition for this problem is given by

$$V^P(T, p_G^*(b,T)) - \frac{\partial C_B(p_B^*)}{\partial p_B} = 0. \tag{6}$$

Equations (4) and (6) determine the unique subgame perfect equilibrium $(p_B^*, p_G^*)$ with a market for a new drug ($y_B(p_B) = 1$). .

To facilitate the analysis of patent policy, we define

$$\phi(p_G) := \epsilon_p(p_G) - \frac{p_G}{1 - p_G}, \tag{7}$$

in which $\epsilon_p(p_G) > 0$ is defined by equation (1). Then, we have the following result:

**Proposition 2:** *Broader patent scope increases incentives to develop new drugs. Increasing (decreasing) patent length increases incentives to develop new drugs if* $\phi(p_G^*) > 0$ $(\phi(p_G^*) < 0)$.

Propositions 1 and 2 suggest, as is intuitive, that the sign of $\partial p_B^*/\partial b$ is the reverse of the sign of $\partial p_G^*/\partial b$: broader patent scope weakens incentives to challenge new drug patents which in turn enhances incentives to develop new drugs.

In contrast, an increase patent length has both a direct and an indirect effect on incentives to develop new drugs. The direct effect is positive: given the generic's incentive for patent challenging, the originator's market exclusivity lasts longer in expectation. However, the indirect effect via $p_G^*$ is negative: a longer patent duration enhances incentives for patent challenging. Hence, an increase in patent length can have a positive or a negative effect on incentives to develop new drugs depending on whether the direct or indirect effect dominates, which in turn depends on the sign of $\phi(p_G^*)$.[5] As shown in Section 7, however, the case $\phi(p_G^*) < 0$ is not only counterintuitive but also unlikely: If $\phi(p_G^*) < 0$, the originator firm would have an incentive to shorten the effective length of its patent. Also, our empirical results suggest $\phi(p_G^*) > 0$.

### 2.3 Welfare Analysis

Let us denote welfare flow from a new drug by $\widetilde{w}_N \in [0, \infty)$ when $N \in \{0, 1, 2\}$ drugs compete in the market. As usual, $\widetilde{w}_{N+1} > \widetilde{w}_N$ and $\widetilde{w}_0 = 0$.

Analogous to the private value of a new drug given by equation (5), we can write the social value of an existing new drug as

$$\begin{aligned} V^S(b,T) &= \int_0^T e^{-rt}\left[\left(1 - p_G^*(b,T)\right)\widetilde{w}_1 + p_G^*(b,T)\,\widetilde{w}_2\right]dt \\ &\quad + \int_T^\infty e^{-rt}\widetilde{w}_2 dt - C_G(p_G^*(b,T), b), \end{aligned} \tag{8}$$

[5] With mild additional assumptions ($\partial\phi/\partial p_G < 0$ and $\lim_{T\to\infty}\phi(p_G^*(T)) < 0$), these direct and indirect effects of patent length would create the inverted-U relationship between patent length and innovation incentives (with the peak at some $T'$ solving $\phi(p_G^*(T')) = 0$), which has been discovered in the literature (see, e.g., Gallini, 2002; Quian, 2007).

in which $p_G^*(b,T)$ is identified by equation (4). The first and second term on the right-hand side of equation (8) give welfare from a new drug before and after its patent expires, respectively. The last term captures the generic's patent challenging cost.

Following the standard practice, we formulate the patent policy problem as follows:

$$\max_{b\in[0,\infty),\, T\in[0,\infty)} V^S(b,T) \tag{9}$$

subject to

$$p_B^*(b,T) = \overline{p}_B.$$

This formulation simplifies the analysis of optimal policy by determining the combination of patent length and scope that provides a desired level of incentives to develop new drugs ($\overline{p}_B$) with the least amount of welfare distortions. An interpretation is that a solution the problem (9) characterizes the optimal patent policy reform while keeping incentives to innovate unchanged. Recalling that $\epsilon_b(p_G) > 0$, the solution to the problem (9) can be expressed as follows:

**Proposition 3**: *i) If* $\phi(p_G^*) < 0$,*reducing both patent length and scope is efficient; ii) If* $\epsilon_b(p_G^*) > \phi(p_G^*) > 0$, *reducing patent length and increasing scope is efficient; iii) If* $\phi(p_G^*) > \epsilon_b(p_G^*)$, *increasing patent length and reducing scope is efficient.*

We may explain Proposition 3 as follows: If $\epsilon_b(p_G^*) > \phi(p_G^*)$, long-lived patents are inefficient irrespective of the sign of $\phi(p_G^*)$. This result tends to arise from the models of costly imitation. In our context, long patent duration is ineffective in promoting new drug development, since it also increases incentives for early generic entry.

When shortening the patent term is desirable, the sign of $\phi(p_G^*)$ determines the optimal changes to patent scope. If $\phi(p_G^*) > 0$, shorter patent length has an adverse effect on incentives to develop new drugs, which should be compensated for originator firms by making patents broader. If $\phi(p_G^*) < 0$, shortening patent length has a *positive* effect on incentives to develop new drugs, and patents can be made narrower without jeopardizing new drug development. Thus the sign of $\phi(p_G^*)$ also determines whether patent length and scope are *substitutable* or *complementary* policy tools with regard to new drug development (see Belleflamme and Peitz, 2015, for this terminology).

Nonetheless, even in the presence of costly imitation, narrow and long-lived patents could be

efficient. Here this scenario happens when $\phi(p_G^*) > \epsilon_b(p_G^*)$. If $\epsilon_b(p_G^*)$ is small, changes in patent scope have only a relatively small impact on incentives for early generic entry but a relatively large impact on its costs. Thus, distortions caused by broader patents can even be larger than distortions caused by longer patents. It is, however, difficult to come up with a cost function that would generate this outcome.

**Example 1.** Assume that the generic firm's cost function takes the form

$$C_G(p_G, b) = \frac{c(b)p_G^{\eta_G}}{\eta_G}, \tag{10}$$

in which $\eta_G > 1$ is a constant capturing the elasticity of the cost function, and $c(b) \geq 0$ denotes a constant scaling the cost function. Assume that this constant is an increasing function of patent scope, $\partial c/\partial b > 0$. This constant elasticity cost function implies that Assumption 1 holds and, as a result, Propositions 1 and 2 also hold.

As to the patent policy, equation (10) implies that $\epsilon_p = \eta_G - 1$, and we can rewrite equation (7) as

$$\phi(p_G) = \eta_G - \frac{1}{1 - p_G}. \tag{11}$$

Applying equation (10) in the definition (2) yields $\epsilon_b = \eta_G$. As a result, $\epsilon_b > \phi(p_G)$. Thus, by Proposition 3, short-lived patents are efficient irrespective of the sign of $\phi(p_G)$. However, the sign of $\phi(p_G)$ determines the sign of $\partial p_B^*/\partial T$ and whether patent length and scope are substitutable or complementary policy tools.

### 2.4 Implications for Empirical Analysis

Propositions 1-3 suggest three hypotheses for the design of patent policy that can be evaluated by merely using data on generic challenges to new drug patents: First, like other models of costly imitation, our model predicts that $\partial p_G^*/\partial T > 0$. If $\partial p_G^*/\partial T > 0$ holds in our data, then the patent policy design for the pharmaceutical industry should take into account the distortions arising from enhanced incentives for patent challenging.

Second, we determine the sign of $\partial p_G^*/\partial b$ in our data by using multiple measures of patent scope. Our model, as is common in the theoretical literature, associates broader scope with stronger

exclusive rights leading to $\partial p_G^*/\partial b < 0$. However, commonly used empirical proxies of scope do not necessarily generate such relation.

Third, the optimal structure of patent length and scope can be characterized by comparing the magnitude of $\phi(p_G^*)$ to zero and $\epsilon_b(p_G^*)$. The optimal policy rule is invariant to many model details such private and social value of new drugs and the originator's R&D costs. But this simplicity comes at a cost: While we can measure $p_G^*$ directly, we need to retrieve the elasticities $\epsilon_p$ and $\epsilon_b$ indirectly. We develop two approaches: one based on the point estimate of $\partial p_G^*/\partial T$ and another based on the point estimate of $\partial p_G^*/\partial b$. This indirect approach renders our policy recommendation sensitive to some calibration details (which will be discussed at the end of Section 7). Fortunately, we can test the first and second hypothesis directly, and the results on their own provide information for the patent policy design.

# 3 Construction of Data and Variables

The FDA is our source of the data concerning patents protecting approved new drugs, generic entry before patent expiration, and new drug characteristics. We obtain information on patent attributes from the USPTO and the European Patent Office (EPO). We next explain the construction of variables used in our main regressions. Online Appendices 2–4 contain further details of our data sources, the dataset development, and the description of variables used in robustness checks.

## 3.1 Identifying New Drug Patents

We construct our sample of new drug patents from 2001 – 2013 annual editions of the Orange Book, which lists patents protecting approved new drugs and their expiration dates. Our sample thus excludes both drug patents that expired before 2001 and patents of drugs whose marketing authorization expired before 2001. Sample truncation arising from the exclusion of these old patents is hardly biasing our estimates since PIV challenges only began to grow in the late 1990s (see Figure 1).

A more serious truncation bias is likely to stem from the patents with long grant lags filed at the end of our observation period, since such patents were still pending in 2013. To mitigate this truncation bias, we only use patents filed before 2009. Our results are similar without this sample

restriction. Long grant lags could also cause a reverse distortion at the beginning of our observation period if a patent was filed before 1980, but our data contains only 14 such patents. We drop all patents with grant lags exceeding five years in robustness analyses.

Our final sample consists of 3517 new drug patents granted between 1980 – 2013 and listed in the Orange Book.

### 3.2 Measuring Early Generic Entry

In a PIV challenge, a generic firm seeks to enter prior to the expiration of a new drug patent listed in the Orange book by filing an FDA application with a certification that the patent is invalid or noninfringed by the generic product (FDA, 2004). Our outcome variable is an indicator for whether a new drug patent listed in the Orange Book has successfully been challenged at least once. Thus, similar to the empirical literature on entry (see, e.g., Ciliberto and Elie, 2021), we focus on actual generic entry before patent expiration, rather than generic firms' attempts (including failed ones) to enter. This outcome variable yields a direct measure of $p_G^*$, the key variable of the theoretical model of Section 2.

We obtain a list of 1020 approved generic drugs with a PIV certification from the FDA. The list, however, contains no patent information. To identify the successfully challenged new drug patents, we read the FDA's generic drug approval letters. Some of the approval letters are readily available from the Drugs@FDA database. We obtain more approval letters by submitting the Freedom of Information Act requests to the FDA. However, we fail to specify the challenged patents for 343 approved generic drugs with a PIV certification.

Although the missing patent observations may lead to an underestimate of the number of successful PIV challenges at a patent level, the measurement error in our outcome variable, the indicator for at least one successful PIV challenge of a patent, is likely to be small. To measure the outcome variable accurately, it suffices to observe only one of potentially many successful PIV challenges. Moreover, when we aggregate successful challenges to the active ingredient level, we almost always observe corresponding challenged patents in our sample. We provide further arguments for why missing patent information is unlikely to bias the results in online Appendix 2.

Figure 1 depicts the number of new drug patents challenged by generic entrants in our sample by the entry year. If we observe multiple PIV challenges of the same new drug patent, we use the

one with the earliest generic drug approval date. While using a different measure, Figure 1 confirms the finding documented by, e.g., Branstetter et al. (2016) that generic entry via PIV certifications became de facto possible only after a series of well-known legal and policy changes at the turn of the millennium.

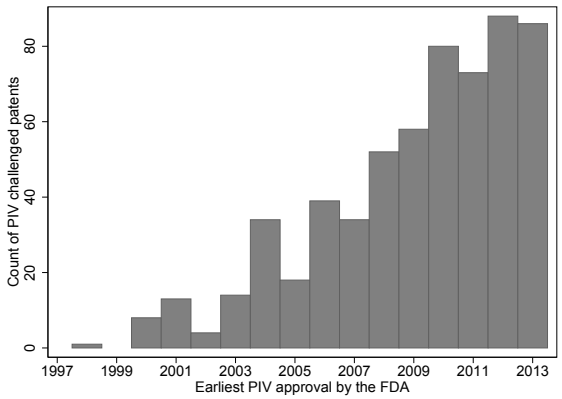



Figure 1: PIV Challenged New Drug Patents.

*Notes:* The figure shows the number of new drug patents that have been challenged via PIV certifications by generic entrants. In the case of several challenges to the same patent, we use the challenge with the earliest approval year.

### 3.3 Measuring Effective Patent Length

The term of a patent can be measured in various ways. Following the model of Section 2, we calculate the *effective length* of a new drug patent – the period when a patent is in force and protects an approved new drug – by subtracting from the expiration date of the patent either its grant date or the approval date of a drug protected by the patent, whichever date is later. If the patent protects several new drugs, we use the first of their approval dates. We use the USPTO Patent Examination Research Dataset (PatEx) to determine patent grant dates and the Orange Book to identify the dates of patent expirations and new drug approvals.

This effective patent length varies for three reasons. First, its starting date depends on whether the FDA drug approval or the USPTO patent grant comes later and is hence affected by approval and grant lags. Note that the USPTO grant lags may also affect the effective length even when it runs from the FDA approval date. For example, originator firms may want to ensure the possession of core patents even before entering clinical trials (see, e.g., Budish et al., 2015). Second, legal reforms changed the standard patent term in the US during our observation period. Third, patent-

specific term extensions and adjustments partially compensate for both the FDA and USPTO lags. (We explain these patent term reforms and USPTO term adjustments in Section 5.1.)

### 3.4 Measuring Patent Scope

We identify several measures of patent claim scope from the USPTO Patent Claims Research Dataset. We calculate the count of "Markus groups" in the first independent claim. Drug patent claims often include such Markush groups – lists of functionally equivalent alternatives (see, e.g., Kuhn and Thompson, 2019). The count of Markush groups in the first independent claim of a patent might reflect different potential uses of the drug protected by the patent, and hence its scope. A common and acceptable form of a Markush group is *"...selected from the group consisting of A, B, and C."*.[6] We thus use the count of the phrase "selected from" in the first independent claim as a proxy for the count of Markush groups. (Using the phrase "consisting of" as a proxy for a Markush group gives similar results.) We also calculate the count of "or" in the first independent claim, since the conjunction "or" might be used to introduce variants or different elements of the drug protected by the patent.

Similarly, we calculate the count of words in the first independent claim. (Using the count of characters gives similar results.) Some studies (e.g., Akcigit and Ates, 2019; Kuhn and Thompson, 2019; Marco et al., 2019) use claim length as an inverse proxy for patent scope. However, Kuhn and Thompson (2019) argue that the use of Markush groups reverses this inverse relationship between claim length and scope in the case of pharmaceutical patents. Following, e.g., Lanjouw and Schankerman (2001, 2004) and Marco et al. (2019), we also use the number of independent claims as a proxy for patent scope.

