A Dynamic Approach to Pharmaceutical Regulation: Value-based Pricing versus Welfare Maximisation

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Abstract

We analyse the impact of pharmaceutical price regulation on welfare taking into account the dynamic nature of this industry. We create a benchmark model where R&D investment and the probability of successful innovations are related, and influenced by price and patent length. We compare this with an alternative that considers value-based pricing regulation, measured through health benefit. We study how variations on patent duration, price and the value-based pricing factor affect welfare, defined as consumer and producer surplus, illustrating our findings through simulation. Our results indicate that the overall welfare optimising price lies between the price that maximises either consumer surplus or producer surplus alone, and that the relationship between welfare and patent life depends on the during-patent price levels. We also find that value-based price regulation, with product prices set as a fixed proportion of their associated health benefit may not yield optimal welfare results. Optimal pricing includes aspects of the product's development costs, as well as notions of health benefit. Testing different innovation production functions indicates that the larger the likelihood of a future innovation, the more focus should be placed on producer surplus to warrant maximisation of overall welfare.

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1 Introduction

Pharmaceutical products are regulated in all of the major markets. Such regulation is primarily applied to ensure product quality, but generally also enforces a product price. The regulation of price is justified as patent protection, which acts as an incentive to invest in R&D given the problems of appropriating returns to such activity, creates monopoly rights to suppliers. Although it is difficult to define the optimal length and breadth of patent protection, any such protection gives the potential for rent-seeking behaviour, allowing suppliers to pursue the maximisation of producers' surplus for a fixed time period, prior to the market entry

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of generic products. Concerns have been raised that this situation, together with the health care industry's susceptibility to moral hazard, means that overall welfare and especially consumer surplus might be sub-optimal.

Regulated prices however, reduce the producers' ability to re-capture their substantial R&D investments. In turn, this may lead to a decline in innovation as there is less incentive for firms to innovate, with a subsequent impact on future levels of welfare. This highlights the interaction between the design of price regulation, aimed at optimising current welfare, and patent protection, which provides incentives to produce new products which impact on future welfare levels. Current welfare concerns, so-called static efficiency, aim to ensure that the distortionary impact of patent protection is minimised; while future welfare concerns, so-called dynamic efficiency, aim to ensure that the distortionary impact of price regulation on innovation is minimised. Determination of both patent length and the regulated product price is required to capture both static and dynamic efficiency.

While there has been increasing interest in pharmaceutical price regulation, remarkably little has been written on the interaction between patent and price regulation. There is a small empirical literature which tends to support the hypothesis that pharmaceutical pricing regulation generally lengthens time to market, erodes patent protection and thus damages access to medicines (Danzon et al, 2000; Danzon et al, 2005; Kyle, 2007) and a related empirical literature that considers the impact of patent length change on time to market (Varol et al, 2011). These empirical studies do not consider welfare aspects, nor do they forward conceptual frameworks to analyse such effects. Vernon (2005) suggests a partial model, based on expected profit, which explicitly models the impact between price regulation and R&D investment, but does not consider the full welfare impacts. The general effect of price on pharmaceutical R&D and innovation has been examined by Civan and Maloney (2007). Their empirical analysis finds that the number of drugs in a therapeutic category depends significantly on the established prices in that same category. They also found that drug development was elastic to prices at values of 28-49%.

There has been a small literature related theoretical literature which analyses optimal pricing strategies under a specific form of pharmaceutical pricing regulation; reference pricing (Merino, 2003; Breeke et al, 2007; Miraldo, 2010; Ghislandi, 2011). These models are particularly concerned with the competitive impact of reference price regulation, emphasizing the endogenous nature of this form of regulation. All the models consider the impact of various pricing strategies, given the endogenous nature of reference pricing, on competition amongst branded and generic pharmaceutical products. The conclusions reflect the assumptions made in the various papers concerning the competitive environment. Although generally, if reference pricing is based on minimum price referencing, consumers' and producers' surplus are reduced on the introduction of the regulation. While these models consider generic products and timing, the explicit duration of patent plays no role.

While reference pricing has been the predominant form of pricing regulation, it is not the only form of regulation and tends not to be the form implemented in the major European markets. Indeed all the major

European markets now appear to support some form of value-based pricing regulation. In France and Germany product reimbursement reflects innovative value, where innovative value is aligned with health benefit (Bridges et al, 2009; Mossialos and Oliver, 2005). While England appears to be moving to a reimbursement system, like Canada and Sweden, based on health benefit as determined through implementation of cost-effectiveness thresholds. Here the value, and the reimbursed price of the product is explicitly linked to the incremental health benefit produced (OFT, 2007; Moise, P. and Docteur, 2007)

As outlined by Claxton (2007) value- based pricing (VBP) approaches based on cost-effectiveness ratios tend to emphasize static patient welfare, in order to balance the market power producers have due to patent rights (Claxton, 2007). Although VBP is supposed to incorporate dynamic incentives to direct research activities into areas with high disease prevalence and large unmet needs, it may not have the desired effect due to long lags between research and product launch (McGuire, Raikou and Kanavos, 2008). This may result in VBP focusing on static welfare gains, jeopardising future welfare, which is tied to current R&D. To our knowledge, there has been no consideration of patent and regulatory price interaction, and little consideration of VBP on dynamic efficiency concerns. This forms part of the motivation for this paper.

While little explicit consideration has been given to welfare and pharmaceutical pricing regulation, there has also been little written on the impact of patent protection on the pharmaceutical market. There is, however, a large literature on the impact of patents generally on markets and welfare. Tirole (2002) summarizes the general literature noting that, given the uncertain returns from the investment, defining optimal levels of R&D is inherently difficult and that the welfare effects of patent protection depend on the strength of such protection. Weak patent protection tends to lead to under-investment in R&D, while strong patent protection tends to lead to duplication and over-investment in R&D.

Most of the patent protection literature can be traced to early work by Arrow (1963) and the seminal work by Nordhaus (1969) who was the first to explicitly model the trade-off between static and dynamic welfare, showing that changing patent duration had ambiguous effects on welfare. For his model, the author assumed full appropriability of profits during patent time. Nordhaus (1972) extended his former model by, in addition to patent length, allowing patent breadth to influence welfare. Patent breadth was defined as the degree to which revenues from an innovation could be appropriated by the innovator. Scherer (1972) reinterpreted Nordhaus' theory (1969) and established an invention possibility function that explained how the ease of innovation depended on the intensity of R&D investment. He showed that welfare gains and losses due to change in patent duration depended on price elasticities of demand, highlighting the interaction between patent protection and pricing mechanisms.

Turning to studies that have explicitly considered the pharmaceutical industry, Arora et al (2003) found a 10% patent premium on pharmaceutical products compared to that earned by other companies, implying a degree of over-protection. Although again defining optimal R&D remains difficult. Hughes et al (2002) compare a patent scenario with that of immediate generic competition, and showed that while a no patent strategy would yield larger surpluses in terms of present consumer welfare, future consumers would lose

three times the gained amount in present value terms. The same relationship was modeled by Horowitz and Lai (1996) who found that the patent length that maximises the rate of innovation exceeded the consumer surplus' maximising patent length.

There are few studies that have developed a theoretical framework to consider the innovation possibility function in the pharmaceutical sector (Camejo, McGrath and Herings, 2011; Bardey, Bommier and Jullien, 2010; Isaac and Reynolds, 1988). These studies generally find that R&D investment is the main factor of innovation and this, in turn is influenced by expected revenues, future cash flow, the level of uncertainty in the market, revenue appropriability, market size and structure, degree of competition, demographic factors, policies such as intellectual property protection or governmental R&D subsidies and duration of R&D investment. To the extent that regulatory environment is considered at, it is generally deemed to have a negative impact on innovation.

