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Working paper

Lower drug prices can improve innovation

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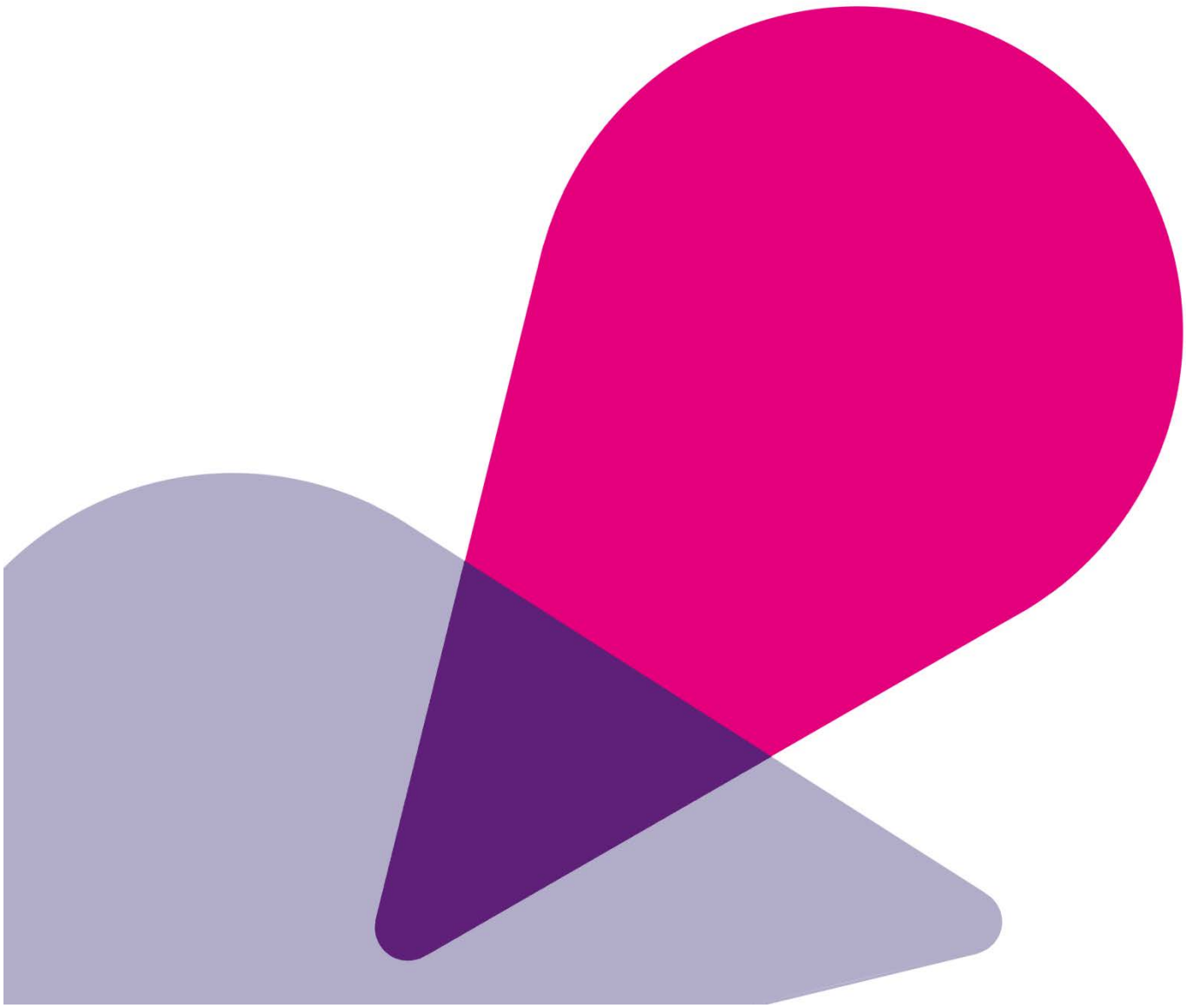

Opportunities and options for businesses and consumers

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Abstract

An often made claim is that high drug prices are necessary for innovation. We qualify this claim: drug prices can be too high, namely when the price exceeds the value of the drug to society. Such prices lead to excessive investment in some projects at the expense of other valuable research projects. We propose a benchmark for identifying these cases in practice and we discuss how competition law can be applied in this area. The practical discussion in the paper focuses on the institutional context of the Netherlands but our results are robust for many other institutional settings.

1. Introduction

While the news is packed with articles on high drug prices[1], governments are often reluctant to counteract high prices with the innovation argument in the back of their mind. The innovation argument tells us that actions by governments, regulators or competition authorities against high drug prices are detrimental to pharmaceutical companies' incentives to innovate. This innovation argument needs to be qualified. Sure enough, pharmaceutical companies' incentives to invest in drug development are affected by the revenues they expect to realise in case of success: the higher the revenue in case of success, the more attractive it is to invest in the project.[2] It is equally well-known that many drug development projects are ultimately unsuccessful (roughly nine out of ten research projects never receive market authorisation[3]). Hence, high drug prices may be necessary to make development projects attractive *ex ante.* Although true, this notion can easily lead to the misunderstanding that more revenue is always better for innovation. We develop a simple analytical framework showing that this is not necessarily the case. We also identify under which conditions drug revenues generate socially optimal investment incentives.

The framework shows that – purely from an innovation perspective - innovation incentives are socially optimal if the pharmaceutical company can appropriate the entire benefit of a new drug to society. In this case the pharmaceutical company internalizes all the public benefits and costs of the drug. If a company extracts less than the entire benefit of a new drug to society, innovation incentives can be too low from a social point of view. Apart from investing too little money in the project, it may result in the company's decision not to develop the drug at all even though this would be in the public interest. However, if companies gain *more* than the benefit of the drug to society, we show that this creates two inefficiencies in innovation. First, companies invest too many resources in projects where they expect to be able to gain more than the drug is worth to society. Second, pharmaceutical companies invest too few resources in other valuable drug development projects. As a result, high drug prices lead to crowding out of valuable drug

[1] See e.g. <https://www.ft.com/content/ed631cf2-3630-11e7-bce4-9023f8c0fd2e> and <https://www.nytimes.com/2018/03/05/health/drug-prices.html>.
[2] See e.g. U.S. Department of Commerce, *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation* (2004), and Daron Acemoglu and Joshua Linn, "Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry" (2004) 119 *Quarterly Journal of Economics* 1049-1090.
[3] Joseph A DiMasi, Henry G Grabowski and Ronald W Hansen "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs" (2016) 47 *Journal of Health Economics* 20-33.