Measures of patent claim scope are frequently used in the literature since they are easy to construct and their legal foundations are clear: the purpose of patent claims is to mark the boundaries of patent rights (e.g., Merges and Nelson, 1990; Freilich, 2015). Therefore, patent claim scope is also at the center of PIV challenges (e.g., Tang, 2013; Voet, 2016). Moreover, claim scope measures allow us to formulate patent-examiner specific instruments in an attempt to identify the effects of patent scope on PIV patent challenges (see Section 6). Yet, measures of claim scope are at best

[6] See, e.g., the USPTO Manual of Patent Examining Procedure ($9^{th}$ edition) §803.02, `https://www.uspto.gov/web/offices/pac/mpep/s803.html#d0e98237` (accessed February 5, 2020).

imperfect proxies for patent scope and, at worst, it is ambiguous whether a change in a claim scope measure (e.g., an additional claim or word) makes a patent broader or narrower. We thus also seek alternative proxies for patent scope.

Using the Orange Book, we create dummies measuring whether or not a patent in our sample protects a drug with new chemical entity (NCE), orphan drug, or pediatric exclusivity. These exclusivities, granted by the FDA upon approval of the drug, prevent generic companies from using clinical trials data of originator drugs during the exclusivity period. NCE exclusivity last four to five years, and orphan drug exclusivity seven years. These exclusivities thus should make a drug patent stronger compared to patents with no exclusivity or with the three year clinical investigation exclusivity. Pediatric drugs may get six months of exclusivity on the top of other exclusivity periods *and* the patent term. Pediatric exclusivity thus makes patent protection both broader and longer.

Finally, we create dummies measuring whether a patent in our data covers an active ingredient, a method of use, or some other pharmaceutical invention (e.g., drug composition or formulation). Active ingredient patents might provide stronger protection than other new drug patents (Hemphill and Sampat, 2011). We infer these patent properties from the abstracts and claims of patents by using text pattern recognition algorithm and manual verification (see online Appendix 2).

### 3.5 Other Patent Characteristics

We control for several characteristics of our sample patents and of the drugs protected by those patents. We determine from the Orange Book whether a patent protects a drug that is available as a capsule, an injection, a tablet or in some other, less common form. A dosage form may affect generic firms' incentives to engage in PIV challenges, since some dosage forms may be easier, e.g., to manufacture or to distribute, or to use by consumers (Hemphill and Sampat, 2011). From the Drugs@FDA database, we identify whether a patent protects a drug priority reviewed by the FDA. Such priority reviews may reflect drug value.

We collect backward and forward patent citations from the USPTO Patent Full-Text and Image Database (PatFT), and patent family sizes from the Open Patent Services of the EPO. Patent family size and citations are common indicators of patent value (Lanjouw and Schankerman, 2004; Gambardella et al., 2008). Backward citations could also serve as proxy for patent scope: for example, careful documentation of prior art can make a patent difficult to invalidate on the grounds of

failure to disclose prior art (Lanjouw and Schankerman, 2001; Harhoff and Reitzig, 2004). However, a high number of backward citations may also indicate a patent protecting an incremental invention, which could make the patent less lucrative for PIV challenges.

From PatEx, we identify patents filed as continuation, continuation-in-part or divisional applications. Such "continuing patents" may differ from other patents across various dimensions (Lemley and Moore, 2004) that may affect propensity to encounter PIV challenges.

We retrieve the main three-digit U.S. Patent Classification (USPC) number and the filing year of each patent in our sample from PatEx, and use them as fixed effects to control for technology specific idiosyncrasies and time trends in patenting. To account for possible negative bias in our length estimates due to different exclusivity periods, we construct fixed effects for the latest exclusivity expiration year (obtained from the Orange Book).[7] To cluster the regression standard errors, we identify from the Orange Book the first FDA-approved active ingredient related to each patent.

### 3.6 Summary Statistics

Table 1 reports the summary statistics for our sample of 3517 new drug patents. Over 17 percent of these patents have been successfully challenged by generic firms via PIV certifications. The effective length of pharmaceutical patents is 12.6 years, varying from one month to 20 years. Using related measures, Hemphill and Sampat (2012) and Gilchrist (2016) report average new drug patent lengths of 15.9 and 11.8 years, respectively.

A new drug patent has three independent claims on average. An average first independent claim contains one Markush group and 117 words of which three are the conjunction "or". The average numbers of backward and forward citations are both roughly around 35, and the mean patent family size is 13. All count variables have highly skewed distributions.

Half of the patents in our sample protect a drug covered by either NCE exclusivity or orphan drug exclusivity. Furthermore, pediatric exclusivity is attached to 18 percent of the patents. Approximately 23 percent of the patents concern active ingredients and 31 percent concern new methods of use. A majority of the patents are filed as continuing applications. Around 20 percent of the

[7] When constructing these fixed effects, we group together patents for which we observe no exclusivity. This group includes both drugs without FDA exclusivity and drugs whose exclusivity expired before 2001. Our results remain similar when estimated only using the sample of patents protecting drugs for which we observe exclusivity (see Table 7 in online Appendix 3).

Table 1: Summary Statistics for New Drug Patents.

| | Mean | Std. Dev. | Min | Max | N |
|---|---|---|---|---|---|
| PIV entry | 0.171 | 0.377 | 0 | 1 | 3517 |
| Effective length | 12.586 | 3.931 | 0.096 | 20 | 3517 |
| Markush groups | 0.704 | 4.151 | 0 | 112 | 3485 |
| Conjuctions "or" | 3.256 | 9.572 | 0 | 184 | 3485 |
| Words | 116.890 | 153.337 | 1 | 2197 | 3485 |
| Independent claims | 3.187 | 3.840 | 1 | 92 | 3488 |
| NCE exclusivity | 0.374 | 0.484 | 0 | 1 | 3517 |
| Orphan drug exclusivity | 0.123 | 0.328 | 0 | 1 | 3517 |
| Pediatric exclusivity | 0.177 | 0.382 | 0 | 1 | 3517 |
| Method patent | 0.311 | 0.463 | 0 | 1 | 3517 |
| Active ingredient patent | 0.226 | 0.419 | 0 | 1 | 3517 |
| Forward citations | 35.705 | 57.889 | 0 | 1297 | 3517 |
| Backward citations | 34.065 | 63.209 | 0 | 1005 | 3517 |
| Patent family size | 13.418 | 12.031 | 1 | 51 | 3511 |
| Continuing patent | 0.589 | 0.492 | 0 | 1 | 3517 |
| Priority review | 0.078 | 0.269 | 0 | 1 | 3517 |
| Tablet | 0.384 | 0.486 | 0 | 1 | 3517 |
| Capsule | 0.160 | 0.366 | 0 | 1 | 3517 |
| Injectable | 0.195 | 0.397 | 0 | 1 | 3517 |

*Notes:* This table reports summary statistics for our sample of 3517 new drug patents. PIV entry equals 0 if a patent has never been successfully challenged via a PIV certification, and 1 otherwise. Effective length is measured in years and defined as "Expiration date - max{Grant date, Drug approval date}". The third, fourth and fifth row depict the counts of Markush groups, conjunctions "or", and words, respectively, in the first independent claim. Each exclusivity indicator equals 1 if a patent covers a drug that has been awarded the corresponding exclusivity. The indicators Method patent and Active ingredient patent equal 1 if a patent protects a method of use and an active ingredient, respectively. The indicators Tablet, Capsule, and Injectable equal 1 if the drug protected by a patent has the corresponding dosage form. The Priority review indicator equals 1 if a patent has been priority reviewed by the FDA, and the Continuing patent indicator equals 1 if a patent is filed as a continuation, a continuation-in-part or a divisional application. Independent claims, Backward citations, Forward citations, and Patent family size give the count of independent claims included in a patent in our sample, of earlier patents cited by a patent in our sample, of later patents citing a patent in our sample, and of countries where the same new drug has been patented, respectively.

patents protect injectable drugs, 16 percent capsules, 38 percent tablets, and around eight percent protect drugs priority reviewed by the FDA.

# 4 Evidence from Ordinary Least Squares Regressions

We begin by estimating the following OLS regression using our patent-level data:

$$\mathbb{1}[\text{PIV entry}_{it}] = \alpha + \beta \log(\text{Effective length}_i) + \gamma' \mathbf{X_i} + \delta_t + \eta_{it}, \tag{12}$$

in which $\mathbb{1}[\text{PIV entry}_{it}]$ is an indicator variable equaling one if patent $i$ filed in year $t$ is successfully challenged via a PIV certification, $\log(\text{Effective length}_i)$ is the natural logarithm of the effective length of patent $i$, the vector $\mathbf{X_i}$ includes other controls except for the patent filing year fixed effects captured by $\delta_t$. Table 2 presents estimates from various specifications of the model.

We find a statistically significant but economically modest relationship between PIV entry and the effective patent length. The estimated coefficient in column (1) implies that doubling the effective term of a patent is associated with a 13 percentage point increase in the probability of PIV entry. The relationship becomes economically weaker but remains statistically significant after adding various controls – see columns (2) and (3) of Table 2.

Table 2 shows a negative, but statistically insignificant, relationship between PIV entry and the count of Markush groups in the first independent claim. (Using another measures of patent claim scope instead of the count of Markus groups yields similar results, except that the logged count of conjunctions "or" in the first independent claim gets a statistically significant coefficient – see Table 8 in online Appendix 4.) Estimates for the other scope measures, however, suggest stronger associations: The probability of PIV entry is over six percentage points lower for patents covering active ingredients, and three percentage points lower for patents covering new methods of use compared to patents protecting, say, new drug formulations. Furthermore, the probability of PIV entry is around eight to nine percentage points lower for patents protecting drugs with NCE or orphan drug exclusivity. Pediatric exclusivity appears to be associated with an increase in the rate of PIV entry. However, pediatric exclusivity provides both broader and longer protection.

The negative estimate of the effect of backward citations might also support a negative association between PIV entry and patent scope, but it could also suggest a positive association between

PIV entry and patent value. This positive association between PIV entry and patent value is also supported by the positive and statistically significant coefficients of log(Patent familiy size$_i$) and the dummy variables Priority review$_i$, Tablet$_i$, and Capsule$_i$.

Table 2: PIV Entry and Patent Characteristics: OLS Estimates.

| | (1) | (2) | (3) |
|---|---|---|---|
| log(Effective length) | 0.129 | 0.069 | 0.065 |
| | (0.015) | (0.013) | (0.013) |
| NCE exclusivity | | -0.091 | -0.075 |
| | | (0.025) | (0.026) |
| Orphan drug exclusivity | | -0.093 | -0.092 |
| | | (0.024) | (0.025) |
| Pediatric exclusivity | | 0.087 | 0.086 |
| | | (0.035) | (0.035) |
| Priority review | | 0.179 | 0.178 |
| | | (0.046) | (0.047) |
| Tablet | | 0.181 | 0.183 |
| | | (0.027) | (0.028) |
| Capsule | | 0.106 | 0.112 |
| | | (0.034) | (0.035) |
| | | (0.024) | (0.024) |
| Injectable | | -0.041 | -0.033 |
| | | (0.024) | (0.024) |
| log(Markush groups+1) | | | -0.012 |
| | | | (0.012) |
| | | | (0.017) |
| Method patent | | | -0.029 |
| | | | (0.017) |
| | | | (0.021) |
| Active ingredient patent | | | -0.063 |
| | | | (0.021) |
| log(Forward citations+1) | | | 0.003 |
| | | | (0.007) |
| log(Backward citations+1) | | | -0.021 |
| | | | (0.008) |
| log(Patent family size) | | | 0.010 |
| | | | (0.006) |
| Continuing patent | | | 0.024 |
| | | | (0.015) |
| Mean dep. variable | 0.171 | 0.171 | 0.173 |
| Observations | 3517 | 3517 | 3483 |
| R-squared | 0.065 | 0.224 | 0.237 |
| Filing year FE | × | × | × |
| Exclusivity expiration year FE | | × | × |
| USPC FE | | | × |

*Notes:* This table reports coefficients from OLS regressions of the PIV entry indicator on log(Effective length), measures of patent scope and controls. FE stands for fixed effects. Standard errors, in parentheses, are clustered at the level of patents protecting the same drug.

Overall the findings from the OLS regressions suggest that PIV entry positively correlates with effective patent length and negatively with patent scope. However, while we attempt to control for, e.g., drug and patent value, these results may still be driven by unobserved heterogeneity.

# 5 Impact of Patent Length

In Section 5.1, we describe how two patent policy reforms, TRIPS of 1994 and AIPA of 1999, affected the effective lengths of patents depending on their grant lags. Using this plausibly exogenous variation in effective length across patents and over time, we estimate the effects of the reforms on the probability of PIV entry in Section 5.2.

## 5.1 Patent Term Reforms in the US and Pharmaceutical Patents

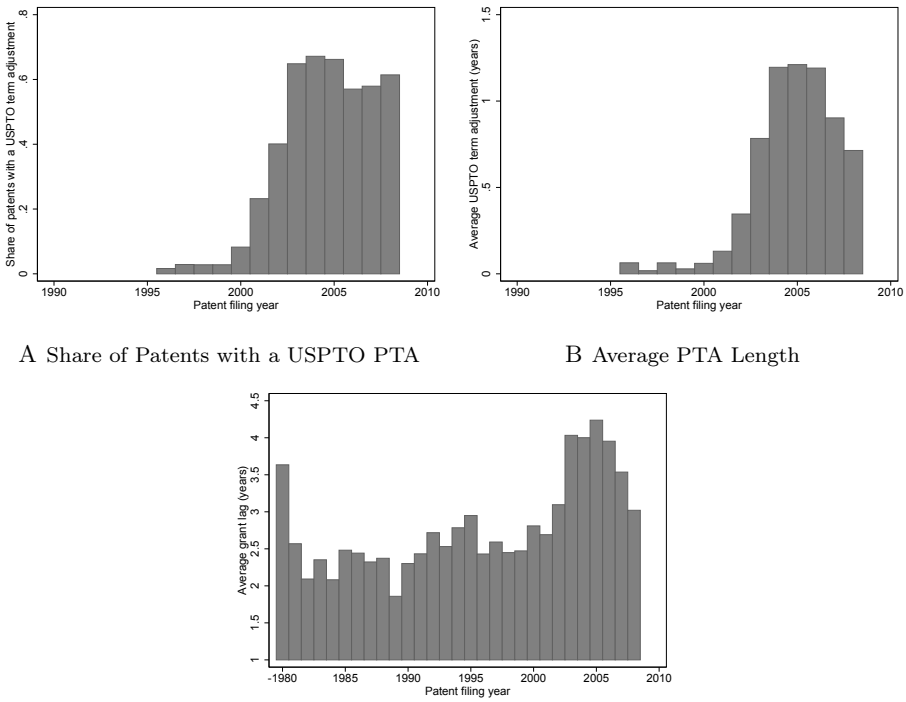
TRIPS introduced a 20-year standard patent term measured from the (earliest) filing date to the US. Prior to TRIPS, the US had a 17-year standard patent term counting from the grant date. The change in the standard patent term was implemented so that the 20-year term from filing applies to the patents filed on and after June 8, 1995. For patents filed prior to June 8, 1995, the standard patent term was changed to either the new 20-year term from filing *or* the old 17-year term from the grant, whichever expires later. (Patents that were issued prior to June 8, 1978, were kept in the old 17-year term regime, but our sample includes no such old patents.)

