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Patent term extensions and commercialization lags in the pharmaceutical industry: A growth-theoretic analysis*

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Abstract

Due to the lags in commercialization, the effective life of a patent is generally less than its statutory term. We introduce commercialization lags into the Schumpeterian growth model and explore the effects of patent term extensions on pharmaceutical R&D and social welfare. Our results show that extending patent terms stimulates the consumption of homogeneous goods but generates an ambiguous effect on the consumption of pharmaceuticals. When patent extensions have an inverted-U effect on social welfare, the optimal patent extension increases with the length of commercialization lags but decreases with the input intensity of commercialization lags. Finally, we calibrate the model and find that increasing patent breadth reduces the optimal patent extension.

JEL classification: I11, L65, O31, O34

Keywords: commercialization lags, patent term extensions, pharmaceutical R&D, economic growth, social welfare

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1. Introduction

Based on the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) signed by the member countries of the World Trade Organization (WTO), the patent protection granted by the member countries is required to be valid for at least 20 years from the date of application.¹ However, a patent's effective life is usually less than its statutory term. One reason is that a patent is subject to a lengthy patent review after its application. For example, according to the United States Patent and Trademark Office (USPTO), the average review time for patent applications is approximately 40.7 months. The prolonged patent review reduces the effective patent term, which in turn discourages firms from investing in R&D.

In the pharmaceutical industry, new drugs need to complete lengthy clinical trials for safety and efficacy. After completing clinical trials, in the United States, new drugs still have to be reviewed and approved by the U.S. Food and Drug Administration (FDA) before they are allowed to enter the market.² Using a sample of US pharmaceutical industries, Sloan and Hsieh (2017) find that it takes an average of 12-15 years for a new drug to complete clinical trials and be approved by the FDA. In addition, Philipson and Sun (2008) suggest that the probability of a new drug being successfully developed and brought to market is only a very low 8%. The lengthy clinical trials and the low survival rate jointly reduce firms' R&D investment in developing new drugs.

Extending patent terms is an important policy instrument for the government to intervene in pharmaceutical R&D. In 1984, the U.S. Congress passed the Drug Price Competition and Patent Term Restoration Act (also known as the Hatch-Waxman Act) to encourage pharmaceutical companies to invest in new drug development. Specifically, the Act allows for a patent term extension of up to five years. Moreover, the Act also grants a data exclusivity period to protect the rights of new drugs after FDA approval.³ The literature on pharmaceutical industries also commonly suggests

¹ From 1861 to 1995, the statutory patent term in the United States was 17 years after the approval of the patent. Since 1995, the term has been modified to 20 years from the application date in accordance with TRIPS.

² For a detailed description of the timeline for a new drug from patent application to market launch, see Mossinghoff (1999, p. 193).

³ The Act allows different data exclusivity periods depending on types of new drugs, such as seven years for orphan drugs, five years for new chemical entities, and an additional six months of coverage for pediatric drugs. More recently, the Patient Protection and Affordable Care Act of 2010 has granted a 12-year data exclusivity period for biologic drugs from the FDA approval date.

that extending patent terms is effective in stimulating drug development; see Grabowski and Kyle (2007), Higgins and Graham (2009), Panattoni (2011), and Budish et al. (2015; 2016). For instance, Budish et al. (2015) find that for pharmaceutical industries, extending the patent term by one year can significantly increase R&D investment in pharmaceuticals by 7-24%.

Following Budish et al. (2015), we refer to the lags in the commercialization of a drug resulting from clinical trials and FDA review as *commercialization lags*. In this study, we introduce commercialization lags into the quality-ladder model and analyze how patent extensions affect innovation in the pharmaceutical industry. Specifically, the representative household consumes two types of goods: homogeneous goods and pharmaceuticals. The quality of homogeneous goods is invariably constant. However, in the economy, there are a number of R&D firms investing in the development of better drugs. In the presence of commercialization lags, when an R&D firm successfully develops a new drug, it still needs to conduct clinical trials on the drug and apply for a patent from the FDA, thereby causing the effective life of the patent to be shorter than its statutory term. To motivate the firm to invest in R&D in pharmaceutical industries, the government will implement the policy of extending the patent term in response.

Within this framework, extending patent terms makes patents more valuable and thus increases the value of assets owned by the household. As a result, the household's asset income rises and it consumes more homogeneous goods. However, extending patent terms has two opposite effects on the consumption of pharmaceuticals. On the one hand, patent extensions encourage firms to employ more labor for R&D and promote technological progress in pharmaceutical industries. On the other hand, the increase in R&D labor caused by patent extensions leads to a decline in the labor input devoted to pharmaceutical production. Therefore, in the presence of commercialization lags, the effect of patent term extensions on pharmaceutical consumption is ambiguous. Together with the positive effect on the consumption of homogeneous goods, extending patent terms may generate an inverted-U effect on social welfare. Furthermore, we find that when there exists an optimal level of patent term extensions, this optimal level rises with the length of commercialization lags. By

contrast, if clinical trials require more labor input, i.e., commercialization lags are more costly, the optimal level of patent term extensions decreases.

Finally, we calibrate the model to provide some numerical analysis. Under our calibrated values, the extension of patent protection does cause an inverted-U effect on social welfare. In addition, we quantitatively analyze how patent breadth – another important patent policy instrument – affects the optimal patent extension. Our results show that increasing patent breadth significantly decreases the optimal patent extension. Intuitively, a higher patent breadth strengthens the protection for an invention against imitations, thereby increasing the market power of monopolistic producers. To correct the distortions caused by imperfect competition, the government has an incentive to set a shorter level of patent term extensions to reduce the effective patent terms.

1.1. Literature review

This paper is related to the literature on Schumpeterian economic growth; for seminal studies, see Grossman and Helpman (1991) and Aghion and Howitt (1992). However, the standard quality-ladder model features the so-called scale effect, which contradicts the empirical evidence.⁴ Jones (1995b, 1999), Segerstrom (1998), and Jones and Williams (2000) eliminate the scale effect by developing the semi-endogenous growth model that features diminishing individual R&D productivity. Alternatively, Dinopoulos and Thompson (1998), Peretto (1998), and Howitt (1999) develop the second-generation R&D-based growth model by combining both vertical and horizontal innovation, while also eliminating the scale effect. In this study, we eliminate the scale effect as in Segerstrom (1998) and focus on the R&D activities in pharmaceutical industries. Studies by Acemoglu and Linn (2004), Sanso and Aisa (2006), Chu (2008), and Grinols and Lin (2011) also investigate pharmaceutical R&D in the Schumpeterian economy. We complement their studies by developing a Schumpeterian growth model with commercialization lags.

⁴ In the literature on R&D-based growth, the scale effect refers to the result that population levels affect the rate of economic growth, which contradicts the empirical evidence. For a discussion on the scale effect, see Jones (1995a, 1999).