Determinants of pharmaceutical R&D investment intensity have been empirically examined by a small number of studies, with the general finding that internal finance, essentially current cash flow, and expected revenue are important determinants. Grabowski and Vernon (1981), for example, find that expected returns as well as cash flows were significant explanatory variables for the level of R&D investment. Vernon (2005) confirms this. Dubois et al (2011) emphasize the related relationship between market size and pharmaceutical innovation. The positive relationship between R&D investment and drug prices has been shown repeatedly, for example by Giacotto et al (2005) who state that the demand for R&D is a derived demand, depending on cash-flow effects stemming from levels of pharmaceutical pricing.

To the extent that price affects cash flow and expected revenue, and these latter variables determine future R&D levels, along with the intensity of R&D investment function, we have a direct link between price regulation and R&D. If price regulation distorts expected revenues, then there will be an adverse influence on R&D investments. If there is strong patent protection this may offset these distortionary effects. One form of regulation thus influences the other. This interaction of regulatory instruments has had little examination in the pharmaceutical sector.

The present study examines the theoretical relationship of pricing, patent duration and welfare in the long run. Our focus lies on pharmaceutical innovations only. The paper is organised as follows. The next section presents a stylised welfare model with one extension. Following this we present the results of the comparative statics analyses of changes in welfare brought about by changes in price, patent length and the VBP factor. In the third section we illustrate our results with a simulation created using a numerical example. Lastly, we discuss and conclude.

2 The Model

In this section, we present a highly stylised welfare function model associated to pharmaceutical innovation. Our benchmark includes the determinants of innovation, R&D intensity and generic entry. We subsequently

extend the model by a variation that incorporates value-based pricing.

2.1 The benchmark model

Our benchmark welfare function is the sum of the producer surplus (PS) that a pharmaceutical product generates and the consumer surplus (CS) associated to it. To focus on the impact of regulation of patent length and price on the inter-temporal R&D investment decisions, we assume that products have a total commercial life-span of time $T > 0$,with a launch date at $t = 0$, and a patent life of s, with $0 \leq s \leq T$. We also incorporate the uncertainty surrounding the outcome of R&D investment by including the term ρ_i as the probability of successful R&D. R&D is a one-off amount which is not discounted and represented by R_i. This is in accordance with the findings by Camejo et al (2011) who stated that decisions are taken in the early stages of drug development. For any given product i, we assume constant marginal costs, mc_i. During the patent life of a medication, all prescribers use the branded pharmaceutical such that the pharmaceutical firm sells quantity q_i and appropriates all PS from product i. After patent expiry, generic entry occurs straight away (Hughes et al., 2002) and the generic sells quantity q_i^g while the branded pharmaceutical sales changes to a post-patent quantity of q_i^p. We assume that pharmaceutical prices stay the same after patent expiration (cf. Bhattacharya & Vogt, 2003). The parameters of our model are assumed to be constant over time and the demand function linear and equal to $p_i = a_i - b_i q_i$ for product i. Thus, for any good $i = 1, 2, ...n$ the associated CS and PS can be written as follows:

$$CS(s, p_i) = \rho_i \left[\int_0^s e^{-rt} \frac{1}{2}(a_i - p_i) q_i dt + \int_s^T e^{-rt} \frac{1}{2}(a_i - p_i) q_i^p dt + \int_s^T e^{-rt} \frac{1}{2}(a_i - p_i^g) q_i^g dt \right] \tag{1}$$

$$PS(s, p_i) = \rho_i \left[\int_0^s e^{-rt}(p_i - mc_i) q_i dt + \int_s^T e^{-rt}(p_i - mc_i) q_i^p dt + \int_s^T e^{-rt}(p_i^g - mc_i) q_i^g dt \right] - R_i \tag{2}$$

And therefore, the welfare function simplifies to:

$$\begin{aligned} W(s, p_i) \quad = \quad & \rho_i \left[\int_0^s e^{-rt}(\frac{1}{2}a_i + \frac{1}{2}p_i - mc_i) q_i dt + \int_s^T e^{-rt}(\frac{1}{2}a_i + \frac{1}{2}p_i - mc_i) q_i^p dt \right. \\ & \left. + \int_s^T e^{-rt}(\frac{1}{2}a_i + \frac{1}{2}p_i^g - mc_i) q_i^g dt \right] - R_i \end{aligned} \tag{3}$$

where r is the discount rate.

We assume that after patent expiration the branded firm faces a 'shifted' demand function, which is a fraction of the original demand function, i.e. $q_i^p = \frac{1}{k} q_i = \frac{1}{k}\left(\frac{a_i - p_i}{b_i}\right)$. We further consider that there is no new innovation in the same therapeutic class and that after patent expiration the generic product is priced at a price p_i^g such that it takes the leftover fraction $(1 - \frac{1}{k})$ of the original demand function. Thus,

$q_i^g = (1 - \frac{1}{k})q_i = (1 - \frac{1}{k})\left(\frac{a_i - p_i}{b_i}\right)$, with $k > 1$.

In order to see the impact of one product's revenues on the other product's R&D investment and its probability of success, we extend the model to a two product scenario, with products $i = 1, 2$. Thus, with probability ρ_2 the new product $i = 2$ is launched at some point in time, $t = \tau$, after patent expiration, $s \leq \tau$, and is itself patented until $t = \tau + s$. This gives a total welfare function:

$$\begin{aligned} W(s, p_i) &= \rho_1 \left[\int_0^s e^{-rt}(\frac{1}{2}a_1 + \frac{1}{2}p_1 - mc_1)q_1 dt + \int_s^T e^{-rt}(\frac{1}{2}a_1 + \frac{1}{2}p_1 - mc_1)q_1^p dt \right. \\ &\quad \left. + \int_s^T e^{-rt}(\frac{1}{2}a_1 + \frac{1}{2}p_1^g - mc_1)q_1^g dt \right] - R_1 \\ &\quad + \rho_2 \left[\int_\tau^{\tau+s} e^{-rt}(\frac{1}{2}a_2 + \frac{1}{2}p_2 - mc_2)q_2 dt + \int_{\tau+s}^{\tau+T} e^{-rt}(\frac{1}{2}a_2 + \frac{1}{2}p_2 - mc_2)q_2^p dt \right. \\ &\quad \left. + \int_{\tau+s}^{\tau+T} e^{-rt}(\frac{1}{2}a_2 + \frac{1}{2}p_2^g - mc_2)q_2^g dt \right] - R_2 \end{aligned} \tag{4}$$

To incorporate the relationship between revenues, R&D investment and innovation, in the following paragraphs we introduce an R&D intensity function and an innovation production function (IPF).

R&D intensity: According to Grabowski & Vernon (1981) and Vernon (2005), the R&D investment decision of a firm depended on two factors: firstly, the cash flow generated by profits of products currently in the market and secondly, the expected return to R&D obtained through future profits. As incorporating the latter would induce circularity, past revenues shall serve as our instrument for expected profits and we allow R_2 to depend on the present value of expected revenues during patent.[1]

We assume that R_2 is a fraction m of revenues generated by the previous product, with $0 \leq m \leq 1$. Hence, $R_2 = m\rho_1 \int_0^s e^{-rt} p_1 q_1 dt$, and simpliefied $R_2 = \frac{\rho_1}{r} m p_1 q_1 (1 - e^{-rs})$.