This change in the standard patent term due to TRIPS treats patents differently depending on whether or not they are granted within three years from filing: Patents granted within three years from filing receive the same 20-year standard term from filing regardless of whether or not they are filed before or after TRIPS (came into force). In contrast, patents with grant lags exceeding three years filed before TRIPS received the 17-year standard term from the grant date, which fully compensates for grant lags. But similar patents filed after TRIPS receive the 20-year standard term from filing, thus losing some of effective protection time because of TRIPS.

To compensate patentees for this loss in effective patent life because of delays in the USPTO approval process, TRIPS also introduced PTAs (which were initially called patent term extensions). These PTAs only apply to patents filed after TRIPS, and can add a maximum of five years to the patent term. The USPTO calculates the length of a PTA automatically, taking into account only

certain delays caused by the USPTO itself. Initially eligible delays were limited (to interference, secrecy orders, successful appeals to the Patent Trial and Appeal Board or to the federal courts) but, subsequently, AIPA expanded the list of reasons which may give rise to PTAs for patents filed on and after May 29, 2000. In particular, AIPA introduced compensation for grant lags exceeding three years, thus at least partially neutralizing the adverse impact of TRIPS on the length of patents with grant lags exceeding three years.

We determine PTAs and grant lags for our sample of drug patents from PatEx. As shown by panels A and B of Figure 2, PTAs were rare and had short duration before AIPA (came into force), which increased their provision substantially. The share of patents with a PTA rises from two percent in 1996 to 66 percent in 2005 in our sample (panel A). The average PTA length increases from less than a month in 1996 to around 15 months in 2005 (panel B). Even after AIPA, the increase in the length of PTAs was gradual, reflecting increasingly slow patent prosecution at the USPTO in the early years of the millenium (panel C). (The long grant lags observed in the early years in panel C are a consequence of the truncation of our sample discussed in Section 3.1).




A Share of Patents with a USPTO PTA

B Average PTA Length

C Average Grant Lag

Figure 2: USPTO Grant Lags and PTAs of Pharmaceutical Patents.

*Notes:* Panel A of this figure shows the share of new drug patents in our sample with a USPTO PTA by patent filing year. Panel B shows the average length of a PTA in our sample by patent filing year, including patents without PTAs. Panel C figure shows the average grant lag of new drug patents in our sample by patent filing year.

Comparing panels A and B with panel C indicates that PTAs fail to fully compensate for the adverse impact of TRIPS on the effective length of new drug patents with long grant lags, especially before AIPA. To confirm this suggestion, we regress the patent grant lag on the effective patent length separately for the periods of pre-TRIPS, post-TRIPS but pre-AIPA, and post-AIPA. Figure 3 shows the results: Before TRIPS, the effective length is relatively invariant to the grant lag. TRIPS disproportionately shortens the effective length of patents that were pending more than three years, especially before AIPA, which partially restores the effective length of such patents. More specifically, estimation results reported in column (6) of Table 3 below show that patents prosecuted at least three years experience a 17 percent decrease in their effective length after TRIPS, compared with other patents. After AIPA the corresponding increase in the effective length is 10 percent.

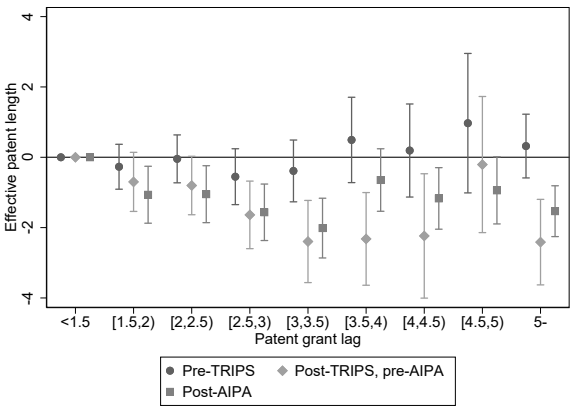



Figure 3: Effective Patent Length Before and After TRIPS and AIPA.

*Notes:* This figure shows OLS estimates and 95 percent confidence intervals of the raw data relationships between the patent grant lag (in the $x$-axes) and the effective patent length (in the $y$-axis). We estimate the relationships separately for three time periods by using our patent-level data and no controls. The pre-TRIPS period includes patents filed before June 8, 1995. The post-TRIPS, pre-AIPA period includes patents filed between June 8, 1995 and May 29, 2000. The post-AIPA period includes patents filed on or after May 29, 2000. Patents with grant lags exceeding five years are binned together (denoted by "5-" on the x-axis). In each regression, the comparison group consists of patents granted less than 1.5 years from the filing date. Each dot shows the averages of the $x$- and $y$-axes variables within each equal-sized bin.

## 5.2 Difference-in-Differences Estimations and Results

In Section 5.1 we document how patents with grant lags exceeding three years have shorter effective lengths than other patents after TRIPS. The model of Section 2 predicts a decrease in the rate of PIV entry encountered by such patents after TRIPS. Furthermore, AIPA should mitigate this negative effect on the rate of PIV entry. Consistent with this prediction, Figure 4 indicates that in the post-TRIPS, pre-AIPA period, the rate of PIV entry is lower for patents prosecuted over three years compared to patents with shorter grant lags. There is no similar difference between the two patent groups in other periods. These patterns in grant lags and PIV entry motivate our research design.

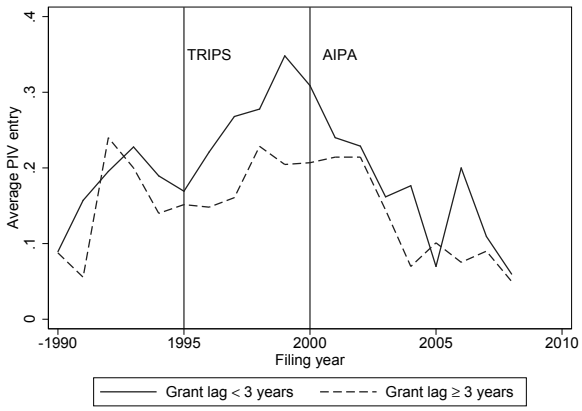



Figure 4: Average PIV Entry by Patent Filing Year and Grant Lag.

*Notes:* This figure shows the average PIV entry by patent filing year. The dashed and solid lines depict the groups of patents with a grant lag more and less than three years, respectively. Patents filed up to and including year 1990 are binned together (denoted by "-1990" on the x-axis). Those oldest patents in our sample encounter only few successful PIV challenges with no systematic difference depending on the grant lag.

We estimate the following DiD model using our patent-level data:

$$\begin{aligned} \mathbb{1}[\text{PIV entry}_{it}] \quad = \quad & \alpha + \beta_1 \mathbb{1}[\text{Grant lag}_i \geq 3\text{years}] + \\ & \beta_2 \mathbb{1}[\text{Grant lag}_i \geq 3\text{years}] \times \mathbb{1}[\text{Post-TRIPS}_i] + \\ & \beta_3 \mathbb{1}[\text{Grant lag}_i \geq 3\text{years}] \times \mathbb{1}[\text{Post-AIPA}_i] + \gamma' \mathbf{X_i} + \delta_t + \varepsilon_{it}, \end{aligned} \tag{13}$$

in which $\mathbb{1}[\text{Grant lag}_i \geq 3\text{years}]$ is an indicator variable equaling one if patent $i$ has at least a three-year grant lag, $\mathbb{1}[\text{Post-TRIPS}_i]$ is an indicator variable equaling one if the filing date of patent $i$ is on or after June 8, 1995, and $\mathbb{1}[\text{Post-AIPA}_i]$ is an indicator variable equaling one if the filing date of patent $i$ is on or after May 29, 2000. The coefficients of interest, $\beta_2$ and $\beta_3$, measure changes in the probability of PIV entry after TRIPS and AIPA, respectively, for patents prosecuted at least three years (treatment group), compared to other patents (control group).

Table 3: PIV Entry, Effective Length, and Patent Law Changes by Patent Grant Lag.

| Outcome | PIV entry (1) | PIV entry (2) | PIV entry (3) | PIV entry (4) | PIV entry (5) | log(Effective length) (6) |
|---|---|---|---|---|---|---|
| Grant lag ≥3 years | -0.021 | 0.016 | 0.026 | 0.021 | 0.022 | 0.044 |
| | (0.027) | (0.025) | (0.025) | (0.026) | (0.028) | (0.028) |
| Grant lag ≥3 years, Post-TRIPS | -0.080 | -0.114 | -0.106 | -0.099 | -0.100 | -0.171 |
| | (0.042) | (0.039) | (0.039) | (0.044) | (0.041) | (0.043) |
| Grant lag ≥3 years, Post-AIPA | 0.072 | 0.084 | 0.072 | 0.066 | 0.072 | 0.100 |
| | (0.041) | (0.037) | (0.037) | (0.042) | (0.039) | (0.045) |
| Mean dependent variable | 0.171 | 0.171 | 0.173 | 0.167 | 0.177 | 2.457 |
| Observations | 3517 | 3517 | 3483 | 2998 | 3066 | 3517 |
| R-squared | 0.045 | 0.221 | 0.234 | 0.234 | 0.240 | 0.020 |
| Filing year FE | × | × | × | × | × | × |
| Drug controls | | × | × | × | × | |
| Exclusivity expiration year FE | | × | × | × | × | |
| Patent controls | | | × | × | × | |
| USPC FE | | | × | × | × | |
| Excluded filing years | None | None | None | 1995, 2000 | None | None |
| Grant lag | Any | Any | Any | Any | ≤ 5 yrs | Any |

*Notes:* This table reports estimates of the effects of TRIPS and AIPA on PIV entry and the effective patent length. Columns (1)–(5) show coefficients from an OLS regression of the PIV entry indicator and column (6) of log(Effective length) on three indicators for patents with a grant lag exceeding three years and controls. FE stands for fixed effects. Drug controls include the indicators NCE exclusivity, Orphan drug exclusivity, Pediatric exclusivity, Priority review, Capsule, Injectable, and Tablet. Patent controls include log(Markush groups+1), log(Backward citations+1), log(Forward citations+1), log(Patent family size), and the indicators Active ingredient patent, Method patent, and Continuing patent. The samples in columns (4) and (5) exclude patents filed in years 1995 and 2000 and patents with a grant lag exceeding five years, respectively. Standard errors, in parentheses, are clustered at the level of patents protecting the same active ingredient.

Column (1) of Table 3 reports coefficients from a regression that uses the full sample of new drug patents but only controls for filing year fixed effects. Patents prosecuted at least three years experience an eight percentage point reduction in the probability of PIV entry after TRIPS (but before AIPA), compared to other patents. AIPA almost neutralizes this effect: the corresponding increase in the probability of PIV entry is seven percentage points after AIPA.

Column (2) of Table 3 reports results after we add characteristics of the drugs protected by the patents in our sample, including exclusivities and their expiration year fixed effects. Column (3) shows results from a specification that further controls for patent characteristics, including

the main US patent class fixed effects. These two specifications attempt to account for potential differences between the treatment and control groups stemming from observable characteristics, unobserved heterogeneity, and possible compositional changes over time across these groups. Adding the fixed effects and other controls makes the effects of TRIPS and AIPA stronger and more precisely estimated compared to column (1).

We also estimate the DiD model of equation (13) using a sample that excludes patents filed in 1995 and 2000. This sample restriction attempts to address the potential anticipation effects of the TRIPS and AIPA reforms. For example, applicants expecting a decrease in patent terms due to TRIPS could have advanced patent filing and, analogously, applicants expecting an increase in patent terms due to AIPA could have postponed filing. The coefficient estimates from this regression, reported in column (4) of Table 3, remain similar to the baseline estimates, suggesting no clear anticipation effects. The coefficient $\beta_3$ is, however, less precisely estimated, perhaps due to a smaller sample.

Next, we estimate the DiD model using a sample of patents prosecuted within five years. This sample restriction further mitigates concerns arising from possible compositional changes in the treatment group. For example, long grant lags observed in the earliest and the latest years of our data increase the number of patents falling into the treatment group (see panel C of Figure 2). This restriction also excludes the patents for which the five-year maximum length of PTAs is binding. The results from this estimation reported in column (5) are similar to the baseline results.

Overall, we find the probability of PIV entry increasing with effective patent length, as predicted by the theory: TRIPS shortens the effective length of patents with long grant lags which discourages PIV entry, whereas AIPA partially restores the effective length of those patents which promotes PIV entry.

**Robustness.** While we use a rich set of controls, and while the raw data trends presented in Figure 4 suggest otherwise, the DiD estimates of the effects of TRIPS and AIPA might nonetheless reflect differential pre-trends in PIV entry between treated and untreated patents. To mitigate this concern, we estimate the following event study specification using the same controls as in the DiD specification in column (3) of Table 3:

$$\begin{aligned}\mathbb{1}[\text{PIV entry}_{it}] &= \alpha + \beta_1 \mathbb{1}[\text{Grant lag}_i \geq 3\text{years}] + \\ &\sum_{l, l \neq -1} \mu_l \mathbb{1}[\text{Grant lag}_i \geq 3\text{years}] \times \mathbb{1}[t - 1995 = l] + \\ &\gamma' \mathbf{X_i} + \delta_t + \varepsilon_{it},\end{aligned}$$

in which $\mathbb{1}[t-1995=l]$ is an indicator variable equaling one if the difference between the filing year $t$ of patent $i$ and the implementation year of TRIPS is $l \subset \mathbb{Z} \setminus \{-1\}$ years. The first lead $l=-1$, i.e., patents filed in 1994, is excluded as a normalization. The coefficients $\mu_l$ for $l \leq -2$, $l = 0, ..., 4$ and $l \geq 5$ capture, respectively, possible pre-trends in the outcome, the effects of TRIPS, and the the effect of AIPA.

The event study estimates reported in Figure 5 are consistent with the DiD estimates: they suggest a decrease in PIV entry after TRIPS but before AIPA on average. There also appears to be no pre-trend in the outcome. The event study estimates are, however, more imprecise than the DiD estimates – the number of patents per filing year is only 103 on average (with a standard deviation of 74) in our sample.

