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Patent Purchase as a Policy for Pharmaceuticals *

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Abstract

We often observe that when the first of a new class of drug is patented it does not halt the development of further drugs of the same class resulting in a number of drugs with similar efficacy and price well above production costs. We construct a life-cycle analysis of the welfare gains from a policy for pharmaceutical patenting where society grants and purchases the patent of the first of a new class of drug (instead of purchasing the drug), awarding no further patents to runner-up drugs, and producing or licensing production with price set to maximise welfare subject to covering costs. We show that under such a policy society could substantially reduce the cost of duplicated R&D and the price of the drug benefiting more patients and producing large health gains. The results are generated based upon a number of stylised facts regarding R&D in the pharmaceutical industry.

Keywords: Patent Purchase; Pharmaceuticals; Life-Cycle; Welfare
JEL classification: D4; L5; O3

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1 Introduction

This paper considers the idea of a patenting policy in the pharmaceutical industry under which society grants and buys the patent of the first of a new class of drug, instead of purchasing the drug, and awards no further patents to runner-up drugs. Society then produces or licenses production with price set to achieve some objective e.g. maximising welfare subject to covering costs.[1] The paper shows, within a drug life-cycle framework, that the proposed approach can yield welfare improvements over what we stylise as current practice.

To give some context, consider PCSK9, an enzyme which plays a role in the production of cholesterol. Blocking it may reduce cholesterol, which is what has led several pharmaceutical companies to invest in the development of PCSK9 blockers. It is expected that within 5 to 10 years there may be three products on the market. The first of these (if successful) will show an unprecedented decrease in cholesterol, and be priced at a premium, say £2,000 a year per patient. The second and third products will have marginal differences in efficacy from the first, and will be priced similarly. At this price, it is likely that not all individuals who may benefit will be treated, because it is not cost effective. So, for example, only high risk patients will be treated. This is a pattern observed across numerous classes of drugs. However, the price may well be much higher than the production costs. If so, by buying the patent and producing the drug (or licensing production under a set price and recouping revenues with a per unit fee), the drug can be sold at or, at least nearer, the marginal cost of production and hence benefit more patients from it yielding larger health gains.

In brief, the gains associated with this policy come from avoiding cost-duplication from rival firms seeking to achieve follow-up patents but also because, after the winning firm has been compensated and the patent purchased, the price that can be charged to cover the associated costs is lower than would prevail in the market subsequent to the awarding of a runner-up rival patent. In the main, the focus of this paper is upon the gains in welfare that can be achieved via the patent purchase policy looking only at life-cycle of a single drug and therefore

[1] Whilst we employ a break-even constraint in this paper this is only illustrative and in practice society may wish to actively subsidise R&D as we discuss later.

taking a strictly partial equilibrium approach which ignores other benefits from the policy in terms of new drug development outside this drug's life-cycle. In this partial equilibrium (one-shot) setting we show that under the patent purchase policy, social welfare is increased, the winner is fully compensated, but the runner-up firm incurs losses. Whilst we later show that the loses to the runner-up firm may be very small under the patent purchase policy, we also consider a break-even compensation rule under which, with repeated plays of the game (applying the patent purchase policy over a number of drug life-cycles), firms' expected profits are unchanged with the introduction of the new patent policy but significant welfare gains can still be achieved. The results are generated based upon a number of stylised facts regarding R&D in the pharmaceutical industry which are discussed in Section 2.

Patent "buyouts", which involve the government buying the patent from the innovating firm and placing it in the public domain, effectively replace Intellectual Property (IP) protection and associated profits with a prize for the innovator (in this paper the prize is a stream of income related to sales per period). By placing the innovation in the public domain the government achieves, in theory, the eradication of monopoly price distortions as well as the disincentivisation of duplicative research efforts. The idea of patent buyouts is not a new one (e.g. the Daguerreotype photography patent was subject to a buyout by the French government in 1839) and the arguments relating to their potential benefits have been documented for some time (e.g. Marshall, 1890; Wright, 1983). Yet patent buyouts have so far failed to become an established policy option for governments. So what are the practical barriers to the implementation of patent buyouts? In addition to the obvious issue of funding the operational and organisational costs of patent buyouts there are important considerations about which patents to buyout and how much to compensate the innovator. On both the "which" and "how much" questions there exist possible difficulties about identifying the value (private and social) of innovations as well as possible distortive rent seeking and lobbying concerns. These are informational considerations arising where the innovator has ex post private information (i.e. in the case of drugs, their efficacy). Indeed, Weyl and Tirole (2012, pp. 1972) draw the following conclusion: 'Despite the extensive theoretical and policy interest in ... the prize

system, many consider it simply impractical. Yet it is hard to see what, other than informational asymmetries, could be the source of such "impracticality."' Their paper focusses on the importance of the screening benefit of market power in revealing the value of an innovation when the innovator has (multidimensional) ex post private information. This follows the line of reasoning expounded by Smith (1762) that market-driven rewards help elicit which opportunities justify the associated development costs. Whilst the prize system yields benefits in terms of avoiding monopoly price distortions associated with *IP*, the downside is that if the pricing mechanism is not market-based then it may be difficult for the government to value and select the most worthy innovations. However, the value of screening diminishes as the extent of ex post private information about the value of the innovation falls. Weyl and Tirole (2012) make the distinction, for instance, between (i) pharmaceutical drug innovations, and (ii) high-tech products such as software and tablet computers, with the former generally being more suitable for prize-based rewards and the latter tending more towards requiring market-based screening. With pharmaceutical innovations it is reasonable to argue that private information of the innovator is typically reduced considerably by clinical trials (which are required for the drug to be registered). With new high-tech products, on the other hand, it is often very difficult to determine value until this has been revealed through the market.

Weyl and Tirole (2012) are not alone in identifying that conditions in the pharmaceutical industry lend it particularly well to the buyout model. Kremer (1998), who advocates an auction-based pricing system for valuing pharmaceutical innovations in a buyout regime, argues that the high mark-ups and low, and typically homogenous, production costs of a drug placed in the public domain are likely to result in large gains from buyouts in the pharmaceutical sector. On the one hand, low levels of private information associated with pharmaceutical innovations reduce the costs of identifying and valuing the innovation and therefore operating an effective buyout regime.[2] On the other hand, the high mark-ups and low and homogenous production

[2]Drug development has many phases which starts at the conceptual pre clinical phase followed by a series of research with human subjects across phase I, phase II and phase III and sometimes phase IV clinical trials. Phase I trials assess safety in healthy volunteers, Phase II are typically designed to identify the optimal dose, to confirm safety and form initial figures on efficacy, and phase III studies are largely to further assess safety and efficacy. Phase IV trials are often designed to observe efficacy in practice. Most often, the results from each phase are published and competitors know how far their rivals are in the development process. Moreover,

costs suggest large end-user gains from the buyout relative to *IP*. Low costs and high rewards increase the likelihood that buyouts in the pharmaceutical sector will be cost effective and may well generate large net benefits. It is not surprising, therefore, that the buyout model for pharmaceutical innovations has attracted particular support in the literature (e.g., Kremer, 1998, 2000a,b; Hollis, 2004). Indeed, Guell and Fischbaum (1995)[3] attempt to place an estimate on the welfare gains from buyouts in the US pharmaceutical sector. Based on static Harberger (1954) dead-weight loss triangle arguments they arrive at a low-end estimate of $3bn, whilst an upper-end estimate of $30bn is achieved by including rent seeking (marketing). They argue that in the low-end scenario the benefits are in line with the costs of implementing the regime, hence for most of the range of estimates, the buyout policy is cost-effective, at the top end very heavily so.

In this paper we seek to address the issue of the potential welfare gains from patent buyouts in the pharmaceutical sector from a partial equilibrium drug life-cycle perspective. Most of the existing literature has sought to examine the welfare gains based on the static price distortion under an *IP* approach and/or the rent seeking associated with marketing expenditures (e.g. Guell and Fischbaum, 1995; Guell, 1997; Guell and Fischbaum, 1997). However, we are interested in understanding how a patent purchase policy will impact on costs and benefits from the development stage of a drug through to its obsolescence, which necessarily captures additional benefits such as the avoidance of duplicatory R&D. Much of the literature on pharmaceutical R&D has concerned pricing mechanisms, in particular, to bring about efficient R&D investment (see, Gravelle, 1998; Kremer, 1998), which often involve subsidies from taxation. However, in the current paper we are not concerned so much with finding an optimal pricing rule as identifying scope for welfare gains largely treating the rate of R&D investment as a constant without the need for subsidies and without necessarily harming expected profits. By showing that the welfare gains under these circumstances are potentially very large with large gains robust to the relaxation of some of our simplifying assumptions, it leaves open the possibility to pursue

new trials are publicly announced and details are published. This is for example the case for the new PKC-9 inhibitors which include evolocumab, bocozizumab, and alirocumab.

[3]See also Guell (1997); Guell and Fischbaum (1997).

further welfare gains not captured in our analysis, such as through an optimal pricing rule with endogenous R&D and subsidies.

