

## Reforming the Patent System

Lisa Larrimore Ouellette and Heidi Williams



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We believe that today's increasingly competitive global economy demands public policy ideas commensurate with the challenges of the 21st Century. The Project's economic strategy reflects a judgment that long-term prosperity is best achieved by fostering economic growth and broad participation in that growth, by enhancing individual economic security, and by embracing a role for effective government in making needed public investments.

Our strategy calls for combining public investment, a secure social safety net, and fiscal discipline. In that framework, the Project puts forward innovative proposals from leading economic thinkers — based on credible evidence and experience, not ideology or doctrine — to introduce new and effective policy options into the national debate.

The Project is named after Alexander Hamilton, the nation's first Treasury Secretary, who laid the foundation for the modern American economy. Hamilton stood for sound fiscal policy, believed that broad-based opportunity for advancement would drive American economic growth, and recognized that “prudent aids and encouragements on the part of government” are necessary to enhance and guide market forces. The guiding principles of the Project remain consistent with these views.





# Reforming the Patent System

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This policy proposal is a proposal from the author(s). As emphasized in The Hamilton Project's original strategy paper, the Project was designed in part to provide a forum for leading thinkers across the nation to put forward innovative and potentially important economic policy ideas that share the Project's broad goals of promoting economic growth, broad-based participation in growth, and economic security. The author(s) are invited to express their own ideas in policy papers, whether or not the Project's staff or advisory council agrees with the specific proposals. This policy paper is offered in that spirit.

**BROOKINGS**

# Abstract

Accelerating technological innovation is necessary for achieving robust long-run economic growth. Hence, a key challenge of social policy is to find ways to improve the design of structures to incentivize innovation—including the design of the U.S. patent system. In this paper we argue that, while there is uncertainty about how and to what degree patents affect innovation and productivity, this uncertainty does not imply that the patent system cannot be improved. We propose three tailored reforms that would improve the patent system without needing to take a stand on the overall contribution of the patent system to innovation and productivity.

Each of our three proposed reforms addresses a failure of the patent system to accomplish one of its stated goals. First, a key goal of the patent system is to disclose accurate information about new discoveries. In service of this goal, we argue that U.S. patent applicants should be required to clearly distinguish hypothetical experimental results from results achieved with real data, which would avoid confusing key audiences—such as scientists, investors, and foreign patent examiners—without impacting the legal rights of patentees. Second, the patent system is meant to provide notification about ownership of patent rights. With this intention in mind, we argue that patent owners should be required to provide disclosure of patent ownership that is both more transparent and more standardized. Finally, the patent system is meant to provide uniform patent terms across inventions. However, there is clear evidence that in practice this goal is not met. For example, drugs that require long clinical trials—such as many preventive medicines—receive shorter effective patent terms because patents are filed prior to the start of clinical trials, while some drugs receive longer effective patent terms because of what is called “pay-for-delay,” or because of other strategic behavior by pharmaceutical firms. We argue that reforms should be considered that would increase uniformity in effective patent terms across inventions.

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# Introduction

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U.S. economic growth has slowed since 2000, and projections from the U.S. Congressional Budget Office (CBO 2018) and others suggest that the U.S. growth rate is unlikely to substantially accelerate in the coming years. As argued by Shackleton (2018; summarizing CBO forecasts) and others, a key component of this recent slowdown in economic growth is a decline in what economists call total factor productivity growth, which refers to the portion of economic growth that is not explained by the traditional inputs of labor and capital. This recent observed decline in total factor productivity growth is of concern, in part because it has coincided with slow growth in real wages and rising wage inequality.

The precise causes of this productivity slowdown are unclear. However, economists are generally in agreement that, for countries that are already at the technological frontier such as the United States, the only way to secure long-run productivity growth is through innovation (see Bloom, Van Reenen, and Williams 2019 for one recent discussion). A key policy challenge facing the United States is hence how to accelerate technological innovation.

Government policies have long sought to spur innovation. In a competitive market, inventors frequently capture only a small share of the social value of their inventions. If firms invest in research only up to the point that their private benefits outweigh the costs—not accounting for the broader social benefits—then private research investments will likely be too low from a social perspective. This concern about underinvestment has motivated attention on the design of public policies that are aimed at better aligning inventors' private benefits with the social value of their inventions. While a variety of policy levers are relevant, including R&D tax credits and publicly funded research subsidies, both historically and globally one of the most widely used policy levers for trying to improve this alignment is the patent system (see Hemel and Ouellette 2013 for one discussion).

Unfortunately, as discussed further below, innovation scholars have been unable to credibly demonstrate that stronger patent rights do, in fact, lead to additional research investments (Williams 2017). In the absence of such evidence, it is not clear that the benefits of the patent system are large

enough to outweigh patents' costs, which include higher prices on patented goods for consumers and subsequent innovators (i.e., those whose inventions build on earlier inventions) during the life of the patent, administrative costs within the patent system, and both search and transaction costs for private parties seeking to operate in technology markets. Whether these costs are outweighed by the value of increased innovation—and thus higher productivity and economic growth—is, in our view, the fundamental question of patent policy.

Concern about some of these costs, particularly costs associated with frivolous patent litigation, has driven substantial U.S. patent reform efforts over the past two decades, both in Congress and at the U.S. Supreme Court. These reforms have generally weakened U.S. patent protection, leading to a countervailing concern from certain stakeholders that the patent system now provides insufficient incentives for innovation, at least in some markets where patent protection has been scaled back. Given the empirical uncertainty about the effect of the patent system on social welfare, however, our view is that it is difficult or even impossible to rigorously predict the effects of policy reforms aimed at altering the overall strength of patent protection. Instead, in this paper we propose three tailored reforms that would improve the patent system without requiring a stance on the overall contribution of patents to innovation and productivity. That is, rather than proposing more or less patent protection, we suggest reforms aimed at better-designed patent protection. We order these reforms based on our confidence in the supporting evidence, together with the clarity of our proposed reform plan.

Our first proposed reform involves the common practice of obtaining patents based on hypothetical experimental methods and results, known as prophetic examples. These examples are often written into patent applications in a way that makes it difficult to distinguish them from real data and experiments. Whether patents on completely untested inventions should be allowed is an important question that merits further study. But as long as prophetic examples are allowed, we argue that there is no reasonable justification for presenting them in ways that are confusing to key audiences, including scientists, investors, and foreign patent examiners. Instead, the U.S. Patent and Trademark Office (USPTO)

should require patent applicants to clearly distinguish these prophetic examples from work that has actually been done (Freilich and Ouellette 2019). The USPTO could implement this reform on its own or at the direction of Congress.

Our second proposed reform is that the USPTO should require greater transparency in patent ownership. Under the status quo, the front page of a U.S. patent indicates the assignee as reported by the patent applicant at the time of application. After the initial filing, patent owners can voluntarily report subsequent changes in ownership, but there is no legal requirement for them to do so. Although direct empirical evidence on the cost of this lack of patent ownership transparency is not available, logic and anecdotal evidence suggest that more transparency in patent ownership could reduce transaction costs in markets for technologies by allowing market participants to more easily identify patent owners and determine whether planned activities require licensing. We provide some conjectures about why prior reform efforts in this area have failed, and propose alternative reforms that seem promising going forward. These reforms could, similarly, be implemented by the USPTO or at the direction of Congress.

Our third proposed reform is motivated by recent empirical evidence from Budish, Roin, and Williams (2015), which suggests that private firms invest less in candidate pharmaceuticals that—by nature of their target patient populations—require longer clinical trials and, thus, are slower to commercialize. Because patents are filed before clinical trials begin and expire 20 years after filing, a drug with longer clinical trials will have a shorter effective patent life (i.e., the patent term that remains once a patented product is on the market). This shorter effective period of market exclusivity likely decreases incentives for investment. For example, the patent system provides private firms with fewer incentives to invest in preventive cancer drugs than in treatments for late-stage cancers. This disparity in effective patent term is counter to the patent system's goal of providing uniform protection across inventions. Although it is unclear what the optimal length of patent protection is, we suggest a pharmaceutical-specific reform that begins the effective market exclusivity period for new drugs at the time of approval for sale in the United States, rather than at the time of patent filing. Combined with reductions in effective pharmaceutical patent terms achieved through crackdowns on strategic behavior such as pay-for-delay, this reform would help to create more uniformity in effective patent life. Beginning the effective market exclusivity period for new drugs at the time of market approval would require legislation passed by Congress.