We make many other robustness checks, some of which are detailed in online Appendix 3. To address the concern that longer patent duration would increase generic entry even if that entry were random, we control for the length of exposure of a patent to PIV challenges. We also show that the estimated effects on the probability of PIV entry cannot be explained by differential changes in patent scope or value after TRIPS and AIPA, nor by the introduction of provisional applications in 1995. Also, sometimes multiple patents cover the same new drug and for them, challenge decisions will be correlated. We therefore identify the chain of patents covering the same new drug and exclude some or all but one of the patents in the chain. When we estimate equation (13) using different subsamples and specifications, the effects of TRIPS and AIPA only become stronger and more precisely estimated.

We also find additional evidence of longer effective patent length encouraging PIV entry: TRIPS disproportionately shortened effective terms of continuing patents, leading to a more negative estimate of $\beta_2$ using the sample of these patents. Finally, we document how AIPA also mandated earlier disclosure of patent applications, resulting in a longer period of public patent applications.

This change may affect the interpretation of the effective patent length in the post-AIPA period.

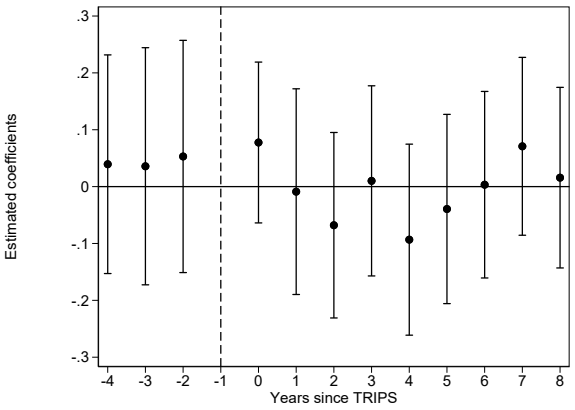



Figure 5: Event Study Estimates.

*Notes:* This figure shows event study estimates and 95 percent confidence intervals of the effects of TRIPS and AIPA on PIV entry. The number of patents per filing year is (only) 103 on average in our sample. The x-axis shows the number of years between patent filing and the implementation of TRIPS in 1995. Five years after TRIPS corresponds to the implementation of AIPA in 2000. The horizontal line represents the omitted coefficient for one year before TRIPS. The specification includes the same controls as the one in column (3) of Table 3. Standard errors are clustered at the level of patents protecting the same active ingredient.

# 6 Impact of Patent Scope

In identifying the effect of a change in patent scope on PIV patent challenges we cannot resort to an ideal experiment of random assignment of scope over patents. Inspired by Kuhn and Thompson (2019), Sampat and Williams (2019), Farre-Mensa et al. (2020), and Feng and Jaravel (2020) we instead develop IVs for patent scope based on the "leniency" of patent examiners. Our approach exploits the differences across examiners in their propensity to grant broader or more claims as a source of variation in patent scope, together with the assignment of patent applications to examiners at the USPTO. Previous research (e.g., Cockburn et al., 2003; Lemley and Sampat, 2012) indicates that examiners differ in their decision making which translates into different patent outcomes. Since patent prosecution typically consists of several rounds of claim rejections and modifications required by an examiner (Kuhn and Thompson, 2019; Marco et al., 2019), systematic differences across examiners plausibly generate systematic differences in patent claim scope. Furthermore, prosecution-history estoppel enhances the role of patent examination in affecting claim scope at the core of PIV challenges (Tang, 2013).

The second stage of our two-stage least squares (2SLS) analysis consists of estimations of equation (12) using instrumented scope measures. We instrument the following four measures of scope of a new drug patent: the counts of Markush groups, the coordination conjunctions "or", and words in the first independent claim, and the count of independent claims. (Kuhn and Thompson, 2019, too, develop a similar IV for the count of words in the first independent claim.) For each scope measure $x_{ijt}$ of new drug patent $i$ reviewed by examiner $j$ and filed in year $t$, we construct the corresponding instrument $z_{ijt}$ as

$$z_{ijt} = \frac{\sum_{\tau=\underline{\tau}_j}^{t-1} \sum_{k=1}^{n_{j\tau}} x_{kj\tau}}{\sum_{\tau=\underline{\tau}_j}^{t-1} n_{j\tau}}, \tag{14}$$

in which $x_{kj\tau}$ is the scope measure of patent $k$ reviewed by examiner $j$ and filed in year $\tau$, $n_{j\tau}$ is the number of patents reviewed by examiner $j$ in filing year $\tau$, and $\underline{\tau}_j$ is the earliest filing year of any patent reviewed by examiner $j$. Hence, $z_{ijt}$ gives the "examiner $j$'s historical average" – the cumulative average of a scope measure over all patents assigned to examiner $j$ up to one year preceding the filing year of new drug patent $i$. Although we include the previous new drug patents granted by examiner $j$ in $z_{ijt}$, we exclude their parents and continuations, which are usually assigned to the same examiner (Righi and Simcoe, 2019).

Table 4 shows marked variation across the examiners of the new drug patents in our sample in granting broader or more claims. For example, the average number of words in the first independent claim is 147, but the toughest examiner only allows 11 words on average, whereas the most lenient examiner allows 456 words on average. This variation unlikely arises from a small sample size: as shown in the last row of Table 4, the average number of patents reviewed by an examiner is 626

Table 4: Heterogeneity Across Examiners in Patent Measures.

| | Mean | Std. Dev. | Min | Max |
|---|---|---|---|---|
| Examiner average of Markush groups | 0.786 | 1.037 | 0.000 | 7.000 |
| Examiner average of conjunctions "or" | 3.633 | 4.100 | 0.000 | 21.737 |
| Examiner average of words | 147.115 | 59.068 | 11.000 | 455.776 |
| Examiner average of independent claims | 2.397 | 0.443 | 1.000 | 4.455 |
| Patents reviewed by an examiner | 625.515 | 660.926 | 1 | 3653 |

*Notes:* This table reports summary statistics for 579 examiners who have reviewed the new drug patents in our sample. Each of the first four rows shows summary statistics for a examiner-specific patent scope measure, averaging over all patents reviewed by an examiner of a new drug patent in our sample. The last row shows summary statistics for the number of patents reviewed by an examiner of a new drug patent in our sample.

In the first-stage of our 2SLS analysis, we regress each of the four claim scope measures on the corresponding instrument and controls. In the main 2SLS specifications we use the same control variables as in column (3) of Table (2). While some of these controls (e.g., patent filing year and US patent class fixed effects) may also capture examiner specialization, we also add USPTO Technology Center fixed effects. Technology Centers are responsible for examination in broad technological areas. Each Technology Center typically contains a few dozen Art Units, which are groups of examiners specializing in narrow technology areas. Within a Technology Center, a patent application is assigned to an Art Unit and finally to an examiner. We use Technology Center fixed effects instead of Art Unit fixed effects because we only observe a small number of new drug patents per Art Unit.

The exclusion restriction in our setting holds if, conditional on covariates, examiners' propensity to grant broader claims is uncorrelated with such application characteristics, e.g., drug or patent value or quality, that correlate with PIV entry. The validity of this exclusion restriction is supported by a growing literature (e.g., Lemley and Sampat, 2012; Sampat and Williams, 2019; Kuhn and Thompson, 2019; Farre-Mensa et al., 2020; Feng and Jaravel, 2020) although, e.g., Righi and Simcoe (2019) are more critical. These previous studies indicate that examiner assignment is independent of application characteristics at the time of filing. For example, examiner assignment is based on the last digit of the application number in Art Units. Such assignment plausibly implies that examiner characteristics are uncorrelated with the value or quality of applications. While Righi and Simcoe (2019) show that examiners specialize in narrow technology fields, they find no evidence that more valuable or broader applications are allocated to certain examiners. Moreover, since our

new drug patents form a relatively homogeneous technology field, examiners might be less likely to be specialized within this sample. Nevertheless, the validity of this exclusion restriction is debatable and our IV results must be interpreted cautiously.

Table 5 reports the 2SLS regression results. The first stage coefficients of panel B and F-statistics suggest strong instruments. Estimates of the instrumented scope measures of panel A suggest a negative effect of broader patent scope on the probability of PIV entry: A 10 percentage increase in the count of Markush groups in the first independent claim decreases the probability of PIV entry by some two percentage points. Additional words in the first independent claim perform similarly, supporting a positive relationship between claim length and scope in the case of pharmaceutical patents as argued by Kuhn and Thompson (2019). A 10 percent increase in the count of conjunctions "or" in the first independent claim reduces the likelihood of PIV entry by around one percentage point. These coefficients of the scope measures are statistically significant but smaller in magnitude compared to the OLS estimates reported in Table 8 in online Appendix 4. Such an upward bias in the OLS estimates could arise, e.g., if originator firms seek broader protection for more valuable

drugs which, at the same time, attract more PIV challenges.

Table 5: Patent Scope and PIV Entry: IV Estimates.

| | (1) | (2) | (3) | (4) |
|---|---|---|---|---|
| *PANEL A: Second stage estimates* | | | | |
| *Instrumented variables:* | | | | |
| log(Markush groups+1) | -0.220 | | | |
| | (0.090) | | | |
| log(Conjunctions "or"+1) | | -0.105 | | |
| | | (0.052) | | |
| log(Words) | | | -0.237 | |
| | | | (0.095) | |
| log(Independent claims) | | | | 0.069 |
| | | | | (0.132) |
| *PANEL B: First stage estimates* | | | | |
| *Instruments:* | | | | |
| log(Examiner historical average of Markush groups+1) | 0.239 | | | |
| | (0.048) | | | |
| log(Examiner historical average of conjunctions "or"+1) | | 0.225 | | |
| | | (0.034) | | |
| log(Examiner historical average of words) | | | 0.238 | |
| | | | (0.062) | |
| log(Examiner historical average of independent claims) | | | | 0.242 |
| | | | | (0.073) |
| Observations | 3445 | 3445 | 3445 | 3447 |
| First stage F-statistic | 25.286 | 44.860 | 14.523 | 10.934 |
| Technology Center FE | × | × | × | × |
| Filing year FE | × | × | × | × |
| Drug controls | × | × | × | × |
| Exclusivity expiration year FE | × | × | × | × |
| Patent controls | × | × | × | × |
| USPC FE | × | × | × | × |

*Notes:* This table reports 2SLS estimates of the effects of patent scope on PIV entry. Panel A shows the main coefficient from the second stage regressions of the PIV entry indicator on the instrumented scope measures and controls. Panel B shows the main coefficient from the first stage regressions of the scope measures on the corresponding instruments and controls. The first stage F-statistic test is on the excluded instruments. FE stands for fixed effects. Drug controls include the indicators NCE exclusivity, Orphan drug exclusivity, Pediatric exclusivity, Priority review, Capsule, Injectable, and Tablet. Patent controls include log(Effective length), log(Backward citations+1), log(Forward citations+1), log(Patent family size), and the indicators Active ingredient patent, Method patent, and Continuing patent. We use a full sample of new drug patents for the regressions, and construct the instruments using data on all granted patents reviewed by the examiners of these new drug patents. Robust standard errors are reported in parentheses.

The question of whether or not independent claim count is a useful proxy for patent claim scope has been debated in the literature (see, e.g., Kuhn and Thompson, 2019 and Marco et al., 2019 for different points of view). Our coefficient estimate of the number of independent claims is close to

zero in magnitude and statistically insignificant, suggesting that additional independent claims in a pharmaceutical patent fail to protect the patent against PIV challenges.

**Robustness.** Overall, we view the IV regression results as suggesting that broadening patent scope hinders PIV entry. We assess the robustness of the results to specification changes in online Appendix 4. The results remain unchanged when we exclude most of the control variables (Table 9) or include of an additional control for trends varying with the Technology Center (Table10).

We also use Art Unit fixed effects instead of Technology Center fixed effects (Table 11). The number of patents per Art Unit is typically small, only 21 on average. Reflecting this challenge, the point estimates from these specifications remain similar in magnitude compared to the main specifications, but are less precisely estimated: only the coefficient of the count of words remains statistically significant.

We have also experimented with modified instruments. Our results do not change if we exclude all new drug patents reviewed by examiner $j$ from $z_{ijt}$, or if we allow $\tau$ to run from $\underline{\tau}_j$ to $\min\{\bar{\tau}_j, 2009\}$, in which $\bar{\tau}_j$ is the last filing year of any patent reviewed by examiner $j$, and only impose $k \neq i$ in equation (14). Also, using two alternative measures of scope, the counts of characters and the phrase "consisting of" in the first independent claim, and corresponding alternative instruments, yields similar IV regression results.

# 7 Implications for Pharmaceutical Patent Policy

Our empirical evidence suggests that longer effective patent length encourages PIV patent challenges, as predicted by the models of costly imitation. This effect weakens the efficiency of patent length as a policy tool to promote innovation. Our evidence also suggests that broader patent scope appears to hinder PIV entry.

However, these findings alone are not enough to determine whether and how pharmaceutical patent policy should be reformed. Ideally, we would also like to know the effects of patent policy on incentives to develop new drugs. Instead of a direct test of incentives to develop new drugs, we resort to the formula $\phi(p_G^*) := \epsilon_p(p_G^*) - p_G^*/(1-p_G^*)$ developed in Section 2. The sign of $\phi(p_G^*)$ tells us whether incentives to develop new drugs are increasing or decreasing in patent length, and also whether patent length and scope are substitutable or complementary policy tools.

In our data the average probability of PIV entry is 0.17 (see Table 1), which directly provides an estimate of $p_G^*$. We develop two approaches to recover $\epsilon_p(p_G^*)$, the elasticity of the generic firms' marginal cost function (see equation (1)): one based on the estimated elasticity of PIV entry with respect to effective patent length, $\xi_T(p_G) := (\partial p_G/p_G)/(\partial T/T)$, and another on the corresponding elasticity with respect to patent scope, $\xi_b(p_G) := (\partial p_G/p_G)/(\partial b/b)$.

**Recovering $\epsilon_p(p_G^*)$ via Patent Length Estimates.** In Appendix 2, we show that $\epsilon_p(p_G)$ can be written as

$$\epsilon_p(p_G^*) = \frac{e^{-rT} rT}{(1 - e^{-rT})\xi_T(p_G^*)}. \tag{15}$$

Hence, to calculate $\epsilon_p(p_G^*)$, we need values for $r$, $T$ and $\xi_T(p_G^*)$.

We set $r = 0.03$, following the value used by Schankerman and Schuett (2021). Next, we set $T = 12.59$ corresponding the average effective patent length in our data (see Table 1). To obtain a value for $\xi_T(p_G^*)$, we compare estimates of $\beta_2$ of equation (13) in columns (1)–(5) of Table 3 to the average probability of PIV entry, 0.17. This comparison suggests that TRIPS reduced the rate of PIV entry by $47 - 65$ percent. These figures, and the estimated effect of TRIPS on effective patent length ($-17$ percent) reported in column (6) of Table 3, suggest that $\xi_T$ could be between $47/17 \approx 2.76$ and $65/17 \approx 3.82$. We use the mean value of this range and set $\xi_T = 3.29$. Inserting $\xi_T = 3.29$, $r = 0.03$, and $T = 12.59$ into equation (15) gives $\epsilon_p \approx 0.25$.