In the following Section we introduce and analyse a simple three-period drug life-cycle model under policy A (representing current practice) and the patent purchase policy B under various pricing scenarios. In Section 3, we carry out a simulation exercise to see what sort of gains in welfare are available under policy B relative to policy A for different hypothetical parameterisations of the basic model. In Section 4 we seek to understand the implications for our earlier analysis of addressing potentially important issues that were assumed away within the basic model including rent seeking/marketing, horizontal differentiation and general equilibrium considerations. Section 5 concludes the paper and identifies issues for future investigation.

2 Simple Model

In this section we outline a simple framework for illustrating the possible sources of welfare gains arising from the implementation of the new patent purchase policy proposal in the context of the pharmaceutical industry over a one-shot drug life-cycle under some stylised assumptions.[4]

The game has three players (in addition to Nature): a welfare maximising World Government, WG, and two profit-maximising multinational pharmaceutical companies, F_i ($i \in \{1, 2\}$). We assume that WG is the only government in the jurisdiction that these firms are operating in. In reality, many firms operate across multiple jurisdictions, so one way to interpret this model would be to think of this government as a "world government" with the exclusive authority to control the patenting of pharmaceuticals globally. All players are risk neutral. The game is one of complete and full information.[5] For simplicity there are no production costs and there is no

[4]The concept of "patent" used in this paper has elements of both the patent and the licence in actual drug policy. Patents for medicines are usually applied for and awarded early on during the R&D process, long before the product is licensed with a marking authorisation. Because the typical licence is applied for after the completion of the R&D process, the "patent" in this paper may appear similar to these. However, since licences can be awarded to more than one drug to cover a given medical need, a licence does not give the producer any exclusive right. The paper does not address the case of multiple indications.

[5]So, all three players know: everybody else's objective function; what moves they have made; if either firm has won; and the quality of the drug. But of course nobody knows who will be assigned by Nature to complete the drug first.

discounting.

Assumption 1. *Patent policy is set by a World Government (WG).*

WG has action set $\{A, B\}$. Policy A is what we stylise as the *Laissez Faire* case where (i) all successful innovations are awarded patents and (ii) firms are free to set prices. We will later refine this scenario. Policy B is the *Patent Purchase* case in which (i) a patent is awarded only to the winning firm, (ii) the winning firm's patent is purchased by the WG, (iii) the "prize" for the winning firm is paid on a "pay-as-you-go" basis in line with sales, (iv) the patented drug is priced to maximise social welfare subject to covering the compensation to the winning firm with WG producing the drug or licensing production and recouping the revenue. We will consider various forms of compensation for the winning firm but it is important to note that unlike other studies in this area we are not concerned with finding a single welfare maximising compensation rule. Rather we are concerned with showing there are a range of possible ways of compensating firms under policy B which are consistent with non-trivial welfare improvement and, most importantly, taking into account a partial equilibrium life-cycle (excluding wider welfare benefits) view of costs and benefits associated with the drug. In practice, the WG will have in mind some overall maximising objective and on a case-by-case basis will compare the merits of policy A and B in best achieving this - it is not intended that patent purchase be applied automatically to all new drugs.

The game is played over three time periods with each period lasting T_k ($k \in \{1, 2, 3\}$). The length of each period is assumed to be exogenously determined, which may seem unrealistic as we move between policy A and B: we return to this issue in the final discussion, Section 4. In the first period two firms compete to develop a new drug, X, each incurring an R&D cost of c per unit time.

Assumption 2. *Firm cost per unit time for R&D expenditures, c, is constant and determined exogenously.*

This assumption is based on the "stylised fact" that pharmaceutical firms invest in R&D at a fixed rate per period representing maximum capacity. Given Assumption 2 each firm incurs

an R&D cost of cT_1 for period 1. At the end of period 1 Nature determines which firm wins the race with firm i winning with probability $\frac{1}{2}$.[6,7] Hence, period 1 ends when one of the firms succeeds with the development of X and is awarded a patent.[8] For convenience we label the winning firm, w, and the laggard or runner-up firm, r.[9] Under the *Laisse Faire* policy, A, the winning firm enjoys a monopoly for the duration of period 2, whilst the laggard firm, should they continue to undertake R&D in an attempt to develop the new drug, continues to incur the cost c per unit time. Period 2 under policy A ends when the laggard firm is successful in developing the new drug X and is awarded a patent.[10] Under policy A in period 3 the two firms co-exist as suppliers in the market for the new drug. Period 3 ends when the new drug becomes obsolete due to the development of (the first of) a new class of drug, $X+$, ending the life-cycle of drug X.[11]

[6]We explicitly rule out the possibility of the race being tied. After all, if two firms apply for a patent at the same time WG can select that which is most promising based upon the trials data. We later consider the possibility that the probability of winning may tend over period 1, through the random research process, to favour one firm and the implications of this for the incentives at play and consequent gains to policy B over policy A.

[7]Within this framework one may question whether large companies have an advantage over smaller companies and as such that there are different probabilities of winning from the outset depending on size. In reality one sees many small companies come out as winners in the development process such as Gilead with their hepatitis C drug and Celgene with their blood cancer drug. One may also refer to a number of biotechnology companies who have been successful in beating "big Pharma" such as in the launch of new products (e.g. Centocor with Centoxin and ReoPro). The advantages of "big Pharma" may be more prevalent after launch, with significant economies of scale when introducing a new agent to the market which explains why Centocor is now part of Johnson & Johnson. Alternatively one may refer to the rise of Celgene, now a global company, who entered the market only 30 years ago and who made a number of acquisitions of even smaller companies on their way to their current size.

[8]In practice, the success of drug development is not reached at one specific point in time - there are a number of incremental milestones to clear. Indeed, important and non-trivial R&D and dissemination efforts often take place after a patent has been awarded - however, in our model we let all relevant R&D and dissemination costs be included under T_1 for the winning firm. Hence we are imposing an artificial on/off concept of drug development. At any point in time during (except at the end of period 1) both firms have no finished product $\{0, 0\}$, and then at the end of T_1 it is $\{1, 0\}$.

[9]Runner-up or laggard firm drugs are also called "me-too".

[10]As with the winning firm, the end of the research period for the laggard firm includes all relevant R&D, some of which in practice occurs after the patent is awarded.

[11]This is a simplifying assumption, since the winning firm's patent could expire before obsolescence. However, we rule out the inclusion of a further period, T_4, which would arise under these circumstances on the basis that it adds insufficient additional insight to justify the additional modelling considerations. First, the outcome in period T_4 under our modelling assumptions would likely be very similar under policies A and B. Once the winning firm's patent expires, which happens at the same time under policy A and B (as does the obsolescence of X by assumption), the only difference between policy A and B is that under the former there is a laggard firm with a "live" patent for its version of drug X. However, this is not likely to be of any consequence for the market for X as new entrants can freely use the winning firm's technology which is no longer protected by a "live" patent under either policy A or B and so the incentives to enter and their impact on market price are unlikely to differ in T_4 under policy A relative to B. Second, the relevant patent period is 20 years, and

Assumption 3. *Under policy A in period* 3 *the laggard firm adopts the prevailing "catalogue" price for drug X, set by the winning firm in period* 2*, upon joining the market.*

Assumption 3 removes any price competition in the market for the new drug under policy A with firms implicitly colluding to maintain the prevailing *monopoly* price. Although this is a strong assumption, we argue that it might not be too irregular in the pharmaceutical industry. Weak price competition in the context of pharmaceuticals has been recognised as a symptom of the special nature of the industry, where often the end users (the patients) are not the ones either paying for the treatments or making choices about treatment selection (e.g., DiMasi and Paquette, 2004; Lee, 2004). Further support for this argument regarding weak price competition is provided by evidence that, typically, drugs offering "little or no therapeutic gain" were introduced in the U.S. at prices in line with existing drugs in the U.S. and roughly double the price of existing drugs in Sweden (see Lu and Comanor, 1998; Ekelund and Persson, 2003). Indeed, the sequential nature of the arrival of firms in the market lends some support to the idea of the adoption of the prevailing price - whereby the prevailing price acts as a focal point for the laggard firm. Also, many countries, such as the Netherlands, have reimbursement limits for classes of drugs. Whenever a new drug comes available within such a class, they get reimbursed against the same price as the first within that class. Finally, a common line of argument in the pharmaceutical industry is that firms spend heavily on advertising to differentiate their brand (we return to this issue in Section 4), where in reality the differences between rival drugs are often minimal, which can weaken price competition. In practice, one finds drugs which are called "first in class": these are the winners in the typical situation which is modelled here. One might call Simvastatin the "first in class" of the statins in the sense that it was the first to show effects on the incidence of myocardial infarction and survival, which resulted in a major advantage over other statins and giving them an enormous boost in sales. Later stains, which showed similar effects, such as Pravastatin, were priced in the same bracket as Simvastatin,

although we assume a zero discount rate for simplicity, in practice any differences between the two policies, which are already likely to be small, are going to be further diminished by time. (The issue of patent length was put in the agenda for international debate in the Uruguay round (1986-94) initiated by the Dunkel Draft (see Chowdhry and Aggarwal, 1994). The Dunkel Draft proposed a patent period of 20 years for both the process and the product directly obtained through the process. This was finally accepted in the Final Act of 1994.)

did not try to compete on price. Other products like Atorvastatin, which entered the market with evidence that it could lower cholesterol more effectively but no data on survival, was also priced on parity. Another example is Infliximab - first in class of the anti TNF-α drugs to treat rheumatoid arthritis. Later agents such as adalimumab and golimumab were priced similarly, if not higher, claiming slightly better efficacy. The so-called new oral anticoagulants rivaroxaban, apixaban and dabigatran, which have efficacy in stroke prevention, atrial defibrillation and acute coronary syndrome, provide a further example. Again one finds similar prices for all three agents and the idea that these drugs are interchangeable is confirmed by a recent meta-analysis pooling those drugs - and not treating them as unique entities - against warfarin.