This study is also related to the literature on patents and economic growth.⁵ Given that patent policy is a multi-dimensional system, this strand of the literature examines the effects of various types of policy instruments. For example, previous studies have explored how innovation and growth are influenced by the patentability requirement (Koléda, 2004; Kiedaisch, 2015); patent length (Judd, 1985; Horowitz and Lai, 1996; Iwaisako and Futagami, 2003; Kwan and Lai, 2003; Futagami and Iwaisako, 2007; Chu, 2008; Zeng et al., 2014; Lin and Shampine, 2018); patent breadth (Goh and Olivier, 2002; Furukawa, 2007; Huang, Lai, and Chen, 2017; Huang, Yang, and Cheng, 2017; Chu and Cozzi, 2018; Iwaisako, 2020; Chu et al., 2021; Yang, 2021; Lu and Lai, 2022); and blocking patents (Chu, 2009; Chu and Pan, 2013; Cozzi and Galli, 2014; Niwa, 2016, 2018; Yang, 2018). As for the relationship between patent length and innovation, there is an ongoing debate in the literature. Judd (1985) argues that the optimal patent length is infinite. On the contrary, Horowitz and Lai (1996), Iwaisako and Futagami (2003), Kwan and Lai (2003), Futagami and Iwaisako (2007), Chu (2008), and Zeng et al. (2014) suggest that there is a finite optimal patent length. A recent study by Lin and Shampine (2018) finds that the optimal patent length can be finite or infinite, depending on the size of the knowledge spillover effect. However, all the studies mentioned above assume that the life of a patent is equal to its statutory term. Armed with actual observations in pharmaceutical industries, the present paper complements these studies by exploring how extending patent terms affects innovation and social welfare when a patent's effective life is less than the statutory patent length.

This study also contributes to the literature on the relationship between patents and commercialization lags. Budish et al. (2015), Wagner and Wakeman (2016), Gong and Peng (2018), and Gaessler and Wagner (2019) provide evidence that the effect of patent protection on innovation is negatively correlated with the lags in commercialization. Moreover, Budish et al. (2015) find that extending patent terms can effectively reduce the adverse effects of commercialization lags. However, there is little in terms of a theoretical framework that is suitable for analyzing the relationship between patent protection and commercialization lags. The novel

⁵ For a recent survey, see Chu (2021).

contribution of this study is to fill this gap.

The rest of the paper proceeds as follows. Section 2 develops a Schumpeterian model with commercialization lags. Section 3 characterizes the decentralized equilibrium. Section 4 deals with the normative analysis by examining the welfare effect of extending patent terms. Some numerical analysis is provided in Section 5. The final section concludes.

2. The model

The novelty of our analytical framework is the incorporation of commercialization lags and patent term extensions into a standard quality-ladder growth model. Moreover, we eliminate the scale effect by considering a diminishing individual R&D productivity as in Segerstrom (1998). In line with Acemoglu and Linn (2004) and Chu (2008), we assume that the household's consumption consists of two types of final goods: homogeneous goods and pharmaceuticals. In the R&D sector, each entrepreneur employs labor to develop a better drug, conduct clinical trials, and apply for a patent.

2.1. Household

In the economy, there is a representative household that has $L_t = e^{n(t)}$ members at time t , where the parameter $n > 0$ represents the exogenous growth rate of the population. The representative household's lifetime utility function is given by

$$U = \int_0^{\infty} e^{-(\rho-n)t} (c_{h,t} + \beta \ln c_{d,t}) dt, \quad (1)$$

where $c_{h,t}$ and $c_{d,t}$ are the per capita consumption of homogeneous goods and pharmaceuticals, respectively. ρ is the subjective discount rate, and we assume that $\rho > n$ to ensure that utility is bounded. The preference parameter $\beta > 0$ determines the importance of pharmaceutical consumption. Throughout this paper, the homogeneous goods serve as the numéraire.

The household maximizes utility subject to the following asset-accumulation equation:

$$\dot{a}_t = (r_t - n)a_t + w_t - c_{h,t} - P_{d,t}c_{d,t}, \quad (2)$$

where a_t represents the real value of financial assets per capita (i.e., the equity of monopolistic firms). At time t , each member of the household inelastically supplies

one unit of labor to earn a real wage w_t . r_t is the real interest rate, and $P_{d,t}$ is the aggregate price index of pharmaceuticals in terms of the homogeneous goods. The intertemporal optimality condition for the pharmaceutical consumption is

$$P_{d,t}c_{d,t} = \beta. \quad (3)$$

By solving the standard dynamic optimization, we obtain the familiar Euler equation as

$$r_t = \rho. \quad (4)$$

2.2. Final goods

There are two kinds of final goods, homogeneous goods as well as pharmaceuticals. Both homogeneous goods and pharmaceuticals are produced by perfectly competitive firms that take market prices as given.

2.2.1. Homogeneous goods

The production technology for the homogeneous goods $Y_{h,t}$ is given by

$$Y_{h,t} = \alpha L_{h,t}, \quad (5)$$

where α denotes the constant returns to scale in the labor input, and $L_{h,t}$ is the labor employed for the production of the homogeneous goods $Y_{h,t}$. The profit maximization yields the marginal cost of production as $MC_{h,t} = w_t/\alpha$. Note that the homogeneous goods act as the numéraire and $Y_{h,t}$ is characterized by marginal-cost pricing (the market for $Y_{h,t}$ is perfectly competitive). As a result, the marginal cost $MC_{h,t} = w_t/\alpha = 1$. Accordingly, the real wage rate is $w_t = \alpha$. The market-clearing condition for the homogeneous goods is $Y_{h,t} = C_{h,t}$, where $C_{h,t}$ represents the total consumption of homogeneous goods by the representative household.

2.2.2. Pharmaceuticals

Competitive firms use a unit continuum of differentiated intermediate drugs indexed by $i \in [0,1]$ to produce the final pharmaceuticals using the following standard Cobb-Douglas aggregator:

$$Y_{d,t} = \exp\left(\int_0^1 \ln X_{d,t}(i) di\right), \quad (6)$$

where $X_{d,t}(i)$ is the amount of intermediate drug i . From the standard cost minimization, the aggregate price index of pharmaceuticals can be expressed as

$$P_{d,t} = \exp\left(\int_0^1 \ln P_{d,t}(i) di\right), \quad (7)$$

where $P_{d,t}(i)$ is the price of intermediate drug i . From equations (6)-(7), we can derive the demand function for intermediate drug $i \in [0,1]$ as

$$X_{d,t}(i) = \left(\frac{P_{d,t}}{P_{d,t}(i)}\right) C_{d,t}, \quad (8)$$

where $C_{d,t}$ represents the total consumption of pharmaceuticals by the household.