**Recovering $\epsilon_p(p_G^*)$ via Patent Scope Estimates.** Our regressions of the PIV entry indicator on the logged patent scope measures imply that an estimate of $\xi_b(p_G^*)$ can directly be obtained by dividing an estimated coefficient of a log scope measure by the average probability of PIV entry, 0.17. The statistically significant coefficient estimates of the IV regressions (columns (1)–(3) of Panel A of Table 5) suggest that $\xi_b \in [-0.65, -1, 41]$. Using the average value of this range, we set $\xi_b = -1.03$.

To link $\xi_b(p_G^*)$ with $\epsilon_p(p_G^*)$, we assume that the generic firm's cost function has the constant elasticity form used in Example 1 of Section 2, and further stipulate that $c(b) = cb$. Using this functional form, we show in Appendix 2 that $\epsilon_p = -1/\xi_b$. Thus, setting $\xi_b = -1.03$ gives $\epsilon_p \approx 0.97$.

**Effect of Patent Length on Incentives to Develop New Drug**. We have two alternative ways to calculate $\epsilon_p(p_G^*)$ in the formula for $\phi(p_G^*)$: using $\xi_T(p_G^*)$ yields $\epsilon_p = 0.25$, whereas using $\xi_b(p_G^*)$ yields $\epsilon_p = 0.97$. Assuming that these calculations mean that $\epsilon_p \in [0.25, 0.97]$, and setting

$p_G^* = 0.17$ yields $\phi(p_G^*) \in [0.05, 0, 77]$. To conclude, the marginal cost of PIV entry appears to be sufficiently inelastic to keep innovation incentives in the pharmaceutical industry increasing in patent length, implying that patent length and scope are substitutes with regard to those innovation incentives.

**Evaluating Patent Policy**. To complete the evaluation of patent policy, we should assess whether $\phi(p_G^*)$ is larger or smaller than $\epsilon_b(p_G^*)$, the elasticity of the effect of patent scope on patent challenging costs (see equation (2)). We can estimate $\epsilon_b(p_G^*)$ in a similar way as $\xi_b(p_G^*)$. In Appendix 2, we show that $\epsilon_b = 1 - 1/\xi_b$. Using $\xi_b = -1.03$ suggests that $\epsilon_b \approx 1.97$. Thus, $\epsilon_b(p_G^*)$ appears to be clearly larger than our estimates of $\phi(p_G^*)$. In sum, our results suggest that $\epsilon_b(p_G^*) > \phi(p_G^*) > 0$, implying that the term of pharmaceutical patents should be made shorter which should be compensated for originator firms by broader patent scope.

**Robustness.** Our sufficient statistics approach to patent policy evaluation is based on some strong assumptions. Evaluating pharmaceutical patent policy based on estimates of the effect of patent scope is robust in the sense that all our estimates of $\xi_b(p_G^*)$ suggest that $\phi(p_G^*)$ is firmly positive but below $\epsilon_b(p_G^*)$. However, these estimates are based on a functional form assumption which we cannot test.

Using patent length estimates to evaluate the patent policy requires no specific functional form of the generic firm's cost function, but requires values for the firms' discount rate, $r$, and for the effective patent length, $T$. Our estimates suggest that $\phi(p_G^*)$ is positive but close to zero. Nonetheless, to render $\phi(p_G^*)$ negative we would need to use significantly higher values of $r$ or $T$. If we used the estimated effects of AIPA on effective patent length instead of those of TRIPS, we would get somewhat higher values of $\xi_T(p_G^*)$ and hence lower values of $\phi(p_G^*)$. (Using our largest estimate of the effect of AIPA from Table 3 would make $\xi_T(p_G^*)$ sufficiently high to render $\phi(p_G^*)$ slightly negative.) However, the interpretation of the effect of AIPA on effective patent length is somewhat ambiguous because of the earlier disclosure of patent applications in the post-AIPA period (see online Appendix 3).

Finally, a revealed-preference argument supports that $\phi(p_G^*) > 0$ is more likely than $\phi(p_G^*) < 0$ – if $\phi(p_G^*)$ were negative, originator firms would have an incentive to find means (e.g., licensing or other contractual solutions) to shorten the effective lengths of their patents. In line with this argument, we show in online Appendix 3 how originator firms shy away from continuing patents

with long grant lags after TRIPS and argue that such a behavior is consistent with $\phi(p_G^*) > 0$ but not with $\phi(p_G^*) < 0$.

We conclude that $\phi(p_G^*)$ is likely to be smaller than $\epsilon_b(p_G^*)$, but hardly negative.

# 8 Conclusion

We evaluate patent policy in the US pharmaceutical industry by only using data on pharmaceutical patents. Our results combining theory and evidence from DiD regressions exploiting variations in patent law and IV regressions exploiting patent examiner leniency differences suggest that new drug patent length should be made shorter, while using broader patent scope to restore incentives to develop new drugs. The main channel leading to this conclusion is the positive effect of longer effective patent term on successful PIV patent challenges by generic entrants.

Our IV regression results concern patent claim scope, which does not necessarily constitute a straightforward policy tool. To broaden the claim scope of drug patents so as to restrict PIV challenges, Tang (2013) proposes wider applications of the doctrine of equivalents or means-plus-function clauses. Ideally, we would (also) like to instrument more clear-cut measures of scope such as the active ingredient.

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# Appendix

## A.1 Proofs

**Proof of Proposition 1:** Applying the implicit function theorem to equation (4) yields

$$\frac{\partial p_G^*}{\partial T} = \frac{re^{-rT}\pi_2}{\partial^2 C_G/\partial p_G^2} > 0 \tag{16}$$

and

$$\frac{\partial p_G^*}{\partial b} = -\frac{\partial^2 C_G/\partial p_G \partial b}{\partial^2 C_G/\partial p_G^2} < 0, \tag{17}$$

in which the inequalities follow from $\partial^2 C_G/\partial p_G^2 > 0$ and Assumption 1. □

**Proof of Proposition 2:** Using the implicit function theorem in equation (6) together with $\partial^2 C_B/\partial p_B^2 > 0$ imply that the signs of $\partial p_B^*/\partial b$ and $\partial p_B^*/\partial T$ are given by the signs of $\partial V^P/\partial b$ and $\partial V^P/\partial T$, respectively. Then, differentiating equation (5) with respect to $b$ and using the definition $\pi_N := \widetilde{\pi}_N/r$ yield

$$\frac{\partial V^P}{\partial b} = -\left(1 - e^{-rT}\right)(\pi_1 - \pi_2)\frac{\partial p_G^*}{\partial b}, \tag{18}$$

in which $\partial p_G^*/\partial b < 0$ by Proposition 1. The claim concerning patent scope follows.

Similarly, differentiating equation (5) with respect to $T$ gives

$$\frac{\partial V^P}{\partial T} = (\pi_1 - \pi_2)\left[re^{-rT}(1 - p_G^*) - \frac{\partial p_G^*}{\partial T}(1 - e^{-rT})\right]. \tag{19}$$

After using equations (1), (4), and (16), we can rewrite this equation as

$$\frac{\partial V^P}{\partial T} = \frac{re^{-rT}}{\epsilon_p}(\pi_1 - \pi_2)\phi(p_G^*)(1 - p_G^*), \tag{20}$$

in which $\phi(p_G)$ is defined by equation (7). Thus the sign of $\partial V^P/\partial T$ is given by the sign of $\phi(p_G^*)$. The claim concerning patent length follows. □

**Proof of Proposition 3:** Using equation (6), which determines $p_B^*(b, T)$, in applying the implicit function theorem to equation (9) yields

$$\frac{\partial T}{\partial b} = -\frac{\partial V^P/\partial b}{\partial V^P/\partial T}. \tag{21}$$

We may now re-express the planner's problem as $\max_{b\in[0,\infty)} V^S(b, T(b))$. Differentiating $V^S(b, T(b))$ with respect to $b$ gives

$$\frac{dV^S}{db} = \frac{\partial V^S}{\partial b} + \frac{\partial V^S}{\partial T}\frac{\partial T}{\partial b}. \tag{22}$$

After substituting equations (18) and (20) for equation (21), we get

$$\frac{\partial T}{\partial b} = \frac{(1 - e^{-rT})\epsilon_p}{re^{-rT}(1 - p_G^*)\phi(p_G^*)}\frac{\partial p_G^*}{\partial b}. \tag{23}$$

Let $w_N := \widetilde{w}_N/r$. Then, differentiating equation (8) with respect to $b$ gives

$$\frac{\partial V^S}{\partial b} = \left[\left(1 - e^{-rT}\right)(w_2 - w_1) - \frac{\partial C_G}{\partial p_G}\right]\frac{\partial p_G^*}{\partial b} - \frac{\partial C_G}{\partial b}. \tag{24}$$

Similarly, for $T$ we get

$$\frac{\partial V^S}{\partial T} = -re^{-rT}(1 - p_G^*)(w_2 - w_1) + \left[\left(1 - e^{-rT}\right)(w_2 - w_1) - \frac{\partial C_G}{\partial p_G}\right]\frac{\partial p_G^*}{\partial T},$$

which can be rewritten after some algebra by using equations (1), (4), (7), and (16) as

$$\frac{\partial V^S}{\partial T} = \frac{-re^{-rT}}{\epsilon_p}\left[(w_2 - w_1)\,\phi(p_G^*)(1 - p_G^*) + p_G^*\pi_2\right]. \tag{25}$$

After using equations (23)–(25), and some algebra, equation (22) can be written as

$$\frac{dV^S}{db} = -\frac{\partial p_G^*}{\partial b}\left[\frac{\partial C_G}{\partial p_G} + \frac{\left(1 - e^{-rT}\right)\pi_2 p_G^*}{\phi(p_G^*)(1 - p_G^*)}\right] - \frac{\partial C_G}{\partial b}.$$

By using equations (1), (2), (4), (17), and (7), this expression can be further rewritten as

$$\frac{dV^S}{db} = \frac{\partial C_G}{\partial b}\left[\frac{\epsilon_b(p_G^*)}{\phi(p_G^*)} - 1\right]. \tag{26}$$

Since $\partial C_G/\partial b > 0$ by assumption, the sign of $dV^S/db$ is given by the sign of the term in the square brackets of equation (26).

An optimal patent policy reform is characterized by the signs of equations (23) and (26). Equation (26) tells us the optimal direction of patent scope and equation (23) tells us the direction where patent length needs to be adjusted to compensate a change in patent scope. As to the sign of equation (23), Proposition 1 implies that $\partial p_G^*/\partial b < 0$. As a result, the sign of $\partial T/\partial b$ is given by the sign of $-\phi(p_G^*)$. As to the sign of equation (26), the term in the square brackets of equation (26) is definitely negative if $\phi(p_G^*) < 0$ and, thus, $dV^S/db < 0$. If $\phi(p_G^*) > 0$, then the first term in the square brackets of equation (26) is positive. Then the term in the square brackets is negative if $\epsilon_b(p_G^*) < \phi(p_G^*)$, and positive if $\epsilon_b(p_G^*) > \phi(p_G^*)$.

To sum up: i) If $\phi(p_G^*) < 0$, $\partial T/\partial b > 0$ and $dV^S/db < 0$. It is efficient to reduce both patent scope and patent length; ii) If $\epsilon_b(p_G^*) > \phi(p_G^*) > 0$, $\partial T/\partial b < 0$ and $dV^S/db > 0$. It is efficient to increase patent scope and reduce patent length; iii) If $\phi(p_G^*) > \epsilon_b(p_G^*)$, $\partial T/\partial b < 0$ and $dV^S/db < 0$. It is efficient to reduce patent scope and increase patent length. □

### A.2 Elasticity Calculations for Section 7

Recall from Section 7 the definitions

$$\xi_j(p_G) := \frac{\partial p_G}{\partial j}\frac{j}{p_G},\ j \in \{b, T\}\,. \tag{27}$$

We now prove the claims of Section 7 concerning the relation of $\xi_j(p_G^*)$ to $\epsilon_p(p_G^*)$ of equation (1), and to $\epsilon_b(p_G^*)$ of equation (2).

Let us start with the relationship between $\xi_T(p_G^*)$ and $\epsilon_p(p_G^*)$. Using the first-order condition (4) to eliminate $\pi_2$ from equation (16) allows us to rewrite equation (16) as

$$\frac{\partial p_G^*}{\partial T} = \frac{re^{-rT}}{(1-e^{-rT})}\frac{\partial C_G/\partial p_G}{\partial^2 C_G/\partial p_G^2}.$$

Multiplying both sides of this equation by $T/p_G^*$ gives

$$\frac{\partial p_G^*}{\partial T}\frac{T}{p_G^*} = \frac{e^{-rT}rT}{(1-e^{-rT})}\frac{\partial C_G/\partial p_G}{p_G^*\partial^2 C_G/\partial p_G^2}.$$

By using the definitions of the elasticities (1) and (27) this equation can be rewritten as

$$\xi_T(p_G^*) = \frac{e^{-rT}rT}{(1-e^{-rT})\epsilon_p(p_G^*)},$$

i.e.,

$$\epsilon_p(p_G^*) = \frac{e^{-rT}rT}{(1-e^{-rT})\xi^T(p_G^*)}.$$

This equation equals equation (15) of Section 7.

To link $\xi_b(p_G^*)$ with $\epsilon_p(p_G^*)$, we assume that the generic firm's cost function is specified by equation (10), and further stipulate that $c(b) = cb$. Then, equation (10) can be expressed as $C_G(p_G, b) = cbp_G^{\eta_G}/\eta_G$. Using this cost function in equation (4) yields after some algebra

$$p_G^*(b,T) = \left[\frac{\left(1-e^{-rT}\right)\pi_2}{cb}\right]^{\frac{1}{\eta_G-1}}. \tag{28}$$

Differentiating equation (28) with respect to $b$ gives

$$\frac{\partial p_G^*}{\partial b} = -\frac{1}{b}\left(\frac{1}{\eta_G-1}\right)\left[\frac{\left(1-e^{-rT}\right)\pi_2}{cb}\right]^{\frac{1}{\eta_G-1}}.$$

Using equation (28) and multiplying both sides of the equation above by $b/p_G^*$ gives

$$\frac{\partial p_G^*}{db}\frac{b}{p_G^*} = \frac{1}{1-\eta_G},$$

which may be rewritten by using equation (27) as

$$\eta_G = 1 - \frac{1}{\xi_b}. \tag{29}$$

Using equation (10) in equation (1) yields $\epsilon_p = \eta_G - 1$ which, according to equation (29), is equivalent to $\epsilon_p = -1/\xi_b$, as claimed in Section 7. Our claim in Section (7) that $\epsilon_b = 1 - 1/\xi_b$ directly follows from equation (29) and Example 1 of Section 2 in which we show that $\epsilon_b = \eta_G$.