The story under the patent purchase policy, B, departs from that outlined under policy A, above, in two important ways. First, at the end of period 1, the winning firm's drug is patented and the patent is purchased by WG but the laggard firm has no incentive to continue its R&D effort towards the development of drug X, since it will not be able to have its drug patented and gain any associated reward. Recalling that firms incur constant cost per unit time for R&D effort, once the new drug has been developed by the winning firm, these R&D expenditures are diverted to the development of other drugs or towards making X obsolete which we assume is not achieved by building on R&D to improve upon X marginally - in the sense that a firm has to first develop its own version of X before moving to discover $X+$.[12] Hence in relation to the costs and benefits associated with the development and consumption of drug X, under policy B there are no period 2 R&D costs. (Whilst we will return to this issue in our later discussion in Section 4, the formal model is concerned only with partial equilibrium costs and benefits relating directly to the development and consumption - in the life-cycle - of the drug, X.) Second, under policy B, whilst the winning firm's drug is now the sole drug on the market

[12]This may not be such an extreme assumption especially in the context of the pharmaceutical industry. First, with the granting of the winning firm's patent comes the disclosure of the details of the new technology - this is in the public domain and available for all firms as a basis for beginning any sequential efforts towards discovering drug $X+$ which makes X obsolete. Second, whilst this is true of all patents, in the pharmaceutical industry a significant proportion of the R&D time and cost associated with drug development is devoted to clinical trials. Unless the laggard firm's trials elicit new information towards the development of $X+$ during T_2 then both arguments suggest there will be resource gains from ceasing laggard R&D efforts towards its own "discovery" of X. In the case that any laggard's trials in T_1 suggest they might be close to discovering $X+$ this can be picked up by the WG or raised with them by the laggard and taken into consideration before the winning firm's drug X is patented and patent purchase policy B applied.

for both periods 2 and 3, the price is determined by WG rather than the winning firm.[13]

Having outlined the policy options available to WG in this paper we now set out the costs and rewards of the game. We adopt a simple quasi-linear (justifying a partial equilibrium analysis) quadratic utility function:

$$U(x, I) = \frac{\alpha}{\beta}x - \frac{1}{2\beta}x^2 + I, \tag{1}$$

where x is the quantity of the new drug X, I represents expenditure on 'other' goods and $\alpha, \beta > 0$. Throughout the paper, we will be interested in drawing welfare conclusions. Welfare is the sum of profit and consumer surplus at a given set of prices. Given the utility function is quasi-linear, consumer surplus, CS, is a valid measure of welfare, where $CS(x, I) = U(x, I) - R(x) - I$ and $R(x)$ is firm revenue. Welfare, W, is therefore $W = CS + R(x) - TC$, where TC is total costs across the firms, hence :

$$W(x, I, TC) = U(x, I) - TC - I \tag{2}$$

Given income M, maximising utility Eq. (1) subject to the budget constraint $xp + I \leq M$, where p is the price of drug X, yields the familiar linear demand function:

$$x = \alpha - \beta p \tag{3}$$

where α and β are positive constants determining the quantity intercept and slope of the demand curve, respectively.

To summarise, our analysis takes place in a stylised setting with constant R&D expen-

[13]Whilst under policy B, there is no material difference between what happens in periods 2 and 3 now that there is no laggard working to catch up and then co-exist in the market with the winner, it is still necessary to include both periods in the analysis as it is the sum of these periods that represents the total time over which revenues from the sale of drug X are received. Under policy B, period 2 ends when the runner-up firm would have successfully developed its own drug X had policy A been in place. The end of period 3 (i.e. the arrival of the "next" drug $X+$ that makes X obsolete) is assumed to happen at the same time regardless of policy A or B. Of course, in practice under policy B given that the laggard's efforts are now diverted from wasteful duplication to rediscover X, it might be expected to speed up the discovery of $X+$ some entirely unrelated new class of drug, Y. We return to this important point in Section 4.

diture per unit time, a world government, an on/off conceptualisation of drug development with exogenous life cycle periods, fully wasteful laggard period 2 R&D towards developing X, "pay-as-you-go" policy B prize payments tied to sales on a revenue-neutral basis, no price competition, zero discounting and zero production costs. Some of these assumptions we believe have some basis in the pharmaceutical sector as we have explained above, whilst others are simplifying assumptions for modelling expedience. Finally, from Eq. (3), drug X is effectively an homogeneous good whether it is produced by firm 1 or firm 2 (any differences that may exist between the two firms' drugs are insignificant in the eyes of the purchaser of drugs - who may not be the end user). This latter modelling assumption may at first seem odd, since in this game both firms require their technologies to be patented in order to enter the market and two firms should not be able to simultaneously hold patients for the same drug. However, for some time now it has been recognised that the issuing of low quality patents (those where the innovation does not meet the Patent Office's statutory patentability requirements, including novelty) is not uncommon. With Patent Offices often overloaded with patent applications there is inadequate resource for proper consideration of the application and thorough search of prior art (see for instance, Shapiro, 2000; Bessen and Maskin, 2007). The assumption also fits well with a common perception of the pharmaceutical industry, that runner up drugs often show very little meaningful improvement on the winning drug (e.g. Lee, 2004).

Beginning with policy A, having incurred R&D costs of cT_1, the winning firm enjoys a monopoly for the duration of period 2. Assuming away production costs, profit per unit time in period 2 is given by $\pi = (\alpha - \beta p)p$. Maximising profit with respect to price yields the monopoly price, $p^m = \frac{\alpha}{2\beta}$, and profit per unit time, $\pi^m = \frac{\alpha^2}{4\beta}$. For simplicity there is no time discounting and the competitive rate of return is assumed to be zero. The costs, revenues and welfare incurred in each time period under policy A are set out in Table 1(a).

Under Policy A the winning firm sets price p^m in period 2 and this is adopted by the laggard in period 3, hence profit over the life cycle of drug X for the winner (w) and laggard (r), with

Table 1: Profit and welfare by time period T_k ($k \in \{1,2,3\}$) under policy A and policy B with full and maximal compensation

		Period		
		T_1	T_2	T_3
(a)	Policy A			
	$\pi_w^A(k)$	$-cT_1$	$\frac{\alpha^2}{4\beta}T_2$	$\frac{\alpha^2}{8\beta}T_3$
	$\pi_r^A(k)$	$-cT_1$	$-cT_2$	$\frac{\alpha^2}{8\beta}T_3$
	$W^A(k)$	$-2cT_1$	$\left[\frac{3\alpha^2}{8\beta} - c\right]T_2$	$\frac{3\alpha^2}{8\beta}T_3$
(b)	Policy B_f			
	$\pi_{fw}^B(k)$	$-cT_1$	$\frac{\alpha^2}{4\beta}T_2$	$\frac{\alpha^2}{8\beta}T_3$
	$\pi_{fr}^B(k)$	$-cT_1$	0	0
	$W_f^B(k)$	$-2cT_1$	$\frac{\alpha^2}{8\beta}\Omega_f\{4-\Omega_f\}T_2$	$\frac{\alpha^2}{8\beta}\Omega_f\{4-\Omega_f\}T_3$
(c)	Policy B_{max}			
	$\pi_{max,w}^B(k)$	$-cT_1$	$\frac{1}{4}\left[\frac{\alpha^2}{\beta} - \frac{cT_2}{(T_2+T_3)}\right]T_2$	$\frac{1}{4}\left[\frac{\alpha^2}{\beta} - \frac{cT_2}{(T_2+T_3)}\right]T_3$
	$\pi_{max,r}^B(k)$	$-cT_1$	0	0
	$W_{max}^B(k)$	$-2cT_1$	$\frac{\Omega_{max}}{2\beta}\left[\alpha - \frac{\Omega_{max}}{4}\right]T_2$	$\frac{\Omega_{max}}{2\beta}\left[\alpha - \frac{\Omega_{max}}{4}\right]T_3$

Key: $\Omega_f \equiv \left[1 + \left(\frac{T_3}{2(T_2+T_3)}\right)^{0.5}\right]$; $\Omega_{max} \equiv \left[\alpha + \beta\left(\frac{cT_2}{\beta(T_2+T_3)}\right)^{0.5}\right]$

profits in period 3 shared evenly, are, respectively:

$$\pi_w^A = \frac{\alpha^2}{8\beta}[2T_2 + T_3] - cT_1, \quad \pi_r^A = \frac{\alpha^2}{8\beta}T_3 - c[T_1 + T_2] \tag{4}$$

Aggregate profit, consumer surplus and welfare under Policy A are then, respectively:

$$\pi^A = \frac{\alpha^2}{4\beta}[T_2 + T_3] - c[2T_1 + T_2], \quad CS^A = \frac{\alpha^2}{8\beta}(T_2 + T_3), \quad W^A = \frac{3\alpha^2}{8\beta}(T_2 + T_3) - c[2T_1 + T_2] \tag{5}$$

Lemma 1. *(i) Under Policy A, having sunk cT_1 in the first period of the patent race for X, the losing firm will only continue R&D towards developing X in period 2 if:*

$$\frac{\alpha^2}{8\beta}T_3 > cT_2 \tag{6}$$

(ii) Further, if policy A is to be sustainable over time, it must be the case that the expected aggregate profit, π^A, be non-negative, hence:

$$T_1 \leq \frac{\alpha^2}{8c\beta}[T_2 + T_3] - \frac{1}{2}T_2 \tag{7}$$

For our analysis comparing the costs and benefits under policy A and B to be valid, we require both conditions in Lemma 1 to hold.