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development projects. In these instances, enforcing lower prices does not harm innovation but improves it, because as a result of lowering those prices future investments will be geared towards projects that are more desirable for society.

For our theoretical results to be of practical relevance, policymakers need to be able to assess the value of a drug to society. The second contribution of the paper is to propose a practical measure of the social value of a drug for the context of the Dutch healthcare system.[4] The pharmaceutical sector is one that allows an assessment of the social value of the product. In the Netherlands, treatments (which can, but need not be pharmaceutical drugs) are assessed on the basis of *inter alia* their cost-effectiveness, measured by the cost per gained Quality-Adjusted Life Year (QALY). Many countries use the concept of QALY to measure health gains of treatments, although countries differ in the maximum monetary cost they are willing to incur for one extra QALY and the institutional setting in which assessments take place. In the Netherlands (and no doubt elsewhere as well) it frequently happens that the price charged or demanded by the pharmaceutical company exceeds the highest reference value (€ 80.000 in the Netherlands).[5] We claim that when industry anticipates to collect such drug prices, this leads to overinvestment in projects concerned and to underinvestment in other socially valuable drugs. As a consequence, in this scenario interventions by a regulator, ministry or competition authority do not thwart innovation but lead to an improvement in innovation decisions.

The third contribution of the paper is to discuss the application of competition law in this area. Even in jurisdictions with provisions against excessive prices, such as the EU, competition authorities have a long-standing tradition not to intervene against high prices of patented products. In our view this caution is justified in many instances but not so if one can establish that the price of a drug is higher than its value to society. We also discuss how this feature, if present, may be used in possible excessive price cases of patented drugs within the confines of the landmark *United Brands* case.

This paper also contributes to the academic theoretical literature on innovation incentives for pharmaceutical companies.[6] Some papers show that pharmaceutical companies invest too much money in small, incremental innovations compared to radical innovations.[7]

Ganuza, Llobet, and Domínguez (2009) develop a model of investment incentives assuming that some doctors may be 'captured' in the sense that they prescribe the drug with the highest

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[4] The argument runs along similar lines for other OECD countries although specific institutional details may matter.
[5] In practice there could be valid reasons to deviate from this reference value, and this frequently happens in the Netherlands. We will come back to this issue in section 3.
[6] Discussed below are: Juan-José Ganuza, Gerard Llobet, and Beatriz Domínguez, "R&D in the Pharmaceutical Industry: a World of Small Innovations" (2009) 55 *Management Science* 539-551; D Bardey, A Bommier and B Jullien, "Retail Price Regulation and Innovation: Reference Pricing in the Pharmaceutical Industry" (2010) 29 *Journal of Health Economics* 303-316; Fernando Antoñanzas, Carmelo Juárez-Castelló, and Roberto Rodríguez-Ibeas, "Innovation, Loyalty and Generic Competition in Pharmaceutical Markets" (2011) 2 *SERIES* 75-95; Paula González, Inés Macho-Stadler, and David Pérez-Castrillo "Private versus Social Incentives for Pharmaceutical Innovations" (2016) 50 *Journal of Health Economics* 286-297.
[7] This point is also made by other commentators, see e.g. <https://www.forbes.com/sites/matthewherper/2014/10/23/could-high-drug-prices-be-bad-for-innovation/>.

therapeutic value regardless of the price, whereas other doctors perform a price-cost analysis. The presence of captured doctors implies that pharmaceutical companies make too little innovation effort from a social point of view. The intuition is that low effort will more likely result in a me-too innovation (with a low value to society) rather than a breakthrough innovation (with a high value to society). The former kind of innovation receives a relatively high profit, however, as it is optimal to set a very high price and only serve the patients of captured doctors.

Antoñanzas, Juárez-Castelló, and Rodríguez-Ibeas (2011) develop a model where a firm that has a drug running out of patent decides on the quality of a new innovation. The authors assume that some doctors may be loyal to the manufacturer, which means that the doctor prescribes the new drug of the firm as long as the patient experiences non-negative utility, whereas other doctors perform a price-cost analysis. In this model, the quality of new innovations is always below the socially optimal level, and there is an inverted-U relationship between the level of innovation and the fraction of loyal doctors.

González, Macho-Stadler, and Pérez-Castrillo (2016) develop a model of horizontally and vertically differentiated pharmaceutical drugs. The authors show that the optimal pricing policy for new drugs implies that the company extracts the full increase in consumer surplus of me-too drugs but only part of the increase in consumer surplus of breakthrough drugs. Similar to Ganuza, Llobet, and Domínguez (2009), this results from a trade-off in pricing: capture only a subset from the differentiated consumer population at a price that extracts from each consumer the premium he or she is willing to pay for the new drugs, or capture more customers at a lower price leaving some of the consumers a surplus? The former option is more often attractive for me-too innovations, as these innovations do not appeal to many consumers because of the relatively minor improvement in quality. Consequently the firm's incentives to invest in breakthrough drugs are too low from a social point of view.

Finally, Bardey, Bommier, and Jullien (2010) focus on the effect of reference pricing on pharmaceutical companies' innovation incentives. This form of price regulation decreases drug prices, the effect of which is that companies' incentives to invest are lower. The authors also show that reference pricing may in particular reduce incentives to invest in me-too drugs compared to breakthrough innovations.