# Online Appendix

### Online A.1 Results Without Assumption 1

As the main text characterize results for the case $\partial^2 C_G/(\partial p_G \partial b) > 0$, we here focus on the case $\partial^2 C_G/(\partial p_G \partial b) \leq 0$. The proofs of Proposition 1 and 2 imply that if $\partial^2 C_G/\partial p_G \partial b = 0$, changes in patent scope have no impact on the incentives of the generic and originator firms and, if $\partial^2 C_G/(\partial p_G \partial b) < 0$, an increase in patent scope *increases* incentives for patent challenges and *reduces* incentives for new drug development. The results of Proposition 1 and 2 concerning the effect of patent length remain unaffected.

We next analyse the optimal structure of patent policy for $\partial^2 C_G/(\partial p_G \partial b) \leq 0$, implying that $\epsilon \leq 0$. We first consider the case $\epsilon < 0$, before moving to the case $\epsilon = 0$.

When $\epsilon < 0$, the counterpart to Proposition 3 can be expressed as follows:

**Proposition 4**: *Assume that $\epsilon_b < 0$. Then, i) if $\phi(p_G^*) > 0$, it is efficient to reduce both patent length and patent scope; ii) If $\epsilon_b < \phi(p_G^*) < 0$, it is efficient to reduce patent length and increase patent scope; iii) If $\phi(p_G^*) < \epsilon_b$, it is efficient to reduce patent scope and increase patent length.*

**Proof:** The proof follows the proof of Proposition 3. The efficient structure of patent policy is still characterized by the signs of equations (23) and (26). As before, equation (26) tells us the optimal direction of patent scope and equation (23) tells us the direction in which patent length needs to be adjusted so as to compensate the change in patent scope.

But now $\partial^2 C_G/(\partial p_G \partial b) < 0$ and, consequently, the proof of Proposition 1 implies that $\partial p_G/\partial b > 0$. Thus, equation (23) shows that the sign of $\partial T/\partial b$ is given by the sign of $f(p_G^*)$.

Note next from equation (26), that if $\phi(p_G^*) > 0$, then $dV^S/db < 0$ because because $\epsilon_b < 0$. If $\phi(p_G^*) < 0$, the first term in the square brackets of equation (26) is positive. Then the term in the square brackets is positive if $\epsilon_b < \phi(p_G^*)\phi(p_G^*)$, implying $dV^S/db < 0$.

To sum up: i) If $\phi(p_G^*) > 0$, $\partial T/\partial b > 0$ and $dV^S/db < 0$. It is efficient to reduce both patent scope and length; ii) If $\epsilon_b < \phi(p_G^*) < 0$, $\partial T/\partial b < 0$ and $dV^S/db > 0$. It is efficient to increase patent scope and reduce length; iii) If $\phi(p_G^*) < \epsilon_b$, $\partial T/\partial b < 0$ and $dV^S/db < 0$. It is efficient to reduce patent scope and increase length. □

Recall that if $\epsilon_b < 0$, an increase in patent scope has counterintuitive effects: Even if an increase in patent scope continues to make patent challenging more expensive, it has a *positive* effect on incentives for patent challenging and, consequently, a *negative* impact on incentives to develop new drugs. With this observation, the explanation of Proposition 4 is analogous to the one of Proposition 3.

Finally, let us consider the case $\epsilon_b = 0$. To simplify the analysis, we use a standard relationship between welfare flow and market structure and define $w_N := N\pi_N + cs_N$ in which $N\pi_N$ and $cs_N$ are industry profits and consumer surplus (when $N \in \{0, 1, 2\}$ drugs compete in the market), respectively. Furthermore, define $T' := \arg\max p_B^*(T)$ and assume for the moment that the conditions stipulated in footnote 5, $\partial\phi/\partial p_G < 0$ and $\lim_{T\to\infty} \phi(p_G^*(T)) < 0$, hold. Then $T'$ is a finite and

strictly positive unique solution to $\phi(p_G^*(T')) = 0$. Under these assumptions, we get the following result:

**Proposition 5**: *Assume that $\epsilon_b = 0$. Then, patents should have a minimum scope. The optimal patent duration is given by $T^* := \arg\max_T W(T) = p_B^*(T) V^S(T) - C_B(p_B^*(T))$. in which $T^* < T'$.*

**Proof:** We may write the total (ex ante) welfare from a new drug as

$$W(b,T) = p_B^*(b,T) V^S(b,T) - C_B(p_B^*(b,T)) \tag{30}$$

in which $p_B^*(b,T)$ and $V^S(b,T)$ are given by equations (6) and (8), respectively, and $C_B(p_B(b,T))$ is the originator's cost of developing a new drug.

Differentiate next $W(b,T)$ from equation (30) with respect to $b$. Note here that when $\epsilon_b = 0$, $\partial^2 C_G/(\partial p_G \partial b) = 0$, and $\partial p_B^*/\partial b = 0$. As a result, the sign of $\partial W(b,T)/\partial b$ is given by the sign of $\partial V^S/\partial b$. Since $\partial p_G^*/\partial b = 0$, equation (24) implies that $\partial V^S/\partial b = -\partial C_G/\partial b < 0$. Thus, it is optimal to have as narrow patents as possible.

Since $\partial p_B^*/\partial b = 0$, equation (23) implies that $\partial T/\partial b = 0$. As a result, $T$ is the only relevant dimension of the patent policy, and the socially optimal $T$ is given by $T^* := \arg\max_T W(T)$. We next characterize the circumstances under which $T^* < \overline{T}$.

With the the help of equation (6), the first-order condition for the optimal $T$ can be written as

$$\frac{\partial W}{\partial T} = \frac{\partial p_B^*(T)}{\partial T}\left[V^S(T) - V^P(T)\right] + p_B^*(T)\frac{\partial V^S(T)}{\partial T} = 0. \tag{31}$$

Let us first prove that $V^S(T) - V^P(T) > 0$, i.e., that the social value of a new drug is larger than its private value. If $V^P(T) \geq V^S(T)$, the issue of the patent policy design would be moot. However, since the social value of the new drug includes the costs of generic entry, the question of whether $V^S(T) > V^P(T)$ holds is not trivial.

Using $x_N := \widetilde{x}_N/r$, $x = w, \pi$, in subtracting equation (5) from equation (8) yields

$$\begin{aligned} & V^S(T) - V^P(T) \qquad (32)\\ = \; & \left(1 - e^{-rT}\right)\left[\left(1 - p_G^*(T)\right)(w_1 - \pi_1) + p_G^*(T)(w_2 - \pi_2)\right] + e^{-rT}(w_2 - \pi_2) - C_G(p_G^*(T)). \end{aligned}$$

From equation (3) we observe that $\Pi_G(p_G^*(T)) \geq 0$ implies that $\left(1 - e^{-rT}\right)\pi_2 p_G^*(T) \geq C_G(p_G^*(T))$. Approximating the right-hand side of equation (32) downwards by substituting $\left(1 - e^{-rT}\right)\pi_2 p_G^*(T)$ for $C_G(p_G(T)^*)$ gives

$$\begin{aligned} & V^S(T) - V^P(T)\\ \geq \; & \left(1 - e^{-rT}\right)\left[\left(1 - p_G^*(T)\right)(w_1 - \pi_1) + p_G^*(T)(w_2 - 2\pi_2)\right] + e^{-rT}(w_2 - \pi_2) > 0, \end{aligned}$$

in which the last inequality follows from $w_N = N\pi_N + cs_N$.

Next, we evaluate $\partial W/\partial T$ at $T = T'$. Then, $\phi(p_G^*(T')) = 0$, and equation (25) implies that

$\partial V^S(T')/\partial T < 0$. From the proof of Proposition 2 we also observe that when $\phi(p_G^*(T')) = 0$, $\partial p_B^*(T')/\partial T = 0$. As a result, equation (31) shows that $\partial W(T')/\partial T < 0$.

Assume then that i) $\partial^2 W/\partial T^2 < 0$ for all $T$ so that the problem is well-behaving. Assume further that ii) $\partial W(0)/\partial T > 0$. A sufficient condition for ii) is $\partial p_B^*(0)/\partial T > p_B^*(0)$. To see this, note first from equation (4) that $p_G^*(0) = 0$. Then, when evaluating $\partial W/\partial T$ at $T = 0$ by using equations (25) and (32) we get

$$\frac{\partial W(0)}{\partial T} = \frac{\partial p_B^*(0)}{\partial T}(w_2 - \pi_2) - p_B^*(0)\, r\,(w_2 - w_1),$$

in which, as indicated by equations, (5), (6), and (19), $\partial p_B^*(0)/\partial T > 0$ and $p_B^*(0) > 0$. Clearly, $w_2 - \pi_2 > r\,(w_2 - w_1)$.

If both conditions i) and ii) hold, then there exists exactly one solution for equation (31) in the range where $T \in (0, T')$ and this solution characterizes the maximum. Note for completeness, that if condition ii) fails to hold, but condition i) holds, then the optimal policy is to set $T^* = 0$. If condition i) fails to hold, then there may be multiple solutions to equation (31). If condition ii) nonetheless holds, there must at least be one local maximum in the range where $T \in (0, T')$. □

The explanation of Proposition 5 is the following: Since $\epsilon_b = 0$, changes in patent scope have no impact on incentives for new drug development, and an increase in patent scope only increases the costs of generic firms with no welfare benefits. As a result, it is optimal to have narrow patents.

When changes in patent scope have no impact on incentives for new drug development, patent length becomes the only relevant patent policy tool. The social planner faces the classic Nordhausian patent length design problem with the twist that an increase in patent length increases incentives to challenge new drug patents, creating wasteful costs of patent challenging. Under some plausible restrictions on functional forms, the optimal length lies in the range $(0, T')$ in which patent length has a positive impact on incentives to develop new drugs and adverse impact on social welfare for a given level of drug development incentives.

Note that the proof of Proposition 5 is based on the assumptions guaranteeing that a finite $T'$ solving $\phi(p_G^*(T')) = 0$ exists. However, if no such $T'$ exists, then Proposition 5 holds trivially since in that case $T' \to \infty$.

## Online A.2 Data Construction

In this appendix we describe the details of our data sources and variable construction. We also address the issue of missing observations in the outcome variable.

### Online A.2.1 FDA Approved Drugs: Orange Book and Drugs@FDA

The main data for our empirical analysis comes from the FDA's publication Approved Drug Products with Therapeutic Equivalent Evaluations, commonly known as the Orange Book. We use the annual editions 21 – 33 (corresponding years 2001–2013) of the Orange Book. The editions 21 – 32 in electronic format were received from the FDA through a Freedom of Information Act (FOIA)

request. The $33^{rd}$ edition was downloaded from the FDA web-pages.[8] The Orange Book digital publications consist of product, patent, and exclusivity data files. The product file identifies each drug with an FDA application number and, among others, lists information on active ingredient, dosage form, strength, producer, trade name and approval date. The patent file lists the patents included in each drug application. If a drug is covered by the FDA exclusivity the type of exclusivity and its latest expiration date are listed in the exclusivity file. Using the drug application numbers we first link the Orange Book data files into one, and then link it with the early 2014 release of the Drugs@FDA database, Application and Product Tabs.[9]

The unit of observation in our analysis is a new drug patent. By definition, only new medicines, so called New Drug Applications (NDAs), may be listed in the Orange Book with corresponding patent information. Each patent thus protects an NDA. To account for the characteristics of NDAs, we aggregate drug application level data into the patent level observations. For example, if a patent protects a drug in a tablet form, we assign value one to the patent level indicator variable Tablet. The indicator variables for two other common drug forms, Capsule and Injectable, are calculated similarly. Some patents protect several active ingredients listed in the Orange Book. So we identify the first FDA-approved active ingredient protected by a given patent. We also identify the first FDA approval date of an NDA protected by a patent.

New chemical and orphan drug exclusivities are marked in the Orange Book by the codes "NCE" and "ODE", respectively. Using these codes, we construct the indicator variables New chemical exclusivity and Orphan drug exclusivity measuring whether or not a patent protects a drug with new chemical or orphan drug exclusivity.

A drug receives pediatric exclusivity if its producer has conducted clinical trials and proved efficacy and safety of its drug for children. In this case, additional six month of exclusive marketing rights are added to all existing patents and exclusivities covering the drug (21 U.S.C. § 355a(b)). A patent listed for an application with pediatric exclusivity has is recorded twice in the Orange Book: first, with the original patent number and its corresponding expiration date, and second, with the original patent number followed by a *PED" mark and a new expiration date six months later than the original expiration date. Based on "*PED" designations, we assign value one to the indicator variable Pediatric exclusivity if the patent protects a drug with pediatric exclusivity. Using the Orange Book, we also compute the latest FDA exclusivity year for each patent, and identify the patent expiration date.

We identify priority reviewed drugs from the Drugs@FDA database. Priority reviewed drugs are assessed by the FDA faster as they, if approved, would represent significant improvements over available therapy, and thus might be particularly valuable. During our data period, such drugs were marked by a letter "P" or "P*" in the Therapeutic Potential column of the Drugs@FDA Application Tab. Based on these codes, we construct the indicator variable Priority measuring whether or not

[8]The latest release of the Orange Book is available at: `https://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm` (accessed April 18, 2020).

[9]The latest release of Drugs@FDA is available at: `https://www.fda.gov/Drugs/InformationOnDrugs/ucm079750.htm` (accessed April 2, 2020).

a patent protects a drug that was priority reviewed by the FDA.

### Online A.2.2 Measuring Patent Challenges: ANDA Approval Letters and Orange Book

We measure generic entry via successful PIV challenges to new drug patents. In a PIV challenge, a generic firm seeks to enter prior to the expiration of a new drug patent by filing an Abbreviated New Drug Application (ANDA) to the FDA containing a certification that the new drug patent is invalid or noninfringed by the generic drug (21 U.S.C. § 355(j)(2)(A)(vii)(IV)). To construct the outcome variable, we first obtain the list of the approved ANDAs containing PIV certifications from the FDA through a FOIA request. To link this list with patent numbers, we seek the FDA's letters approving these ANDAs. Each originator drug is usually protected by multiple patents, and these approval letters specify all originator drug patents that have successfully been challenged. Some of the letters are readily available from the FDA web-pages through the Drugs@FDA search engine. To collect more letters, we submit FOIA requests to the FDA. The data collection process has been slow, since the FDA only accepts a few FOIAs per month.

We read each approval letter and record patent numbers together with corresponding PIV certifications mentioned in the letters. Using patent numbers, we then link the data on PIV challenges from ANDA approval letters to the data on all new drug patents listed in the Orange Book. Some patents are challenged by multiple generics, so we calculate the earliest PIV ANDA approval date for each patent from the Orange Book files. We then construct our outcome variable, PIV entry, as an indicator which equals one if a new drug patent has successfully been challenged via PIV certification at least once.

PIV challenges by definition only concern patents before they expire. However, six patents in our sample are listed in the FDA approval letters as challenged through PIV certification even though the patents expired before the approval of the first generic drug. For consistency, we classify them as non-challenged, but the results do not significantly change if we assign them as challenged.