2.3. Intermediate pharmaceutical industries

There is a unit continuum of pharmaceutical industries, which produce differentiated intermediate drugs. Each pharmaceutical industry $i \in [0, \omega_t]$ is temporarily dominated by an industry leader that holds a patent on the latest version of drug i until this patent expires. In other words, during the statutory patent life, industry leader i will not be replaced and exit the market due to the creative destruction of new entrants. This setup captures the fact that the effective patent length for a pharmaceutical product usually coincides with its statutory life (Chu, 2008).⁶ Meanwhile, as the most recent patent has expired, each industry $i \in (\omega_t, 1]$ is perfectly competitive until a better drug successfully passes clinical trials and the FDA review.⁷ The production function in pharmaceutical industry i is given by

$$X_{d,t}(i) = z^{q_t(i)} L_{d,t}(i), \quad (9)$$

where $z > 1$ denotes the exogenous step size of quality improvements, and $L_{d,t}(i)$ is the labor employed to produce drug i . $q_t(i)$ is the number of quality improvements that have occurred in pharmaceutical industry i at time t , and hence $z^{q_t(i)}$ represents the current quality of drug i .

Given the technology level $z^{q_t(i)}$, the marginal cost of production for firms in industry i is $MC_{d,t}(i) = w_t / z^{q_t(i)}$. In line with O'Donoghue and Zweimuller (2004) and Chu (2009), we assume that a monopolistic industry leader charges a markup $\mu(z, \eta) \equiv z^\eta$ over this marginal cost, where $\eta > 0$ is a policy parameter determined by the strength of patent protection against imitations (i.e., patent breadth). Then, the

⁶ This formulation originates from Grossman and Lai (2004); subsequent studies, Dinopoulos et al. (2007) and Chu (2008), incorporate this formulation into the Schumpeterian growth model.

⁷ As we will show later, ω_t is endogenously determined by commercialization lags and the government's patent extension.

profit-maximizing price for monopolistic producer $i \in [0, \omega_t]$ is

$$P_{d,t}(i) = \mu MC_{d,t}(i) = \frac{\mu\alpha}{z^{q_t(i)}}, \quad (10)$$

where the second equality uses $w_t = \alpha$. Accordingly, the monopolistic profit of an industry leader is $\pi_{d,t}(i) = (\mu - 1)\alpha L_{d,t}(i)$.

Substituting (9) into (6) yields the aggregate production function given by

$$Y_{d,t} = A_t I_{d,t}^e, \quad (11)$$

where $A_t \equiv \exp\left(\int_0^1 q_t(i) di \ln z\right)$ and $L_{d,t}^e \equiv \exp\left(\int_0^1 L_{d,t}(i) di\right)$ represent the aggregate technology level and the index of effective labor of the pharmaceutical industries, respectively.⁸ Substituting (10) into (7) to obtain the aggregate price index of the pharmaceutical industries given by

$$P_{d,t} = \frac{\alpha\mu^{\omega_t}}{A_t}. \quad (12)$$

Substituting (12) into (3) and multiplying by L_t , we can derive the aggregate consumption of pharmaceuticals as

$$C_{d,t} = \frac{A_t}{\mu^{\omega_t}} \frac{\beta L_t}{\alpha}. \quad (13)$$

Equation (13) clearly shows that the aggregate consumption of pharmaceuticals $C_{d,t}$ decreases with the fraction of the monopolistic pharmaceutical firms ω_t but increases with the technology level A_t . Combining (11), (13), and the market-clearing condition for pharmaceuticals $Y_{d,t} = C_{d,t}$, we obtain $I_{d,t}^e = (\beta L_t) / (\alpha \mu^{\omega_t})$. Henceforth, we let $i \in [0, \omega_t]$ denotes a monopolistic producer and $i' \in (\omega_t, 1]$ denotes a competitive firm. From (9)-(10) and (12)-(13), we can derive the actual labor employed in monopolistic pharmaceutical firm i as $L_{d,t}(i) = (\beta L_t) / (\alpha \mu)$. Together with $I_{d,t}^e = (\beta L_t) / (\alpha \mu^{\omega_t})$, we have $L_{d,t}(i) / L_{d,t}^e = \mu^{\omega_t - 1}$. Then, the ratio of the labor input in a competitive firm and a monopolistic producer is $L_{d,t}(i') / L_{d,t}(i) = \mu$. Accordingly, the total labor employed in the pharmaceutical industries is

$$L_{d,t} = \omega_t L_{d,t}(i) + (1 - \omega_t) L_{d,t}(i') = \frac{\omega_t + (1 - \omega_t)\mu}{\mu} \frac{\beta L_t}{\alpha}. \quad (14)$$

Moreover, by substituting $L_{d,t}(i) = (\beta L_t) / (\alpha \mu)$ into $\pi_{d,t}(i) = (\mu - 1)\alpha L_{d,t}(i)$,

⁸ There are two types of intermediate firms in the economy, monopolistic and fully competitive, and these two types of firms employ different amounts of labor. Therefore, the index $L_{d,t}^e$ here is not the actual amount of the labor input.

the profit of a monopolistic pharmaceutical firm can be rewritten as

$$\pi_{d,t}(i) = \left(\frac{\mu-1}{\mu} \right) \beta L_t, \quad (15)$$

which implies that $\pi_{d,t}(i)$ is the same for $i \in [0, \omega_t]$. Then, the total profit of all monopolistic firms is given by

$$\pi_{d,t} = \int_0^{\omega_t} \pi_{d,t}(i) = \omega_t \left(\frac{\mu-1}{\mu} \right) \beta L_t. \quad (16)$$

Equations (15) and (16) imply that the profit of monopolistic pharmaceutical producers increases over time at the population growth rate.

2.4. R&D

In the presence of commercialization lags, R&D firms can use their new technology to produce better drugs only after passing clinical trials and the FDA review. To model the cost of commercialization lags, we assume that after an R&D firm has successfully developed a new pharmaceutical technology, it still requires an additional labor input to conduct clinical trials. To make our analysis clearer, Figure 1 is constructed to illustrate the timeline of the patent life.

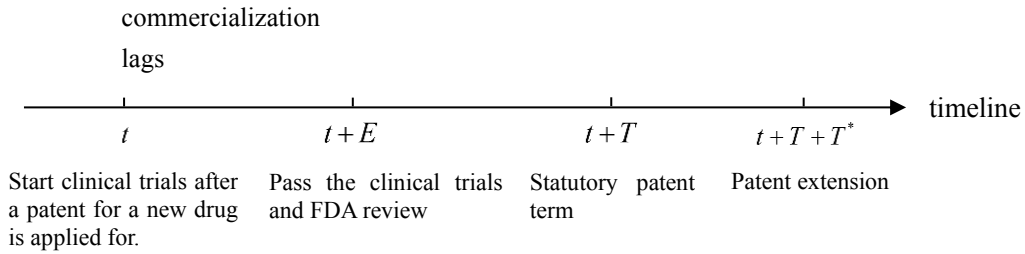


Figure 1. The timeline of the patent life.