The crucial assumption driving our result is that we assume that the threshold value (in the Netherlands € 80.000, possibly corrected for a variety of ethical and other considerations) is the true willingness to pay by society. Henceforth, if for some political or other reason the payer (i.e., the govemment) decides to pay more than this threshold value, we claim that the payer pays more than society's willingness to pay. Ganuza, Llobet, and Domínguez (2009) and Antoñanzas, Juárez-Castelló, and Rodríguez-Ibeas (2011) also allow for this possibility. In their papers the feature arises because of captured doctors and loyal doctors, respectively. In contrast, we assume that even in the setting of centrally led negotiations about price, sub-optimally high prices can result. Because of the highly contentious nature of decisions regarding life-saving drugs, agency problems need not only arise at the level of physicians, but can also arise at the level of

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those negotiating a price on behalf of a country.[8] In this context we highlight the role of market power that results from patents and (in particular) orphan drug designations as a potential cause of misdirected innovation incentives.[9] This paper also makes a suggestion how to identify sub-optimally high drug prices in practice, and discusses the application of competition law in this area.

The paper is organized as follows. Section 2 provides the model and a few extensions. Section 3 operationalizes the theoretical concept within the context of the Dutch healthcare system. Section 4 discusses the implications for the application of competition law in this area, and section 5 concludes.

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2. A simple model of drug development investment incentives

2.1 Setup of the baseline model

Assume a pharmaceutical company has two drug development projects to invest in. Projects are denoted by subscripts $i \in 1,2$. Each project has a Probability of Success (PoS), denoted by p_i, that it will generate a successful drug that receives market authorisation. The PoS is a function of project-specific research and development costs I_i, hence we write $p_i(I_i)$. Apart from the costs of investments I_i, the company incurs a fixed cost F_i for each project.[10] Note that we assume there are no common costs for the two projects. This is a reasonable assumption in light of the fact that a large part of pharmaceutical companies' investments are directed towards testing the effects of a particular drug on a target population. Specific innovation incentives will change if there are substantial common costs, but our qualitative results will not to be affected as long as these costs are relatively small. For simplicity we assume them to be absent.

We make some standard assumptions about the PoS-function to ensure that investing is (at least sometimes) attractive and has decreasing marginal returns. First, an investment level of zero implies that the project will be unsuccessful with certainty: $p_i(0) = 0$. Second, investing more money in a project increases the PoS: $p_i'(I_i) > 0$. Third, to make the model worthwhile, when investments are zero, investing a positive amount has an infinite marginal benefit: $p_i'(0) = \infty$. Fourth, the benefit of investing more decreases: $p_i''(I_i) < 0$. Fifth, in the limit when investments go to infinity, it is not attractive to invest more: $p_i'(I_i \to \infty) = 0$. Sixth and last, in the limit when

[8] The market for pharmaceutical drugs differs from most markets, as stated by Frederick M. Abbott, "Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health" (2016) 6 *UC Irvine Law Review* at 301: "New drugs that treat previously untreatable diseases, or treat them in a significantly better way, will be demanded by patients regardless of their price. The drugs are not subject to price elasticity in the same way as virtually any other goods. If the maker of a breakthrough television sets a price far above those of existing/ordinary television sets, only consumers with high levels of readily disposable income will buy them. Others will find a way to manage without better TV quality. That is not the case with drugs essential to life and well-being."

[9] As is well-known, a patent protects the company from others copying the active substance of the drug. Orphan drug designation is an additional protection measure that grants a ten-year period of market exclusivity for a specific disease. Orphan status thus very closely approximates a true monopoly. The purpose of the orphan drug regime is to stimulate research into drugs for rare diseases, see Regulation (EC) 141/2000 (n4).

[10] Both types of costs may be called 'research and development costs', but we want to make a distinction between costs that affect the PoS and costs that don't.

investments go to infinity, the project will succeed with some positive probability $\overline{p_i}$: $p_i(I_i \to \infty) \to \overline{p_i}$, where $0 < \overline{p_i} < 1$.

When the drug is successful and enters the market, it yields a benefit to society equal to B_i. To make the model non-trivial we assume that all projects have positive expected value for society if investments are made in a socially optimal way.[11] This benefit can be thought of as the health gains society enjoys when drugs become available. The pharmaceutical company sells the drug at some price which generates revenues. There is no need to explicitly model the company's price setting behaviour. The reason is that we focus on drugs that are so expensive that they are not paid for by the individuals concerned but by societies. In many countries the government decides whether a particular drug should be available to the population and negotiates directly with the pharmaceutical company about price. It does not matter for our analysis how countries finance their health care system (e.g. complete public financing or (partly) through private health care insurers), as long as societies bear the cost of a drug rather than individuals.[12]

The implication of these assumptions is that we can model the outcome of price negotiations with one single parameter s_i. This parameter reflects the share of the benefits from the drug to society the pharmaceutical company can extract through its pricing. Clearly, the more protected the company is from competition by regulatory measures such as patents and orphan drug designations, the higher the share s_i is likely to be. Importantly, we allow the share s_i to be greater than 1 (allowing for this possibility drives the results of the paper). In words, the pricing of a drug can be such that the pharmaceutical company extracts revenues that exceed the value of health gains from the drug to society, i.e. the payer pays more than his proper willingness to pay. For a more thorough discussion of this assumption, see section 3 below. For s_i to have an effect on innovation decisions, companies must have some knowledge of s_i when they decide on investments. We assume that companies may not know s_i in advance but can form an unbiased expectation of s_i. For simplicity, we do not introduce additional notation to refer to the expectation of s_i but simply refer to s_i.

2.2 Analysis of the baseline case

In the baseline model we derive the highly familiar result that private investment incentives can be sub-optimal from a social point of view. For each project, the first-best (socially optimal) level of investment is defined by the equality of marginal cost of investing and the marginal benefit of investing. Since the investment costs are given by I_i and the (expected) benefits by $p_i(I_i)B_i$, the first-best level of investment is defined by:

[11] This implies that when investment is first-best (denoted by I_i^{FB}), it holds that $p_i(I_i^{FB})B_i - I_i^{FB} - F_i > 0$. First-best investment is defined by $p_i'(I_i superscript\ FB) = \frac{1}{B_i}$ (see section 2.2).

