Optimal patent policy for pharmaceuticals: Balancing innovation and access to new drugs

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There is a fundamental trade-off between incentives to develop new drugs and access to cheaper medicines. How should patent rights be designed in the pharmaceutical industry to optimally balance this trade-off? This column suggests that longer patent terms are an inefficient way of promoting the development of new drugs since they also increase incentives for challenging patents. Government policies should make patents shorter-lived, but broader in scope.

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New drugs are expensive to develop. The average research and development investment required to bring a new drug to market has recently been estimated to be over $1.3 billion, after accounting for the costs of failed trials (Wouters et al. 2020). However, once created, new drugs are fairly easy for generic firms to imitate. As a result, competitive markets may underinvest in drug development from society's point of view. This market failure is particularly pronounced in the case of research investments for vaccines (Kremer et al. 2016, de Rassenfosse et al. 2020).

Patent policies aim to overcome this market failure by providing inventors with temporary exclusive rights. By making the inventor's market power temporary, patent policies ensure access to affordable generic medicines and health care after patents expire. This trade-off between innovation and competition is at the core of patent policies and long-standing theoretical work, dating back to Nordhaus (1969).

The global outbreak of COVID-19 calls for effective treatment. Once a new treatment has been discovered, it will take time to obtain patent protection and bring it to market. Regulatory delays may shorten the effective patent term and dilute the incentives to develop the new treatment. For this reason, many countries provide new drug patents with term extensions to compensate for the effective reduction in patent term due to regulatory delays.

However, as in the case of HIV treatments (Hoe et al. 2011), another concern is that the inventor's patent rights and associated market power may deter access to essential COVID-19 medications, especially in low-income households or countries (de Rassenfosse et al. 2020, Unitaid 2020). Promising mechanisms for balancing innovation and affordable access to new treatments are innovation prizes (Athey et al. 2020) and the pooling of patent rights and data (Hoe et al. 2011, Medicines Patent Pool 2020, Unitaid, 2020). In a recent paper (Izhak et al. 2020), we propose evidence supporting a complementary mechanism: government policies should make new drug patents shorter-lived, but broader in scope. This optimal policy encourages innovation while ensuring swifter access to generic drugs, without the costly investments in inventing around the new drug patents.

Theory of innovation and competition

Our empirical work is guided by a theoretical model of innovation and competition, building on the theory of costly imitation pioneered by Gallini (2002). Using this model, we show that characterising the optimal patent policy requires as key inputs an estimate of the elasticity of a patent challenge with respect to the effective patent term or patent scope.

Data and identification

To estimate these elasticities, we use comprehensive administrative data from the U.S. Food and Drug Administration and the U.S. Patent and Trademark Office (USPTO). The data identify new drug patents and successful challenges of these patents via so-called Paragraph IV certifications of generic drugs. For identification, we use two quasi-experimental approaches: one based on changes in patent law, and the other on the assignment of patent examiners to patent applications at the USPTO.

We use two policy interventions affecting the effective term of pharmaceutical patents. 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. After TRIPS, delays in patent prosecution at the USPTO effectively shortened the term of patents whose prosecution lags exceeded three years. The American Inventors Protection Act (AIPA) of 1999 introduced patent term adjustments to address this loss in effective patent term due to the USPTO delays.

We document how TRIPS shortened the effective terms of new drug patents that were prosecuted for more than three years at the USPTO, especially before AIPA. In contrast, the effective terms of new drug patents issued within three years were hardly affected by the reforms.

In the sample of new drug patents, long grant lags are common, with the average grant lag being three years from patent filing. Figure 1 plots the variation in these regulatory delays across new drug patents. However, until the implementation of TRIPS the 17-year term (from the patent grant) automatically compensated for delays in patent prosecution. After TRIPS, patents with long prosecution lags obtained virtually no compensation.

Figure 1 Histogram of patent grant lags (years) in the sample of new drug patents