Turning to policy B, in order to determine the levels and distribution of surpluses across firms and consumers it is necessary to specify the rules governing the compensation to the winning firm and the pricing strategy of WG. Regarding the latter, we assume a budget neutral policy so that the revenue from the sale of the drug by WG exactly pays for the compensation to the winning firm: there are no transfers from elsewhere in the economy to run policy B.[14]

Regarding compensation, we begin with a rule which we label "*full*" compensation, C_f. We label policy B with this compensation rule, B_f. This rule is not cost-based (its implementation requires only information about what the monopoly price would have been) and seeks to fully compensate the winner in the one-shot patent race for X (this compensation leaves the winner with exactly the same overall reward under policy B that they would have gained as the winner under policy A):

$$C_f \equiv \frac{\alpha^2}{8\beta}[2T_2 + T_3] \tag{8}$$

Under this compensation rule the *expected* profit of a firm beginning the one-shot game is lower than under policy A. However, the expected profit for a firm approaches that under policy A from below as the probability of winning increases from $\frac{1}{2}$ towards 1 which we might expect to happen as one firm takes a lead over the period T_1, as we discuss later.

Next, we introduce a compensation rule which ensures that the *expected* profit under policy B is the same for each firm at the start of period T_1 as under policy A ensuring that each firm - who over time (in repeated plays of the game) expects to win as many races as they lose given the probability of winning the period 1 race is $\frac{1}{2}$ - can be compensated for having no reward in the cases they lose with the prizes they obtain in the races they win.[15] We label policy B with

[14]The budget neutrality assumption is not essential, and we discuss relaxing it in Section 4. However, it does aid the assumption of a unified WG in terms of reducing the possible incentives of regional jurisdictions within WG trying to free ride or opt out of the policy due to the need to share the funding of policy B.

[15]Of course, this is only illustrative and for simplicity this repeated game idea is undertaken making the simplifying assumption that all successful drug developments have the same cost and reward profiles. In practice, reward profiles for drugs will vary from case to case as will the number and identity of the players in each game. Indeed, firms must be compensated not only for drug development races that they might lose but also those that are unsuccessful in that they do not result in a viable product. However, we can just assume the latter is covered by the period 1 cost of developing X i.e. cT_1 includes the costs of all the failed R&D efforts or dead

this compensation rule, B_{max}. Assuming that WG does not permit compensation beyond the aggregate amount available to the firms under policy A, this then is the maximal compensation, which we call "*maximal*" or "*incentive neutral*" compensation, $C_{max} \equiv \frac{\alpha^2}{4\beta}[T_2 + T_3] - cT_2$, in which all the profit that would have accrued to the winning and laggard firm under policy A are paid to the winning firm under policy B. Under "maximal" compensation, the winning firm receives a payment C_{max}, and break-even requires that the price $\tilde{p}_{max}$ charged for the drug generates revenue that exactly covers this payment, hence:

$$\tilde{p}_{max}(\alpha - \beta\tilde{p}_{max})[T_2 + T_3] = \frac{\alpha^2}{4\beta}[T_2 + T_3] - cT_2 \tag{9}$$

Minimising p_{max} subject to achieving the break-even constraint, Eq. (9):

$$\tilde{p}_{max} = \frac{\alpha}{2\beta} - \frac{1}{2}\left(\frac{cT_2}{b(T_2 + T_3)}\right)^{0.5} \tag{10}$$

Profits and welfare accruing per period under policy B with maximal compensation are reported in Table 1(c). We have labelled this compensation rule under policy B "incentive neutral" since the expected profit for each firm over repeated plays of the game is exactly the same as under policy A and hence we would not expect it to yield any incentives to vary from R&D intensity relative to that in the benchmark case of policy A. Whilst we have assumed away any incentive effects on R&D in this Section we will return to this issue in Section 4.

There are many possible compensation rules that can be justified, with and without the break-even constraint we impose, but for modelling expedience there is a need to have a cut off point. Suppose WG wants to avoid expected profit for either firm at the outset of the one-shot game being negative. This principle defines "*minimal*" compensation $C_{min} \equiv 2cT_1$, which exactly covers the expected cost to a firm from competing in the development of new drugs over time (see Eq. 7).[16] This reasoning results in the following closed interval of compensation

ends visited on the way to developing X.

[16]On average a firm can expect to win one patent race and lose a patent race in fixed proportions hence the payment $2cT_1$ exactly covers the expenditure of one successful and one unsuccessful patent race for a firm.

payments:[17]

$$\left[2cT_1, \frac{\alpha^2}{4\beta}[T_2 + T_3] - cT_2\right] \tag{11}$$

We now consider some properties of the compensation rules we have introduced.

Proposition 1. [18] *Under policy B with "maximal" compensation (C_{max}), the break-even price, $\tilde{p}_{max}$, is strictly lower, and consumer surplus and welfare are strictly higher, than under policy A.*

What this serves to illustrate is that even under the most generous of the compensation rules that we consider (and ignoring potentially significant general equilibrium benefits of policy B), which on average entirely compensates the firms for profits they would have experienced under policy A, welfare and consumer surplus can be improved under policy B. Indeed, as the *Proof* illustrates the improvement in welfare comes through two channels, referring to Eq. (2): directly, through the reduction of costs, and indirectly, through the increase in quantity associated with the lower break-even price required to restore full expected profit to the firms.

C_{max} represents the most generous of the compensatory packages that we consider in this paper. We now turn attention to the other possible compensations in Eq. (11).

Proposition 2. *Under policy B the break-even price $\tilde{p}$ (consumer surplus and welfare) is (are) strictly increasing (decreasing) with compensation in the interval $[C_{min}, C_{max})$.*

Corollary 1. *If firms' R&D investment efforts are determined exogenously and are not incentive driven (i.e. not a function of expected profits), as we have so far assumed, then welfare is maximised under C_{min}.*

Corollary 1 highlights an important point. We have assumed that the intervals T_k and the intensity of R&D are exogenous. Yet, in practice as we reduce the compensation below the maximal level this may reduce R&D effort potentially offsetting some of the gains from

[17] As we will discuss later there may be arguments as to why a compensation greater than C_{max} (although here we treat R&D intensity as a constant and so do not capture any possible associated benefits from this in our model) and less than C_{min} might be suitable. Indeed, compensation C_f will, under some circumstances lie outside this interval. This need not be a problem at all but we will wish to know where this may happens in order to understand the possible trade-offs involved.

[18] Proofs to propositions are reported in the Appendix.

the increased surplus associated with the lower break-even price for X. Of course, there are also obvious problems with compensation that is cost-based (C_{min}): firms have an incentive to inflate the costs of their R&D to exploit the payment rule $2cT_1$. However, C_{min} and C_{max} have been identified as limit cases consistent with a set of objectives and are not necessarily being recommended as effective compensation rules. Recall though, C_f is not cost-based.

Lemma 2. *"Full" compensation is strictly smaller than "maximal" compensation, $C_{max} > C_f$, but may be bigger or smaller than "minimal" compensation. A sufficient condition for $C_f \geq C_{min}$ is:*

$$cT_1 \leq \frac{\alpha^2}{8\beta}[T_2 + \frac{1}{2}cT_3] \tag{12}$$

If the condition in Lemma 2 is met then "full" compensation under policy B is consistent with our tentative requirement that over time, in repeated patent competitions, firms under policy B should expect to at least break even.[19] Under full compensation, the winning firm receives a payment C_f, and break-even requires that the price $\tilde{p}_f$ charged for the drug generates revenue that exactly covers this payment, hence:

$$\tilde{p}_f(\alpha - \beta\tilde{p}_f)[T_2 + T_3] = \frac{\alpha^2}{8\beta}[2T_2 + T_3] \tag{13}$$

Minimising $\tilde{p}_f$ subject to the constraint, (13):

$$\tilde{p}_f = \frac{\alpha}{2\beta}\left[1 - \left(\frac{T_3}{2(T_2 + T_3)}\right)^{0.5}\right] \tag{14}$$

Per period profit and welfare under policy B with compensation C_f are reported in Table 1(b).

We now consider the relative gains and losses under policy B with "full" compensation relative to policy A.