[12] On a first note, a small percentage of the population may be able to afford these drugs themselves. However, even these people typically have health care insurance that pays for the drug when prescribed. On a second note, even when insured, people may contribute to the cost of the drug through deductibles. Deductibles are higher in some countries than in others, but typically they will only be a fraction of the price of the drug.

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$$p_i'(I_i^{FB}) = \frac{1}{B_i},$$

where the superscript FB denotes 'first-best'. Naturally, the above equation implies that the higher the social benefit of a drug, the higher the optimal investment is. From the social point of view, any project that has a social positive expected payoff should be executed. This condition reads:

$$p_i(I_i)B_i - I_i - F_i \geq 0.$$

The next step is to compare the socially optimal investment levels and project selection with their private counterparts. The pharmaceutical company's expected profits are:

$$\Pi = p_i(I_i)s_iB_i - I_i - F_i + p_j(I_j)s_jB_j - I_j - F_j.$$

Hence, maximizing over investments levels I_i yields:

$$p_i'(I_i^*) = \frac{1}{s_iB_i},$$

where the superscript $*$ denotes 'profit-maximizing'. Comparing the profit-maximizing investments to the first-best level reveals that the company will only invest the first-best level when it fully reaps the value of the drug to society, that is, $s_i = 1$. Moreover, it will invest too much or too little if $s_i > 1$ or $s_i < 1$, respectively.[13] The company will select a project if and only if:

$$p_i(I_i^*)s_iB_i - I_i^* - F_i \geq 0$$

We call this condition the 'participation constraint'. The participation constraint shows that the company only selects a project if the share s_i is sufficiently high. A higher share makes the project more likely to be executed by the company for two reasons. First, a higher share increases the company's revenues in case of success for any level of investments. Second, a higher share incentivizes the company to invest more, which increases the probability of success. The company selects projects in a socially optimal way if $s_i = 1$. For shares $s_i < 1$, the company does not fully recoup the value of its investments. This not only leads to sub-optimally low investment incentives, but it may also imply that the company does not execute the project even though it would be socially optimal to do so.

The statement that the company invests 'too much' if $s_i > 1$ begs the question what else the company could or should have done with the excess funds. The baseline model is so abstract that it cannot tell us more than 'something else'. Moreover, the baseline model implicitly assumes that

[13] Note that this result ignores the matter of distribution. In reality, there often is a trade-off between efficiency and distribution. We ignore this trade-off here but if it were considered, optimal investments incentives would arise for some $s_i < 1$. The reason is that $s_i = 1$ transfers all value of the drug to the firm and hence implies zero consumer surplus.

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the company has unlimited resources to invest, which essentially implies that there is no real cost in the model to investing 'too much'. In reality there will always be scarcity and opportunity costs somewhere, leading to misallocations if private incentives do not match social preferences. In the next sub-section we therefore enrich the model by imposing a bound on the investments the company can make.

2.3 The case of limited investment capital

This sub-section explicitly models opportunity costs of investing in a particular project by introducing a restriction on the amount of money the company can invest. Specifically, we assume that the company has to raise capital in order to be able to invest. Due to agency problems in the lender-borrower relationship, raising investment capital is costly and so there is a restriction on the investment level. We do not explicitly model this interaction but simply assume that some exogenously given amount of C is available (in section 2.4 we discuss the case where the budget C increases in the share s_i). Formally, the budget constraint reads:

$$I_i + F_i + I_j + F_j \leq C.$$

When we solve for the optimal investment levels, the solutions must not only satisfy the budget constraint but also each project's participation constraint. We solve the model in steps and start under the assumption that the participation constraints are met.

Both projects generate a non-negative expected value

Assuming the participation constraints are met, the Lagrangian of the company's constrained maximization problem reads:

$$\mathcal{L} = p_i(I_i)s_iB_i - I_i - F_i + p_j(I_j)s_jB_j - I_j - F_j + \lambda_{BC}(C - I_i - F_i - I_j - F_j),$$

where λ_{BC} is the Lagrange multiplier on the budget constraint. The first-order conditions are:

$$\frac{\partial \mathcal{L}}{\partial I_i} = p_i'(I_i)s_iB_i - 1 - \lambda_{BC} = 0,$$

$$\frac{\partial \mathcal{L}}{\partial I_j} = p_j'(I_j)s_jB_j - 1 - \lambda_{BC} = 0,$$

$$\frac{\partial \mathcal{L}}{\partial \lambda_{BC}} = G - I_i - F_i - I_j - F_j = 0.$$

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Since the PoS functions $p_i(I_i)$ are general, the solutions of I_i^* and I_j^* will remain implicit. However, by totally differentiating the system of first-order conditions to s_i, we can derive how a change in the share s_i affects the profit-maximizing investment levels. This yields the following system of equations:

$$p_i'(I_i^*)B_i + p_i''(I_i^*)s_iB_i\frac{\partial I_i^*}{\partial s_i} = \frac{\partial \lambda_{BC}}{\partial s_i},$$

$$p_j''(I_j^*)s_jB_j\frac{\partial I_j^*}{\partial s_i} = \frac{\partial \lambda_{BC}}{\partial s_i},$$

$$\frac{\partial I_i^*}{\partial s_i} = -\frac{\partial I_j^*}{\partial s_i}.$$

Solving the system for the partial derivative of I_i^* to s_i yields:

$$\frac{\partial I_i^*}{\partial s_i} = -\frac{p_i'(I_i^*)B_i}{p_i''(I_i^*)s_iB_i + p_j''(I_j^*)s_jB_j} > 0,$$

where the sign follows from $p_i'(I_i^*) > 0$, $p_i''(I_i^*) < 0$, and $p_j''(I_j^*) < 0$. Hence, investments in project i increase in the share s_i. Also note that investments in project j decrease in s_i. This is a consequence of the fact that there is a limited budget. Therefore, if more money is invested in project i this goes at the expense of money invested in project j. We call this phenomenon 'crowding out'.