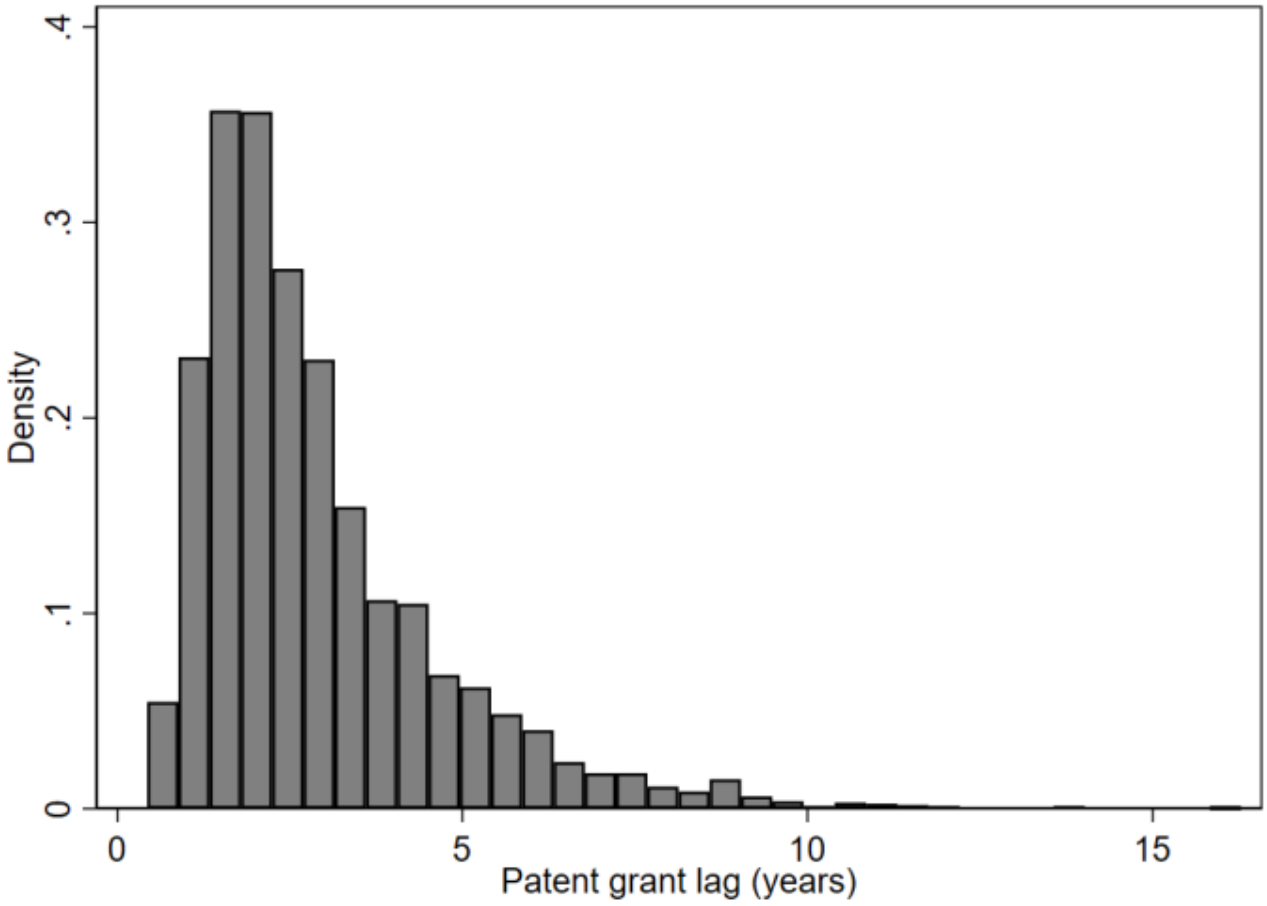
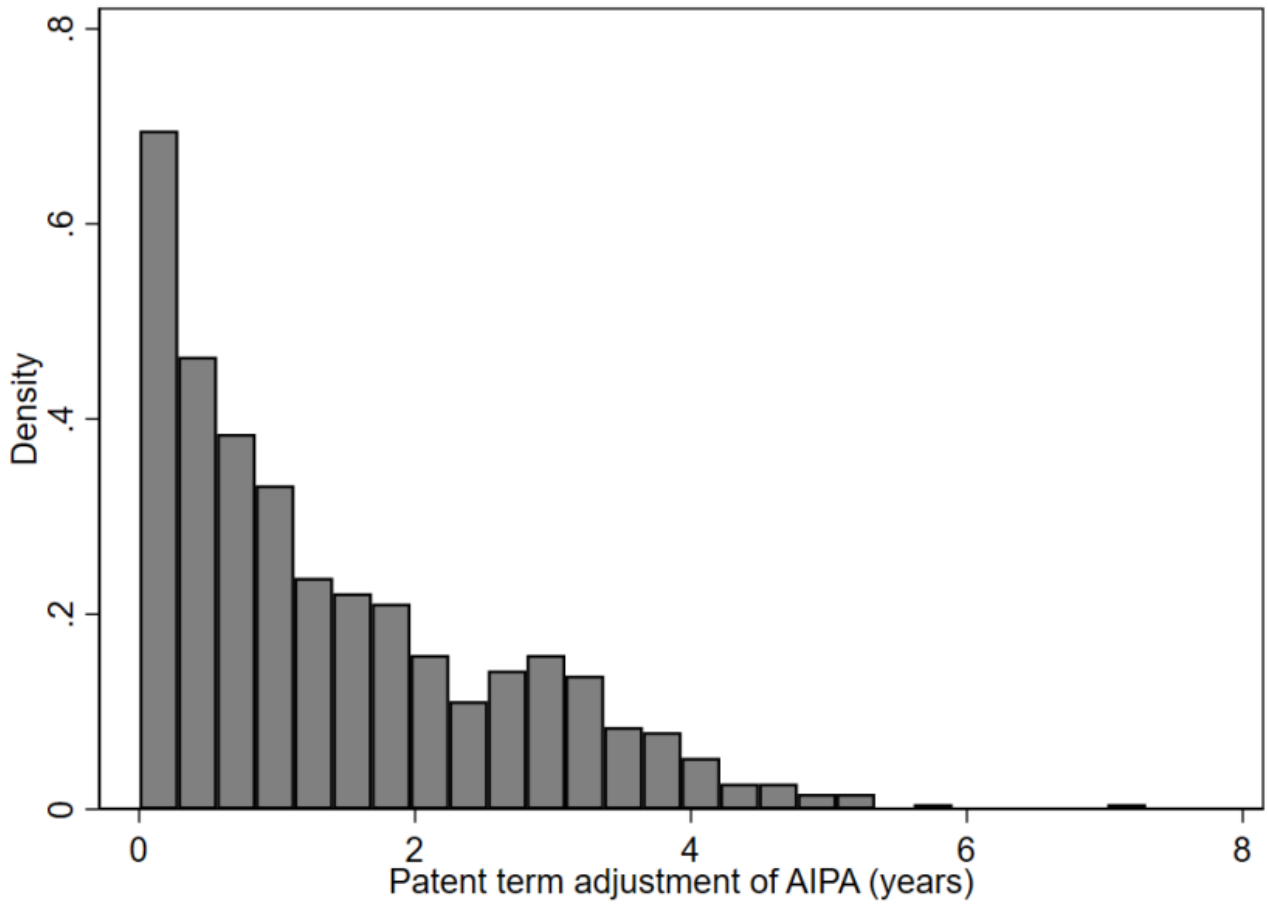