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# The Challenge

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Patents grant inventors a temporary right to exclude others from marketing their invention in exchange for disclosure of their invention to the public. In the past when economists have analyzed optimal patent policy, they have focused on the trade-off between increased invention of new technologies and reduced consumption due to the higher prices that firms are able to charge during the patent term (Nordhaus 1969).<sup>1</sup> In other words, society tolerates high prices for patented products in the short term, with the hope of incentivizing more invention in the long term. In such models, one can easily relate the optimal length of a patent to several intuitive considerations, such as the degree to which research investments change in response to changes in the length of the patent term (see Budish, Roin, and Williams 2016 for a simplified exposition of the Nordhaus 1969 framework). The closely related question of optimal patent breadth—determining *which* competitor’s entry should be excluded by a patent—has also been studied (Gilbert and Shapiro 1990; Klemperer 1990). For example, for pharmaceuticals, should only chemically exact copies be kept off the market, or should a broader set of competitors (e.g., any drug targeting the same biological mechanism) be considered to be in violation of patent rights?

These types of theoretical models typically generate the intuitive prediction that stronger (i.e., longer or broader) patent terms will induce additional research investments. However, economists have long raised concerns that patent monopolies can be used to control and then stifle an industry (Machlup 1958). Starting in the 1990s, Suzanne Scotchmer and collaborators began questioning the link between patents and research investments using models of sequential innovation, in which any given invention is also an input into later follow-on discoveries. In such cases, optimal patent design will depend in part on how patents on existing technologies affect follow-on innovation.<sup>2</sup> Put simply, it is not clear whether stronger (i.e., longer or broader) patent terms will increase or decrease innovation.

These theoretically ambiguous predictions about whether patents do, in fact, spur additional research investments—much less about whether any benefit is large enough to outweigh patents’ costs—naturally suggest turning to empirical evidence for guidance. Unfortunately, the available

evidence linking patents and research investments is quite mixed. On one hand, Boldrin and Levine (2013) argue that there is no empirical evidence that patents increase innovation, and their 2008 book *Against Intellectual Monopoly* expounds several (largely historical) case studies suggesting the opposite (i.e., that patents can discourage research investments and innovation). Based on this evidence, they argue for abolishing the patent system.

Along similar lines, using data from World’s Fair exhibitions from 1951 and 1876, Moser (2005) documents evidence that many high-quality (i.e., those that won awards at these fairs) innovations came from countries without patent laws. In subsequent work, Moser (2013) has framed this historical pattern as evidence that patents may discourage research investments. Several papers (Lerner 2009; Qian 2007; Sakakibara and Branstetter 2001) have investigated whether country-specific patent law changes cause changes in domestic R&D investment; these papers generally failed to detect any relationship. On the other hand, Budish, Roin, and Williams (2015) leverage variation in effective patent terms across different types of cancer drugs and document evidence consistent with—although not conclusively in favor of—a strong positive relationship between patent terms and research investments. Haber takes a much stronger position in this direction, arguing, “The weight of the evidence supports the claim of a positive causal relationship between the strength of patent rights and innovation” (Haber 2016, 814).

Somewhat unfortunately, the lack of a clear empirical consensus on the link between patents and research investments has led to a situation where patent policy debates tend to be based on ideologies and theories rather than on data and evidence. Take as one example the debates over non-practicing entities (NPEs), also called patent trolls, that generate profits solely through patent licensing and litigation. A number of researchers have documented evidence consistent with NPEs being problematic. For example, Feng and Jaravel (2020) find that NPEs primarily purchase and litigate patents issued by lenient USPTO examiners; those patents are more likely to be found invalid. Cohen, Gurun, and Kominers (2018) characterize firms targeted by NPEs and conclude that NPE litigation is opportunistic rather than value creating.

On the other hand, Maurer and Haber (2018) argue that NPEs improve the functioning of patent markets by developing or purchasing patents that they then license to operating companies. Similarly, Haber and Levine (2014) argue that NPEs increase the efficiency of technology markets and that the rise in patent litigation over the past few decades is not the result of strategic behavior by NPEs but rather reflects courts establishing the boundaries of patent rights for new, innovative technologies. To the best of our knowledge, no research teams have made a clear case that allowing NPEs to operate is either welfare-increasing or welfare-reducing.

Despite this empirical uncertainty, legal and policy decisions to limit their actions are moving ahead. Critics of the patent troll industry, who suggest that a raft of weak patents are hindering innovation, were largely pleased with recent U.S. Supreme Court rulings (*Alice Corp. v. CLS Bank*, *Mayo v. Prometheus*, and *Association for Molecular Pathology v. Myriad Genetics*) that imposed sharp limits on inventors' abilities to patent certain technologies (software, medical diagnostics, and human genes) where patents have been argued to be problematic. Technically, these cases were decided on the grounds of § 101 of the U.S. Patent Act, which defines the set of patent eligible technologies. In practice, however, one could interpret these decisions as essentially

carving out markets where the Court considers the social costs of patents to be more substantial than the social benefits.

On the other hand, advocates of the view that patents are critical to innovation in sectors such as software and medicine were largely pleased with a piece of legislation proposed in 2019 by Senators Thom Tillis (R-NC) and Chris Coons (D-DE) that seeks to abrogate these Supreme Court decisions regarding patent-eligible subject matter and reinstate firms' abilities to patent these types of technologies (see box 1).

Choosing a side in this § 101 debate essentially requires taking a stand on whether patent protection in a given field of technology is good or bad for society: If patent protection is socially beneficial, § 101 reforms like the Tillis-Coons legislation make sense. If patent protection—at least in some markets—is imposing social costs that outweigh their social benefits, then decisions like the U.S. Supreme Court's *Alice*, *Mayo*, and *Myriad* decisions make sense. However, each of us has argued (Ouellette 2015a; Williams 2017) that we lack sufficient evidence to inform this big picture question of whether strengthening the patent system—through longer or stronger patents—would increase or decrease research investments and innovation, much less whether this benefit is large enough to outweigh patents' costs. Our focus instead in this paper is on a series of policy reforms which, we argue, would unambiguously improve welfare, irrespective of the larger patent policy debate.<sup>3</sup>

## BOX 1.

### Patentable Subject Matter Reform

This paper proposes three reforms to the patent system that do not depend on knowing the overall effects of patents on social welfare. In order to be concrete about the types of patent policy debates that we argue *cannot* be either justified or opposed based on the current empirical evidence, we describe one example: patentable subject matter reform.

Although § 101 of the U.S. Patent Act defines patentable subject matter broadly as “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof,” the U.S. Supreme Court has held repeatedly that this statutory language has implicit exceptions for “laws of nature, natural phenomena, and abstract ideas.” In recent cases, the Supreme Court has held that inventions falling into these patent-ineligible categories include a diagnostic method for calibrating the correct dosage of an autoimmune disease drug (*Mayo v. Prometheus* 2012), an isolated segment of naturally occurring DNA (*Association for Molecular Pathology v. Myriad Genetics* 2013), and a generic computer implementation of the abstract idea of intermediated settlement (*Alice Corp. v. CLS Bank* 2014). These kinds of inventions are thus currently ineligible for patent protection even if they are novel, nonobvious, and useful.

Defenders of these court decisions argue that patentable subject matter is an important doctrinal tool for efficiently invalidating patents that should not have been granted in the first place, and that these decisions provide a lever for lowering the costs of frivolous patent litigation.<sup>3</sup> The overwhelming majority of patentable subject matter cases have involved software and information technology—areas in which arguably frivolous patent litigation has caused particular concern (Lemley and Zyontz 2020). Critics contend, however, that reduced patent protection as well as unpredictability around the current legal definition of patent eligibility will negatively impact incentives to innovate, especially in areas such as medical diagnostics.

In response to these concerns, some members of Congress are considering a bipartisan proposal to amend § 101 of the U.S. Patent Act to eliminate these implicit exceptions to patentability (Hickey 2019). A draft bill was released by Senators Thom Tillis (R-NC) and Chris Coons (D-DE) in May 2019, and the Senate Subcommittee on Intellectual Property held three days of hearings on the bill in June 2019. The draft was revised in response to these hearings, but it is unclear when a bill will be formally introduced.