Proposition 3. *Aggregate (or expected) profit under policy B with "full" compensation is*

[19] Though we will be interested throughout to see whether the conditions of Lemma 2 are met we will later see that this condition may be too restrictive since under policy B laggard firms may not in practice incur all of the development costs in period 1 cT_1 that they would have under policy A, and hence the required remuneration under policy B may be smaller than we assume here.

strictly lower than aggregate (or expected) profit under policy A: $\pi_f^B < \pi^A$.

Since we have placed the restriction (in Lemma 1) that entering in to period 2 R&D for the laggard firm must have a positive expected return under policy A, it must be the case that aggregate profit under policy B with compensation C_f is strictly lower than under policy A.

Proposition 4. *Welfare and consumer surplus under policy B with "full" and "maximal" compensation are strictly increasing in* T_2 *and* T_3.

Welfare improves under policy B relative to A because wasteful duplicative R&D costs are avoided in period 2 and price is lower across periods 2 and 3. The longer is $T_2 + T_3$, the greater is the time over which the price-reduction is enjoyed. Further, the longer is period 2 the greater is the extent of wasteful duplicative R&D under policy A and hence the greater the gain from policy B. The benefits from policy B are higher in situations where the laggard is a long way behind the winner (T_2 is long) and the market life of the drug is long.

3 Simulations

In order to get some idea about the potential magnitude of the partial equilibrium, one-shot gains to welfare under policy B, we now undertake some simulations, employing cases B_f and B_{max}, whereby it becomes necessary to make some further simplifying assumptions.[20] We begin by setting $\alpha, \beta = 1$, reducing demand, Eq. (3), to the unit linear form, $x = 1 - p$. Next, we will assume that the time taken to develop a new technology for the winning firm is, $T_1 \in \{0.75, 1.50\}$, and that the period of time the firm(s) are able to enjoy the patent before it becomes obsolete is $T_2 + T_3 = 1.5$.[21] We specify three parameterisations of $T_2 \in \{0.10, 0.50, 0.75\}$ with the foremost representing a laggard who is very close behind in the patent race and the

[20] It is important to note that simulations reported in the Tables cannot be given comparative static interpretation - that is changes in the value of the welfare gain with a higher level of a parameter cannot be used to infer the comparative static for the welfare gain in relation to that parameter. This is because the simulations are bound by underlying assumptions which, for instance, keep rates of return constant with varying realisations of other parameters.

[21] These parameterisations allow us to model scenarios in which the development period for X is smaller or equal to the market life of the drug. With the patent period of 20 years as an upper limit on the time period $T_2 + T_3$ we can see that setting T_1 at 0.75 and 1.5 implies *maximum* development times of 10 to 20 years, respectively

last, a laggard that is a significant way behind. Hence, aggregate profit under policy A (based on Eq. (5)) is $\pi^A = \frac{3}{8} - c[2T_1 + T_2]$. Finally, we let the *expected* rate of return for a firm take the values $\rho \in \{10\%, 20\%, 50\%\}$. Hence, $c = \frac{3}{8(1+\rho)[2T_1+T_2]}$. Table 2 reports our simulations.

Table 2: Percentage gain in welfare under policy B with "full" and "maximal" compensation relative to policy A

			$T_1 = 0.75$			$T_1 = 1.50$		
			T_2			T_2		
			0.10	0.50	0.75	0.10	0.50	0.75
(a) Policy B_f	ρ	0.1	86.1 †	110.4 †	119.4 †	81.4 †	93.9 †	98.9 †
		0.2	75.6 †	95.0	102.1	71.8 †	81.6 †	85.4
		0.5	59.2	71.0	75.0	56.8 †	62.4	64.3
(b) Policy B_{max}	ρ	0.1	38.9	87.5	118.8	31.5	72.0	87.5
		0.2	32.9	73.7	99.9	26.6	60.7	73.7
		0.5	23.3	51.8	69.9	18.9	42.7	51.8

Key: † denotes when $C_f < C_{min}$

It is clear from the Table that the percentage gains from full and maximal compensation are large across the parameter selection. For instance, with $T_1 = 0.75$, $T_2 = 0.5$ and the expected rate of return ρ under policy A at 20%, the gains under policy B relative to A with maximal and full compensation are, respectively 74% and 95%, adding close to three-quarters or doubling welfare under policy B.

However, there are cases, indicated by "†" where policy B with full compensation does not meet the requirement that $C_f \geq C_{min}$.[22] This may or may not be important (see Section 4.3). Our results in this Section are based on very simplifying assumptions and in the next Section we see how these figures hold up as we take in to account other factors of potential importance.

4 Further issues

In this Section we relax in turn each of five key assumptions to see how the gains from policy B identified in Section 3 stand up.

[22]Note that the two conditions in Lemma 1 are met for all the parameterisations in Table 2. That is to say, all the reported outcomes are consistent with sustainability of the game under policy A and the laggard firm optimally continuing R&D expenditures towards developing drug X in period 2 under policy A.

4.1 Marketing

It has been argued in the literature that a large part of the costs incurred by pharmaceutical firms are made up of marketing, to provide information/ dissemination but also to differentiate their product from rivals. In this model we include all informational/disseminational marketing costs under cT_1 for the winning firm and $c(T_1 + T_2)$ for the laggard under policy A. However, if we augment our model so that the coexistence of firms in period 3 under policy A induces marketing competition - inflating firm costs but offering no informational value (since the goods are effectively perfect substitutes) - then this would further enhance the welfare gains under policy B. Again, welfare in Eq. (2) is increasing in x and decreasing in costs. Hence, policy B, by eliminating the co-existence of firms in period 3 would increase welfare (i) directly, by eliminating wasteful marketing costs, and (ii) indirectly, by reducing the revenue (and break-even price) needed to compensate the winning firm, raising quantity and thereby welfare. As such, policy B, in addition to reducing wasteful duplicative R&D, would also correct the incentive mechanism that leads to wasteful marketing expenditures under policy A. Repeating the analysis of the welfare gains from policy B assuming policy A results in wasteful R&D with marketing expenditures per firm of 15% of the period 3 sales revenue, leads to the welfare gains reported in Table 3.[23]

Table 3: Percentage gain in welfare under policy B with "full" and "maximal" compensation relative to policy A with wasteful period 3 marketing under policy A of 15% of period 3 revenue

			$T_1 = 0.75$			$T_1 = 1.5$		
			T_2			T_2		
			0.10	0.50	0.75	0.10	0.50	0.75
(a) Policy B_f	ρ	0.1	139.7 †	167.1 †	175.1 †	133.6 †	146.7 †	150.7 †
		0.2	118.6 †	140.8 †	147.5	113.8 †	124.7 †	128.1 †
		0.5	88.5 †	‡	‡	85.6 †	†‡	‡
(b) Policy B_{max}	ρ	0.1	112.7	129.4	132.0	106.6	109.0	107.6
		0.2	95.5	108.3	110.1	90.7	92.2	90.7
		0.5	71.0	‡	‡	68.1	‡	‡

Key: † denotes when $C_f < C_{min}$; ‡ denotes when condition Lemma 1(i) is not met.

[23]Estimates have placed marketing expenditures at between 15% (Pharmaceutical Manufacturers Association, 1988) and 22% of sales (Ballance et al., 1992). Hence, our figure of 15% is not the maximum justifiable on this basis, and against the latter leaves some room to accommodate elements of period 3 marketing that might have informational value.

It is clear from comparison of Tables 3 and 2 that taking into account possible wasteful marketing distortions results in notable increases in the potential gains to policy B. Note in particular the improvement in the gains under maximal compensation.[24] For instance, with $T_1 = 0.75$, $T_2 = 0.5$ and the expected rate of return ρ under policy A at 20%, the gains under policy B relative to A with full (maximal) compensation increase from those with no wasteful marketing, in Table 2, from 95% to 141% (74% to 108%).

4.2 Multi-firm R&D competition and Product Differentiation

So far we have assumed that there are two rival firms competing in an R&D race to develop the drug, X. In practice, in any single pharmaceutical patent race there can be several firms. We are now going to look at the gains to policy B where the number of rival firms exceeds 2. In the case of a homogenous drug X, the benefits of policy B quickly mount up with the inclusion of more firms - for whom, so long as period 3 revenues offset the period 1 and 2 R&D costs - will optimally select to undertake duplicative and wasteful research. Hence, at this stage we allow for firms' drugs to have some degree of horizontal differentiation so we can examine the trade-offs of policy B where rejecting runner up drugs which have genuine value-added has a downward effect on welfare. As before, we assume an absence of price competition in period 3 under policy A with the winner succeeding at the end of period 1 and the $n-1$ runner up firms catching up simultaneously at the end of period 2. Let utility take the simple quasi-linear form (e.g. Singh and Vives, 1984):

$$U(\mathbf{x}, I) = \sum_{i=1}^{n} x_i - \frac{1}{2}\left[\sum_{i=1}^{n} x_i^2 + 2\gamma \sum_{i \neq j} x_i x_j\right] + I,$$

which yields the following horizontally differentiated demands for firm i:

$$x_i = \Psi^{-1}[1 - \gamma - (1 + \gamma(n-2))p_i + \gamma \sum_{j \neq i} p_j]$$

[24] Entries with ‡ are not reported since under these parameterisations, the laggard under policy A would not continue to period 2 R&D.