In the next step we show that social efficiency never requires that $s_i > 1$. To show this, we first establish that if shares are not equal, $s_i \neq s_j$, this is detrimental to social welfare. Note that social welfare, given the profit-maximizing investment levels, is written as:

$$W(I_i^*) = p_i(I_i^*)B_i - I_i^* - F_i + p_j(I_j^*)B_j - I_j^* - F_j.$$

Taking the partial derivative of $W(I_i^*)$ to s_i yields:

$$\frac{\partial W(I_i^*)}{\partial s_i} = p_i'(I_i^*)B_i\frac{\partial I_i^*}{\partial s_i} - \frac{\partial I_i^*}{\partial s_i} + p_j'(I_j^*)B_j\frac{\partial I_j^*}{\partial s_i} - \frac{\partial I_j^*}{\partial s_i}.$$

Using $\frac{\partial I_i^*}{\partial s_i} = -\frac{\partial I_j^*}{\partial s_i}$, this reduces to:

$$\frac{\partial W(I_i^*)}{\partial s_i} = \frac{\partial I_i^*}{\partial s_i}\left[p_i'(I_i^*)B_i - p_j'(I_j^*)B_j\right].$$

The sign of the derivative depends on the difference between the marginal social benefit of investing in project i and the marginal social benefit of investing in project j. Whether and how these differ depends on the values of s_i and s_j. Note that the first two first-order conditions imply

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that, at the profit-maximizing investment levels, it must hold that:

$$p_i'(I_i^*)s_iB_i = p_j'(I_j^*)s_jB_j.$$

This means that if both projects yield the same share s to the company in case of success, the company equates the marginal expected benefit of investing of the two projects.[14] In that case, the partial derivative of social welfare to s_i is equal to 0. If $s_i < s_j$, the company puts more weight on project j. In that case, the company selects a lower level of I_i^* and a higher level of I_j^*. This implies that the difference $p_i'(I_i^*)B_i - p_j'(I_j^*)B_j$ is positive, which in turn implies that the partial derivative of social welfare to s_i is positive. Therefore, if $s_i < s_j$, it is socially optimal to increase s_i until it equates s_j. The reverse holds when $s_i > s_j$. The result that the socially optimal shares have the property that $s_i = s_j$ has a simple intuition: society only cares differently for the projects to the extent that there are differences in the values B_i and the shape of the PoS functions. Hence, these are also the only differences that the company should take into account.

Finally, note that the intensity of the company's incentives (the absolute values of the shares s_i and s_j), does not affect total investments $I_i^* + I_j^*$. These are, by assumption, restricted by the budget constraint. Given this restriction, the value of s_i and s_j does not matter for social efficiency as long as $s_i = s_j$. It therefore also does not hurt social welfare if, from a position where $s_i = s_j > 1$, the shares are reduced to $s_i = s_j = 1$. (In fact, if in the starting position $s_i \neq s_j$, social efficiency is improved because of a more efficient distribution of investment capital over the projects.) Clearly, if reducing the shares implies that the budget constraint is no longer binding (because the company wants to invest a smaller amount which happens to be within the budget C), we are back in the baseline case. There we established that the social optimum is defined by $s_i = s_j = 1$.

One of the projects generates a negative expected value

Above we assumed that each project generates a positive expected value at the optimum, which implies that both projects are selected by the company. If, given the investment levels that maximize the expected value of both projects, fixed costs are too high to make one or both of the projects profitable, the optimal investment levels are different than the ones characterized above. In addition to this, the company will either perform one or none of the projects. We ignore the uninteresting latter possibility, and only solve for the case where at least one project is sufficiently profitable to execute.

Without loss of generality, we assume that it is project j that renders a non-positive expected value at the investment levels derived in the previous paragraph. This implies that the company will only invest in project i. Now there are two possibilities: either the company will invest the entire budget C in project i, or it will invest less. In the second case, investment is given by the values derived in the baseline case, so s=1 provides optimal incentives. In the first case, the

[14] Note that equating the marginal expected benefit of investing in the two projects does not imply that $I_i^* = I_j^*$. The reason is that B_i may differ from B_j. If for example $B_i > B_j$, the company will invest more in project i than in project j.

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budget is apparently too small to allow the company to maximize its expected profits from project i. Investments are therefore given by $I_i^* = C - F_i$. Note that the share s_i can be higher or lower than 1 but it can be reduced without affecting the company's investments. The reason is that investments are effectively constrained by the budget C. In this case a change in s_i does not affect social welfare, because there cannot be crowding out when only one project is executed.

Is increasing the company's share attractive from a social point of view because it generates more projects?

Above we established that, due to limited investment capital, the company may choose not to perform one of the projects. A natural question is whether it is socially optimal to raise the share of the project that would not be executed, s_j, to the point where the project will be executed. In the present case where investments are constrained, total investments do not increase as s_j increases, although the distribution of the available budget over the projects changes in favour of project j. We limit our attention to the case where $s_i = s_j = 1$. The reason is that we want to know whether there could be a rationale for offering shares greater than 1.

Clearly, if the company was *not* financially constrained, it would never be optimal to increase the share s_j above 1. In the unconstrained case, the company invests the first-best investment level in project j when $s_j = 1$.[15] If the project nevertheless has a negative expected value it is simply a socially wasteful project. However, in the case discussed here, for $s_j = 1$, the investment level is below the first-best level to such an extent that the project yields a negative expected value to the company, that is, $s_j p_j(I_j^*)B_j - I_j^* - F_j < 0$. A higher share s_j is therefore needed to make the project more profitable to the company. A higher share implies a higher payoff given success, and increases the probability of success. From a social point of view, however, increasing s_j is never optimal. The argument goes in three steps.

First, assuming the project will be executed, recall we can write social welfare as:

$$W = p_i(I_i^*)B_i - I_i^* - F_i + p_j(I_j^*)B_j - I_j^* - F_j.$$

Second, if the project yields a negative expected value to the company at $s_j = 1$, the project also yields a negative expected value to society, that is, $p_j(I_j^*)B_j - I_j^* - F_j < 0$. Hence, social welfare would be higher if project j would not be executed. Third, raising s_j is thus necessary to make project j attractive from a social point of view. However, we established before that starting from any situation where $s_i = s_j = s$, raising s_j *decreases* social welfare. In other words, raising s_j may increase the social expected value from project j, but the overall effect on social welfare from raising s_j is negative.