In January 2020 the Supreme Court denied petitions to hear new appeals about the bounds of patentable subject matter, including two cases in which it had asked for the solicitor general’s view, and a third case, which the solicitor general recommended hearing. These denials leave the Court of Appeals for the Federal Circuit—the federal court that hears all appeals in patent cases—as the main institution tasked with interpreting the Supreme Court’s guidance on subject matter eligibility. But the Federal Circuit cannot overrule Supreme Court precedent, so those interested in eliminating these exceptions to patentability must look to Congress.

It is unclear, however, whether cabinining the Supreme Court’s implicit exceptions to patentability would improve social welfare. This legislative reform would allow more inventions in areas such as software and medical diagnostics to be patented. But, as we have already argued, existing evidence does not answer the question of whether stronger patent rights increase research investments, much less whether that benefit for innovation outweighs the static inefficiencies and transaction costs that patents introduce. Ongoing academic research such as Chien and Rai (2018) has started to generate empirical evidence on the practical implications of these recent Supreme Court decisions, but much more work is needed to inform future reform efforts in this area.

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# The Proposals

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In this section we propose three specific reforms to the U.S. patent system. Each reform addresses a failure of the patent system to accomplish some of its stated goals. We order these reforms in descending order based on our confidence in the evidence supporting them, together with the specificity of our proposed reform plan.

First, in order to address a failure of the patent system to disclose accurate information about new technologies, the USPTO should require patent applicants to clearly distinguish predicted experimental results from data that were actually collected to avoid confusing scientists, investors, and foreign patent examiners without harming the legal rights of U.S. patentees. Second, to address a failure to provide notification about patent owners, the USPTO should require greater transparency in patent ownership in an effort to decrease the transaction costs of the patent system. Third, to address a failure to provide uniform terms of exclusivity across technologies, Congress should amend the Drug Price Competition and Patent Term Restoration Act (known as the Hatch–Waxman Act) to start the effective exclusivity period for pharmaceuticals at the time of product commercialization instead of at the time of patent filing.

## FIXING PROPHETIC EXAMPLES

One goal of the patent system is to provide accurate information about new inventions, which can facilitate transactions in technology markets and knowledge spillovers to other researchers. We think that the current practice of including prophetic examples in patents can interfere with this disclosure goal. Our impression is that most economists and lawyers—even economists and lawyers who closely study the patent system—were unfamiliar with prophetic examples until a recent set of papers described their use: Freilich (2019) and Freilich and Ouellette (2019). As we explain below, prophetic examples create the risk of confusing those reading patents, without any clear social benefit. Given this, the USPTO should require clearer labeling for prophetic examples.

### *Patents often contain predicted experimental results known as prophetic examples.*

The U.S. Patent Act requires that patent applicants describe their invention at a sufficient level of detail that an individual who possesses ordinary technical skill in the field could make and use the invention (“enablement”) and could recognize that the inventor in fact possessed the invention (“written description”). To satisfy these disclosure requirements, patents often include working examples, which are drawn from real data and previously conducted experiments. However, under current law it is not necessary to demonstrate that an invention actually works in practice to receive a patent. For inventions that have not been implemented in practice, patents often include prophetic examples that—in contrast to working examples—report experiments, procedures, and protocols that have not actually been conducted. Instead, inventors predict or “prophesize” the results of an experiment. Although it may be surprising that this is permissible, both the USPTO and the U.S. federal courts agree that prophetic examples can satisfy the enablement and written description requirements of the U.S. Patent Act.

In principle, readers can distinguish between working and prophetic examples in the text of a patent by noting the verb tense used throughout the description: examples presented in the *past* tense are working examples, while examples in the *present* or *future* tenses are likely prophetic. However, Freilich and Ouellette (2019) argue this verb tense rule is not widely known, and also describe ways in which prophetic examples can mimic working examples in their tone and level of detail. For example, U.S. Patent 6,869,610 includes the following prophetic example (note the present tense):

A 46 year old woman presents with pain localized at the deltoid region due to an arthritic condition. The muscle is not in spasm, nor does it exhibit a hypertonic condition. The patient is treated by a bolus injection of between about 50 Units and 200 units of intramuscular botulinum toxin type A. Within 1–7 days after neurotoxin administration the patient’s pain is substantially alleviated. The duration of significant pain alleviation is from about 2 to about 6 months.

How frequently are prophetic examples used? The only attempt to count their frequency that we know of is Freilich (2019), who estimates that, among U.S. patents filed and granted in chemistry and biology in recent decades, 17 percent of examples are prophetic; of patents with examples, at least 24 percent contain some examples that are prophetic.

### *Labeling prophetic examples only by verb tense creates the risk of confusion.*

Freilich (2019) documents empirical evidence that the potential costs of prophetic examples are quite large. The obvious concern that arises with prophetic examples is that people either cannot or do not distinguish between prophetic examples and working examples in practice. As noted above, the two types of examples *can* be distinguished in theory, because USPTO policy requires working examples to be written in past tense, whereas prophetic examples are generally written in either present or future tense. Despite this distinction, Freilich (2019) documents that prophetic examples are most often cited as if they were in fact real working examples: of 100 randomly selected patents that use only prophetic examples and that are cited in a scientific publication for a specific proposition, 99 are cited in a way that—incorrectly—treats the prophetic example as a real example, such as by saying that an experiment “had been carried out” by authors of the cited patent.

Freilich and Ouellette (2019) also point out that lack of knowledge about the verb tense rule that distinguishes types of examples is made worse in cases where patents are translated for filing in international patent offices, since differences in tenses in English-language patents may quite literally be lost in translation. With these translated versions, patent examiners and scientists in other countries may be unable to distinguish real and hypothetical data. Flagging prophetic examples only through verb tense may also confuse other audiences that are unfamiliar with this subtlety of U.S. patent law, such as investors who use patents to better understand a firm’s technology, or even scholars of the patent system.

In contrast with these social costs, there is no legal benefit to patentees from labeling their predictions only by verb tense (Freilich and Ouellette 2019). Inventors who want to file patents on untested inventions can do so without presenting their predictions in the form of fictitious experiments—they can also obtain a patent with more general discussion about contexts in which the invention is expected to work (e.g., “Based on these animal trial results, this compound is expected to reduce the mass of pancreatic cancer tumors in adult humans”).

Taken together, we think there is a straightforward case for requiring that prophetic examples be more clearly delineated

as such. The only benefit for patentees that would be lost through this change is any benefit that comes from misleading investors and other patent readers, which is not a net benefit from society’s perspective. Clearer labeling would reduce the costs that stem from confusion, enhancing the patent system’s goals of inducing researchers to disclose accurate information about new inventions and reducing duplication of inventor effort.

### *The USPTO should require clearer labeling for prophetic examples.*

The risk of confusion created by prophetic examples could be reduced with clearer labeling. Freilich and Ouellette (2019) propose a change in the labeling required for prophetic patents to make them more explicit; for example, a heading such as hypothetical experiment or an introductory phrase such as, “It is expected that these experiments would provide these results.” Freilich and Ouellette are careful to clarify that this is *not* an additional labeling requirement, but rather a modification of the existing tense rule requirement. This distinction is important because it clarifies that this modification is within the USPTO’s authority to implement, although the change could also be made at the direction of Congress. The consequence for noncompliance would also remain the same as under the tense rule: presenting prophetic examples without a clear label would render the patent unenforceable, but labels could be added for mistakes discovered during examination of the patent.

The current *Manual of Patent Examining Procedure* (MPEP) contains the following guidance for USPTO examiners concerning prophetic examples:

Simulated or predicted test results and prophetic examples (paper examples) are permitted in patent applications. Working examples correspond to work actually performed and may describe tests which have actually been conducted and results that were achieved. Paper examples describe the manner and process of making an embodiment of the invention which has not actually been conducted. Paper examples should not be represented as work actually done. No results should be represented as actual results unless they have actually been achieved. Paper examples should not be described using the past tense. (USPTO 2018, § 608.01(p))

As a guidance document, this language is exempt from requirements imposed by the Administrative Procedure Act. The USPTO can amend it independently, or it can publish a proposed revision for notice and comment to provide an opportunity for public input (Wasserman 2011). The USPTO should amend the final sentence of this provision to clarify that, for newly filed patent applications, avoiding the past

tense is not sufficient to prevent prophetic examples from being represented as work actually done. Instead, patent applicants should label prophetic examples with a more explicit heading.