Innovation production function: The literature on R&D investment and its relationship to innovation is limited. Jensen (1987) found a correlation between R&D expenditures and the probability of drug discovery and that probability decreased over the examined time. Later studies have confirmed this (Pammolli, Riccaboni & Magazzini, 2010). Everson (1993) stated that opportunities of drug discovery might be finite with easy targets exhausted first. This would lead to increasing efforts required to achieve a research success. These hypotheses encourage the use of an IPF with decreasing marginal productivity. As Baily (1972) noted, the IPF should not depend on R&D expenditure alone but if so, then the function should exhibit diminishing marginal returns. Further work on the IPF has been done by Arora et al (2003) who modelled the number of innovations depending on R&D expenditure employing the elasticity of innovation as a main factor. We model a similar IPF that depends on R&D and exhibits diminishing marginal returns.

[1] There is some discussion on whether there are cash-flow effects at all as, according to neoclassical theory, the marginal cost of capital corresponds with the interest rate (Modigliani & Miller, 1958). However, Vernon (2005) and Grabowski & Vernon (1981) found that significant cash-flow effects on pharmaceutical R&D investment that were explained with these having a lower cost of capital than external debt in the real world.

This simplified IPF for product 2 can be written as: $\rho_2 = u * (R_2)^v$, i.e.$\rho_2 = u * \left(\frac{\rho_1}{r} m p_1 q_1 (1 - e^{-rs})\right)^v$, where $u > 0$ is a constant scale parameter and $0 < v < 1$ the R&D elasticity of innovation. This equation gives probabilities between 0 and 1 when choosing appropriate values of u and v and can also exceed 1.

Inserting both the R&D intensity function and the IPF, the welfare function becomes:

$$\begin{aligned} W(s,p_i) &= \frac{\rho_1}{r} q_1 \left[\left(\frac{1}{2}(a_1 + p_1) - mc_1 \right) \left(1 - e^{-rs}\right) + \left(\frac{1}{2}(a_1 + \frac{1}{k} p_1 + (1 - \frac{1}{k}) p_1^g) - mc_1 \right) \left(e^{-rs} - e^{-rT}\right) \right] - R_1 \\ &+ u * \left(\frac{\rho_1}{r} m p_1 q_1 (1 - e^{-rs}) \right)^v \frac{q_2}{r} \left[\left(\frac{1}{2}(a_2 + p_2) - mc_2 \right) \left(e^{-r\tau} - e^{-r(\tau+s)} \right) \right. \\ &\left. + \left(\frac{1}{2}(a_2 + \frac{1}{k} p_2 + (1 - \frac{1}{k}) p_2^g) - mc_2 \right) \left(e^{-r(\tau+s)} - e^{-r(\tau+T)} \right) \right] - \frac{\rho_1}{r} m p_1 q_1 (1 - e^{-rs}) \end{aligned} \quad (5)$$

Next, we introduce a variation of our model in which the price of a pharmaceutical product is decided as a factor of its associated health benefit.

2.2 The Value-Based Pricing Model

We create an alternative model for which the price of a product p_i shall be replaced by the VBP term $z * h_i$, where $z > 0$ is a constant scale parameter and $h_i > 0$ is the health benefit of product i. The generic price p_i^g is not affected by this change as it is set independently, presumably based on marginal cost of production.

Welfare then writes as:

$$\begin{aligned} W(s,z) &= \frac{\rho_1}{r} q_1 \left[\left(\frac{1}{2}(a_1 + z h_1) - mc_1 \right) \left(1 - e^{-rs}\right) + \left(\frac{1}{2}(a_1 + \frac{1}{k} z h_1 + (1 - \frac{1}{k}) p_1^g) - mc_1 \right) \left(e^{-rs} - e^{-rT}\right) \right] - R_1 \\ &+ u * \left(\frac{\rho_1}{r} m (z h_1 q_1)(1 - e^{-rs}) \right)^v \frac{q_2}{r} \left[\left(\frac{1}{2}(a_2 + z h_2) - mc_2 \right) \left(e^{-r\tau} - e^{-r(\tau+s)} \right) \right. \\ &\left. + \left(\frac{1}{2}(a_2 + \frac{1}{k} z h_2 + (1 - \frac{1}{k}) p_2^g) - mc_2 \right) \left(e^{-r(\tau+s)} - e^{-r(\tau+T)} \right) \right] - \frac{\rho_1}{r} m (z h_1 q_1)(1 - e^{-rs}) \end{aligned} \quad (6)$$

3 The impact of price and patent length on welfare

In this section, we examine the effect of changing prices, patent length and the VBP factor z_i on welfare, CS and PS. The derivatives involved are analytically complex and therefore we use simplifying notations: Equations (1) and (2) can be rewritten as $CS(1)$, $CS(2)$, $PS(1)$ and $PS(2)$, which are the discounted CS and PS associated with product 1 and 2, respectively. This does not include probability of success and R&D investment which will be looked at separately (definitions can be found in the appendix in Equ. 8, 9, 13, 14).

3.1 Welfare and Price

An increase of the during patent price of product 1 will directly affect CS (decreasing, $\frac{\partial CS(1)}{\partial p_1} < 0$) and PS (increasing, $\frac{\partial PS(1)}{\partial p_1} > 0$) associated to that product. The patent revenues of product 1 will be higher and this

will have a positive impact on the level of R&D invested in the development of a second product ($\frac{\partial R_2}{\partial p_1} > 0$) and the probability that this investment is successful ($\frac{\partial \rho_2}{\partial p_1} > 0$). All other components in the welfare function will not be affected by an increase in the first product price. Therefore, we can write:

$$\frac{\partial CS}{\partial p_1} = \rho_1 \frac{\partial CS(1)}{\partial p_1} + \frac{\partial \rho_2}{\partial p_1} CS(2)$$

$$\frac{\partial PS}{\partial p_1} = \rho_1 \frac{\partial PS(1)}{\partial p_1} + \frac{\partial \rho_2}{\partial p_1} PS(2) - \frac{\partial R_2}{\partial p_1}$$

Thus,

$\frac{\partial W}{\partial p_1} > 0$ iff $\left|\rho_1 \frac{\partial CS(1)}{\partial p_1} - \frac{\partial R_2}{\partial p_1}\right| < \rho_1 \frac{\partial PS(1)}{\partial p_1} + \frac{\partial \rho_2}{\partial p_1}(CS(2) + PS(2))$.[2] This expression tells us that welfare increases with price only if the loss at present due to decrease in CS and increase in R&D investment is smaller than the gain from increase in PS at present plus increase in expected welfare of the future product. R&D investment thus has an ambiguous effect on welfare: The larger it is, the smaller becomes producer surplus in a direct effect but the larger becomes future welfare due its impact on the probability of success.