[15] Note that it would *not* help to raise s_i, since raising s_i would lead to even more crowding out of project j. This insight runs counter an argument often raised by pharmaceutical companies in favour of higher drug prices, namely that a higher price for drug i is necessary to make up for losses on other projects. Our model with limited investment capital shows that giving incentives to perform a project depends *negatively* on the revenues of other projects.

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A final option to consider is whether or not it is attractive from a social point of view to raise both s_i and s_j above 1. However, this is ineffective as raising both s_i and s_j will not affect the distribution of investment capital over the projects. By conclusion, it is never optimal to raise shares above 1 in order to induce the company to pick up projects it would not execute if $s_i = s_j = 1$.

2.4 What if the budget C increases in the shares s_i and s_j?

So far we assumed that the budget C is independent of the shares s_i and s_j. In this section we discuss the possibility that the budget increases if the shares s_i or s_j increase. It can be quite easily shown that if the budget increases in the shares s_i and s_j, increasing both shares by the same amount increases the efficiency of investment incentives, and therefore social welfare W as defined above. The intuition is that the shares remain identical, and so there is no crowding out, but the total investment budget increases. However, we argue that this is not a convincing argument for raising s_i above 1.

If ameliorating capital restrictions can only be achieved by raising drug prices (which is not that realistic, given the rife options available in tax cuts or direct subsidies to compensate for fixed costs), it is socially optimal to do so by raising relatively low values of s_i rather than raising high values of s_i. This has the double benefit of reducing crowding out and increasing the available investment capital. Another argument justifying our assumption is that one may interpret B_i as the opportunity costs of buying a drug. Most governments have a fixed budget available for pharmaceutical products. This budget is implicitly determined by what else can be done with the money. Buying drug i thus goes at the expense of buying other drugs. And even if you increase the budget for pharmaceuticals it would then crowd out other health expenses. This is another kind of 'crowding out'. In this variant, it does not occur in the pharmaceutical companies' investment decisions but rather at the buying side of the market: expensive drugs imply that other drugs cannot be purchased or other health expenses will be lowered. Given that the opportunity of not buying drug i yields a benefit of B_i, a government should pay at most B_i for the drugs (implying $s_i = 1$).

The example of limited liability is just one way of introducing a scarcity or opportunity cost in the model. There can be many other ways in which the inefficiency derived in the base model plays out, such as inefficient advertisement, management capacity or even inefficiencies at the level of investors. For our main point, it really does not matter in which form the inefficiency occurs.

3. Application of key insight to drug prices in the Netherlands

Our theoretical framework implies that interventions against high drug prices can improve innovation whenever $s_i > 1$. In this section we operationalise this theoretical concept. We focus on the case of the Netherlands. The reason for this is that institutional details matter, although the steps identified here are robust for institutional settings in many other countries as well. Before we start, a few words on whether intervention against high drug prices at the national level is the appropriate level.

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Drug prices can typically be expressed in terms of price per patient per year. We want to evaluate the innovation-efficiency of this variable from the perspective of one country, the Netherlands. However, drugs are usually offered in many countries at different prices. Pharmaceutical companies' incentives to invest in drug development are therefore determined by global revenues. Moreover, countries typically only know their own price and differ in the willingness to pay for pharmaceutical drugs. The model developed in section 2 abstracts from differences between countries in the parameters s_i and B_i, and essentially treats these parameters as set on a global scale. In practice the efficiency of innovation incentives can only be determined on a global scale.

So is our analysis flawed because we miss this important point? We do not think so. Individual countries can act against high drug prices as well. First, countries may pay different prices and have different valuations for pharmaceutical drugs. In the economic literature this is known as Ramsey pricing and is often deemed efficient since it improves allocative efficiency compared to uniform prices. Second, suppose that the company demands a country share $s_{i,c} > 1$ in some country c. Such high prices could be needed to prevent that innovation incentives on a global scale are sub-optimally low. Given the way the parameter s_i is constructed a share $s_{i,c} > 1$ then implies a cross-subsidy, i.e. at least one country other than c pays a share $s_{i,-c} < 1$. Our model implies that a country share greater than 1 may be beneficial for innovation, but this comes at a price. Possible differences in drug prices (or more precisely: the share $s_{i,c}$) between countries may result in free-riding problems between countries. Each country may have an incentive to let other countries pay for the development of the drug. In a repeated game, an efficient strategy for countries may therefore well be to decrease its share if other countries pay a lower share as a way of preventing free-riding. Also from an ethical point of view the cross-subsidies (in values) are doubtful[16]. Third and last, countries usually do not observe prices paid in other countries due to a lack of transparency. Countries therefore lack necessary information to differentiate between cases where $s_{i,c} > 1$ is necessary for efficient innovation incentives or not. In the remainder of the paper, we will consider the efficiency of drug prices as if it is purely a national issue.

The next step is to find a measure of the value of a drug to the Dutch society. An important part of the Dutch health care system is the basic benefits package. This package covers a wide array of health care, must be offered by all health care insurers, and is mandatory for Dutch citizens. The Dutch Minister of Health decides whether or not a new pharmaceutical drugs is admitted to the basic benefits package. The Minister can negotiate with pharmaceutical companies about the price per patient per year. Given the price demanded by the company, an independent expert committee (the "Advies Commissie Pakket", henceforth ACP) publishes an advice on whether or not the drug should be admitted and why.

An important element in the ACP's consideration is whether or not the drug is sufficiently cost-

[16] In general cross subsidies or differential prices between countries happens all the time and can even be welfare enhancing, but the issue here is not differential pricing per se but differences in values, i.e. some country pays above its own value s=1 to compensate for others paying less than their value. There is no Ramsey pricing justification for that.

effective.[17] To make this assessment, the ACP uses a maximum reference value of € 80.000 per QALY gained from using the drug. Next to cost-effectiveness, the ACP also evaluates the necessity of admitting the drug to the basic benefits package. The evaluation is operationalised by using different reference values per QALY, depending on the severity of the disease. For low severity, medium, and high severity, the reference values are € 20.000, € 50.000, and € 80.000 per QALY, respectively.[18]

Given its findings on effectiveness, necessity and cost-effectiveness, the ACP checks if basing its advice solely on these factors would, unintendedly, conflict with considerations of justice and solidarity. In this phase, the ACP takes into account possible reasons to allow less (or demand more) cost-effectiveness. Such reasons may be whether a drug cures or only extends life, the robustness of the effectiveness reported by the company, the existence of alternatives for the drug, whether the drug is mostly used by young or old people, and the impact on the total health care budget. When the ACP advises negatively on admittance to the basic benefit package, it may stipulate the price decrease necessary for changing its advice.