After the proposed amendments are added to the MPEP, if a patent applicant describes a prophetic example without the requested explicit label but without any intent to deceive the USPTO, that applicant would be allowed to amend the specification without penalty under section 2163.07 of the MPEP (USPTO 2018) as an obvious error with support in the original specification.

### *Should prophetic examples be permitted at all?*

In addition to requiring clearer labeling for prophetic examples, we think patent policymakers should start a longer-term discussion about whether it makes sense for patents to be granted based purely on prophetic examples to the extent currently allowed. In principle, prophetic examples could generate social benefits. For example, prophetic examples could allow firms to file patent applications earlier in their research processes before they have had time to complete actual experiments. Although this might be socially beneficial, it is equally straightforward to construct cases in which early patenting is socially harmful. For example, allowing patents on untested inventions may discourage researchers from doing the work needed to implement an invention in practice (Lemley 2016; Ouellette 2016). Freilich (2019) finds little evidence that patents with more prophetic examples have clear benefits for patentees; rather, they appear to be more narrow, less valuable, less likely to be used by small firms, and more likely to be abandoned. And Freilich and Ouellette (2019) note that prophetic examples are viewed more skeptically by other patent offices, including those in Canada, China, Europe, and Japan. Understanding how prophetic examples affect innovation is an important question for further study. But, in any case, if prophetic examples are retained in the future, policymakers should at least require that they be clearly flagged and distinguished from working examples.

### **INCREASING TRANSPARENCY IN PATENT OWNERSHIP**

Our second proposal addresses the failure of the patent system to provide accurate notification about ownership of patent rights. Currently, the first page of a patent indicates the assignee as reported by the patent applicant at the time the application is granted. Assignees may voluntarily record any subsequent assignment changes in correspondence with the USPTO, but there is no legal requirement to provide updates when ownership changes (USPTO 2014). Moreover, there is no standardized method for designating patent owners, implying that a given owner is often referred to by different names in different patents.

This combination of the failure to record changes in ownership and the lack of standardized ownership designation means that USPTO records often provide poor notice of patent ownership (Chien 2012; Federal Trade Commission [FTC] 2011). A 2014 regulatory effort to address this problem stalled, primarily because its focus on patent owners who use shell companies to shield their identities led to concerns from patent holders about increased regulatory costs (see box 2). We suggest that the USPTO or Congress initiate a more tailored reform. For all patents, linking patent records to unique IDs and requiring titleholders to update ownership records regularly would reduce the administrative and transaction costs of the patent system with relatively little burden for patentees. For patents asserted in litigation, requiring disclosure of hidden owners would facilitate settlement and limit litigation abuse.

### *Lack of patent ownership transparency increases the transaction costs of the patent system*

Stakeholders have reported problems stemming from three distinct issues with USPTO patent ownership records:

1. Lack of standardization and internal consistency in how a given entity appears in USPTO records (e.g., due to variation in how assignees are abbreviated or spelled);
2. Incompleteness due to failures to record changes in patent ownership; and
3. Hidden owners such as ultimate parent entities that are not listed in current records (which include only titleholders).

These problems arguably increase transaction costs throughout the patent system. For example, before marketing a new product, companies often conduct a freedom-to-operate search to determine whether the product infringes any patents that need to be licensed. Lack of transparency about patent ownership makes freedom-to-operate searches more difficult because assignment records are often used to locate relevant patents (FTC 2011). Licensing is also more costly when patent records do not accurately indicate the relevant party for negotiations or the full set of patents that should be the subject of a given license.

The problem of hidden owners has been a particular concern in the litigation context. Chien (2012) found that in about one-third of the 915 patents asserted in litigation from 2000 to 2008, the plaintiff was not the owner of record at the start of litigation. Clearer ownership records would make it easier for a defendant to determine whether it already has a portfolio license covering the patent at issue and whether a litigation settlement covers all relevant patents owned by a given entity.

Unclear patent ownership records also make it more difficult to answer some of the open empirical questions about the patent system, such as demographic gaps in who patents and

the welfare implications of allowing NPEs to operate, given that NPE ownership and funding structures can arguably be difficult for even industry insiders to untangle (Stroud 2019).

#### BOX 2.

### Prior Reform Efforts Faltered Due to Stakeholder Concerns About Regulatory Burden

Concern over these problems has already spurred policy reform discussions. In 2013 three congressional bills were introduced that were intended to increase ownership transparency. The End Anonymous Patents Act and the Patent Transparency and Improvements Act would have required updating ownership information for all patents, but neither made it out of committee. The Innovation Act would have required disclosure of complete ownership information for litigated patents; it passed a vote in the House of Representatives but not in the Senate.

The USPTO need not wait for new legislation; it already has authority to require its records to be accurate and complete (Chien 2012). In January 2014, at the request of the White House, the USPTO published notice of a proposed rule, “Changes to Require Identification of Attributable Owner,” to increase transparency in patent ownership. The rule identified attributable owners of a patent as titleholders, entities with enforcement rights, ultimate parent entities, and entities trying to avoid disclosure by temporarily divesting themselves of ownership rights. Any attributable owners of patents filed after the rule went into effect would need to be identified to the USPTO during the pendency of a patent application, upon payment of issuance or maintenance fees, and during certain post-issuance proceedings at the USPTO.

As summarized by Anderson (2015), in response to the USPTO’s request for comments, stakeholders such as large technology firms and consumer-focused nonprofits argued that the reform did not go far enough. For example, the Coalition for Patent Fairness (now the High Tech Inventors Alliance, whose members include Adobe, Cisco, Dell, Google, Oracle, and Samsung) argued that the definition of attributable owners was not broad enough to curb abusive behavior, and the Electronic Frontier Foundation argued that the USPTO should require notification of any transfers in patent ownership within 30 days of patent transfer. However, stakeholders whose interests aligned more closely with patent owners—including pharmaceutical firms, universities, the Intellectual Property Owners Association (IPO), and the American Intellectual Property Law Association (AIPLA)—argued that the proposed reform would be excessively burdensome. According to these opponents, the rule was overly vague, the cost of analyzing the relevant business structures would exceed the \$100 per patent estimated by the USPTO, and compliance with the rule would require violation of confidential licensing terms. After receiving these mixed responses from stakeholders, the USPTO abandoned this proposal in October 2014 (Menell 2019).

### ***Ownership transparency reform #1: Congress or the USPTO should require standardization of entity and inventor names across patent records***

The failed 2014 reform effort described in box 2 did not address the challenges posed by the lack of standardization and internal consistency of owner identities. In our view, this may be the easiest, least controversial, and least costly improvement to USPTO ownership records. As Chien (2012) suggests, internal consistency could be improved by asking owners to identify themselves by reference to an existing patent record (e.g., “This application is owned by the owner of record of patent X,XXX,XXX”). In addition, linking patents to unique entity IDs could greatly reduce patent search costs. For example, the Employer Identification Number (EIN), also known as a Taxpayer Identification Number (TIN), is a permanent nine-digit identifier assigned by the IRS to legal entities including corporations, partnerships, nonprofits, and government agencies. Firms could also be given the opportunity to list other identifiers, such as the Value-Added Tax Number (VATIN), which is used in more than 65 countries, including countries in the European Union, for tax identification.

A distinct but closely related concern is the challenge posed by the lack of standardization (and internal consistency) of inventor identities. Individual inventors could be required to report persistent identifiers such as the Open Researcher and Contributor ID (ORCID), which are currently being collected by more than 7,000 scientific journals.

As Chien (2012) explains, requiring standardized and transparent patent ownership records is within the USPTO’s rulemaking authority. The 2014 administrative reform effort failed due to stakeholder objections, not legal hurdles. Alternatively, Congress could pass legislation to mandate this reform.

### ***Ownership transparency reform #2: Congress or the USPTO should increase incentives to record changes in patent assignments***

The problem of out-of-date patent ownership information could be addressed by making assignment changes mandatory rather than optional during the patent term. The USPTO’s 2014 proposed rule would have required the attributable owner of a patent, including the ultimate parent entity, to be identified while a patent application is being examined and to be updated when maintenance fees are paid on an issued patent. A natural alternative would be a requirement for patentees to update USPTO records within a certain period of time after an assignment change. Setting aside the timing of when updates would be required, criticisms of the 2014 proposed rule focused on the broad definition of attributable owners, which many patent owners argued would impose a large regulatory burden. Our proposal, in contrast, is to focus

on a simpler requirement for direct titleholders to update ownership records—without attempting to uncover ultimate parent entities—that would achieve many of the gains of this 2014 proposed rule while imposing much lower costs on patentees. Like our first proposed reform, this proposal could be implemented through USPTO rulemaking or congressional legislation.