At time t , an R&D firm successfully develops a new drug, applies for the patent, and conducts clinical trials. After a period of commercialization lags, at time $t+E$, the new drug passes the clinical trials and FDA review. Therefore, the patent will expire at time $t+T$, where T represents the fixed patent length exogenously determined by the government. However, due to the value loss resulting from commercialization lags, the government extends the patent length from T to $T+T^*$. As a result of this patent extension, the monopolistic pharmaceutical firm can produce the new drug and earn a profit during the period from $t+E$ to $t+T+T^*$.

From (15), the value function of a new drug that successfully passes the FDA review and receives a patent at time $t + E$ is given by

$$V_t = \int_{t+E}^{t+T+T^*} e^{-\rho(\tau-t)} \pi_{d,t}(i) d\tau = \frac{\Omega_1(T^*, E)}{\rho - n} \left(\frac{\mu - 1}{\mu} \right) \beta L_t, \quad (17)$$

where $\Omega_1(T^*, E) = e^{-(\rho-n)E} - e^{-(\rho-n)(T+T^*)} > 0$.

In the economy, there is a unit continuum of R&D firms. R&D firm $j \in [0,1]$ employs $L_{r,t}^R(j)$ units of labor to develop a new drug. The Poisson arrival rate of a new drug is

$$\lambda_{1,t}(j) = \psi_t L_{r,t}^R(j), \quad (18)$$

where ψ_t determines the individual R&D productivity. To eliminate the scale effect, we follow Segerstrom (1998) to assume that $\psi_t = \delta (L_{r,t}^R)^{\gamma-1} / A_t^{1-\phi}$, where $L_{r,t}^R$ represents the total R&D labor. The parameter $\phi \in (0,1)$ captures the *standing on shoulders effect* while the parameter $\gamma \in (0,1]$ represents the *stepping on toes effect*.⁹ Following the standard approach in the literature, we focus on the symmetric equilibrium which is characterized by an equal innovation arrival rate across industries.¹⁰ As a result, we immediately have $L_{r,t}^R(j) = L_{r,t}^R, j \in [0,1]$.

As for the labor input used for the patent application and clinical trials $L_{r,t}^c$, we assume that it is a proportion of the labor input used for R&D, such that $L_{r,t}^c = \theta L_{r,t}^R$, where $\theta > 0$ represents the relative cost between commercialization lags and R&D. Hereafter, we refer to θ as the input intensity of commercialization lags. Thus, for a new drug, the present value of the labor cost caused by commercialization lags S_t is given by¹¹

$$S_t = \lambda_{1,t} \int_t^{t+E} e^{-r(\tau-t)} w_\tau L_{r,\tau}^c d\tau = \frac{\lambda_{1,t} \Omega_2(E) \theta}{\rho - n} \alpha L_{r,t}^R, \quad (19)$$

where $\Omega_2(E) = 1 - e^{-(\rho-n)E} > 0$. Denote λ_2 as the exogenous probability of a new drug passing the clinical trials and FDA review. Moreover, using the law of large numbers, we have $\ln A_t = \int_0^1 q_t(i) di \ln z = \int_0^t \lambda_{1,\tau} \lambda_{2,\tau+E} d\tau \ln z$. Accordingly, the law of motion for the aggregate technology level of pharmaceutical industries can be written as

⁹ See Jones and Williams (2000) for a discussion of the standing on shoulders effect and the stepping on toes effect.

¹⁰ See Cozzi et al. (2007) for a discussion of the symmetric equilibrium.

¹¹ Recall that the real wage rate $w_t = \alpha$.

$$\dot{A}_t = A_t \lambda_1 \lambda_2 \ln z = A_t^\phi (L_{r,t}^R)^\gamma \lambda_2 \delta \ln z. \quad (20)$$

From (17) and (19), we obtain an R&D firm's expected profit:

$$\pi_{r,t}(j) = \lambda_1 \lambda_2 \frac{\Omega_1(T^*, E)}{\rho - n} \left(\frac{\mu - 1}{\mu} \right) \beta L_t - \left(1 + \frac{\lambda_1 \Omega_2(E) \theta}{\rho - n} \right) \alpha L_{r,t}^R. \quad (21)$$

Then, the free-entry condition for R&D is given by

$$\frac{\psi_t \lambda_2}{\rho - n} \Omega_1(T^*, E) \left(\frac{\mu - 1}{\mu} \right) \beta L_t = \alpha \left(1 + \frac{\psi_t \Omega_2(E)}{\rho - n} \theta L_{r,t}^R \right). \quad (22)$$

3. Decentralized equilibrium

The decentralized equilibrium consists of a time path of allocations $\{a_t, c_{h,t}, c_{d,t}, Y_{h,t}, X_{d,t}(i), Y_{d,t}, L_{h,t}, L_{d,t}(i), L_{r,t}^R, L_{r,t}^c\}_{t=0}^\infty$ and a time path of prices $\{w_t, r_t, P_{d,t}(i), MC_{d,t}(i), V_t\}_{t=0}^\infty$. In addition, at each instant of time,

- the household supplies labor and chooses $\{a_t, c_{h,t}, c_{d,t}\}$ to maximize utility taking $\{w_t, r_t, P_{d,t}(i)\}$ as given;
- competitive firms in the homogeneous goods sector produce $\{Y_{h,t}\}$ and choose $\{L_{h,t}\}$ taking $\{w_t\}$ as given;
- competitive firms in the final pharmaceuticals sector produce $\{Y_{d,t}\}$ and choose $\{X_{d,t}(i)\}$ taking $\{P_{d,t}(i)\}$ as given;
- each monopolistic industry leader in pharmaceutical industry $i \in [0, \omega_t]$ chooses $\{P_{d,t}(i), L_{d,t}(i)\}$ to maximize profit taking $\{MC_{d,t}(i), X_{d,t}(i)\}$ as given;
- competitive firms in pharmaceutical industry $i' \in (\omega_t, 1]$ choose $\{L_{d,t}(i')\}$ to maximize profit taking $\{P_{d,t}(i'), MC_{d,t}(i'), X_{d,t}(i')\}$ as given;
- each R&D firm chooses $\{L_{r,t}^R, L_{r,t}^c\}$ to maximize profit taking $\{w_t, V_t, \psi_t\}$ as given;
- the homogeneous goods market, pharmaceuticals market, and labor market all clear, such that $Y_{h,t} = C_{h,t}$, $Y_{d,t} = C_{d,t}$, and $L_{h,t} + L_{d,t} + L_{r,t}^R + L_{r,t}^c = L_t$.