where $\Psi \equiv (1-\gamma)(1+\gamma(n-1))$ and $\gamma \in [0,1]$ represents the degree of substitutability of drug i with respect to drug j. The drugs are perfect substitutes (unrelated) under $\gamma = 1$ ($\gamma = 0$). $\mathbf{x}$ is an n-vector of demands for each of the firms' horizontally differentiated drugs, X_i.[25] Under policy A in period 2 the winning firm, w, sets price equal to p^m and earns profit π^m per unit time as there are no rival drugs on the market (γ is effectively zero in period 2 for the winning firm). In period 3 the $n-1$ rival firms have caught up and placed their variants of the winning drug on the market.[26] We assume that they adopt the price that would prevail under joint profit maximisation, p_i^m, with associated output, x_i^m,respectively:

$$p_i^m = \frac{1-\gamma}{2+\gamma(n-3)} < p^m, \quad x_i^m = \frac{1+\gamma(n-2)}{(1+\gamma(n-1))(2+\gamma(n-3))}$$

Welfare under policy A is then:[27]

$$W^A(n) = \frac{3}{8}T_2 + \left[nx_i^m - \frac{1}{2}\left(n(x_i^m)^2 + 2\gamma\frac{n(n-1)}{2}(x_i^m)^2\right)\right]T_3 - ncT_1 - (n-1)cT_2$$

Under policy B, the $n-1$ rival firms are denied access to the market in period 3 and hence have no incentive to continue period 2 R&D investments towards developing drug X_r ($r \neq w = 1, ..., n$). Under policy B_f the winning firm is compensated with $C_f(n) = x^m p^m T_2 + x_i^m p_i^m T_3$ but with only one drug on the market, using Eq. 3, the break-even price and welfare are then, respectively:

$$\tilde{p_f}(n) = \frac{1}{2}\left[1 - \left(1 - \frac{4C_f(n)}{T_2+T_3}\right)^{0.5}\right], \quad W_f^B(n) = \tilde{x}_f(n) - \frac{1}{2}\tilde{x}_f(n)^2 - ncT_1 \tag{15}$$

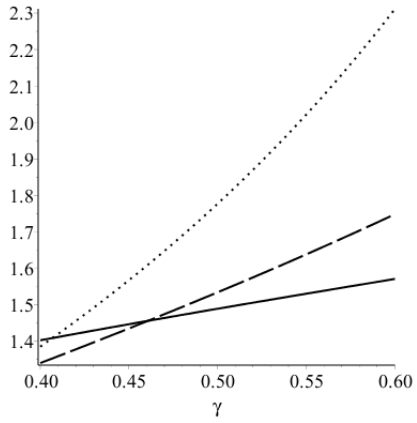
where $\tilde{x}_f(n) = 1 - \tilde{p}_f(n)$. To illustrate that policy B under full compensation can still offer welfare gains over policy A, where policy B prevents the arrival in period 3 of firms producing differentiated goods and hence add genuine value, consider Figure 1.

[25]This differentiation can be thought of in the context that drug X_i might not work 100% of the time for 100% of patients, so the different variants X_j of the same drug might work for different patients, or have different side effects.

[26]For simplicity, we assume that no privilege is given to the winning firm.

[27]In equilibrium, $\sum_{i\neq j} x_i x_j = \frac{n(n-1)}{2}(x_i^m)^2$, given the sum of integers from 1 to $n-1$ is given by $\frac{n(n-1)}{2}$.

Figure 1: Ratio of Welfare under Policy B_f to Policy A with degree of substitutability γ



Key: $n = 2$ solid line; $n = 3$ longdash; $n = 4$ dots

Whilst in Figure 1 we maintain our earlier modelling assumptions determining c and T_3 (see Section 3), in order to ensure that we have interior solutions (also satisfying the conditions in Lemma 1), whilst at the same time not disfavouring the viability of multiple firms, we set $T_1 = 0.75$, $T_2 = 0.1$ and $\rho = 0.75$.[28] The high rate of return is required to allow multiple firms to exist profitably in period 3 within our modelling set up whilst the short time periods reduce the penalty for multiple firms' R&D efforts under policy A. What this figure shows is that, in the relevant range, the welfare gains from policy B_f are upwards of 30%, despite the fact that this policy denies entry into the market of 2 to 3 additional drugs that would have added value. This happens for two reasons. First, the additional drugs, though adding value, would have been charged at the monopoly price so that the full benefits of these drugs would not have fully permeated through to the end users. Second, there are additional R&D efforts of $n-1$ firms in period 2 under policy A. Even though these R&D efforts are not completely duplicative (indeed in Figure 1, γ is chosen so it is not close to 1, hence these drugs are not very close substitutes), the net benefit is lower than under policy B_f which excludes these costs, loses the added value

[28]Unlike before, we do not seek to satisfy the condition that compensation exceeds the expected costs to firms in repeated plays of the game under policy B. Whilst this condition is met in the scenario of Figure 1 for $n = 2$ it is not met for $n = 3$ or higher. However, without further analysis it is not obvious that it would be in the interests of welfare maximisation to have so many firms compete for each prize in the first place with each incurring the period 1 R&D costs. To sustain a higher number of firms on average requires a higher winning compensation. There is a trade-off between the number of firms needed for an efficient patent race and duplicated costs incurred of period 1 R&D.

of multiple differentiated drugs, but, employs a lower (break-even) price.[29] As before, given our modelling assumptions, which tie together per period cost and rate of returns, we cannot use Figure 1 to make comparative static judgements.

4.3 Early laggard withdrawal under policy B

So far we have assumed that rival firms compete right to the end of period 1 in the hope of winning the prize under policy B. However, unlike under policy A, where the laggard can expect to receive some reward so long as they complete their R&D until the end of period 2, under policy B there is no reward for the losing firm. Hence, not only does the losing firm have no incentive to continue into period 2 under policy B, if a firm believes it is far enough behind its rival to the extent that the probability of winning is sufficiently low at some point during T_1, then it may be optimal to exit the race before the end of period 1. In our early discussion of the phases of clinical trials we saw that there is potentially quite a lot of information in the public domain during period 1 to inform the firms about where they stand in the race, which under policy B may be sufficient to yield the early withdrawal of the laggard firm, yielding additional benefits in welfare.

Under early (in period 1) laggard withdrawal, it is now possible that "full" compensation can exceed "maximal" compensation.

Proposition 5. *With early period* 1 *laggard withdrawal, "full" compensation will exceed "maximal" compensation if:*

$$\mu > \frac{\alpha^2 T_3}{8\beta c T_1} - \frac{T_2}{T_1}$$

where $\mu \in [0, 1]$ *is the proportion of period* T_1 *that is left when the laggard firm withdraws from the patent race.*

The benefits of early laggard withdrawal are threefold. First, the laggard does not incur the full cT_1 cost of R&D - directly raising welfare under policy B. Second, the average cost

[29] Solving for policy B_{max} involves time-consuming search for corner solutions but it can also be shown to have welfare improving capability.

that a firm expects to incur over multiple plays of the game are smaller, which reduces the threshold at which C_f compensation exceeds expected costs over time. This may have important implications for the long-term viability of multiple firms under policy B allowing more to be sustained under compensation C_f as discussed in the previous section. Finally, if firms are not pursuing R&D towards discovering drug X then these resources can be directed towards discovering other new classes of drugs, Y, or making X obsolete discovering $X+$, which we would expect to have further benefits and discuss below.

To help illustrate the potential impact of early laggard withdrawal from period 1 R&D, we reproduce the simulations in Table 2 under the assumption that, under policy B, the laggard only incurs $\frac{cT_1}{2}$ before withdrawing from the race. Note that welfare under policy B will be increased directly due to the fall in R&D costs of $\frac{cT_1}{2}$ in the one-shot game, but also if early withdrawal in this way were the norm under policy B then C_{max} and C_{min} would also fall due to the lower average expected cost of engagement in each patent race.[30] The compensation and price under "full" compensation are unchanged.

Table 4: Percentage gain in welfare under policy B with "full" and "maximal" compensation relative to policy A with early laggard period 1 withdrawal ($\mu = 0.5$)

				$T_1 = 0.75$			$T_1 = 1.50$		
				T_2			T_2		
				0.10	0.50	0.75	0.10	0.50	0.75
(a)	Policy $B(f)$	ρ	0.1	122.1 †	139.2 †	145.1	118.6 †	126.8 †	129.7
			0.2	104.9	118.4	122.9	102.0	108.4	110.4
			0.5	78.0	86.0	88.3	76.1	79.6	80.3
(b)	Policy $B(max)$	ρ	0.1	110.8	140.4	152.6	105.6	123.9	132.8
			0.2	93.2	117.9	128.1	88.8	104.2	111.6
			0.5	65.3	82.3	89.3	62.3	72.8	78.0

Key: † denotes when $C_f < C_{min}$

Comparison of Tables 4 and 2 show that the early laggard withdrawal can add significantly to the welfare gains under policy B. For instance, with $T_1 = 0.75$, $T_2 = 0.5$ and the expected rate of return ρ under policy A at 20%, the gains under policy B relative to A with full (maximal) compensation increase from those with no early withdrawal, in Table 2, from 95% to 118%

[30] Specifically, $C_{min} \equiv \frac{3}{2}cT_1$ and $\tilde{p}_{max} \equiv \frac{1}{2}\left[\frac{\alpha}{\beta} - \left(\frac{c(2T_2+T_1)}{2\beta(T_2+T_3)}\right)^{0.5}\right]$.