Of course, either (or both) of the two ownership transparency reforms proposed above would have to specify some consequence for noncompliance. Under the 2014 proposed rule, failure to identify attributable owners during examination would result in abandonment of the application, though the application could be revived if the failure was unintentional. No penalty was specified for failure to identify attributable owners after a patent was issued. Anderson (2015) lays out some possible remedies, such as limiting recovery of attorneys’ fees and enhanced damages or barring damages awards for infringement during periods when ownership information was not properly maintained. An even stronger incentive would involve making out-of-date contact information for a patent’s owner a defense to infringement of that patent until the record is corrected.

### ***Ownership transparency reform #3: Work toward more disclosure of hidden owners***

The problem of hidden owners could be addressed by broadening the kind of ownership interests that must be disclosed to include more than direct titleholders. As noted, the broad definition of attributable owners under the USPTO’s 2014 proposed rule was criticized by patent owners concerned about the regulatory burden. This compliance cost could be substantially mitigated by only applying these most stringent ownership disclosure rules to litigated patents, the small minority of patents for which ownership transparency is arguably most socially valuable. Of course, it is possible that, in the course of instituting such a requirement for litigated patents, a strategy for implementing this type of rule more broadly with lower compliance costs could be clarified.

## **MAKING PATENT TERMS MORE UNIFORM FOR PHARMACEUTICALS**

Our third proposal addresses the fact that, even though the patent system is meant to provide uniform patent terms across inventions, it fails to do so in practice. Perhaps the clearest evidence of this failure comes from pharmaceuticals, so we focus our reform proposal on that sector.

In the pharmaceutical sector, failure to provide uniform patent terms may cause underinvestment in candidate drug compounds that require long clinical trials. In the United States and most other countries, patent terms generally last 20 years after an application is filed. But the *effective* patent term (i.e., the patent term that remains once a patented product

is on the market) can be much shorter than 20 years when there is a long lag between patent application filing and first sale of the patented product to consumers. Drug patents are filed prior to the start of clinical trials, but effective patent terms do not start until after the trials have been completed and the drug has been approved by the U.S. Food and Drug Administration (FDA) for sale to U.S. consumers (Lietzan and Lybecker 2020; Roin 2014). Patents thus paradoxically provide the weakest incentive for inventions that take the longest time to develop, whereas simple theoretical models would suggest that society might prefer the opposite.

Budish, Roin, and Williams (2015) discuss two examples that—while not definitive evidence of this distortion—illustrate how this problem could manifest itself in practice. Consider two clinical studies investigating treatments for prostate cancer, both of which were published in the *New England Journal of Medicine* in 2011. The first study (de Bono et al. 2011) analyzed a treatment for metastatic prostate cancer patients whose cancer had spread beyond the initial tumor and who had relatively poor survival prospects (in their data, a five-year survival rate of around 20 percent). The study needed to measure patient survival for just over a year in order to document a statistically significant improvement in survival in the (randomized) treatment group, and the total trial length was around three years. The second study (Jones et al. 2011) analyzed a treatment for localized prostate cancer patients whose cancer had not yet spread beyond the prostate and who had better survival prospects (in their data, a five-year survival rate of around 80 percent). Because these patients were in better health, this study needed to measure patient survival for a full nine years, and the total trial length was 18 years. In practice, drugs need more than one clinical trial to receive FDA approval, but taking the simple case where drugs get a 20-year patent term and patents are filed prior to the start of a single clinical trial, the first drug would receive 17 (20 minus 3) years of effective patent life, whereas the second drug would receive only 2 (20 minus 18) years. Perhaps because of the much shorter effective patent term provided in the second case, the first (metastatic) clinical trial was funded by a small biotech company, whereas the second (localized) clinical trial was publicly funded.

This potential concern has long been recognized by policymakers, and the 1984 Hatch–Waxman Act included a provision that granted some qualifying firms a partial extension of their patent life to compensate for the time drugs spent in clinical trials. Specifically, Hatch–Waxman awards qualifying firms one half-year of additional patent life for each year spent in clinical trials, up to a maximum of five additional years, but not to exceed a total of 14 years after FDA approval. In practice, however, the structure of the current Hatch–Waxman provision appears flawed in the sense of not fully correcting for this distortion. Lietzan

and Lybecker (2020) document that, for all 642 drugs that had their patent term restored between September 28, 1984 and April 1, 2017, the average effective patent life was less than 12 years, with drugs that required longer clinical trials receiving shorter effective terms. Congress could address this flaw by reforming Hatch–Waxman, for example by starting the exclusivity period (of some length; as we discuss below, potentially shorter than the current 20-year patent term) for pharmaceuticals at the time the drug is approved by the FDA for sale to patients. Simultaneously, patent and antitrust law should be vigorously enforced to limit opportunistic extensions of effective exclusivity periods that do not contribute to social value, such as so-called evergreening practices (Feldman 2018).

### *Are short effective patent terms for some pharmaceuticals a problem in practice?*

As we have argued, there is tremendous empirical uncertainty about whether longer patent terms encourage innovation. This naturally raises the question: Would changes to effective patent terms have real effects on pharmaceutical investments?

It is important to stress that our (preferred) justification for this proposed reform does *not* rest on an affirmative answer to that question. Rather, our preferred justification is more direct: the patent system is meant to provide uniform patent terms across inventions, but fails to do so in practice. Pharmaceutical markets are the obvious case where direct evidence of this failure exists, and there are practical policy levers that could address this failure without distorting other (nonpharmaceutical) markets.

That said, we of course recognize that policymakers will be interested in whether the policy reform we are proposing would have real effects on pharmaceutical investments. While there is no definitive evidence on this question, the closest available evidence comes from Budish, Roin, and Williams (2015). The authors start by empirically establishing that longer commercialization lags are associated with less R&D investment in cancer drugs. As suggested by the two *New England Journal of Medicine* examples discussed above, clinical trials can be completed more quickly for late-stage cancers with low survival rates, such as recurrent and metastatic cancers, because differences in survival in a treatment group relative to a control group in a randomized trial can be observed more rapidly. Given that patents essentially must be filed before the start of clinical trials, late-stage cancer drugs thus receive longer effective patent terms than do early-stage cancer drugs that require lengthier clinical trials. As illustrated in figure 1, this difference in commercialization time correlates with the number of clinical trials conducted for different cancer stages. The same pattern holds when adjusting for measures of market size.

Two additional empirical tests conducted by Budish, Roin, and Williams (2015) suggest that, when taken together, figure 1 reflects a distortion of private R&D investments in cancer drugs away from the ideal balance. First, the negative correlation between commercialization lags and R&D does not hold when firms are permitted to rely on surrogate endpoints for clinical trials (i.e., outcomes other than survival rates, which can be observed more quickly), suggesting that the relationship is causal rather than reflecting, for example, fewer scientific opportunities for early-stage treatments. Second, the observed negative correlation is stronger for private investments than it is for publicly funded research investments, suggesting again that the relationship does not merely reflect the lack of scientific opportunities to develop early-stage cancer drugs. As further support for this interpretation, all six FDA-approved cancer prevention drugs—the cancer drugs with the longest commercialization lags—either relied on surrogate endpoints or were approved by the FDA entirely on the basis of publicly funded clinical trials.

What Budish, Roin, and Williams (2015) do *not* show is definitive evidence that longer effective patent terms would fix this distortion. As they discuss, at least one other potential mechanism—namely, private firms preferring to invest in projects that pay out over a short time horizon—could explain these results. While both mechanisms could merit a public policy response, reforms to Hatch–Waxman would only address the problems generated by the first mechanism.