3.1. Balanced growth path

Dividing both sides of (20) by A_t yields the equilibrium technological growth rate as

$$g \equiv \frac{\dot{A}_t}{A_t} = \lambda_1 \lambda_2 \ln z = \frac{(L_{r,t}^R)^\gamma}{A_t^{1-\phi}} \lambda_2 \delta \ln z = \frac{\gamma n}{1-\phi}. \quad (23)$$

The fraction of monopolistic pharmaceutical industries at time t , namely, ω_t , is equal to the sum of innovations that have passed the patent applications and FDA review during the last $T+T^*-E$ periods. As a result, ω_t is endogenously determined by $\omega_t = \int_E^{T+T^*} \lambda_{1,t-\tau} \lambda_2 d\tau$. Then, the steady-state value of the fraction of monopolistic industries is

$$\omega = \lambda_1 \lambda_2 (T + T^* - E). \quad (24)$$

To ensure that $\omega < 1$ in equilibrium, we impose the following condition.

$$\text{Condition } E: T + T^* - E \leq \frac{(1 - \phi - \sigma) \ln z}{\gamma n}.$$

From (14), (21), and (24), we can solve for the equilibrium allocations of labor at time t as

$$s_h = 1 - \left[\frac{(1 + \lambda_1 \theta E) \lambda_1 \lambda_2 \Omega_1(T^*, E) \mu - 1}{\Delta(E, \theta) \mu} + \frac{\mu + (1 - \mu) \lambda_1 \lambda_2 (T + T^* - E)}{\mu} \right] \frac{\beta}{\alpha}, \quad (25a)$$

$$s_d = \frac{\lambda_1 \lambda_2 (T + T^* - E) + [1 - \lambda_1 \lambda_2 (T + T^* - E)] \mu \beta}{\mu \alpha}, \quad (25b)$$

$$s_r^R = \frac{\lambda_1 \lambda_2 \Omega_1(T^*, E) \mu - 1}{\Delta(E, \theta) \mu} \frac{\beta}{\alpha}, \quad (25c)$$

$$s_r^c = \theta \frac{\lambda_1 \lambda_2 \Omega_1(T^*, E) \mu - 1}{\Delta(E, \theta) \mu} \frac{\beta}{\alpha}, \quad (25d)$$

where $\Delta(E, \theta) = \rho - n + \lambda_1 \theta \Omega_2(E) > 0$, $s_h = L_{h,t}/L_t$, $s_d = L_{d,t}/L_t$, $s_r^R = L_{r,t}^R/L_t$, and $s_r^c = L_{r,t}^c/L_t$. From (25a)-(25d), we immediately have the following proposition:

Proposition 1. *In the presence of commercialization lags, patent term extensions increase the equilibrium shares of the labor input for homogeneous goods production, R&D, and clinical trials, but decrease the equilibrium share of labor input for pharmaceutical production.*

The intuition behind Proposition 1 can be explained as follows. First, extending patent terms increases the value of patents and firms' incentives for R&D, leading to a higher share of labor employed in the R&D sector (including labor employed for R&D and clinical trials). Second, the extension of patents will increase the fraction of monopolistic pharmaceutical industries, thereby reducing the total labor employed in

pharmaceutical industries.¹² Finally, the decline in the share of the labor employed in pharmaceutical industries induced by a patent extension is greater than the associated increase in the share of the labor employed in the R&D sector. Therefore, patent extensions lead to a higher share of labor employed in the homogeneous goods sector.

4. Optimal patent extension

In this section, we discuss the optimal patent extension in terms of raising social welfare. Along the balanced growth path, the social welfare function is defined as

$$W(T^*, E) = \frac{1}{\rho - n} [c_{h,0}(T^*, E) + \beta \ln c_{d,0}(T^*, E)] + \beta \int_0^\infty e^{-(\rho-n)t} (gt) dt, \quad (26)$$

where $c_{h,0}$ and $c_{d,0}$ represent the steady-state consumption levels of homogeneous goods and pharmaceuticals at time 0, respectively. Given that $g = \gamma n / (1 - \phi)$ in (23), extending patent terms will affect social welfare via both $c_{h,0}$ and $c_{d,0}$.

Combining (2), (12), (13), (19) and (25c) yields the steady-state consumption of homogeneous goods given by¹³

$$c_{h,0} = \alpha - \beta + \lambda_1 \lambda_2 \beta \left(\frac{\mu - 1}{\mu} \right) \left[T + T^* - E - \frac{\Omega_1(T^*, E)}{\rho - n} - \frac{\lambda_1 \theta \Omega_1(T^*, E)}{\Delta(E, \theta)} \left(E - \frac{\Omega_2(E)}{\rho - n} \right) \right]. \quad (27)$$

Differentiating (27) with respect to T^* , we have

$$\frac{\partial c_{h,0}}{\partial T^*} = \lambda_1 \lambda_2 \beta \frac{\mu - 1}{\mu} \left[1 - \frac{(1 + \lambda_1 \theta E)(\rho - n)e^{-(\rho-n)(T+T^*)}}{\Delta(E, \theta)} \right] > 0. \quad (28)$$

Equation (28) clearly shows that extending patent terms will increase the consumption of homogeneous goods. Intuitively, the extension of a patent increases the value of the patent, thereby increasing the real value of assets held by the household. As a result, the household will receive more asset income and thus consume more homogeneous goods.

Then, combining (13), (23), and (24), we obtain

$$\ln c_{d,0} = \ln A_0(T^*, E) - \lambda_1 \lambda_2 (T + T^* - E) \ln \mu + \ln \frac{\beta}{\alpha}, \quad (29)$$

where $A_0(T^*, E) = (\delta \ln z / g)^{1/(1-\phi-\sigma)} (L_{r,0}^R(T^*, E))^{\gamma/(1-\phi-\sigma)}$. Differentiating (29) with respect to T^* , we obtain

¹² Given that the markup $\mu > 1$, from (14), we immediately have $\partial L_d / \partial \omega < 0$.

¹³ See the Appendix for a detailed derivation.

$$\frac{\partial \ln c_{d,0}}{\partial T^*} = \frac{\gamma}{1-\phi-\sigma} \left[\frac{(\rho-n)e^{-(\rho-n)(T+T^*)}}{\Omega_1(T^*, E)} - n\eta \right] \begin{matrix} > \\ < \end{matrix} 0, \text{ if } \frac{(\rho-n)e^{-(\rho-n)(T+T^*)}}{\Omega_1(T^*, E)} \begin{matrix} > \\ < \end{matrix} n\eta. \quad (30)$$

Consequently, the effect of patent term extensions on the consumption of pharmaceuticals is ambiguous, and depends on the relative magnitudes of $(\rho-n)e^{-(\rho-n)(T+T^*)}/\Omega_1$ and $n\eta$. Intuitively, an extension of patent terms would generate two opposing effects on pharmaceutical consumption.¹⁴ On the one hand, as mentioned earlier, extending patent terms reduces the labor employed in pharmaceutical industries, which in turn reduces output and household consumption of pharmaceuticals. On the other hand, extending patent terms increases the labor used to develop better drugs, resulting in a higher aggregate technology level, which further increases the output and consumption of pharmaceuticals.