**Missing Observations in PIV Challenged Patent Numbers**. Some of the PIV challenged patent numbers are missing from our dataset. The FDA provided us with a list of 1020 ANDAs containing PIV certifications and we have collected the 677 approval letters for these ANDAs. There are thus 343 ANDAs in our sample for which the exact numbers of challenged patents are missing.

While we continue to file the FOIA requests to the FDA to update our data, we believe that our estimation sample is comprehensive enough to allow for an accurate measurement of both our outcome variable, PIV entry, and its timing: First, to measure PIV entry correctly, we only have to observe one of potentially many successful challenges of a new drug patent. Second, we aggregate the challenges to the active ingredient level, and measure whether or not we observe both 180-day generic exclusivity and a PIV challenged patent for each challenged active ingredient. That 180-day exclusivity is granted to the first filer of an ANDA and reliably measures the first successful PIV challenge of an active ingredient. ANDAs which have received 180-day exclusivity are marked by "PC" designation in the Orange Book. Our sample includes 1009 unique active ingredients and 150 of them are associated with ANDAs holding 180-day exclusivity. Out of those 150 active ingredients,

we fail to observe a PIV challenged patent number only in 13 cases. Third, when looking at those 150 PIV challenged active ingredients, the average year of the first PIV entry is in practice the same regardless of whether we calculate it based on the earliest approval date of generic drugs with 180-day exclusivity or based on the earliest approval date of generic drugs with non-missing challenged patent numbers. We thus also appear to measure the *timing* of (the first) PIV entry reliably. Fourth, when filing the FOIA requests to the FDA in stages, we *randomize* over the target ANDA approval letters. Since the FDA sends us exactly what we ask for, each month we receive approval letters of several randomly chosen ANDAs and add the challenged patent numbers from these letters to our sample. For some time now, our outcome variable of interest, PIV entry, has remained virtually unchanged as we add missing patent numbers.

### Online A.2.3 Measuring Effective Patent Length, Grant Lags, PTAs, and Some Patent Characteristics: USPTO PatEx and Orange Book

**Effective Patent Length**. Our primary measure of the effective length of patent $i$ is

$$\text{Effective length}_i = \text{Expiration date}_i - \max\{\text{Grant date}_i, \text{Drug approval date}_i\},$$

in which $\text{Expiration date}_i$ is the date when patent $i$ expired, $\text{Drug approval date}_i$ is the date when the FDA approved the first of potentially many new drugs protected by patent $i$, and $\text{Grant date}_i$ is the date when the USPTO issued patent $i$. We identify patent grant dates from the Application Data Tab of the USPTO PatEx, and the FDA approval and patent expiration dates from the product and patent files of the Orange Book.

**Patent Grant Lags**. We calculate the grant lag of patent $i$ simply as

$$\text{Grant lag}_i = \text{Grant date}_i - \text{Filing date}_i,$$

in which $\text{Filing date}_i$ is the date on which USPTO received the application that was subsequently issued as patent $i$. Like grant dates, we identify patent filing dates and application numbers from the Application Data Tab of PatEx.

**PTAs**. We use patent application numbers to collect PTAs from the Patent Term Adjustment Tab of PatEx. Compensations for patent term forgone due to the USPTO regulatory delays are labeled as patent term extensions for patents filed after the adoption of TRIPS on June 8, 1995 but before the implementation of AIPA, on May 29, 2000, after which the compensations are labeled as patent term adjustments.[10] For brevity and following the variable label in the PatEx files, we call both of these term modifications PTAs.

**Other Patent Characteristics from PatEx**. We assign the value one to the indicator variable $\text{Continuing patent}_i$ if patent $i$ has been filed as a continuation, a continuation-in-part or a divisional application. We identify this information using application numbers from the Continuity

[10] See, e.g., `https://www.uspto.gov/web/offices/pac/mpep/s2720.html` and `https://www.uspto.gov/web/offices/pac/mpep/s2730.html` (accessed April 3, 2020).

Data Tab of PatEx where continuation, continuation-in-part and divisional applications are recorded as "CON", "CIP" and "DIV", respectively.

We use the Application Data Tab of PatEx to retrieve the USPC numbers and examiners' Art Unit codes. We identify the Technology Centers from the first two digits of the Art Unit codes. As the number of patents and their examiners in some Technology Centers is small, we combine patents prosecuted in the Technology Centers that have issued less than 100 new drug patents into one group (with 188 patents).

### Online A.2.4 Measuring Claim Scope: USPTO Patent Claims Research Dataset

Our measures of patent claim scope are the count of words, the counts of Markush groups and conjunctions "or" in the first independent claim, and the count of independent claims in each patent. The data on these measures of claim scope is available from the USPTO Patent Claims Research Dataset and we link it to our main dataset using patent numbers.

We instrument these measures of claim scope with the "examiner's historical average" calculated according to equation (14). To construct the instruments, we first identify the examiners of new drug patents from the Application Tab of PatEx. We then find all patents reviewed by these examiners and link the data using the patent number to the USPTO Patent Claims Research Dataset. Finally, we identify the scope outcomes for all granted patents reviewed by these examiners.

### Online A.2.5 Measuring Method and Active Ingredient Patents: Google Patent

We combine text recognition algorithms and manual verification to identify method and active ingredient patents. Our classification approach employs the texts of the abstracts and first claims of patents. We collected the full texts of patent abstracts and the first claims using Google Patent Search Engine and data scrapping algorithms (written in Python using `BeautifulSoup` and `urlib2` packages.)

Method patents covering drugs mostly pertain to the method of use of a drug or the ultimate intended effect of a patented chemical. Typically the first claim of a method patent begins with a word "method" or "process". For example, the first claim of the USPTO patent number *4870105* begins with: "A method for inhibiting gastrointestinal absorption ...". Hence, we assign the Method patent$_i$ dummy equal to one, if the text of the first claim of a patent begins with the words "method" or "process". We manually verified texts of multiple patents to ensure the accuracy of the assignment.

We assign the value one to the Active ingredient$_i$ dummy if the first claim of a patent pertains a chemical formula. We classify the first claim as a chemical formula when its first four symbols are a combination of single letters, dashes, commas or digits, for example, "N,N" or "R-R". Active ingredient$_i$ also equals one if the first three words of the first claim indicate a chemical compound and its variations. Word combinations used in chemical compound patents are, e.g., "composition of matter", "compound", "chemical compound", "antiviral compound", "amine", and "peptide". We also identify patents claiming solid forms (crystallines) of compounds, derivatives

of compounds, and some other cases based as active ingredient patents. (In identifying the active ingredient patents, we used Python package `re` and heavily relied on regular expressions.)

Manual checks suggest that the patents in our sample not classified as methods nor active ingredients mostly pertain to drug delivery systems, devices, or formulations.

#### Online A.2.6 Measuring Backward and Forward Citations: USPTO PatFT

We collect the data on forward and backward citations from PatFT using a Python algorithm. We define the variable Backward citations$_i$ as the total number of patent documents (including foreign) listed on under the headline "References Cited" of patent $i$ in our sample, and the variable Forward citations$_i$ as the number of the US issued patents mentioning patent $i$ in their "References Cited" list. Forward citation data was collected from PatFT using "Referenced By" retrieval tool in October 2017.

#### Online A.2.7 Measuring Patent Family: EPO Open Patent Services

Various definitions of the patent family size are used in the literature. One commonly used definition of the patent family size (see, e.g., Lanjouw and Schankerman, 2004; Sampat and Williams, 2019) is the number of distinct countries where the same invention has been patented. We follow this definition and construct the variable Patent family size$_i$ as follows: We first collect the "DOCDB simple patent families" of the new drug patents in our sample from the Open Patent Services of the EPO in October 2017 [11]. To collect the data, we used an algorithm and the Application Programming Interface granted to authors by the EPO. (The algorithm is written in Python using `epo_ops` and `xml` packages).

A "DOCDB simple patent family" may contain multiple patents from one patent office since it, e.g., includes continuing patents in addition to their parent patents. To solve the problem, we count the unique countries based on the country codes, which are the two letters preceding patent numbers retrievable from the Open Patent Services (e.g., Canadian patents contain a prefix CA, Japanese JP, Finnish FI, *etc.*). Thus, even if the DOCDB simple patent family lists several patents with the country code JP, we count Japan in our family size variable only once.

### Online A.3 Patent Length Estimations: Robustness

#### Online A.3.1 Other Impacts of TRIPS and AIPA

Besides the changes affecting the effective patent length described in Section 5.1, TRIPS and AIPA introduced other changes to the U.S. patent law. In what we analyze some of these other changes that could threaten our identification of the effects of the effective patent length on PIV entry, affect the interpretation of our results, or be used to further support our main results.

[11] https://www.epo.org/searching-for-patents/helpful-resources/first-time-here/patent-families/docdb.html (accessed April 24, 2020)

**Provisional Patent Applications.** Another major change associated with the implementation of TRIPS was the introduction of a provisional patent application as a simplified version of a regular utility patent application. Provisional applications include no claims nor description of prior art, are not subject to examination, and automatically expire after one year (35 U.S.C. § 111 (b)). The purpose of a provisional application is to give priority rights on invention without starting the patent clock: If a regular utility patent application is filed for the same invention before the expiration of its provisional application, the priority date is the provisional application date but the patent term is calculated from the utility patent application date.

A threat to our identification might arise if the use of provisional applications varies across patents depending on their prosecution time. To address this concern, we first create the indicator Provisional application$_i$ which equals one if patent $i$ claims the priority date of a provisional application. We identify these patents based on the "PRO" designations listed in the Continuity Data Tab of PatEx. We then estimate the DiD model of equation (13) using the Provisional application$_i$ indicator as the dependent variable.

The results reported in column (1) of Table 6 suggest no systematic relationship between the probability of a patent claiming the priority date of a provisional application and its grant lag in the different policy regimes. Another robustness check confirms this conclusion: when we estimate equation (13) using a sample excluding all patents with Provisional application$_i = 1$, the effects of TRIPS and AIPA, reported in column (1) of Table 7 in the next subsection, become stronger and more precisely estimated than in Table 3.

Table 6: Patent Law Changes and Patent Characteristics by Patent Grant Lag.

| Outcome | Provi-sional | Conti-nuing | log(Markush groups+1) | Active ingredient | log(Public length) | log(Family size) | log(Backward citations+1) |
|---|---|---|---|---|---|---|---|
| | (1) | (2) | (3) | (4) | (5) | (6) | (7) |
| Grant lag ≥3 years | 0.000 | 0.076 | 0.030 | 0.001 | -0.081 | -0.174 | 0.385 |
| | (0.000) | (0.030) | (0.038) | (0.033) | (0.013) | (0.091) | (0.078) |
| Grant lag ≥3 years, Post-TRIPS | 0.024 | -0.138 | -0.032 | -0.012 | -0.088 | 0.013 | 0.140 |
| | (0.030) | (0.055) | (0.054) | (0.041) | (0.023) | (0.141) | (0.123) |
| Grant lag ≥3 years, Post-AIPA | 0.019 | -0.193 | -0.036 | -0.063 | 0.294 | 0.216 | -0.078 |
| | (0.045) | (0.052) | (0.058) | (0.037) | (0.026) | (0.140) | (0.133) |
| Mean dep. variable | 0.214 | 0.589 | 0.247 | 0.226 | 2.777 | 1.905 | 2.760 |
| Observations | 3517 | 3517 | 3485 | 3517 | 3517 | 3511 | 3517 |
| Filing year FE | × | × | × | × | × | × | × |

*Notes:* This table reports estimates of the effects of TRIPS and AIPA on patent characteristics. Columns (1)–(7) show coefficients from an OLS regression of the Provisional application indicator, the Continuing patent indicator, log(Markush groups+1), the Active ingredient patent indicator, log(Public length), log(Patent family size), and log(Backward citations+1), respectively, on three different indicators for patents with at least a three-year grant lag and filing year fixed effects (FEs). Standard errors, in parentheses, are clustered at the level of patents protecting the same active ingredient.

**Continuing Patents.** In the case of continuing patents – which represent close to 60 percent of our sample (see Table 1) – TRIPS had an impact on the effective patent length besides those

effects discussed in Section 5.1. Before TRIPS, the terms of continuing patents and other patents were calculated in the same way, implying that continuing patents typically expired later than their (earlier-filed) parent patents. After TRIPS, continuing patents expire simultaneously with their parent patent (35 U.S.C. §154 (a)(2)). Thus, TRIPS shortened the effective patent length of continuing patents more than that of other patents, and this shortening is stronger for continuing patents prosecuted over three years. As a result, long patent prosecution times might incentivize originator firms to opt for separate patent applications instead of continuing applications after TRIPS. Supporting this idea, patents with long prosecution lags are less likely to be continuing after TRIPS, compared to other patents in our sample, as shown in column (2) of Table 6.

A smaller share of continuing patents in the post-TRIPS period of our sample has several implications: First, it implies a stronger variation in the effective patent length stemming from the variation in patent grant lags. Second, since continuing patent applications might be used as a tool to make patent protection stronger (see, e.g., Lemley and Moore 2004), it raises the concern that our baseline estimates of the effect of TRIPS on patents with long prosecution lags would partially reflect narrower patent protection. To address this concern, we estimate the DiD model of equation (13) using a sample of continuing patents. The results, reported in column (2) of Table 7, support our main result of the positive impact of longer effective patent length on the probability of PIV entry: the effects of TRIPS and AIPA on the patents prosecuted at least three years are stronger than in any other specification. The results in columns (3) (4), and (7), discussed at the end of the subsection, also mitigate the concern that potentially narrower patent protection in the post-TRIPS period would be driving our main results.

Third, taken together, the results in columns (2) of Table 6 and Table 7 suggest that TRIPS made continuing patents with long grant lags less valuable for originator firms even if it simultaneously reduced the threat of PIV challenges to these patents. We interpret these results as reflecting the strong negative effect of TRIPS on the effective length of continuing patents with long grant lags. Then, by revealed preference, the results also support our policy conclusion of Section (7) that $f(p_G^*) > 0$ is more likely than $f(p_G^*) < 0$ – if $f(p_G^*)$ were negative, we should have observed the proportion of continuing patents to increase in the post-TRIPS period.

**Disclosure of Patent Applications.** AIPA affected the timing of disclosure of patent applications (see, e.g., Johnson and Popp 2003). Prior to AIPA, patent applications were not published before they were issued. AIPA harmonized disclosure in the US with international standards according to which a pending patent application is published 18 months after its filing date. For patents with long grant lags, the resulting loss in secrecy can be substantial, whereas patents granted (and, by implication, published) within 18 months loose little. Earlier disclosure of a patent application may lengthen the effective time for generic entry prior to the patent expiration, and hence affect the interpretation of our results concerning the effect of AIPA.