3.2 Welfare and Patent Length

Extending the patent period will directly affect CS and PS by extending the duration of the non-competitive period. This will also have an effect on the R&D investment in developing a second product and its probability of success, and it will alter the discount factor applied to the second product consumer and producer surpluses by shifting it forward in the future by the increment in s.

$$\frac{\partial CS}{\partial s} = \rho_1 \frac{\partial CS(1)}{\partial s} + \frac{\partial \rho_2}{\partial s} CS(2) + \rho_2 \frac{\partial CS(2)}{\partial s}$$

$$\frac{\partial PS}{\partial s} = \rho_1 \frac{\partial PS(1)}{\partial s} + \frac{\partial \rho_2}{\partial s} PS(2) + \rho_2 \frac{\partial PS(2)}{\partial s} - \frac{\partial R_2}{\partial s}$$

Holding all else fixed, $\frac{\partial CS(1)}{\partial s} < 0$ and $\frac{\partial PS(1)}{\partial s} > 0$ due to the increased duration of the period of higher prices faced by consumers/received by the producer. Also $\frac{\partial R_2}{\partial s} > 0$ and $\frac{\partial \rho_2}{\partial s} > 0$ because of the larger during-patent revenues. Effects of longer patents on CS are negative as they both extend the period when consumers face a higher price for product 2, and decrease the weight of CS in the welfare function by shifting it further in the future. The sign of $\frac{\partial PS(2)}{\partial s}$ is ambiguous as increasing s increases $PS(2)$ by guaranteeing higher prices for a longer period but also reduces the weight of this gain by shifting it further in the future. Given a sufficiently small discount factor (long enough s), the overall effect will be positive so we will assume, $\frac{\partial PS(2)}{\partial s} > 0$.

Therefore, we have that $\frac{\partial W}{\partial s} > 0$ iff $\left|\rho_1 \frac{\partial CS(1)}{\partial s} + \rho_2 \frac{\partial CS(2)}{\partial s} - \frac{\partial R_2}{\partial s}\right| < \rho_1 \frac{\partial PS(1)}{\partial s} + \rho_2 \frac{\partial PS(2)}{\partial s} + \frac{\partial \rho_2}{\partial s}(CS(2) + PS(2))$. This means that welfare increases with patent length only if the loss of decrease in expected CS

[2] Proofs are available in the Appendix.

at present and in future and the increase of R&D investment is smaller than the increase of expected PS now and in future and the increase in probability of success which depends positively on the increased R&D investment. This illustrates how taking into consideration the dynamic nature of the R&D investment makes finding the conditions for which the welfare gain or loss associated to a longer patent length much more complicated than in a static model.

3.3 VBP factor and Welfare

Given that z appears in the VBP model's price multiplying the health benefit associated to a product, h_i, the derivative of the welfare function with respect to VBP factor z is very closely related to that with respect to price, and thus $\frac{\partial W}{\partial z} > 0$ iff $\left|\frac{\partial CS(1)}{\partial z} - \frac{\partial R_2}{\partial z}\right| < \rho_1 \frac{\partial PS(1)}{\partial z} + \frac{\partial \rho_2}{\partial z}(CS(2) + PS(2))$.

4 Numerical Simulation

The signs of the derivatives above depend non-linearly on the parameter ranges, including the demand functions of products 1 and 2 and the differences between levels of patented prices, generic prices and marginal cost. Therefore, the final impact of patent length and price on welfare is analytically ambiguous. To circumvent this problem, we simulate the derivatives above by assigning parameter values identified through the literature review.

4.1 Calibration of the model

To calibrate our model, we assume the price of the two products to be the same: $p_2 = p_1$. Product 1 already exists, and thus its R&D expenditure is fixed. We assume that both products have equal associated health benefit in terms of monetary value, $h_2 = h_1$. One interpretation of this is that one unit of any product provides a Quality-adjusted Life Year (QALY).

4.2 Parameter values

We populated our model using parameters extracted from the existing literature.

Probability of success, $\rho_1 = 1$: As product 1 already exists, we set the probability of successful R&D of product 1 to 1. No value is fixed for ρ_2 as it is defined by the IPF.

Discount rate, $r = 0.035$: The discount rate is 3.5%. For comparison purposes, the discount rate chosen is 3.5% as this is used for both costs and benefits in NICE guidance (2008).

Total useful product life, $T = 30$: The average life time of any product is 30 years, orientated at 25 years estimated by Hughes et al. (2002).

Launch time of product 2, $\tau = 10$: The assumed time of launch of product 2 if successful is 10 years after launch of product 1.

Health benefit, $h_2 = h_1 = 30,000$: The health benefit of both products $i = 1, 2$ expressed in monetary value is GBP 30,000. We assumed the health benefit to be 1 QALY. The literature on assigning a monetary value to a QALY is relatively sparse and issues such as the margin at which QALYs are bought rarely taken into account. Different approaches include using the existing WTP-based 'value of preventing a statistical fatality' (Mason et al, 2009). Their results indicate a value range of approximately GBP 24,000 to GBP 70,000 per QALY. Other approaches found were direct valuation (cf. Gyrd-Hansen, 2003), and the use of statistical value of a life (cf. Murphy and Topel, 1999) and different approaches might yield different results. We therefore test two other values of health benefit, $h_i = 10,000$ and $h_i = 50,000$.

Marginal cost, $mc_i = 3,000$ The marginal cost per unit is assumed to be GBP 3,000. Camejo and colleagues (2011) stated that marginal cost of production was negligible compared with the large R&D costs. The value is chosen somewhat arbitrarily.

R&D expenditure, $R_1 = 500,000,000$: The estimated R&D invested into product 1 is GBP 0.5 billion. DiMasi et al (2003) estimated drug development costs and found that they were at US$ 800 million at the time. Estimates from the CBO Report (2006) suggest similarly that drug development costs were between US$ 800 million and 1 billion at the time and indicated that they were still rising. Converting US$ 800 million yields approximately GBP 500 million for R&D investment R_1.[3] The R&D cost R_2 of product 2 will be defined by the R&D intensity function.

R&D intensity, $m = 0.2$: Fraction of present value revenues invested in R&D. This is the R&D expenditure as percentage of present value of accumulated revenues. The value of 20% is a rounded estimate resulting from values retrieved from the OHE report on the pharmaceutical industry (2007) (between 17% to 31%) and the CBO Report (2006) that estimated 19%.

Innovation Production Function (IPF), $u = 0.000035$: Constant scale parameter. $v = 0.5$: R&D elasticity of innovation or probability of success. This function is a rather crude estimate. The choice of parameter u yielded a probability of approximately $\rho_2 = 0.8$ at $v = 0.5$ and an R&D investment of GBP 500 million. At an investment of approximately GBP 800 million, the probability would be at 100%. The choice of u was thus based on trial and error. Arora et al (2003) had found that the smaller the elasticity v, the steeper the decline in the marginal innovative productivity of R&D. To know v is therefore as crucial as to know u; but unfortunately it is not obvious (Vernon, 2005). A sensitivity analysis was conducted changing the parameter u to two different values. Prices, level of welfare, PS and CS were compared with different values of u and graphs were created. The lower value used was

[3] The exchange rate was retrieved from http://www.ukforex.co.uk/cgi-bin/currency-converter.asp on Sep 01, 2011. For simplicity, the present exchange rates were used.

$u = 0.000015$ and the larger value was $u = 0.000045$. The former, at a level of R&D investment of GBP 500 million yielded a probability of innovation of approximately $\rho_2 = 0.34$, the latter a probability of approximately $\rho_2 = 1$.

Prices, $p_2 = p_1$: The price of product 2 is equal to price of product 1, $p_i \geq mc_i > 0$ for $i = 1, 2, ..., n$. When looking for the optimal patent length, price is fixed at $p_i = 20,000$, a cost per QALY commonly used by NICE as a cost-effectiveness threshold.

$p_i^g = 3,500$: The price of generics is assumed to be GBP 3,500. In perfect competition, prices of generics would tend to equal marginal cost. It is assumed that competition is not perfect and price of generics is slightly higher.

Patent length, $s = 10$: The average patent life for all products is set at 10 when optimal prices are observed. Hughes et al (2002) found an average commercial patent life of eight to ten years.