We now show that patent term extensions may have an inverted-U effect on social welfare. Using (23), (25c), (26), (27) and (29), the first-order optimality condition for the patent extension T^* is

$$\frac{n}{\ln z} \frac{\mu-1}{\mu} \left[1 - \frac{(1+\lambda_1\theta E)(\rho-n)e^{-(\rho-n)(T+T^*)}}{\Delta(E, \theta)} \right] + \frac{(\rho-n)e^{-(\rho-n)(T+T^*)}}{\Omega_1(T^*, E)} = n\eta. \quad (31)$$

Moreover, we can derive the second-order condition for a relative maximum of social welfare as

$$\Theta(T^*, E, \theta) \equiv \frac{n}{\ln z} \frac{\mu-1}{\mu} \frac{(1+\lambda_1\theta E)}{\Delta(E, \theta)} - \frac{e^{-(\rho-n)E}}{\Omega_1(T^*, E)^2}. \quad (32)$$

Given that $e^{-(\rho-n)E} \geq \Omega_1(T^*, E)^2$, we immediately have $\Theta(T^*, E, \theta) < 0$ if $n(1+\lambda_1\theta E)/\Delta(E, \theta) < \mu \ln z / (\mu-1)$.¹⁵ We summarize the above results below:

Proposition 2. *In the presence of commercialization lags, patent term extensions stimulate the consumption of homogeneous goods but generate an ambiguous effect on the consumption of pharmaceuticals. Therefore, extending patent terms may generate an inverted-U effect on social welfare so that there exists an optimal patent extension.*

In the remainder of this section, we focus on how the length and input intensity

¹⁴ Note the production function in (9).

¹⁵ Note that this is a sufficient but not necessary condition for the existence of an optimal patent extension.

of commercialization lags affect the optimal patent extension when extending patent protection has an inverted-U effect on social welfare. First, we differentiate (31) with respect to the length of commercialization lags E to obtain

$$\frac{dT^{**}}{dE} = -\frac{\Psi(T^{**}, E, \theta)}{\Theta(T^{**}, E, \theta)}, \quad (33)$$

where T^{**} represents the optimal patent extension, and

$$\Psi(T^{**}, E, \theta) = \frac{e^{-(\rho-n)E}}{\Omega_1(T^{**}, E)^2} - \frac{\lambda_1 \theta n}{\ln z} \frac{\mu-1}{\mu} \frac{\Delta(E, \theta) - (\rho-n)e^{-(\rho-n)E}(1+\lambda_1 \theta E)}{(\rho-n)\Delta(E, \theta)^2}. \quad (34)$$

Then, from (32) and (34), we obtain

$$\Psi(T^{**}, E, \theta) + \Theta(T^{**}, E, \theta) = \frac{n}{\ln z} \frac{\mu-1}{\mu} \frac{(\rho-n)^2(1+\lambda_1 \theta E) + \lambda_1^2 \theta^2 [(\rho-n)E - \Omega_2(E)]}{(\rho-n)\Delta(E, \theta)^2}. \quad (35)$$

Given that $\mu > 1$ and $\rho > n$, we have $\text{sign}(\Psi + \Theta) = \text{sign}[(\rho-n)E - \Omega_2] > 0$.¹⁶ Together with the second-order condition $\Theta(T^{**}, E, \theta) < 0$, we obtain $\Psi(T^{**}, E, \theta) > 0$ and thus $dT^{**}/dE > 0$. Therefore, the optimal patent extension increases with the length of commercialization lags. Intuitively, longer commercialization lags reduce the value of patents and thus the value of assets held by the household and the household's asset income. As a result, the household's consumption of homogeneous goods declines, thereby reducing social welfare. In response to the decline in social welfare resulting from longer commercialization lags, the government has an incentive to maximize social welfare by extending patent terms.

Next, differentiating (31) with respect to the input intensity of commercialization lags θ yields

$$\frac{dT^{**}}{d\theta} = \frac{n}{\ln z} \frac{\mu-1}{\mu} \frac{\lambda_1 (\rho-n) e^{-(\rho-n)(T+T^{**})}}{\Delta(E, \theta)} \frac{(\rho-n)E - \Omega_2(E)}{\Theta(T^{**}, E, \theta)} < 0. \quad (36)$$

Given that $(\rho-n)E - \Omega_2(E) > 0$ and $\Theta(T^{**}, E, \theta) < 0$, we have $dT^{**}/d\theta < 0$. Thus, the optimal patent extension decreases with the input intensity of commercialization lags. The intuition behind this result is also straightforward. A higher input intensity of commercialization lags implies that R&D firms will employ

¹⁶ Let $x = (\rho-n)E > 0$ and $f(x) = x - (1 - e^{-x})$. Given that $f'(x) = \partial f(x)/\partial x = 1 - e^{-x} > 0, \forall x > 0$, we can derive that $f(x) = x - (1 - e^{-x}) = (\rho-n)E - \Omega_2(E) > 0$.

too much labor in clinical trials compared to the social optimum. To remedy the over-employment in R&D firms, the government is inclined to decrease patent term extensions so as to reduce labor employed in R&D firms to the social optimum level. Based on the above results, we have the following proposition:

Proposition 3. *In the presence of commercialization lags, if there exists an optimal patent extension, then the optimal patent extension increases with the length of commercialization lags but decreases with the input intensity of commercialization lags.*

5. Quantitative analysis

In this section, we perform a numerical analysis to illustrate how the optimal patent extension will react in response to changes in the length of commercialization lags and the level of patent breadth. We first calibrate the model to the U.S. data in Subsection 5.1 and then quantify the effects of patent term extensions in Subsection 5.2. Finally, we examine how patent breadth affects the optimal patent extension in Subsection 5.3.