Notably, before the ACP decides on its advice, the Dutch Health Institute has organized a full-fledged stakeholder hearing. Moreover, the advices and deliberations by the ACP are open to the public. Patient organisations, doctors, pharmaceutical companies and other stakeholders have the right to formally present their points of view prior to the decision and discussion by the ACP. It frequently happens that stakeholders use this opportunity.

We claim that the full advice of the ACP on whether or not a drug is sufficiently cost-effective should be taken as a measure of the willingness to pay of the Dutch society. The claim is warranted from the fact that the ACP is an independent expert committee that bases its advice on all factors relevant to the Dutch society. In the following, we discuss some critiques of this approach.

First, it is sometimes argued that QALY threshold values are unfit for policy decisions, for methodological reasons. Much of the empirical research on the value of a QALY aims to identify individuals' Willingness to Pay (WTP) for health improvements. This literature exhibits significant variation in QALY estimates. Differences in the size of health gains, the way questions are posed, and the way answers are aggregated all affect the results. A recent overview article shows that the highest estimate found for the Netherlands lies in the range of € 80.000 - € 113.000 (2014 euros) but many estimates lie (far) lower than € 80.000.[19]

Second, within the context of a national health care system, considerations of equity play an important role. Estimates of individuals' WTP for a health improvement may therefore not

[17] Other criteria are effectiveness and ease of implementation.
[18] See (in Dutch) Raad voor de Volksgezondheid en Zorg, *Rechtvaardige en Duurzame Zorg* (2007), <https://www.raadrvs.nl/uploads/docs/Advies_-_Rechtvaardige_en_duurzame_zorg.pdf>.
[19] Laura Vallejo-Torres et al., "On the Estimation of the Cost-Effectiveness Threshold: Why, What, How?" (2016) 19 *Value in Health* 558-566.

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accurately reflect peoples' preferences for publically financed health care. Bobinac et al. (2013) therefore aim to elicit a societal QALY value rather than individual WTPs. The authors find a QALY value for the Netherlands of at most € 83.000.[20] Since this paper is concerned with high drug prices, all that is needed for application is that a drug price is higher than a reasonable estimate of the *maximum* QALY value to society.[21] Also note that the reference value is just that: a reference value. The ACP aims to take all relevant ethical considerations into account apart from cost-effectiveness. The ACP thus also explicitly aims to correct for important factors not captured in the QALY value.

Third, one may suggest that in case the Minister admits a drug to the basic insurance package despite a negative advice of the ACP, the Minister's decision is a more accurate reflection of the benefit of the drug to society. We disagree for the following reasons. The ACP's advice is based on all relevant ethical and economic aspects for the Dutch society. The Minister, however, is subject to political forces that may affect decision-making in a sub-optimal way. Not admitting a drug to the basic benefits package is a highly sensitive decision because this can have dramatic consequences for a small group of affected individuals. This group obviously has a very strong interest in having access to the drugs and to make its case publicly. The overwhelming majority of society does not need the drug, however, and therefore has a relatively insignificant interest in whether or not the drug is admitted. This makes it politically and emotionally difficult for decision-makers to bargain hard over drug prices. This 'TV pressure' (sometimes called 'blackmail' or 'taking hostage') and the preference for visible victims over anonymous (but more numerous) victims is a variant of the well-known "identifiable victim effect" and is aggravated by the secrecy of the deal. The Minister can claim that he has made a good deal, whilst in reality he has not and nobody is able to check it. We therefore do not consider the Minister's decision a more accurate reflection of the value of a drug to Dutch society.

Last, innovation incentives are ultimately determined by the (expected) lifetime revenue of the drug. In practice one can only observe the historic price per QALY. Is it possible to make reliable statements on the efficiency of innovation incentives before the end of the lifetime of a drug? There is no hard evidence neither theoretical nor empirical that the current patent length is optimal. Boldrin and Levine (2008) make a heroic attempt (and conclude coincidentally that about 10 years is optimal), but nobody knows for sure how to assess the trade-off between protection and competition. Clearly in some cases the protection can be too short (when market size is small, hence the extra orphan protections) whilst in others it can be too long. Nor is there strong evidence that the current system fails to strike the balance. In absence of solid evidence we do what most economist do: rely on the scarce literature and assume that the current system is optimal, although we realize that we don't really know for sure. Hence we assume to extrapolate historic prices over the period of patent and especially orphan designation (as there is no chance

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[20] Ana Bobinac, N. Job A. van Exel, Frans F.H. Rutten, Werner B.F. Brouwer, "Valuing QALY Gains by Applying a Societal Perspective" (2013) 22 *Health Economics* 1272-1281.
[21] Drug prices higher than 100.000 per QALY are not rare in the Netherlands. See (in Dutch) Zorginstituut Nederland, *Monitor Weesgeneesmiddelen 2017,* <https://www.zorginstituutnederland.nl/publicaties/publicatie/2017/12/21/monitor-weesgeneesmiddelen-2017>.