Demand function, $q_i = 12,000 - 0.1p_i$: The demand function has parameters $a_i = 120,000$ and $b_i = 10$ for both products $i = 1, 2$. The demand function was chosen such that it exhibited an elasticity of demand with respect to price of -20% at a point estimate of $p_i = 20,000$. This was based on the RAND Health Insurance Experiment (2005) and on Costa-Font, McGuire & Stanley (2012) who found that health care was a highly inelastic good, meaning that it is a necessity.

$q_i^p = \frac{1}{5}(12,000 - 0.1p_i)$: The pharmaceutical demand function after patent expiry. With $\frac{1}{k} = 0.2$ such that the branded quantity demanded after patent expiry is 20% of the demand during the patent period. Hughes et al (2002) found that market shares of incumbents fell to about 20% within one year after the patent expired. The remaining fraction of prescribers opt for generic products and hence:

$q_i^g = \frac{4}{5}(12,000 - 0.1p_i)$: The remaining market, $(1 - \frac{1}{k}) = (1 - \frac{1}{5}) = \frac{4}{5}$, is served by the generic firm/s.

4.3 Results

4.3.1 Optimal price and patent length in the benchmark model

Using above parameter values, we calculate the welfare-optimal price and patent length. Welfare is shown to first increase and then decrease with price, but the impact of patent length is less obvious (Figure 1.).

Plotting PS and CS separately shows that PS becomes larger with increasing price and patent length up to a maximum (due to price elasticity of demand). CS on the other hand, reaches a maximum and then declines with increasing price and patent length. This is shown in Figure 2.

Figure 2. also suggests that producer and consumer both would set their prices differently from the welfare-optimal price. Fixing patent length at the average of $s = 10$, we take derivatives for welfare, CS and PS with respect to price to obtain numerical values (Table 1.).

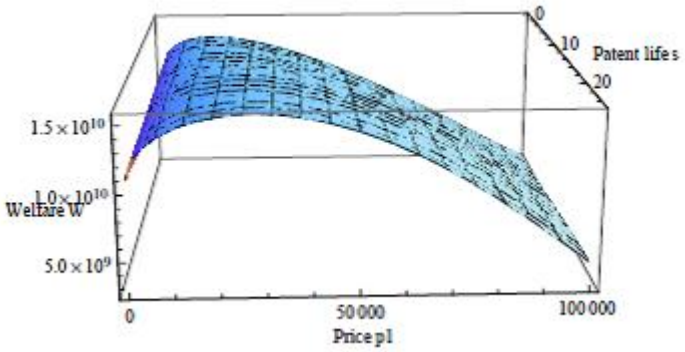

Figure 1: Welfare with price and patent length

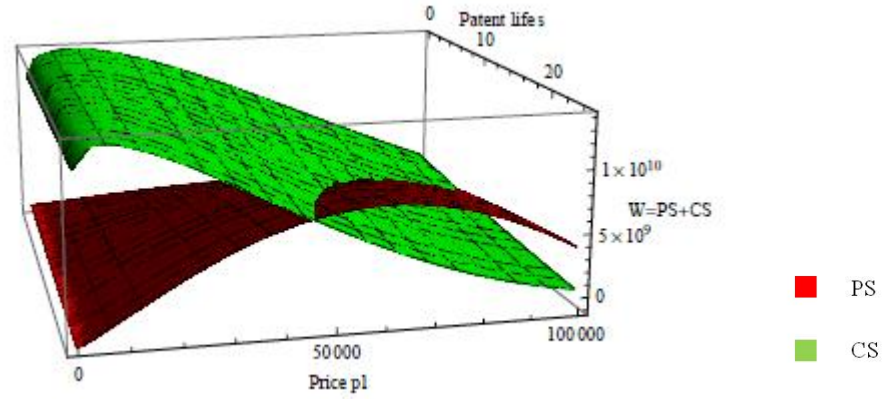

Figure 2: CS and PS with price and patent length

in GBP '000	Maximising welfare	Maximising PS	Maximising CS
Price	20.26	61.24	7.47
Welfare	14,595,000	10,889,700	13,899,900
PS	1,732,900	4,471,180	62,040
CS	12,862,000	6,418,560	13,873,900

Table 1: Welfare, producer and consumer surplus optimising scenarios

Health benefit	Welfare-optimal VBP factor	Welfare-optimal price
$h_i = 10,000$	$z = 1.13$	$p_i = 10,460$
$h_i = 30,000$	$z = 0.68$	$p_i = 20,260$
$h_i = 50,000$	$z = 0.47$	$p_i = 23,270$

Table 2: VBP factor variations with health benefit

These results suggest that the decision taken by the producer could lead to a price much higher than the welfare-maximising price. CS would turn out to be quite small and overall welfare significantly lower than at the welfare-maximising price. If consumers could determine prices, PS would be lowered and social welfare decrease.

With regards to optimal patent length, no welfare-optimal patent length could be found. The direction welfare takes with patent length variations depends on the level of price.

4.3.2 Larger probability of innovation justifies stronger focus on producer surplus

We furthermore explore variations in the probability of success in order to address the uncertainty introduced by the estimate of the IPF. Welfare-optimal price and its associated levels of welfare, PS and CS were calculated and compared, holding s and v fixed.

The larger the probability of a new innovation, the larger is the optimal price and the greater social welfare - but the smaller the share of CS over welfare. This may indicate that a stronger focus on producer surplus is welfare-enhancing when the likelihood of a ground-breaking innovation is greater.

4.3.3 Welfare depends on health benefit when value-based pricing is employed

To find the optimal VBP factor z we fix patent life at $s = 10$. Using different values for health benefit, we find results shown in Table 2.

For different levels of health benefit, the optimal VBP factor varies and it cannot be determined whether prices should be higher, lower or equal to health benefit. This result suggests that using one single factor for VBP regulation that applies to all pharmaceuticals, is not welfare-maximising. For smaller health benefits, it is optimal to pay more for larger health benefits it is optimal to pay less than the actual benefit to the patient. Therefore, z may be a declining function of h_i (Figure 3).

5 Discussion

The aim of this study was to create a dynamic model that explains the impact of pharmaceutical regulation (price and patent length) on social welfare. A benchmark model that established the relationship between prices, R&D intensity and innovative productivity was created and extended to determine the optimal level of value-based price (VBP) regulation.

The benchmark model analysis showed that the welfare-optimal price lies between the consumer- and

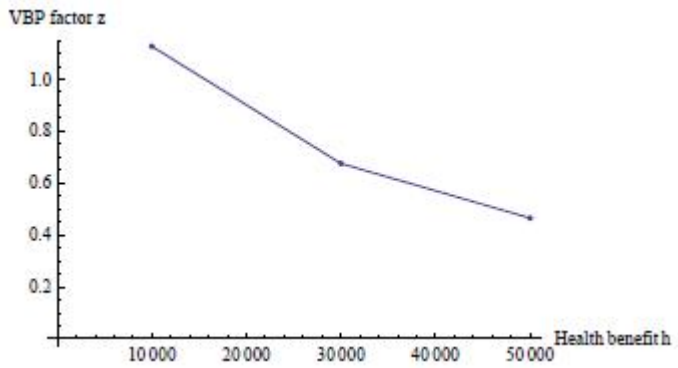

Figure 3: VBP as function of health benefit

producer-optimal prices. If consumers or producers could decide freely on their surplus-maximising level of price, major welfare losses would be encountered. The welfare-optimising level of price was shown to depend not only on patent length and health benefit, but also crucially on the price elasticity of demand as well as on R&D costs and other factors. Welfare decreased with patent duration at certain prices.