5.1. Calibration

According to the World Development Indicators (WDI) database, the average population growth rate in the United States from 1960-2014 was 1.06%. Therefore, we calibrate n to a value of 0.0106. For the parameter γ that reflects the *stepping on toes* effect, we consider a value of 0.435, which is within the reasonable range estimated by existing empirical studies.¹⁷ Combining (11) and (23) and using $L_{d,t}^e = (\beta L_t) / (\alpha \mu^{\omega_t})$, we derive the growth rate of pharmaceuticals as

$$g_{Y_d} = \left(1 + \frac{\gamma}{1 - \phi}\right) n. \quad (37)$$

According to the Statista database, the average gross output growth rate of the pharmaceutical manufacturing industry in the U.S. during the period 2000-2014 was about 4.74%. Thus, we calibrate g_{Y_d} to a value of 0.0474. Then, the parameter ϕ

¹⁷ Porter and Stern (2000) estimate γ ranging from 0.2 to 0.81, and Pessoa (2005) estimates γ ranging from 0.126 to 0.744 for OECD countries.

that captures the *standing on shoulders* effect is set to 0.8747, which is also within the reasonable range estimated by the existing literature.¹⁸

Grinols and Lin (2011) suggest that people have a high time-preference rate for new drugs for the prevention and treatment of diseases or cancers. Following Grinols and Lin (2011), we set the subjective discount rate to $\rho = 0.12$. Without loss of generality, the productivity parameter α is normalized to 1. Equation (3) implies that β is determined by the household's expenditure on pharmaceuticals. According to the WDI database, we calibrate β to 0.15 to match the data for the U.S. economy during the period 1995-2014. For the statutory patent length T , we consider a standard value of 20 years. We calibrate the arrival rate $\lambda_1 = 0.33$ to capture the average time for inventing a new drug to be approximately three years, as estimated by Mossinghoff (1999). Hay et al. (2014) provide evidence that the probability of a new drug successfully completing clinical trials and being approved by the FDA is approximately 10.43%. Therefore, we calibrate λ_2 to a value of 0.1043. Then, by (23), the quality increment size of pharmaceuticals z is set to 2.9131.

For the level of patent breadth, we set $\eta = 2.3548$ as the benchmark value such that the markup in the pharmaceutical sector $\mu = z^\eta$ is about 12.4, as estimated by Grinols and Lin (2011)¹⁹. Empirical studies show that the time required for a new drug to complete clinical trials and pass the FDA review is approximately 12 to 15 years (Danzon et al., 2005; Sloan and Hsieh, 2017). Accordingly, we choose a median value of $E = 13.5$ as the benchmark. DiMasi et al. (2016) suggest that the cost of developing a new drug at a discount rate of 12% is \$2.795 billion, including \$1.246 billion before human trials and \$1.549 billion during clinical trials. Based on the DiMasi et al. (2016) estimation, we assume that half of the cost before human trials is caused by the preparation for clinical trials, which is a part of the cost due to

¹⁸ Porter and Stern (2000) estimate ϕ ranging from 0.48 to 1.19, and Pessoa (2005) estimates ϕ ranging from 0.725 to 0.937 for OECD countries.

¹⁹ Estimates of the markup ratio in pharmaceutical industries range widely. For example, Saha et al. (2006), using a sample of 40 proprietary drugs in the U.S. pharmaceutical market, find that two years after the first generic drug enters the market, the average price ratio of the generic drug to the proprietary drug is 0.41, which implies a markup ratio of 2.44. Using data from the IMS Retail and Non-Retail National Sales Perspective and the IMS Retail National Prescription Audit, Berndt et al. (2007) find that two years after the first generic drug has successfully passed the Phase IV clinical certification, the average price ratio of the generic drug to the proprietary drug is about 0.28, which implies a markup ratio of 3.57. In Subsection 3.3, we will perform sensitivity analysis on the markup ratio μ .

commercialization lags. Therefore, we calibrate the input intensity of commercialization lags θ to a value of 0.26. A summary of our benchmark parameter values is reported in Table 1.

Table 1. Benchmark parameter values

| parameters | value | parameters | value |
|------------|--------|-------------|--------|
| g_{Y_d} | 0.0474 | T | 20 |
| n | 0.0106 | λ_1 | 0.33 |
| γ | 0.435 | λ_2 | 0.1043 |
| ϕ | 0.8747 | z | 2.9131 |
| ρ | 0.12 | μ | 12.4 |
| α | 1 | η | 2.3548 |
| β | 0.15 | E | 13.5 |
| | | θ | 0.26 |

5.2. Results

Under our benchmark calibration values, extending patent terms generates an inverted-U effect on social welfare, as illustrated in the upper-left panel of Figure 2. Thus, there exists an optimal level of patent extension in the presence of commercialization lags. Specifically, when $E = 13.5$, the optimal patent extension is 12.2177, which is about 90.5% of the length of the commercialization lag. The economic intuition behind this result is as follows. On the one hand, when the level of the patent extension T^{**} is relatively small, extending patent terms has a positive effect on the total consumption. On the other hand, extending patent terms significantly reduces the labor input devoted to pharmaceutical production at higher levels of patent extensions. As a result, a higher level of patent extension T^{**} decreases the consumption of pharmaceuticals, and this negative effect dominates the positive effect on the consumption of homogeneous goods.

Furthermore, the upper-right panel of Fig. 2 shows how the welfare level will react when the benchmark value of commercialization lags $E = 13.5$ either decreases to $E = 12$ or increases to $E = 15$. When E falls to 12, the optimal patent extension

T^{**} declines to 10.6941. When E rises to 15, the optimal patent extension T^{**} rises to 13.7386. Thus, the optimal patent extension increases with the length of commercialization lags, as shown in Proposition 3. The positive relationship between T^{**} and E is depicted in the lower-left panel of Fig. 2.²⁰ In addition, the lower-right panel of Figure 2 shows that the optimal level of patent extension decreases with the input intensity of commercialization lags θ , which is consistent with the results in Proposition 3.