Figure 2 Patent term adjustment of new drug patents filed after the implementation of AIPA (29 May 2000)



Note: The figure excludes zeros in patent term adjustments.

After AIPA, a patent is entitled to a term adjustment if the USPTO fails to issue the patent within three years from the filing date. In our sample, approximately half of new drug patents are adjusted, reflecting the long delays in patent prosecution. The patent term adjustment of AIPA is 1.4 years on average and adjustments of more than two years are quite common, as shown in Figure 2.

Results

We use difference-in-differences (DiD) regressions on the impacts of TRIPS and AIPA on the effective term and Paragraph IV challenges of new drug patents. We find robust evidence that longer-lived patents encourage Paragraph IV challenges. Based on the regressions, we extrapolate the elasticity of a successful patent challenge with respect to effective length to be approximately three.

Inspired by recent work (e.g. Sampat and Williams 2019), we also use instrumental variable (IV) regressions based on differences in the propensity of some patent examiners to grant broader or more claims. Our IV estimates suggest that the corresponding elasticity with respect to various measures of claim scope is approximately -1. We also provide complementary descriptive evidence that supports the negative effect of broader patents on patent challenges.

Socially optimal policy

We predict the effects of changes in patent term and scope on innovation and welfare, using the estimated elasticities from the DiD and IV regressions as inputs into our theoretical formulas. Consistent with the theoretical results in Gallini (1992), we find that longer-lived patents increase costly patent challenges, and are inefficient for promoting new drug development. Shorter patent terms would reduce costly patent challenges, while broader patents would restore incentives to develop new drugs. Also, shorter-lived patents would expire earlier, thereby ensuring swifter access to generics. To restore the incentives to innovate the shortened patent term should be compensated by broadening the scope of new drug patent protection, for example, by awarding product patents instead of method patents, awarding longer market and data exclusivity periods for broader categories of new drugs, and restricting provisions for compulsory licensing.

Previous empirical studies such as Sakakibara and Branstetter (2001), Moser (2005), and Lerner (2009) analyse the effects of policy reforms on innovation. While we take a step forward in empirically characterising socially optimal patent policy, our predictions are coarse and the scope measures imperfect. To further improve the robustness of policy recommendations, we need more empirical estimates of the elasticities of innovation and imitation with respect to changes in patent policy.

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