To evaluate the effects of AIPA on patent information disclosure in our setting, we measure the new drug patent length beginning from its disclosure. We define the public length of patent $i$ filed

in year $t$ as

$$\text{Public length}_{it} = \begin{cases} \text{Expiration date}_i - \text{Grant date}_i, \\ \qquad \text{if } \mathbb{1}[\text{Grant lag}_i \geq 18 \text{ months}] \times \mathbb{1}[\text{Post-AIPA}_i] = 0 \\ \text{Expiration date}_i - \text{Filing date}_i + 18 \text{ months}, \\ \qquad \text{if } \mathbb{1}[\text{Grant lag}_i \geq 18 \text{ months}] \times \mathbb{1}[\text{Post-AIPA}_i] = 1, \end{cases}$$

in which the indicator variable $\mathbb{1}[\text{Grant lag}_i \geq 18 \text{ months}]$ gets, analogous to $\mathbb{1}[\text{Grant lag}_i \geq 3 \text{ years}]$ of equation (13), value one if the grant lag of patent $i$ is at least 18 months.

Our calculation only provides a crude measure of the effect of AIPA on public patent length. For instance, the calculation ignores the disclosure of the US inventors' international applications after 18 months prior to AIPA, the exception to the post-AIPA publication requirement concerning applicants who waive the possibility of international patenting (35 U.S.C. § 122 (b)(2)(B)(i)), and the requirement that the filing date of patent $i$ should be measured from its *earliest* filing date in the post-AIPA period (35 U.S.C. § 122 (b)(1)(A)).

We then estimate the DiD model of equation (13) using $\log(\text{Public length}_i)$ as the dependent variable. Column (5) of Table 6 reports the results. Compared to the estimate reported in column (6) of Table 3, the coefficient estimate of the term $\mathbb{1}[\text{Grant lag}_i \geq 3 \text{ years}] \times \mathbb{1}[\text{Post-AIPA}_i]$ is now larger. While this result may arise from the imprecise measurement of public length, it may also indicate that an increase in public length partially contributes to the estimated positive effect of the longer effective length on PIV entry. Overall, however, estimates of the effects of TRIPS and AIPA depending on grant lags reported in column (6) of Table 3 and column (5) of Table 6 are similar.

**Other Changes due to TRIPS and AIPA.** Finally, we explore whether our results concerning the differential impacts of TRIPS and AIPA on PIV entry depending on grant lags could be explained by simultaneous differential changes in patent scope or value induced by various patent law modifications of TRIPS and AIPA. In this respect, estimates reported columns (3), (4), (6), and (7) of Table 6 are comforting: we observe no clear impacts of TRIPS and AIPA on the relationship between grant lags and patent scope or value, as measured by the count of Markush group in the first independent claim, the proportion of active ingredient patents, the patent family size, and the count of backward citations.

### Online A.3.2 Other Subsamples and Specifications

Table 7 provides results from the estimation of the DiD model of equation (13) using different subsamples and specifications. We first report estimates using samples that only include patents which do not claim the priority date of a provisional application (column (1)) and continuing patents (column (2)).

The results in column (3) are generated by a sample that excludes all other new drug patents sharing the common parent application except for the latest one. We identify the excluded patents using information on parent applications from the Continuity Data Tab of PatEx.

In column (4) the results arise from a sample that only includes patents for which we observe FDA exclusivity. These patents might be more valuable or – as our results of Table (2) indicate – more difficult to challenge than patents for which we observe no FDA exclusivity. Column (5) reports estimates from a model that, analogous to survival models, includes fixed effects to control for the length of exposure of a patent to PIV challenges. In this specification we, in addition to a full set of other controls, include a dummy measuring the time (in years) between the grant date of a patent and the earliest successful PIV patent challenge date or the patent expiration date whichever is earlier. Finally, we estimate a model allowing for richer interactions between grant lags and patent policy reforms, and report the results in column (6).

The signs and magnitudes of the coefficient estimates reported in Table 7 are similar to those coefficients reported in columns (1)–(5) of Table 3. If anything, the effects of TRIPS and AIPA are now stronger and more precisely estimated. Coefficients of the additional interaction terms involving patents with a grant lag exceeding five years reported in Column (6) are imprecisely estimated, possibly because we have only 417 such patents in our sample.

Table 7: PIV Entry and Patent Law Changes by Patent Grant Lag: Robustness Analysis.

| | (1) | (2) | (3) | (4) | (5) | (6) |
|---|---|---|---|---|---|---|
| | | | | | | (0.039) |
| Grant lag ≥3 years | 0.025 | 0.030 | 0.016 | 0.032 | 0.040 | |
| | (0.025) | (0.029) | (0.029) | (0.031) | (0.024) | |
| Grant lag ≥3 years, | | | | | | |
| Post-TRIPS | -0.123 | -0.180 | -0.126 | -0.118 | -0.132 | |
| | (0.041) | (0.052) | (0.044) | (0.046) | (0.035) | |
| Grant lag ≥3 years, | | | | | | |
| Post-AIPA | 0.089 | 0.154 | 0.105 | 0.087 | 0.090 | |
| | (0.044) | (0.051) | (0.041) | (0.039) | (0.030) | |
| Grant lag 3-5 years | | | | | | 0.023 |
| | | | | | | (0.027) |
| Grant lag 3-5 years, | | | | | | |
| Post-TRIPS | | | | | | -0.102 |
| | | | | | | (0.041) |
| Grant lag 3-5 years, | | | | | | |
| Post-AIPA | | | | | | 0.075 |
| | | | | | | (0.039) |
| Grant lag > 5 years | | | | | | 0.033 |
| | | | | | | (0.039) |
| Grant lag > 5 years, | | | | | | |
| Post-TRIPS | | | | | | -0.117 |
| | | | | | | (0.071) |
| Grant lag > 5 years, | | | | | | |
| Post-AIPA | | | | | | 0.065 |
| | | | | | | (0.063) |
| Mean dependent variable | 0.179 | 0.176 | 0.167 | 0.180 | 0.173 | 0.173 |
| Observations | 2731 | 2054 | 2627 | 2668 | 3478 | 3483 |
| R-squared | 0.233 | 0.268 | 0.210 | 0.262 | 0.385 | 0.234 |
| Exposure length FE | | | | | × | |
| Filing year FE | × | × | × | × | × | × |
| Drug controls | × | × | × | × | × | × |
| Exclusivity expiration year FE | × | × | × | × | × | × |
| Patent controls | × | × | × | × | × | × |
| USPC FE | × | × | × | × | × | × |
| Sample | No prior provisional | Continuing | Latest filed | FDA exclusivity | Full | Full |

*Notes:* This table reports estimates of the effects of TRIPS and AIPA on PIV entry. Columns (1)–(5) show coefficients from an OLS regression of the PIV entry indicator on three and column (6) on five indicators for patents with at least a three-year grant lag and controls. FE stands for fixed effects. Drug controls include the indicators New chemical exclusivity, Orphan drug exclusivity, Pediatric exclusivity, Priority review, Capsule, Injectable, and Tablet. Patent controls include log(Markush groups+1), log(Backward citations+1), log(Forward citations+1), log(Patent family size), and the indicators Active ingredient patent, Method patent, and Continuing patent. In columns (1)–(4) the samples exclude patents claiming the priority date of a provisional application, first-filed patents covering the same invention, all but the latest-filed patents covering the same invention, and patents protecting drugs without (observed) FDA exclusivity, respectively. Standard errors, in parentheses, are clustered at the level of patents protecting the same active ingredient.

### Online A.4 Patent Scope Estimations: Robustness

In this section we explore the robustness of our patent claim scope estimates. Table 8 reports estimates of various claim scope measures from the OLS model of equation (12). Column (1) shows an estimate using the specification of column (3) in Table (2). We then replace the count of Markush groups in the first independent claim with alternative measures of patent claim scope: the count of the conjunction "or" in the first independent claim (column (2)), the count of words in the first independent claim (column (3)), the count of independent claims (column (4)). The coefficient estimate in columm (3) suggests a statistically significant but small negative relationship between PIV entry and patent scope, as measure by the count of the conjunction "or" in the first independent claim. When compared with our IV estimates from Table (5), there appears to be an upward bias in most of these OLS estimates.

Tables (9)–(11) report the results from our exploration of 2SLS estimates of patent scope measures. Tables (9) and (10) show that the results reported in Table (5) are robust, respectively, to the exclusion of control variables, and to the inclusion of the interaction of Technology Center fixed effects with filing year fixed effects, to control for Technology Center specific trends. Table (11) reports estimates from a regression in which we replace Technology Center fixed effects with Art Unit fixed effects. The number of patents per Art Unit is small, only 21 on average. Even if we group Art Units with less than 10 patents into one group of 266 patents, coefficients of the scope measures become less precisely estimated (although remaining similar in magnitude) than in Table (5). The only scope measure generating statistically significant effects is the count of words in the first independent claim.

Our results are also robust to using the following alternative measures of claim scope: the count of claims, and the counts of characters and the phrase "consisting of" in the first independent claim. We omit these regression results for brevity.

Table 8: PIV Entry and Patent Scope: OLS Estimates.

| | (1) | (2) | (3) | (4) |
|---|---|---|---|---|
| log(Markush groups+1) | -0.013 | | | |
| | (0.012) | | | |
| log(Conjunctions "or"+1) | | -0.020 | | |
| | | (0.007) | | |
| log(Words) | | | -0.001 | |
| | | | (0.007) | |
| log(Independent claims) | | | | -0.009 |
| | | | | (0.008) |
| Mean dependent variable | 0.173 | 0.173 | 0.173 | 0.173 |
| Observations | 3483 | 3483 | 3483 | 3485 |
| R-squared | 0.242 | 0.241 | 0.243 | 0.241 |
| Technology Center FE | × | × | × | × |
| Filing year FE | × | × | × | × |
| Drug controls | × | × | × | × |
| Exclusivity expiration year FE | × | × | × | × |
| Patent controls | × | × | × | × |
| USPC FE | × | × | × | × |

*Notes:* This table reports coefficients from OLS regressions of the PIV entry indicator on scope measures and controls. FE stands for fixed effects. Drug controls include the indicators New chemical exclusivity, Orphan drug exclusivity, Pediatric exclusivity, Priority review, Capsule, Injectable, and Tablet. Patent controls include log(Effective length), log(Backward citations+1), log(Forward citations+1), log(Patent family size), and the indicators Active ingredient patent, Method patent, and Continuing patent. Standard errors, in parentheses, are clustered at the level of patents protecting the same active ingredient.

Table 9: PIV Entry and Patent Scope:
Robustness of IV Estimates to Exclusion of Control Variables.

| | (1) | (2) | (3) | (4) |
|---|---|---|---|---|
| log(Markush groups+1) | -0.244 | | | |
| | (0.071) | | | |
| log(Conjunctions "or"+1) | | -0.095 | | |
| | | (0.030) | | |
| log(Words) | | | -0.484 | |
| | | | (0.233) | |
| log(Independent claims) | | | | -0.154 |
| | | | | (0.123) |
| Mean dependent variable | 0.173 | 0.173 | 0.173 | 0.173 |
| Observations | 3447 | 3447 | 3447 | 3449 |
| First-stage F-statistic | 41.446 | 127.960 | 5.417 | 15.264 |
| Technology Center FE | × | × | × | × |
| Filing year FE | × | × | × | × |
| USPC FE | × | × | × | × |

*Notes:* This table reports coefficients from 2SLS regressions of the PIV entry indicator on instrumented scope measures and controls. The instruments are the cumulative averages of the scope measures of all patents reviewed by the examiner of a new drug patent, until one year preceding the filing year of the new drug patent. The first stage F-statistic tests is on the excluded instruments. FE stands for fixed effects, respectively. Robust standard errors are in parentheses.

Table 10: PIV Entry and Patent Scope:
Robustness of IV Estimates to Technology Center Specific Trends.

| | (1) | (2) | (3) | (4) |
|---|---|---|---|---|
| log(Markush groups+1) | -0.218 | | | |
| | (0.091) | | | |
| log(Conjunctions "or"+1) | | -0.101 | | |
| | | (0.052) | | |
| log(Words) | | | -0.219 | |
| | | | (0.091) | |
| log(Independent claims) | | | | 0.062 |
| | | | | (0.132) |
| Mean dependent variable | 0.173 | 0.173 | 0.173 | 0.173 |
| Observations | 3445 | 3445 | 3445 | 3447 |
| First-stage F-statistic | 24.520 | 43.897 | 14.769 | 10.592 |
| Technology Center FE × Filing year FE | × | × | × | × |
| Drug controls | × | × | × | × |
| Exclusivity expiration year FE | × | × | × | × |
| Patent controls | × | × | × | × |
| USPC FE | × | × | × | × |

*Notes:* This table reports coefficients from 2SLS regressions of the PIV entry indicator on instrumented scope measures and controls. The instruments are the cumulative averages of the scope measures of all patents reviewed by the examiner of a new drug patent, until one year preceding the filing year of the new drug patent. The first stage F-statistic tests is on the excluded instruments. FE stands for fixed effects. Drug controls include the indicators New chemical exclusivity, Orphan drug exclusivity, Pediatric exclusivity, Priority review, Capsule, Injectable, and Tablet. Patent controls include log(Effective length), log(Backward citations+1), log(Forward citations+1), log(Patent family size), and the indicators Active ingredient patent, Method patent, and Continuing patent. Robust standard errors are in parentheses.

Table 11: PIV Enry and Patent Scope:
Robustness of IV Estimates to Art Unit Fixed Effects.

| | (1) | (2) | (3) | (4) |
|---|---|---|---|---|
| log(Markush groups + 1) | -0.257 | | | |
| | (0.214) | | | |
| log(Conjunctions "or"+1) | | -0.073 | | |
| | | (0.065) | | |
| log(Words) | | | -0.190 | |
| | | | (0.077) | |
| log(Independent claims) | | | | 0.117 |
| | | | | (0.172) |
| Mean dependent variable | 0.173 | 0.173 | 0.173 | 0.173 |
| Observations | 3445 | 3445 | 3445 | 3447 |
| First-stage F-statistic | 6.202 | 30.447 | 18.815 | 6.669 |
| Art Unit FE | × | × | × | × |
| Filing year FE | × | × | × | × |
| Drug controls | × | × | × | × |
| Exclusivity expiration year FE | × | × | × | × |
| Patent controls | × | × | × | × |
| USPC FE | × | × | × | × |

*Notes:* This table reports coefficients from 2SLS regressions of the PIV entry indicator on instrumented scope measures and controls. The instruments are the cumulative averages of the scope measures of all patents reviewed by the examiner of a new drug patent, until one year preceding the filing year of the new drug patent. The first-stage F-statistic tests is on the excluded instruments. FE stands for fixed effects. Drug controls include the indicators New chemical exclusivity, Orphan drug exclusivity, Pediatric exclusivity, Priority review, Capsule, Injectable, and Tablet. Patent controls include log(Effective length), log(Backward citations+1), log(Forward citations+1), log(Patent family size), and the indicators Active ingredient patent, Method patent, and Continuing patent. Robust standard errors are in parentheses.

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