Testing different forms of the innovation production function suggested that a larger probability of success resulted in a larger welfare-optimal price and increasing welfare, producer and consumer surpluses. The share of consumer surplus decreased with larger probabilities, indicating that with larger probabilities focus might shift towards producer surplus. The overall directions of welfare variations with patent length or price were not altered with different IPFs.

The extension of a value-based pricing factor and testing it for different levels of health benefit yielded that there was not one value of the VBP factor z that was welfare-optimising for all values of health benefit. The result suggests that VBP applied as a factor to health benefit does not optimise social welfare. It was shown that the VBP factor declined with increasing health benefit, but at a reduced rate. The VBP factor may also depend on other factors that were not modelled here. Instead, results suggested that optimal pricing may reflect all costs associated with the product, the health benefit it delivers over time and take into account the relationship of innovative productivity and price.

The present study is the first that attempts to create a theoretical framework for the impact of pharmaceutical regulation on the present value of welfare considering insights on innovative productivity and R&D investment. As such, it adds to previous studies on a trade-off of static and dynamic consumer surplus (Hughes et al, 2002) and welfare (Nordhaus, 1969; Nordhaus, 1972, Scherer, 1972) considering different levels of patent length. The findings support the view that pharmaceutical regulation can be used in order to maximise social welfare. Results caution for a careful consideration of the optimal type and level of regulation as it was shown that the solution is not as simple as setting prices equal to a factor of marginal health benefit.

The limitations of the present study are seen in assumptions with regards to competition and the IPF and in the lack of dynamic flexibility of the model. It may be considered in future research to account for different types of competition and reflect that in a flexible price elasticity of demand as well as in the speed

with which R&D is conducted (cf. Patent race model by Belleflamme & Peitz, 2010). The relevance of the therapeutic classes or technological areas that R&D could be conducted in was not considered but, as Gerlach and colleagues (2005) emphasised, there might be a need to direct R&D efforts from safe to risky R&D technology. This could be reflected in the marginal health benefit which would in turn yield higher appropriate prices and re-direct R&D efforts to areas where research is under-provided (cf. Lichtenberg & Philipson, 2002).

One of the greatest difficulties was the non-existence of IPF estimates. Probabilities of success may vary considerably by therapeutic class. The chance of discovering a blockbuster is much lower than that of discovering a drug that presents a marginal improvement over an existing one. The nature of a blockbuster could be reflected in the health benefit. Extending the model by multiple products in the pipeline would bring it closer to reality.

R&D investment was used as the main factor influencing research outcome. While this seems to be a good instrument for many factors such as skills of researchers, it does not account for others. Time-to-market, R&D synergies and a random element influencing outcome were omitted. The latter could be addressed by making the model stochastic. The R&D investment decision was made dependant only on current revenues but should depend on future revenues as well. This extension might cause some difficulty due to endogeneity but would provide an improvement as it would permit including the number of products a firm has currently in the pipeline as an additional variable.

For illustration purposes, the model was based on the simplifying assumption of non-changing parameters and demand functions over time. Dynamic Optimisation methods may help in addressing this and make the model more flexible. Finally, the simulation could be done in a probabilistic manner, assigning probability distributions to the main variable inputs.

6 Conclusion

Price and patent regulation can be used as meaningful instruments to maximise welfare derived from pharmaceuticals in the long-run and much is to be gained from an improved system of welfare-optimising regulation. The question of how much and what type of regulation is optimal depends on various factors, the main ones being: price elasticity of demand, competitive setting, form of the innovation production function and the health benefit derived from an innovation as well as R&D costs. The results suggest that regulation should take into account both patent length and price regulation. Using value-based pricing based on health benefit only is found to deliver non-welfare optimal results. Optimal pricing may not only be based on health benefit but also reflect a product's development costs and health benefit over time. A stronger focus on producer surplus may be warranted when the likelihood of a future innovation is larger.

The present model, being the first of its kind, may serve as a starting point in the search for a more informed way of pharmaceutical regulation. Future research may include addressing the simplifying assump-

tions made, extending the model by various variables and introducing more dynamic flexibility.

References

[1] Arora, A., Ceccagnoli, M., and Cohen, W. M. (2003). R& D and the Patent Premium. NBER Working Paper Series.

[2] Arrow, Kenneth J., (1962). Economic Welfare and the Allocation of Resources for Invention, in R. R. Nelson (ed.), The Rate and Direction of Inventive Activity: Economic and Social Factors (Princeton: Princeton University Press) 609-625.

[3] Baily, M. N. (1972). Research and Development Costs and Returns : The U.S. Pharmaceutical Industry. Journal of Political Economy, 80(1), 70-85.

[4] Bardey, D., Bommier, A., & Jullien, B. (2010). Retail price regulation and innovation: reference pricing in the pharmaceutical industry. Journal of Health Economics, 29(2): 303-16.

[5] Belleflamme, P. and Peitz, M. (2010). Industrial Organization: Markets and Strategies. Cambridge: Cambridge University Press.

[6] Bhattacharya, J., Vogt, W. (2003). A simple model of pharmaceutical price dynamics. Journal of Law and Economics, 46(2): 599-626.

[7] Bridges, J., Cohen, J., Grist, P and Muhlbacker, A., (2009). International experience with comparative effectiveness research: Case studies for England/Wales and Germany, Advances in Health Economics and Health Services Research, 22., 29-50

[8] Brekke, K.R., Koningbauer, I., Straune, O.R., (2007). Reference pricing of pharmaceuticals, Journal of Health Economics 26 (3), 613–642.

[9] Camejo, RR., McGrath, C., and Herings, R. (2011). A dynamic perspective on pharmaceutical competition, drug development and cost effectiveness. Health Policy, 100(1): 18-24.

[10] Civan, A., & Maloney, M. T. (2007). The Effect of Price on Pharmaceutical R&D. The B.E. Journal of Economic Analysis & Policy, 9(1): 1-14.

[11] Claxton, K. (2007). OFT , VBP : QED ? Health Economics, 558: 545-558.

[12] Congressional Budget Office. (2006). Research and Development in the Pharmaceutical Industry.

[13] Costa-Font, J., McGuire, A. and Stanley, T. (2012). Publication Selection in Health Policy Research. The Winner's Curse Hypothesis. Working paper 25/2012. LSE.

[14] Danzon, P.M., Chao, Li-Wei., (2000). Does regulation drive out competition in the pharmaceutical industry? Journal of Law and Economics 43(2), 311-358.

[15] Danzon, P. M., Y. Wang, et al. (2005). 'The Impact of Price Regulation on the Launch Delay of New Drugs - Evidence from Twenty-Five Major Markets in the 1990s', Health Economics 14, 269-292.

[16] DiMasi, J. a, Hansen, R. W., & Grabowski, H. G. (2003). The price of innovation: new estimates of drug development costs. Journal of Health Economics, 22(2): 151-85.

[17] Dubois, P., DeMouzon, O., Scott-Morton, F. (2011). Market Size and Pharmaceutical Innovation. C.E.P.R. Discussion Papers. Toulouse.

[18] Everson, R. (2003). Patents, R&D and Invention Potential: International Evidence. American Economic Review: Papers and Proceedings, 83: 463-468.

[19] Gerlach, H.A., Ronde, T. and Stahl, K. (2005). Project choice and risk in R&D. Journal of Industrial Economics, 53: 53-81.

[20] Ghislandi, S., (2011). Competition and the Reference Pricing Scheme for pharmaceuticals, Journal of Health Economics, 30, 1137– 1149

[21] Giaccotto, C., Santerre, R. E., Vernon, J. A., Journal, S., & April, N. (2005). Drug prices and Research and Development Behaviour in the Pharmaceutical Industry. Journal of Law and Economics, 48(1): 195-214.