Even with that caveat, Budish, Roin, and Williams (2015) are nonetheless able to estimate that underinvestment by private

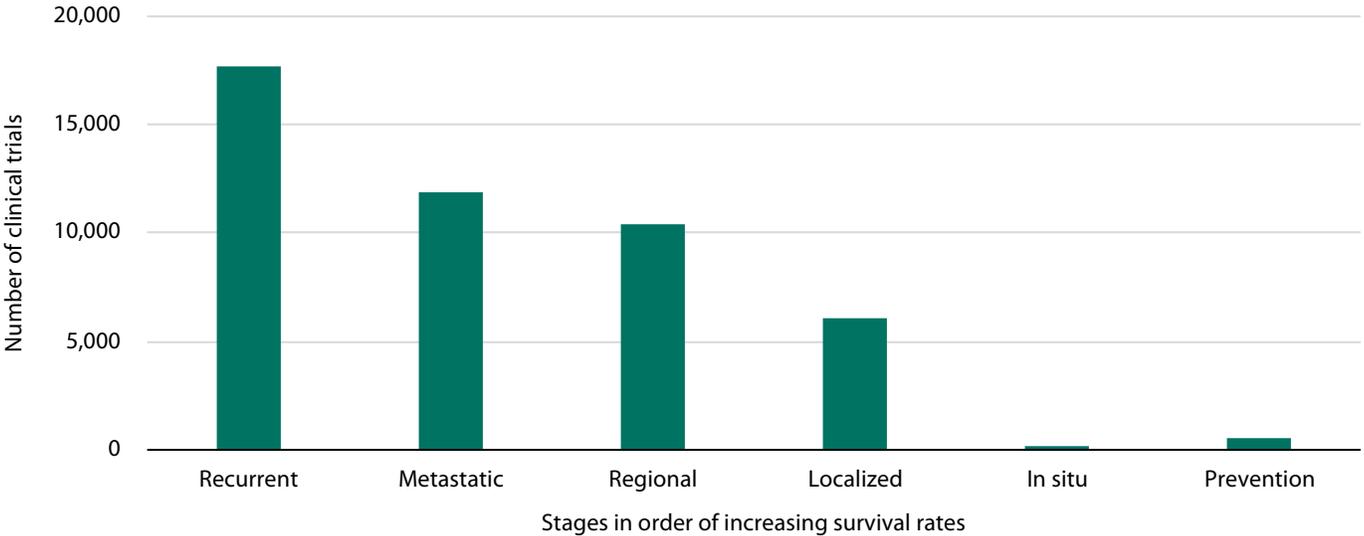
firms in long-term cancer research—generated by either or both of these mechanisms—generates a quantitatively large loss in patient health. The authors estimate that, even focused solely on the subset of U.S. cancer patients diagnosed in 2003, this distortion generated around 890,000 lost life-years, which translates to a total net present value of life-years at stake of between \$170 billion and \$4.2 trillion. While these specific estimates should of course be taken with a grain (perhaps a spoonful) of salt, they suggest that this distortion is empirically important enough that policymakers should seriously consider potential reforms.

*How can the Hatch–Waxman Act be amended to address the patent-term distortion?*

In practical terms, Congress could address the current asymmetry in pharmaceutical patent terms by amending one of two provisions included in the Hatch–Waxman Act of 1984. Before discussing these two approaches, it is critical to stress that our goal is *not* to increase exclusivity for pharmaceuticals in general. Rather, our goal is simply to *equalize* the periods of exclusivity provided to different types of drugs. The optimal amount of exclusivity is a separate question that should itself be informed by empirical evidence, as discussed above and below.

The first potential reform to Hatch–Waxman would amend the patent term restoration provision. Patent term restoration under Hatch–Waxman currently allows a firm to extend one patent per drug for half the time spent in clinical trials, up to a maximum of five years, and with the total life not to exceed 14 years after FDA approval. This patent term restoration was

FIGURE 1. Clinical Trial Activity by Cancer Stage, 1973–2011



Source: Budish, Roin, and Williams 2015.

Note: This figure plots measures of clinical trial activity for each stage of cancer from 1973 to 2011, arranged in order of five-year survival rates among patients diagnosed with each stage between 1973 and 2004 (the cohorts for which five-year survival is uncensored). For details on the sample, see Budish, Roin, and Williams (2015).



intended to account for commercialization lags, but recent empirical evidence suggests it did not go far enough since longer clinical trials are still associated with shorter effective patent life (Lietzan and Lybecker 2020). Congress could amend the structure of the patent term restoration provision to more successfully equalize effective patent terms across candidate drug compounds.

The second potential reform to Hatch–Waxman would amend the regulatory exclusivity provision. The regulatory exclusivity provision under Hatch–Waxman provides a patent-like period of five years of exclusivity after FDA approval to any drug with a new active ingredient, three years for other drugs that require new clinical trials, and an additional six months for drugs subjected to certain pediatric trials. This data exclusivity prevents a company that manufactures generic drugs from relying on the brand-name company’s clinical trial data for approval, which effectively prevents generic entry in most cases due to the cost and ethical concerns (i.e., the harm experienced by patients in the control group who would be denied a treatment known to help) around conducting new trials for an approved compound.

Anecdotally, five years of data exclusivity may be insufficient to incentivize drug development, because firms regularly report ceasing development on drugs that would have only that form of intellectual property protection from their R&D pipelines (Roin 2009). But a longer period of regulatory exclusivity could potentially be structured to address this asymmetry: regulatory exclusivity by construction can be designed to offer uniform protection across approved drugs. Congress could also strengthen this period of protection by replacing the current data exclusivity with market exclusivity—such as the seven-year period firms receive under the Orphan Drug Act—which would not allow entry of a generic competitor even if the competitor conducted its own clinical trials.

In our view, changing the period of regulatory exclusivity would be administratively easier to implement than would be either reforms to patent term restoration or other direct reforms to the patent system. Of course, the choice of legislative pathway will be constrained by political considerations, but it is worth noting that the European Union provides up to 11 years of regulatory exclusivity for new pharmaceuticals, and the United States already provides 12 years of exclusivity for biologic products (see Gaessler and Wagner 2019).

### *More-ambitious pharmaceutical patent reforms*

In our view, this proposal raises several important issues for longer-term debate and discussion.

Even if one agrees in principle with the idea that changing the period of regulatory exclusivity might be an effective way to provide patent-like protection that is more uniform

across inventions, there are a number of key issues that would need to be addressed. Most central is the question of how to choose the optimal period of regulatory exclusivity. As stressed throughout this paper, very little empirical evidence is currently available to guide that choice. Although patent terms extend 20 years from patent filing, current policy design choices by the European Union (for new pharmaceuticals) and the United States (for biologics) suggest that there may be a policymaker preference for implementing exclusivity periods that are closer to 10–12 years rather than 20 years.<sup>4</sup> This is a natural illustration of the idea we expressed above that reforms in this area need not increase the duration of exclusivity for pharmaceuticals.

If policymakers want to decrease the longest effective patent terms, they may also want to consider additional reforms. The pharmaceuticals that currently have the longest effective terms are usually ones whose protection has been evergreened with additional patents to last well beyond the 20-year term of the first related patent (Feldman 2018). For example, patents are often filed on new drug formulations or slight chemical variations. Pharmaceutical firms also sometimes engage in product hopping to effectively extend their exclusivity periods by shifting patients from a drug with expiring patents to a market substitute with longer protection but little additional benefit to patients (Carrier and Shadowen 2016). Many of the lengthier exclusivity periods could be shortened through more-vigorous enforcement of patent and antitrust laws, which could be done by courts independently or at the direction of Congress.

A more ambitious effort could consider potential reforms aimed at reducing the pharmaceutical industry’s reliance on patents by shifting the industry to instead rely solely on FDA-provided exclusivity. This would allow policymakers to more easily tailor pharmaceutical policy to the conditions in that sector.

Of course, a key question is how such a reform could be designed in practice, particularly given that efforts to correct this issue in the United States must address an international dimension: many drugs are patented and marketed in other countries, and numerous international agreements constrain the ability of the United States to limit pharmaceutical patents. But, in our view, this type of shift has the potential to avoid many distortions and controversies that currently arise related to the use and abuse of patents in the pharmaceutical industry, such as pay-for-delay contracts (Hemphill 2006), evergreening of drugs (Feldman 2018; Hemphill and Sampat 2012), and cases such as that of Martin Shkreli, and thus is well worth considering.<sup>5</sup>

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# Questions and Concerns

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## *1. Should patent terms be reformed to be equalized in nonpharmaceutical sectors as well?*

In our view, the pharmaceutical industry is the poster child for the idea that the patent system is failing to provide uniform patent terms across inventions. Convincing empirical evidence, described above, now exists to support the objective of rendering effective patent terms more uniform in the pharmaceutical sector. Unless and until direct empirical evidence as in Lietzan and Lybecker (2020) is available for other sectors, our inclination would be to hold off on implementing broader reforms. But a similar dynamic could very well be at work in other sectors.