(74% to 118%). Notably, in line with Proposition 5, welfare under "maximal" compensation may now exceed that under "full" compensation. This is because the former seeks to match the expected profit to each firm under repeated plays of the game but the under early withdrawal of the laggard in period 1 the required compensation falls below that required under "full" compensation which only focusses on matching the one-shot rewards for the winner under policies A and B.

4.4 Period 3 competition

As discussed above, there is much evidence to suggest that price competition does not result in period 3 of the drug life-cycle in many cases. Accordingly, we have assumed thus far that the arrival of the laggard in period 3 under policy A leads to the adoption of the prevailing price and hence sharing of monopoly profits. We now briefly consider the implications of relaxing this assumption in favour of (softer) period 3 Cournot quantity competition.

Under our simulation assumptions (as outlined in Section 3), the winning firm's profit and aggregate profit under policy A with period 3 Cournot competition are, respectively, $\pi_w^{A(C)} = \frac{T_3}{9} + \frac{T_2}{4} - c[T_1]$ and $\pi^{A(C)} = \frac{2T_3}{9} + \frac{T_2}{4} - c[2T_1 + T_2]$. The break-even prices under policy B with full and maximal compensation are then, respectively, $\tilde{p}_f^C = \frac{1}{2}\left[1 - \left(\frac{5T_3}{9(T_2+T_3)}\right)^{0.5}\right]$ and $\tilde{p}_{max}^C = \frac{1}{2}\left[1 - \left(\frac{T_3}{9(T_2+T_3)}\right)^{0.5}\right]$.

Reproducing the simulations for the gain in welfare under policy B relative to A:

Table 5: Percentage gain in welfare under policy B with "full" and "maximal" compensation relative to policy A with period 3 Cournot quantity competition

				$T_1 = 0.75$			$T_1 = 1.5$		
				T_2			T_2		
				0.10	0.50	0.75	0.10	0.50	0.75
(a)	Policy B_f		0.1	29.9 †	57.1 †	71.3 †	26.7 †	44.9 †	55.4 †
		ρ	0.2	27.0 †	50.0 †	61.9	24.2 †	39.8 †	48.6
			0.5	21.9	38.0	46.1	20.1 †	31.1 †	37.3
(b)	Policy B_{max}		0.1	7.6	33.3	46.9	4.4	21.1	31.0
		ρ	0.2	6.5	28.02	39.6	3.8	18.0	26.4
			0.5	4.5	19.7	27.5	2.7	12.9	18.7

Key: † denotes when $C_f < C_{min}$

From Table 5 it is clear that substantial gains still exist from pursuing policy B even when

one of our key assumptions, on price rigidity, is relaxed. For instance, with $T_1 = 0.75$, $T_2 = 0.5$ and an expected rate of return under policy A of 20%, the gain under policy B relative to A with full (maximal) compensation is 50% (28%), reduced from the gains under no period 3 competition with policy A, but still substantial.

4.5 General equilibrium and welfare maximising R&D

So far our analysis of the welfare benefits of policy B relative to A has been undertaken within the partial-equilibrium one-shot drug life-cycle framework. However, it is clear that there are potentially important general equilibrium effects associated with such a change in patenting policy. For instance, eliminating period 2 laggard R&D under policy B may also have benefits beyond the one-shot partial equilibrium patent game for drug X. Whilst at the end of period 1 the winning firm devotes its full R&D effort to the next best project regardless of the policy, A or B, under policy A the laggard continues to devote their full effort (wastefully) to drug X. Under policy B the laggard also switches R&D effort to the next best project at the end of period 1 as there are no possible rewards for them continuing with this investment in the development of drug X. This diverted effort may increase the speed at which some unrelated new class of drug (Y) is discovered and developed - i.e. count towards the period 1 R&D in the life-cycle of the new drug Y. In Table 6 we report the percentage gains under policy B relative to A in the case that the laggard's period 2 R&D expenditures under policy A, cT_2, are devoted, in policy B, to the development of a new unrelated drug Y, with welfare gains associated with it on a pro-rata basis to the gains in the one-shot life-cycle for drug X based on the investment $2cT_1$. Specifically, let ∇ denote the total welfare under policy B for any given parameter combination, based on the firms each investing cT_1 (these are the basis for the welfare gains reported in Table 2). Welfare per unit investment is therefore $\nabla \frac{cT_2}{2cT_1}$. Hence in the case that laggard period 2 investments under policy A are diverted to the discovery of the new drug Y, welfare under policy B, on a pro-rata return basis is:

$$\nabla \left(1 + \frac{cT_2}{2cT_1}\right) \tag{16}$$

The figures reported in Table 6 use Eq. 16 as a basis for calculating welfare under policy B.

Table 6: Percentage gain in welfare under policy B with "full" and "maximal" compensation relative to policy A with pro-rata value added welfare on period 2 R&D

				$T_1 = 0.75$			$T_1 = 1.5$		
				T_2			T_2		
				0.10	0.50	0.75	0.10	0.50	0.75
(a)	Policy $B(f)$	ρ	0.1	98.5 †	180.5 †	229.2	87.5 †	126.2 †	148.7
			0.2	87.3	160.0	203.1	77.5	111.9	131.8
			0.5	69.8	128.0	162.5	62.0	89.5	105.4
(b)	Policy $B(max)$	ρ	0.1	54.8	166.5	228.2	35.8	100.6	134.4
			0.2	47.3	145.5	199.8	30.8	87.5	117.2
			0.5	35.5	112.0	154.9	22.9	66.5	89.8

Key: † denotes when $C_f < C_{min}$

From Table 6 it is clear that even taking into account this one possible general equilibrium factor has the potential to significantly boost the welfare gains from policy B relative to policy A. Comparison of Tables 6 and 2 show that allowing the laggard's cT_2 R&D to be diverted to alternative projects with the same expected gain in welfare on a pro-rata basis as $2cT_1$ with $T_1 = 0.75$, $T_2 = 0.5$ and the expected rate of return ρ under policy A at 20%, the gains under policy B relative to A with full (maximal) compensation increase, in Table 2, from 95% to 160% (74% to 146%).[31]

However, given what we have seen earlier about incentives for the laggard to withdraw early from the period 1 race, the figures in Table 6 may well understate the extent of the gains to policy B arising from this one general equilibrium dimension: the relevant factor for pro-rata calculations would be $\frac{c(\mu T_1+T_2)}{c(2-\mu)T_1} > \frac{cT_2}{2cT_1}$ and the original partial equilibrium welfare gains to be factored up are $\Delta \geq \nabla$, where, for any parameter combination, Δ is the total welfare gain from policy B reported in Table 4. On the other hand, the picture may be a little more complicated since the laggard's diverted cT_2 R&D may go towards speeding up the obsolescence of drug X if the investment goes towards drug $X+$ thus shortening period 3.[32]

Finally, as discussed in the introduction, much attention has been given to the reward

[31] These gains mean appear disproportionate in size given the size of T_2 relative to T_1. However, to illustrate where these figures come from, note that under the above parameterisation, $W^A \approx 0.333$, whilst partial equilibrium welfare under policy B_f is $\nabla \approx 0.650$. From Eq. (16), the general equilibrium calculation of welfare under B_f is $\nabla(1 + 1/3) \approx 1.217$, yielding a welfare gain, relative to policy A of roughly 160%.

[32] The endogeneity of T_3 lies beyond the scope of the current paper.

system in buyouts and their impact on the effectiveness of the policy. Gallini and Scotchmer (2001) stress the importance of the prize being linked to the social value of the innovation. Hollis (2004) who offers a detailed discussion of many of the issues surrounding patent buyouts, suggests an efficient pricing system for pharmaceuticals based on incremental value. Shavell and van Ypersele (2001) propose a system in which the reward exceeds profit but lies below the social value of the innovation - thereby having the potential to raise welfare and stimulate further R&D. In our life-cycle model we have assumed a constant investment rate for R&D based on an industry stylised fact and backed this up to some extent by choosing compensation rules which steer towards incentive neutrality on R&D across policies A and B. Hence, we have explicitly abstracted away from these price incentive considerations. However, the question of rewarding innovators with compensations close to full surplus achieves its gains through R&D breakthroughs happening more quickly, for which the subsidies required to fund this need to be balanced against the gains, where these general equilibrium considerations (in capturing the increased speed of the introduction of new technologies on to the market over time) play an essential role.