[22] Grabowski, HG. & Vernon, JM. (1992). Brand Loyalty, Entry and Price Competition in Pharmaceuticals after 1984 Drug Act, 35 Journal of Law & Economics 331.

[23] Gyrd-Hansen, D. (2003). Willingness to pay for a QALY. Health Economics, 12(12): 1049-1060

[24] Horowitz, A. W. and Lai, E. L. (1996). Patent Length and the Rate of Innovation. International Economic Review, 37(4): 785-801.

[25] Hughes, J. W., Moore, M. J., & Snyder, E. A. (2002). "Napsterizing Pharmaceuticals: Access, Innovation and Consumer Welfare. Cambridge, MA.

[26] Isaac, R.M., and Reynolds, S. S. (1988). Appropriability and Market Structure in a Stochastic Invention Model Author. The Quarterly Journal of Economics, 103(4): 647-671.

[27] Jensen, E. (1987). Research Expenditures and the Discovery of New Drugs. Journal of Industrial Economics, 36(1), 83-95.

[28] Kyle, M., (2007). 'Pharmaceutical Price Controls and Entry Strategies', The Review of Economics and Statistics 89(1), pp. 88-99.

[29] Lichtenberg, F. R., & Philipson, T. J. (2002). The Dual Effects of Intellectual Property Regulations: Within- and Between-Patent Competition in the U.S. Pharmaceuticals Industry, 45(2): 643-672.

[30] Mason, H., Jones-lee, M., & Donaldson, C. A. M. (2009). Modelling the monetary value of a QALY: a new approach based on UK data. Health Economics, 950(October 2008): 933-950.

[31] McGuire, A., Raikou, M. and Kanavos, P. (2008). Pricing pharmaceuticals: value-based pricing in what sense? Eurohealth Pharmaceutical Policy, 14(2).

[32] Merino, A., (2003). Impact of Reference Price System on the Pharmaceutical Market: A Theoretical Approach. Working Paper Pompeu Fabra.

[33] Miraldo, M., (2009). Reference pricing and firms' pricing strategies. Journal of Health Economics 28, 176–197

[34] Modigliani, F. and Miller, M.H. (1958). The Cost of Capital, Corporation Finance and the Theory of Investment. The American Economic Review, 48(3): 261-297.

[35] Moise, P. and Docteur, E., (2007). Pharmaceutical Pricing and Reimbursement Policies in Sweden, OECD WP 27, OECD, Paris.

[36] Mossialos, E. and Oliver, A., (2005). An overview of pharmaceutical policy in four countries: France, Germany, the Netherlands and the UK, International Journal of Health Planning and Management, 20(4), 291-306

[37] Murphy, K.M. and Topel, R. (1999). The Economic Value of Medical Research. Chicago.

[38] NICE Guide for the Methods of Technology Appraisal, 2008, retrieved from: http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/guidetothemethodsoftechnologyap 19B9-E0B5-D48284D172BD8459 on Sep 01, 2011

[39] Nordhaus, W. D. (1972). The Optimum Life of a Patent : Reply The Optimum Life of a Patent : Reply. The American Economic Review, 62(3): 428-431.

[40] Nordhaus, W. (1969). Invention, Growth and Welfare. Cambridge, Massachusetts: MIT Press.

[41] Office of Health Economics Report. (2007). Sussex, J. and Mestre-Ferrandiz, J., London: Office of Health Economics.

[42] Office of Fair Trading (2007). The Pharmaceutical Price Regulation Scheme: An OFT market study, London: OFT

[43] Pammolli, F., Riccaboni, M., & Magazzini, L. (2010). The productivity crisis in pharmaceutical R & D. Department of Economics. University of Verona.

[44] RAND Health Insurance Experiment. Ringel, J.S., Hosek, S.D., Volhaard, B.A. and Mahnovski, S. (2005). The Elasticity of Demand for Health Care.

[45] Scherer, F. (1972). Nordhaus Theory of Optimal Patent Life : A Geometric Reinterpretation. The American Economic Review, 62(3); 422-427.

[46] Tirole, J., (1988). The Theory of Industrial Organization. MIT Press, New York.

[47] Vernon, J. (2005). Examining the link between price regulation and pharmaceutical R&D investment. Health economics, 14(1); 1-16.

7 Appendix

Consumer Surplus:

$$\begin{aligned} CS(s,p_1,p_2) &= \frac{\rho_1}{r}\left(\frac{1}{2}q_1\right)\left[(a_1-p_1)\left(1-e^{-rs}\right)+\left(a_1-\frac{1}{k}p_1-(1-\frac{1}{k})p_1^g\right)\left(e^{-rs}-e^{-rT}\right)\right] \\ &\quad +u*\left(\frac{\rho_1}{r}mp_1q_1(1-e^{-rs})\right)^v\left(\frac{1}{2}\frac{q_2}{r}\right) \\ &\quad *\left[(a_2-p_2)\left(e^{-r\tau}-e^{-r(\tau+s)}\right)+\left(a_2-\frac{1}{k}p_2-(1-\frac{1}{k})p_2^g\right)\left(e^{-r(\tau+s)}-e^{-r(\tau+T)}\right)\right] \quad (7) \end{aligned}$$

Simplified expressions of consumer surplus:

$$CS(1) = \frac{1}{r}\left(\frac{1}{2}q_1\right)\left[(a_1-p_1)\left(1-e^{-rs}\right)+\left(a_1-\frac{1}{k}p_1-(1-\frac{1}{k})p_1^g\right)\left(e^{-rs}-e^{-rT}\right)\right] \quad (8)$$

$$CS(2) = \left(\frac{1}{2}\frac{q_2}{r}\right)\left[(a_2-p_2)\left(e^{-r\tau}-e^{-r(\tau+s)}\right)+\left(a_2-\frac{1}{k}p_2-(1-\frac{1}{k})p_2^g\right)\left(e^{-r(\tau+s)}-e^{-r(\tau+T)}\right)\right] \quad (9)$$

Derivative of consumer surplus with respect to price:

$$\begin{aligned} \frac{\partial CS(s,p_1,p_2)}{\partial p_1} &= -\tfrac{\rho_1}{r}\left[q_1\left(1-e^{-rs}\right)+\tfrac{1}{2}\left(\tfrac{1}{k}q_1+\tfrac{1}{b}(a_1-\tfrac{1}{k}p_1-(1-\tfrac{1}{k})p_1^g)\right)\left(e^{-rs}-e^{-rT}\right)\right] \\ &\quad +uv\left(\tfrac{\rho_1}{r}mp_1q_1(1-e^{-rs})\right)^{(v-1)}\left(\tfrac{\rho_1}{r}m(q_1-\tfrac{p_1}{b_1})(1-e^{-rs})\right)*K_1 \\ \iff \frac{\partial CS(s,p_1,p_2)}{\partial p_1} &= \overbrace{-\frac{\rho_1}{r}\left[\overbrace{q_1\left(1-e^{-rs}\right)}^{+}+\frac{1}{2}\left(\frac{1}{k}q_1+\frac{1}{b_1}\overbrace{(a_1-\frac{1}{k}p_1-(1-\frac{1}{k})p_1^g)}^{+^{a)}}\right)\left(e^{-rs}-e^{-rT}\right)\right]}^{-} \\ &\quad \overbrace{+uv\left(\frac{\rho_1}{r}mp_1q_1(1-e^{-rs})\right)^{(v-1)}}^{+}\overbrace{\frac{\rho_1}{r}m\left(\frac{a_1-2p_1}{b_1}\right)(1-e^{-rs})}^{+^{b)}}\overbrace{*K_1}^{+} \quad (10) \end{aligned}$$