## *2. Should pharmaceutical incentives be shifted to rely more on FDA regulatory exclusivity and less on the patent system?*

While we do not have a specific proposal of how that transition could occur, we can provide one line of reasoning that suggests why this type of transition could be worth exploring. Several influential surveys (Cohen, Nelson, and Walsh 2000; Levin et al. 1987; Mansfield 1986) documented that firms self-report that patents are essential motivators for research investments in chemicals and pharmaceuticals, much more frequently than in other sectors. These surveys align well with casual observations that the pharmaceutical industry frequently takes different positions on patent policy debates than do other sectors. The 2014 patent ownership transparency reform effort discussed above is a clear example of this sector-specific divide: firms such as Adobe, Cisco, Dell, Google, Oracle, and Samsung took a polar opposite stance in the debate as compared to the pharmaceutical sector. Lobbying from the pharmaceutical industry—if successful—thus could be distorting the design of the patent system in a way that negatively impacts other sectors. If the pharmaceutical sector truly is an outlier due to the unusual regulatory burden of bringing new drugs to market, it could well make sense to find a way to transition the pharmaceutical industry to a system more tailored to those regulatory costs, and to allow the traditional patent system to be designed in a way that is most appropriate for other sectors of the economy.

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# Conclusion

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Improving the patent system is a key policy priority, but is challenging to achieve in practice. Because of empirical uncertainty over questions such as whether strengthening patent rights would increase or decrease research investments, we cannot credibly predict the effect of policy reforms focused on changing the overall strength of patent protection. Instead, we have set forth three more-tailored reforms that—in our view—are easier to justify based on existing theory and evidence: requiring clearer labeling of prophetic examples, increasing transparency in patent ownership, and fixing an asymmetry in the effective patent term for pharmaceuticals.

We conclude by noting that, while we think it is important for policymakers to understand the degree of uncertainty about the effects of patents, we do not think this uncertainty is an excuse for inaction. In addition to implementing the more-tailored reforms we focus on here, institutions focused on increasing innovation—including federal and state government agencies as well as private sector institutions—

should look for opportunities to test interventions in ways that deepen the evidence base for innovation policy.

For example, the patent examiners tasked with determining whether each patent application should be granted face substantial informational constraints, including difficulty finding nonpatent scientific literature.<sup>6</sup> Proposals to improve patent examination can be studied through randomized field experiments, as illustrated by Ho and Ouellette (2020) in the context of external scientific peer review. The USPTO could similarly test proposals, such as using internal peer review or automated prior art searches to improve the consistency and accuracy of examination decisions. Ouellette (2015a) provides additional examples of how randomization can be used to improve evidence-based policymaking in patent law. Many academic teams would likely welcome the opportunity to collaborate with innovation institutions on piloting and rigorously evaluating the most promising policy interventions.

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# Endnotes

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1. A separate literature has explored the role patents may play in facilitating technology transfer between firms (see, e.g., Gans, Hsu, and Stern 2002); we do not focus on that literature here.
2. A subsequent literature documented theoretically ambiguous predictions of how patents affect follow-on innovation. See Galasso and Schankerman (2015) for a concise theoretical framework incorporating several key ideas from this literature.
3. We focus here on arguments related to social welfare, but we note that some arguments in favor of patentable subject matter restrictions have been based instead on moral concerns. For example, amicus parties argued that the gene patents in *Myriad* commodified human life and impinged on rights of privacy, that the diagnostic method claims in *Mayo* violated the freedom of thought, and that software claims such as those invalidated in *Alice* limited the freedom to express oneself using a computer (Ouellette 2015b).
4. Importantly, for some potential reforms like data exclusivity, exclusivity extensions provide a floor and not a ceiling, so variation in effective patent terms is still likely to exist across drugs.
5. Shkreli is the founder and former CEO of Turing Pharmaceuticals, which was heavily criticized for obtaining a manufacturing license for the antiparasitic drug Daraprim and then raising its price by a factor of 56 (from \$13.50 to \$750 per pill).
6. A Hamilton Project proposal by Frakes and Wasserman (2017) put forth several reforms aiming to make the USPTO issue fewer weak patents.

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# References

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- Administrative Procedure Act, Pub.L. 79–404, 60 Stat. 237 (1946).
- Anderson, Nathan P. 2015. “Striking a Balance: The Pursuit of Transparent Patent Ownership.” *Berkeley Technology Law Journal* 30 (4): 395–443.
- Bloom, Nicholas, John Van Reenen, and Heidi Williams. 2019. “A Toolkit of Policies to Promote Innovation.” *Journal of Economic Perspectives* 33 (3): 163–84.
- Boldrin, Michele, and David K. Levine. 2008. *Against Intellectual Monopoly*. Cambridge, UK: Cambridge University Press.
- . 2013. “The Case Against Patents.” *Journal of Economic Perspectives* 27 (1): 3–22.
- Budish, Eric, Benjamin N. Roin, and Heidi L. Williams. 2015. “Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials.” *American Economic Review* 105 (7): 2044–85.
- . 2016. “Patents and Research Investments: Assessing the Empirical Evidence.” *American Economic Review Papers and Proceedings* 106 (5): 183–87.
- Carrier, Michael A., and Steve D. Shadowen. 2016. “Product Hopping: A New Framework.” *Notre Dame Law Review* 92 (1): 167–230.
- Chien, Colleen V. 2012. “The Who Owns What Problem in Patent Law.” Available at the Social Science Research Network (SSRN).
- Chien, Colleen V., and Arti K. Rai. 2018. “An Empirical Analysis of Diagnostic Patenting Post-Mayo.” Working Paper.
- Cohen, Lauren, Umit G. Gurun, and Scott Duke Kominers. 2018. “Patent Trolls: Evidence from Targeted Firms.” Harvard Business School Finance Working Paper No. 15-002. Available at the Social Science Research Network (SSRN).
- Cohen, Wesley, Richard Nelson, and John Walsh. 2000. “Protecting Their Intellectual Assets: Appropriability Conditions and Why US Manufacturing Firms Patent (or Not).” Working Paper 7552, National Bureau of Economic Research, Cambridge, MA .
- de Bono, Johann S., Christopher J. Logothetis, Arturo Molina, Karim Fizazi, Scott North, Luis Chu, Kim N. Chi, Robert J. Jones, Oscar B. Goodman, Jr. et al. 2011. “Abiraterone and Increased Survival in Metastatic Prostate Cancer.” *New England Journal of Medicine* 364 (21): 1995–2005.
- Drug Price Competition and Patent Term Restoration Act (Pub.L. 98-417, 98 Stat. 1585) (Hatch–Waxman Act) (1984).
- End Anonymous Patents Act, H.R.2024, 113th Congress (2013–14); introduced May 16, 2013, by Rep. Deutch (D-FL-21), House Judiciary Committee.
- Federal Trade Commission (FTC). 2011. “The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition.” Federal Trade Commission, Washington, DC.
- Feldman, Robin. 2018. “May Your Drug Price Be Evergreen.” *Journal of Law and the Biosciences* 5 (3): 590–647.
- Feng, Josh, and Xavier Jaravel. 2020. “Crafting Intellectual Property Rights: Implications for Patent Assertion Entities, Litigation, and Innovation.” *American Economic Journal: Applied Economics* 12 (1): 140–81.
- Frakes, Michael D., and Melissa F. Wasserman. 2017. “Decreasing the Patent Office’s Incentives to Grant Invalid Patents.” Policy Proposal, The Hamilton Project, Brookings Institution, Washington, DC.
- Freilich, Janet. 2019. “Prophetic Patents.” *U.C. Davis Law Review* 53 (2): 663–731.
- Freilich, Janet, and Lisa Larrimore Ouellette. 2019. “Science Fiction: Fictitious Experiments in Patents.” *Science* 364 (6445): 1036–37.
- Gaessler, Fabian, and Stefan Wagner. 2019. “Patents, Data Exclusivity, and the Development of New Drugs.” Available at the Social Science Research Network (SSRN).
- Galasso, Alberto, and Mark Schankerman. 2015. “Patents and Cumulative Innovation: Causal Evidence from the Courts.” *Quarterly Journal of Economics* 130 (1): 317–369.
- Gans, Joshua, David Hsu, and Scott Stern. 2002. “When Does Start-Up Innovation Spur the Gale of Creative Destruction?” *RAND Journal of Economics* 33: 571–86.
- Gilbert, Richard, and Carl Shapiro. 1990. “Optimal Patent Length and Breadth.” *RAND Journal of Economics* 21 (1): 106–12.
- Government Patent Policy Act of 1980 (Bayh–Dole Act), Pub.L. 96-517, 94 Stat. 3015 (1980).
- Haber, Stephen. 2016. “Patents and the Wealth of Nations.” *George Mason Law Review* 23 (4): 811–35.
- Haber, Stephen, and Ross Levine. 2014. “The Myth of the Wicked Patent Troll.” *Wall Street Journal*, June 29.
- Hemel, Daniel J., and Lisa Larrimore Ouellette. 2013. “Beyond the Patents–Prizes Debate.” *Texas Law Review* 92 (2): 303–82.
- Hemphill, C. Scott. 2006. “Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem.” *New York University Law Review* 81 (5): 1553–623.
- Hemphill, C. Scott and Bhaven Sampat. 2012. “Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals.” *Journal of Health Economics* 31 (2): 327–29.
- Hickey, Kevin J. 2019. “Patent-Eligible Subject Matter Reform in the 116th Congress.” Report R45918, Congressional Research Service, Washington DC.