5 Conclusions & Discussion

The system of rewarding innovations in the pharmaceutical sector is frequently singled out for criticism on the basis that it tends to exhibit two major failings: (i) innovating firms have inadequate incentive to focus efforts on developing technologies which make non-trivial incremental gains, since rewards can be earned from innovations with little incremental value, and (ii) rates of return remain for long periods at, close to, monopoly levels. There is a small, but significant, literature which has begun to address these failings, including work exploring alternative ways of rewarding innovation and estimates of the welfare losses due to the exercise of monopoly power in the sector. Our paper contributes to this literature by examining the innovation issue in a one-shot drug life-cycle framework. We study the potential gains in welfare arising from a policy (B) in which only the winning firm's drug is patented, the patent

is purchased by the government and a price for the drug set so as to cover the compensation to the wining firm. Though the main concern of the paper is not to identify an optimal pricing rule, we illustrate the benefits of the new policy (B) under two alternative compensation rules: "full" and "maximal" compensation. The former (latter) exactly compensates the winning firm in the race for the patent in the one-shot life-cycle of the drug (exactly compensates the firm over repeated plays of this life-cycle game or, in other words, yields an expected profit to the firms which is unchanged from that under the original patent policy, A). We show that policy B yields welfare gains which derive through several sources. First, laggard firms have no incentive to undertake wasteful duplicative R&D and so the associated costs are avoided. Second, in the absence of duplicatory costs, the break-even price required to cover (even "maximal") compensation for the winning firm, is lower than the price that would have prevailed under policy A. We produce simulations to show that the extent of the welfare gains arising through these channels can be substantial. For instance, in the basic model which excludes, amongst other things, potentially large positive general equilibrium benefits, improvements in welfare of upwards of 50% exist over a wide range of parameter values.

It is easy to see how our policy proposal would have been relevant for some of the statins, with simvastatin being the only one being patented and traded. The current PKCS-9 inhibitors, promising more effective cholesterol lowering, may be another example. Historically, one may think about a range of ACE-inhibitors, or more recently the new oral anticoagulants. While much energy is spent to distinguish them, the real differences seem small and societies might have been better off if development of some of these had stopped earlier and resources been diverted elsewhere.

It might appear that an obvious weakness of the proposed policy is that the "winning" firm's drug is the one that is selected when the runner-up drug might have been significantly better. However, it is again the particular nature of R&D in the pharmaceutical industry which mitigates against such problems. Through the clinical trials process, quite a lot of information is available in the public domain during the development stage. If the authority responsible for implementing the policy can see that the laggard drug is very close to completion and/or looks

significantly better than the winning firm's drug then this can be taken into account before employing the patent purchase policy on the winning drug. Our point is not that the patent purchase approach should be used rigidly in the case of every new class of drug, but rather that where the evidence suggests (e.g. as revealed through clinical trials) that the laggard firm is significantly behind the winning firm and/or the laggard firm's drug looks likely to offer very little in terms of added benefits, then potentially large gains can be made from the patent purchase model.

In the main, our analysis is undertaken under simplifying assumptions, some of which are for modelling expedience and transparency, whilst others, we believe, have some basis in the pharmaceutical sector. However, in Section 4 we carry out analysis including simulations allowing some of these assumptions to be relaxed (e.g. introducing rival drug competition, drug heterogeneity, wasteful marketing expenditures and general equilibrium effects) and show that non-trivial gains still exist from employing the patent purchase model. Indeed, by including marketing and one general equilibrium consideration welfare gains are shown to rise steeply.

For simplicity we assume a World Government WG and employ a "pay-as-you-go" prize scheme for the winning innovator based on drug sales so that the patent purchase policy doesn't require WG to be involved in large-scale funding of the policy (beyond operational costs) or face the costs and risks of predicting market take-up. The "pay-as-you-go" system also reduces the number of challenges involved in getting buy-in from each regional jurisdiction within WG which is important if the duplication costs of laggard R&D are to be avoided. The assumption, is however, not an essential part of the model.

Whilst under our case of "maximal" compensation, firms would expect to be no worse off under policy B than A, despite welfare being higher in the former case, we do not attempt (except for a basic exercise in Section 4) to take into account wider general equilibrium benefits from policy B deriving from possible earlier development of new drugs. Indeed, it is possible to generate situations in which both firms and society are better off under policy B relative to A. However, we have focussed on compensation rules which have some degree of incentive neutrality over policies A and B to reduce the extent to which the assumption of a constant

rate of R&D (which is made throughout and we partly justify in the case of pharmaceuticals) is realistic. Of course, in reality, by offering a more generous compensation rule it might be possible to speed up the development of X as well as $X+$ (the drug that makes X obsolete) and/or Y (a new unrelated drug), but this lies beyond the scope of the current paper.

There are a number of issues that policy-makers will need to resolve in terms of implementing the patent purchase policy, not least, which "new" drugs to target with the policy. For certain there will need to be an overhaul of the system of patenting for pharmaceuticals since under the patent purchase policy much more will ride on the decision to award a patent. However, as we have seen in the introductory discussion, unlike many other sectors, the quality of information available in the public domain through the development stage of "new" drugs makes pharmaceuticals something of a special case which lends itself particularly well to the patent purchase idea. That said, there are a number of issues which lie beyond the scope of the current paper but which require investigation in future research. Foremost amongst these are (i) how multiple indications fit within the patent purchase policy, (ii) how a policy of maximising R&D incentives for firms by rewarding the winner with compensation closer to full surplus using subsidies would work (requiring a general equilibrium analysis and, of course, subsidies), (iii) under what conditions free-rider effects would arise amongst regional jurisdictions such that the assumption of WG as a single decision-making authority would be compromised, and (iv) how the policy framework would need to be adapted to account for complementary rather than substitute R&D.

Appendix A Proofs to Propositions

Proof to Proposition 1. First, note that total revenue is strictly increasing in p for $p \in [0, p^m)$. Second, under policy A total revenue ($\frac{\alpha^2}{4\beta}[T_2+T_3]$) is strictly greater than the highest compensation, C_{max} ($\frac{\alpha^2}{4\beta}[T_2+T_3]-cT_2$), under policy B. Hence, the break-even price, $\tilde{p}_{max}$, under policy B required to generate revenue equal to C_{max} is strictly lower than the price under policy A: $\tilde{p}_{max} < p^m$. Accordingly, the break-even quantity under policy B is $\tilde{x}_{max} \in (x^m, \alpha)$. Since from Eq. (1) consumer surplus is strictly increasing in x for $x < \alpha$ and given $\tilde{x}_{max} \in (x^m, \alpha)$, then consumer surplus under C_{max} must be strictly greater than that under policy A. Regarding welfare, policy B with C_{max} is strictly superior over policy A for two reasons. From Eq. (2) welfare is strictly increasing in x and decreasing in costs. However, under policy B with C_{max}, x is strictly greater and total costs are strictly smaller (by the amount cT_2) relative to policy A. □

Proof to Proposition 2. Given C_{max} is the most generous of the feasible compensation rules and given total revenue is strictly increasing in p in the relevant range, $\tilde{p}$ is strictly monotonically falling with less generous compensation rules. Correspondingly, consumer surplus and welfare are monotonically increasing as compensation falls below C_{max}, completing the proof. □

Proof to Proposition 3. Let H_f be the gain in aggregate profit under policy B with "full" compensation relative to policy A, hence:

$$H_f = \frac{\alpha^2}{8\beta}T_3 - cT_2 \tag{17}$$

which is strictly negative from Lemma 1(i). □

Proof to Proposition 4. Let G_f be the gain in welfare under policy B with "full" compensation relative to policy A, hence:

$$G_f = \frac{\alpha^2}{8\beta}\left[\frac{T_3}{2} + \left(2T_3(T_2-T_3)^{0.5}\right)\right] + cT_2 \tag{18}$$

which is strictly positive, and clearly $\partial G_f/\partial T_2 > 0$. However:

$$\frac{\partial G_f}{\partial T_3} = \frac{\alpha^2}{8\beta}\left[(T_2+T_3)[2T_3(T_2+T_3)]^{0.5} - \frac{1}{2}\right] \tag{19}$$

which is positive iff $(T_2+T_3)[2T_3(T_2+T_3)]^{0.5} > \frac{1}{2}$, which must must hold for $T_2, T_3 > 0$. Let G_{max} be the gain in welfare under policy B with "maximal" compensation relative to policy A, hence:

$$G_{max} = \frac{1}{2\beta}\left[\beta cT_2 + (\alpha\beta cT_2(T_2+T_3))^{0.5}\right] \tag{20}$$

which is strictly positive, and clearly $\partial G_{max}/\partial T_2 > 0$ and $\partial G_{max}/\partial T_3 > 0$. Finally, since welfare is strictly greater under policy B than policy A but aggregate profit is weakly smaller, the gain in welfare under both B_f

and B_{max} must derive from increasing consumer surplus hence the gains in consumer surplus under policy B_f and B_{max} relative to policy A must be strictly increasing with T_2 and T_3, completing the proof. □

Proof to Proposition 5. With early laggard withdrawal in period 1 with proportion μ of period 1 remaining, the break-even price under maximal compensation with policy B is:

$$\tilde{p}_{max} \equiv \frac{1}{2}\left[\frac{\alpha}{\beta} - \left(\frac{c(T_2 + \mu T_1)}{\beta(T_2 + T_3)}\right)^{0.5}\right] \tag{21}$$

whilst the break-even price under "full" compensation, $\tilde{p}_f$, which is unchanged by the early laggard withdrawal, and is given by Eq. (14). Setting $\tilde{p}_f > \tilde{p}_{max}$ and re-arranging completes the proof. □

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