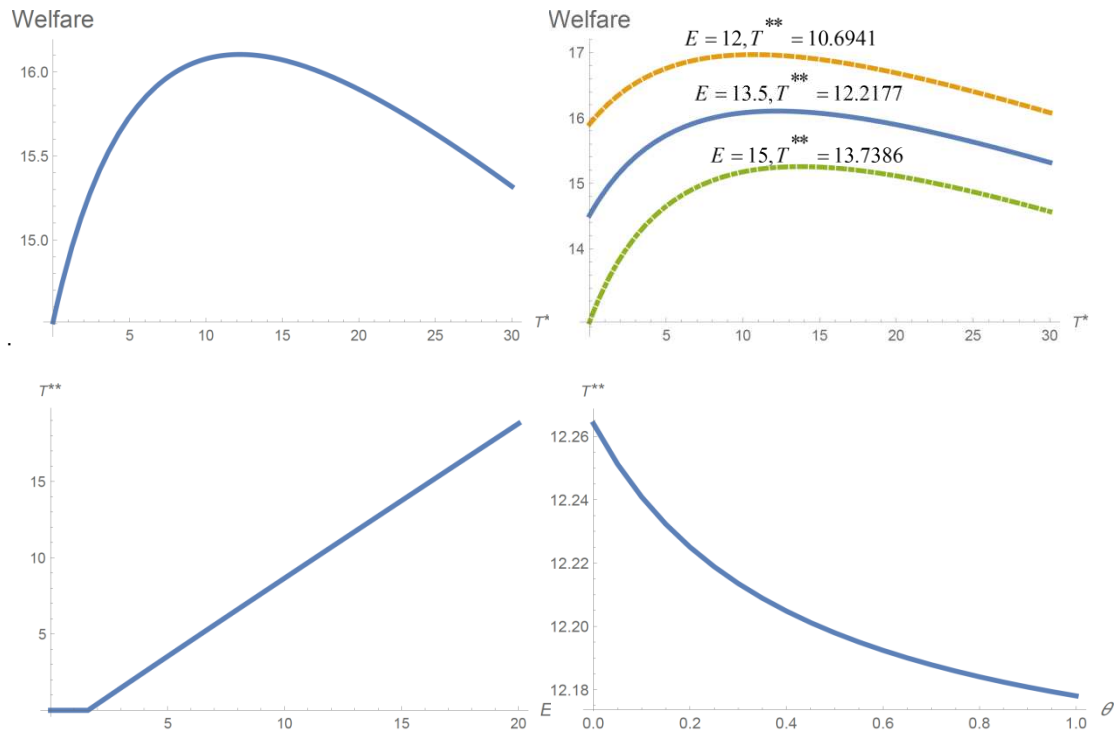


Figure 2. The optimal level of patent term extensions.

5.3. Sensitivity analysis: Different levels of patent breadth

Given that both patent breadth and patent term extensions are important patent policy instruments, it is interesting to examine how patent breadth affects the optimal level of patent extension. Moreover, patent breadth determines a monopolistic producer’s markup ratio. As mentioned earlier, the markup varies widely in pharmaceutical industries. Therefore, in this subsection, we perform sensitivity

²⁰ In the horizontal part of the lower-left panel of Fig. 2, the length of the commercialization lags is relatively small, and the optimal level of patent extensions is zero. In this case, extending the patent term will reduce social welfare.

analysis on the patent breadth η . Table 2 shows that an increase in patent breadth η leads to a higher markup ratio μ , which further reduces the optimal level of patent extension T^{**} , the maximum social welfare, and the fraction of monopolistic producers ω^* . Intuitively, increasing the level of patent breadth η enhances the market power of monopolistic producers, thereby leading to a larger distortion caused by imperfect competition. To correct this distortion, policymakers would like to choose a shorter level of patent term extension to reduce the effective patent life and the proportion of monopolistic firms. As a result, in the presence of commercialization lags, the optimal patent extension decreases with the level of patent breadth.

Table 2. Different levels of patent breadth

| | μ | T^{**} | welfare | ω^* |
|---------------|---------|----------|---------|------------|
| $\eta = 1.15$ | 3.4197 | 21.6474 | 16.0262 | 0.9688 |
| $\eta = 1.35$ | 4.2350 | 19.3518 | 16.1832 | 0.8898 |
| $\eta = 1.55$ | 5.2447 | 17.4536 | 16.2552 | 0.8245 |
| $\eta = 1.75$ | 6.4951 | 15.8521 | 16.2686 | 0.7693 |
| $\eta = 1.95$ | 8.0436 | 14.4794 | 16.2408 | 0.7221 |
| $\eta = 2.15$ | 9.9613 | 13.2875 | 16.1838 | 0.6811 |
| $\eta = 2.35$ | 12.3362 | 12.2414 | 16.106 | 0.6451 |
| $\eta = 2.55$ | 15.2774 | 11.3147 | 16.0135 | 0.6132 |
| $\eta = 2.75$ | 18.9198 | 10.4873 | 15.9107 | 0.5847 |

6. Concluding remarks

In the pharmaceutical industry, new drugs must complete lengthy clinical trials and pass a patent review before entering the market. The lags in commercialization usually result in the effective life of a new drug being less than its statutory term. We develop a Schumpeterian model with commercialization lags and explore the effects of patent extensions on pharmaceutical R&D and social welfare. We find that while patent extensions stimulate the consumption of homogeneous goods, they have an ambiguous effect on the consumption of pharmaceuticals. Therefore, patent term

extensions may have an inverted-U effect on social welfare. Moreover, our analysis shows that the optimal patent extension increases with the length of commercialization lags but decreases with the input intensity of commercialization lags and the level of patent breadth.

There are some potential extensions of our model that may be further considered in future research. In this paper, we focus on the relationship between patent term extensions and commercialization lags. It would be meaningful to investigate whether other patent policy instruments, as well as other innovation policies such as monetary policy and subsidies, can reduce the adverse effects caused by the lags in commercialization. In addition, it would be interesting to examine whether patent term extensions are still effective in stimulating R&D and raising social welfare for other variants of the Schumpeterian growth model.

Appendix: Derivations of (27)

From (17), we can solve for the value of all drugs with valid patents as

$$\bar{V}_t = \frac{\lambda_1 \lambda_2 \beta L_t}{\rho - n} \left(\frac{\mu - 1}{\mu} \right) \left[T + T^* - E - \frac{\Omega_1(T^*, E)}{\rho - n} \right]. \quad (\text{A1})$$

Moreover, from (19), we can derive the total cost of commercialization lags as

$$S_t = \lambda_1 \left(E - \frac{\Omega_2(E)}{\rho - n} \right) \frac{\alpha \theta L_t^R}{\rho - n}. \quad (\text{A2})$$

Combining (A1) and (A2) yields the value of the household's total assets:

$$\bar{V}_t - S_t = \frac{\lambda_1 \lambda_2 \beta L_t}{\rho - n} \left(\frac{\mu - 1}{\mu} \right) \left[T + T^* - E - \frac{\Omega_1(T^*, E)}{\rho - n} \right] - \lambda_1 \left(E - \frac{\Omega_2(E)}{\rho - n} \right) \frac{\alpha \theta L_t^R}{\rho - n}. \quad (\text{A3})$$

Dividing both sides of (A3) by L_t gives the value of assets per capita as

$$a_t = \frac{\lambda_1 \lambda_2 \beta}{\rho - n} \left(\frac{\mu - 1}{\mu} \right) \left[T + T^* - E - \frac{\Omega_1(T^*, E)}{\rho - n} - \frac{\lambda_1 \theta \Omega_1(T^*, E)}{\Delta(E, \theta)} \left(E - \frac{\Omega_2(E)}{\rho - n} \right) \right]. \quad (\text{A4})$$

Combining (2), (12)-(13), and (A4), we obtain

$$c_{h,0} = \alpha - \beta + \frac{\lambda_1 \lambda_2 \beta}{\rho - n} \left(\frac{\mu - 1}{\mu} \right) \left[T + T^* - E - \frac{\Omega_1(T^*, E)}{\rho - n} - \frac{\lambda_1 \theta \Omega_1(T^*, E)}{\Delta(E, \theta)} \left(E - \frac{\Omega_2(E)}{\rho - n} \right) \right]. \quad (\text{A5})$$

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