- Ho, Daniel E., and Lisa Larrimore Ouellette. 2020. "Improving Scientific Judgments in Law and Government: A Field Experiment of Patent Peer Review." *Journal of Empirical Legal Studies* (forthcoming). Available at the Social Science Research Network (SSRN).
- Innovation Act, H. Rept. 114-235, 114th Congress (2015–16), H.R.9; introduced February 5, 2015, by Rep. Goodlatte (R-VA-6), House: Judiciary Committee.
- Jones, Christopher U., Daniel Hunt, David G. McGowan, Mahul B. Amin, Michael P. Chetner, Deborah W. Bruner, Mark H. Leibenhaut, Siraj M. Husain, Marvin Rotman et al. 2011. "Radiotherapy and Short-Term Androgen Deprivation for Localized Prostate Cancer." *New England Journal of Medicine* 365 (2): 107–18.
- Klemperer, Paul. 1990. "How Broad Should the Scope of Patent Protection Be?" *RAND Journal of Economics* 21 (1): 113–30.
- Lemley, Mark A. 2016. "Ready for Patenting." *Boston University Law Review* 96 (3): 1171–95.
- Lemley, Mark A., and Samantha Zyontz. 2020. "Does Alice Target Patent Trolls?" Available at the Social Science Research Network (SSRN).
- Lerner, Josh. 2009. "The Empirical Impact of Intellectual Property Rights on Innovation: Puzzles and Clues." *American Economic Review* 99 (2): 343–48.
- Levin, Richard, Alvin Klevorick, Richard Nelson, and Sydney Winter. 1987. "Appropriating the Returns from Industrial Research and Development." *Brookings Papers on Economic Activity* 3: 783–831.
- Lietzan, Erika, and Kristina M. L. Aciri née Lybecker. 2020. "Distorted Drug Patents." *Washington Law Review* 95 (forthcoming Oct. 2020). Available at the Social Science Research Network (SSRN).
- Machlup, Fritz. 1958. "An Economic Review of the Patent System." Study of the Subcommittee on Patents, Trademarks, and Copyrights of the Senate Committee on the Judiciary. 85th Congress, 2nd Session.
- Mansfield, Edwin. 1986. "Patents and Innovation: An Empirical Study." *Management Science* 32 (2): 173–81.
- Maurer, Noel, and Stephen Haber. 2018. "An Empirical Analysis of the Patent Troll Hypothesis: Evidence from Publicly-Traded Firms." Working Paper 18114, Hoover Institution, Stanford, CA.
- Menell, Peter S. 2019. "Economic Analysis of Intellectual Property Notice and Disclosure." In *Research Handbook on the Economics of Intellectual Property Law*, vol. 1, edited by Ben Depoorter and Peter S. Menell, 424–71. Cheltenham, UK: Edward Elgar.
- Moser, Petra. 2005. "How Do Patent Laws Influence Innovation? Evidence from Nineteenth-Century World's Fairs." *American Economic Review* 95 (4): 1214–36.
- . 2013. "Patents and Innovation: Evidence from Economic History." *Journal of Economic Perspectives* 27 (1): 23–44.
- Nordhaus, William D. 1969. *Invention, Growth, and Welfare: A Theoretical Treatment of Technological Change*. Cambridge, MA: MIT Press.
- Orphan Drug Act (ODA), Pub.L. 97-414, 96 Stat. 2049 (1983).
- Ouellette, Lisa Larrimore. 2015a. "Patent Experimentalism." *Virginia Law Review* 101 (1): 65–128.
- . 2015b. "Patentable Subject Matter and Nonpatent Innovation Incentives." *U.C. Irvine Law Review* 5 (5): 1115–45.
- . 2016. "Pierson, Peer Review, and Patent Law." *Vanderbilt Law Review* 69 (6): 1825–48.
- Patent Transparency and Improvements Act, S. 1720, 113th Congress (2013–14); introduced November 18, 2013, by Sen. Leahy (D-VT), Senate: Judiciary Committee.
- Qian, Yi. 2007. "Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection, 1978–2002." *Review of Economics and Statistics* 89 (3): 436–53.
- Roin, Benjamin N. 2009. "Unpatentable Drugs and the Standards of Patentability." *Texas Law Review* 87 (3): 503–70.
- . 2014. "The Case for Tailoring Patent Awards Based on Time-to-Market." *UCLA Law Review* 61 (3): 672–759.
- Sakakibara, Mariko, and Lee Branstetter. 2001. "Do Stronger Patent Rights Induce More Innovation? Evidence from the 1988 Japanese Patent Law Reforms." *RAND Journal of Economics* 32 (1): 77–100.
- Shackleton, Robert. 2018. "Productivity and Growth in CBO's Forecasts." Presented to the National Association for Business Economics (NABE) Foundation 15th Annual Economic Measurement Seminar, Washington, DC, July.
- Stroud, Jonathan. 2019. "Pulling Back the Curtain on Complex Funding of Patent Assertion Entities." *Landslide* 12 (2).
- U.S. Congressional Budget Office (CBO). 2018. "An Update to the Economic Outlook: 2018 to 2028." U.S. Congressional Budget Office, Washington, DC.
- U.S. Patent and Trademark Office (USPTO). 2014. "Changes to Require Identification of Attributable Owner." *Federal Register* 79 (16): 4105–6.
- . 2018. *Manual of Patent Examining Procedure*. Washington, DC: U.S. Patent and Trademark Office.

Wasserman, Melissa F. 2011. "The PTO's Asymmetric Incentives: Pressure to Expand Substantive Patent Law." *Ohio State Law Journal* 72 (2): 379–435.

Williams, Heidi L. 2017. "How Do Patents Affect Research Investments?" *Annual Review of Economics* 9: 441–69.



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## Highlights

Technological innovation helps drive long-run economic and productivity growth. While governments additionally rely on research and development tax credits and publicly-funded research subsidies, the patent system is the most prominent policy lever available to spur innovation. In this proposal Lisa Larrimore Ouellette and Heidi Williams of Stanford University offers several reforms that would make the patent system work more effectively and would facilitate technological innovation.

## The Proposal

**Require U.S. patent applications to distinguish hypothetical, experimental results from real data.** Inventors often obtain patents based on prophetic examples, which predict the outcomes of various experiments without actually conducting the research. More clearly identifying prophetic examples would avoid confusing key audiences while still maintaining patentees' legal rights.

**Mandate patent owners provide more transparent and standardized disclosure of patent ownership.** Increased transparency in patent ownership could help reduce transaction costs in technology markets by identifying patent owners, allowing market participants to determine whether their planned activities require licensing.

**Increase uniformity in patent terms across innovations.** Amending the Hatch-Waxman Act to start the effective market exclusivity period for new drugs at the time of approval for sale (rather than at the time of patent filing) combined with crackdowns on strategic behavior such as pay-for-delay would help to create more uniformity in effective patent life.

## Benefits

Although the impact of the quantity of patents on innovation remains empirically uncertain, the authors conclude that improving how the patent system works is worthwhile. The current patent system offers several opportunities to enhance efficiency and transparency, thereby spurring innovation and contributing to long-run economic and productivity growth.



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