where $K_1=\frac{q_2}{2r}\left[(a_2-p_2)\left(e^{-r\tau}-e^{-r(\tau+s)}\right)+\left(a_2-\frac{1}{k}p_2-(1-\frac{1}{k})p_2^g\right)\left(e^{-r(\tau+s)}-e^{-r(\tau+T)}\right)\right]>0$

a) As long as: $a_1 > \frac{1}{k}p_1 + (1-\frac{1}{k})p_1^g \Leftrightarrow p_1 < k * \left(a_1 - (1-\frac{1}{k})p_1^g\right)$
b) As long as: $a_1 - 2p_1 > 0 \Leftrightarrow p_1 < \frac{1}{2}a_1$
Derivative of consumer surplus with respect to patent length:

$$\begin{aligned}\frac{\partial CS(s,p_1,p_2)}{\partial s} &= \overbrace{-\rho_1\left(\frac{1}{2}q_1\right)(1-\frac{1}{k})(p_1-p_1^g)\left(e^{-rs}\right)}^{-} \\ &\quad \overbrace{+\rho_1 uvmp_1q_1(e^{-rs})\left(\frac{\rho_1}{r}mp_1q_1(1-e^{-rs})\right)^{(v-1)} * K_1}^{+} \\ &\quad \overbrace{-u\left(\frac{\rho_1}{r}mp_1q_1(1-e^{-rs})\right)^{v} * q_2(1-\frac{1}{k})(p_2-p_2^g)\left(e^{-r(\tau+s)}\right)}^{-} \end{aligned} \quad (11)$$

Producer surplus:

$$\begin{aligned}PS(s,p_1,p_2) &= \frac{\rho_1 q_1}{r}\left[(p_1-mc_1)(1-e^{-rs}) + \left(\frac{1}{k}p_1 + (1-\frac{1}{k})p_1^g - mc_1\right)\left(e^{-rs}-e^{-rT}\right)\right] - R_1 \\ &\quad + u * \left(\frac{\rho_1}{r}mp_1q_1(1-e^{-rs})\right)^{v} * \frac{q_2}{r}\left[(p_2-mc_2)\left(e^{-r\tau}-e^{-r(\tau+s)}\right)\right. \\ &\quad \left. + \left(\frac{1}{k}p_2 + (1-\frac{1}{k})p_2^g - mc_2\right)\left(e^{-r(\tau+s)}-e^{-r(\tau+T)}\right)\right] - \frac{\rho_1}{r}mp_1q_1(1-e^{-rs}) \end{aligned} \quad (12)$$

Simplified expressions of producer surplus:

$$PS(1) = \frac{q_1}{r}\left[(p_1-mc_1)(1-e^{-rs}) + \left(\frac{1}{k}p_1 + (1-\frac{1}{k})p_1^g - mc_1\right)\left(e^{-rs}-e^{-rT}\right)\right] \quad (13)$$

$$PS(2) = \frac{q_2}{r}\left[(p_2-mc_2)\left(e^{-r\tau}-e^{-r(\tau+s)}\right) + \left(\frac{1}{k}p_2 + (1-\frac{1}{k})p_2^g - mc_2\right)\left(e^{-r(\tau+s)}-e^{-r(\tau+T)}\right)\right] \quad (14)$$

Derivative of producer surplus with respect to price:

$$\begin{aligned}
\frac{\partial PS(s,p_1,p_2)}{\partial p_1} &= \frac{\rho_1}{r}\frac{1}{b_1}\left[(a_1-2p_1+mc_1)(1-e^{-rs})+\left(\frac{1}{k}a_1-\frac{2}{k}p_1-(1-\frac{1}{k})p_1^g+mc_1\right)\left(e^{-rs}-e^{-rT}\right)\right] \\
&\quad +uv\left(\frac{\rho_1}{r}mp_1q_1(1-e^{-rs})\right)^{(v-1)}\frac{\rho_1}{r}m(q_1-\frac{p_1}{b_1})(1-e^{-rs})*K_2 \\
&\quad -\frac{\rho_1}{r}m(q_1-\frac{p_1}{b_1})(1-e^{-rs}) \\
\Longleftrightarrow \frac{\partial PS(s,p_1,p_2)}{\partial p_1} &= \frac{\rho_1}{r}\left[\overbrace{\left(q_1-\frac{(p_1-mc_1)}{b_1}\right)(1-e^{-rs})}^{+^{c)}}+\overbrace{\left(\frac{1}{k}q_1-\frac{1}{b}\left(\frac{1}{k}p_1+(1-\frac{1}{k})p_1^g-mc_1\right)\right)\left(e^{-rs}-e^{-rT}\right)}^{+^{d)}}\right] \\
&\quad \overbrace{+uv\left(\frac{\rho_1}{r}mp_1q_1(1-e^{-rs})\right)^{(v-1)}\frac{\rho_1}{r}m\left(\frac{a_1-2p_1}{b_1}\right)(1-e^{-rs})}^{+}\overbrace{}^{+^{b)}} \\
&\quad *K_2\overbrace{-\frac{\rho_1}{r}m(q_1-\frac{p_1}{b_1})(1-e^{-rs})}^{-}
\end{aligned} \tag{15}$$

where $K_2=q_2\left[(p_2-mc_2)\left(e^{-r\tau}-e^{-r(s+\tau)}\right)+(\frac{1}{k}p_2+(1-\frac{1}{k})p_2^g-mc_2)\left(e^{-r(\tau+s)}-e^{-r(\tau+T)}\right)\right]>0$

c) As long as: $q_1-\frac{(p_1-mc_1)}{b_1}>0\Leftrightarrow\frac{(a_1-p_1)}{b_1}>\frac{(p_1-mc_1)}{b_1}\Leftrightarrow p_1<\frac{1}{2}(a_1+mc_1)$

d) As long as:

$$\frac{1}{k}q_1>\frac{1}{b}\left(\frac{1}{k}p_1+(1-\frac{1}{k})p_1^g-mc_1\right)\Leftrightarrow\frac{1}{k}(a_1-p_1)>\left(\frac{1}{k}p_1+(1-\frac{1}{k})p_1^g-mc_1\right)\Leftrightarrow p_1<\frac{1}{2}\left(a_1+mc_1-(k-1)p_1^g\right)$$

b) As long as: $a_1-2p_1>0\Leftrightarrow p_1<\frac{1}{2}a_1$

Derivative of producer surplus with respect to patent length:

$$\begin{aligned}
\frac{\partial PS(s,p_1,p_2)}{\partial s} &= \overbrace{\rho_1q_1(1-\frac{1}{k})(p_1-p_1^g)(1-\frac{1}{k})e^{-rs}}^{+} \\
&\quad \overbrace{+\rho_1uvmp_1q_1(e^{-rs})\left(\frac{\rho_1}{r}mp_1q_1(1-e^{-rs})\right)^{(v-1)}*K_2}^{+} \\
&\quad \overbrace{+u\left(\frac{\rho_1}{r}mp_1q_1(1-e^{-rs})\right)^{v}*q_2(1-\frac{1}{k})(p_2-p_2^g)\left(e^{-r(\tau+s)}\right)}^{+}\overbrace{-\rho_1mp_1q_1\left(e^{-rs}\right)}^{-}
\end{aligned} \tag{16}$$