that there will be a competing product during the period of orphan designation). However, the price may drop once the patent and orphan designation are expired. This allows for the theoretical possibility that in the protected period prices higher than the social value of the drug are necessary to compensate for lower prices afterwards. We offer two arguments why this theoretical possibility should not be considered in practice. First, taking the profits after patent protection or orphan designation into account would require investors to plan ahead for time periods more than 20 years after initial investments. The uncertainty regarding such distant time periods is so large that it does not seem credible that they materially affect investment incentives. Second, patent protection and orphan drug designation are meant to stimulate innovation. Nevertheless the period of protection is finite. The main reason for this is that innovations may build on each other, and that a completely new and improved product may be invented. It is therefore normal practice *ex ante* to allow for the possibility that another party takes the floor after some period of protection.[22] That is why we assume that the patent period gets it right on average, i.e. it may sometimes be too short but equally likely too long to give the proper innovation incentives. Note that this argument is stronger for orphan drugs compared to non-orphan drugs, as only in the case of orphan drugs a completely new product would be barred from the market during orphan status of an existing drug. Concluding, we take the view that when examining the efficiency of innovation incentives, one should only take into account the period of patent protection and if applicable orphan drug designation.[23]

We conclude that it is possible to apply our main result to the institutional setting of an individual country (in this particular case the Netherlands), that there is a reasonable approximation of the value to society, that there is every chance that, within this framework, the Netherlands regularly pays a price that is higher than the proper value to society and that the patent (or orphan) protection period is assumed to be the right reference to base innovation incentives on.

4. Patented drug prices and competition law

Any player capable of influencing drug prices, both private and public, can use the results derived above to improve market outcomes. In this section we discuss the implications of our results for the applicability of competition law. Competition authorities have increasingly become active in the area of drug prices.[24] Most (if not all) cases concerned prices of out-of-patent drugs. The logic

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[22] Gilbert and Shapiro derived the optimality of infinite patent length. However the authors themselves conclude that under a variety of assumptions (and those happen to be relevant for pharma) limited and shorter patent periods are optimal. Richard Gilbert and Carl Shapiro, "Optimal Patent Length and Breadth" (1990) 21 *The RAND Journal of Economics* at 112.

[23] In its recent excessive pricing case *Pfizer/Flynn*, the UK Competition and Markets Authority (CMA) has adopted a very similar approach. The CMA did not investigate a drug under patent as we are discussing here. Yet, this was precisely the reason why the CMA rejected Pfizer's claim that a reasonable share of R&D costs should be included in the CMA's cost calculation. See case CE/9742-13 *Pfizer*, CMA Decision of 7 December 2016, Annex L.

[24] E.g. *Pfizer/Flynn*; Case A480 *Aspen Pharmaceuticals,* AGCM Decision of 29 September 2016; European Commission, "Antitrust: Commission opens formal investigation into Aspen Pharma's pricing practices for cancer medicines" (press release 15 May 2017) <http://europa.eu/rapid/press-release_IP-17-1323_en.htm> accessed 4 April 2018; South African Competition Commission, "International pharmaceutical companies investigated for cancer medicine prices" (press release 13 June 2017) <http://www.compcom.co.za/wp-content/uploads/2017/01/International-pharmaceutical-companies-investigated-for-cancer-medicine-prices.pdf>.

often goes as follows. Some pharmaceutical company acquires a product that is off-patent, and then decides to raise prices, sometimes more than 10 fold.[25] Typically, the competition authority can then credibly claim that recoupment of initial R&D costs cannot be the driver of these price jumps, and that normal competitive forces would not allow for
those sudden jumps in prices. These cases are arguably 'easier' than cases where medicines are still under patent, since the innovation argument (the medicine is off-patent) becomes irrelevant and there is a natural reference price (the old price). With medicines under patent a completely different logic applies. It is the high price itself that might be deemed excessive, with the complication that the innovation argument can become relevant and no natural reference price exists (there is no 'old price'). Despite these complications pharmaceutical companies that charge high prices are not immune from the scrutiny of competition authorities. This section henceforth focuses on applying competition law to drugs with some form of protection from competition, such as patents and orphan drug designation. We discuss both the desirability and feasibility of applying competition law in this area.

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4.1 Desirability

Excessive prices is a controversial topic in competition law. Within the US legal framework there is no provision against high prices. Within EU competition law, a dominant firm can abuse its position by charging unfairly high prices but these cases are very rare. In line with this practice, commentators have suggested various, usually stringent, sets of specific circumstances under which excessive price cases could be pursued. We share the conviction that excessive price cases should only be pursued in a limited set of circumstances. Below we will argue that high drug prices can be one of the potentially relevant areas.

Almost all commentators point out that a dominant position may be the result of prior investments or innovation and that the resulting high price is a reward for the risky undertaking to create new valuable products or services. Excessive price cases could then reduce innovation incentives which may harm welfare in the long run. This leads Fletcher and Jardine (2007) to conclude that "there should be no intervention against excessive prices for an innovative product within that product's patent life".[26] Motta and de Streel (2007) leave room for cases where the competition authority shows that the allocation of the patent was manifestly unjustified.[27] Evans and Padilla (2005) favour a *per se* legality rule for high prices but they also consider a structured rule-of-reason test for high prices. Part of this test is that innovation and investments incentives play no, or at least a limited, role.[28] We have shown that an absolute rule to abstain from intervention against high prices when innovation incentives play a role is not warranted. If price levels can be identified that are inefficiently high *from an innovation perspective alone*, as we argued can be the

[25] https://www.lexology.com/library/detail.aspx?g=8ef46701-3dbc-4373-8af6-2aacf54330ef
[26] Amelia Fletcher and Alina Jardine, "Towards an Appropriate Policy for Excessive Pricing", in Claus-Dieter Ehlermann and Mel Marquis (eds.), *European Competition Law Annual 2007: A Reformed Approach to Article 82 EC*, (Hart Publishing, 2008). Hart Publishing, Oxford/Portland, Oregon (in preparation).
[27] Massimo Motta and Alexandre de Streel, "Excessive Pricing in Competition Law: Never say Never?" in Swedish Competition Authority (ed.), *The Pros and Cons of High Prices* (Stockholm 2007) 14-46
[28] David S. Evans and A. Jorge Padilla, "Excessive Prices: Using Economics to Define Administrable Legal Rules" (2005) 1 *Journal of Competition Law and Economics* 97-122.

case for patented drug prices, intervention by competition authorities can actually improve market outcomes. The other conditions for intervention against high drug prices by competition authorities often proposed are very high entry barriers and the absence of sector-specific regulation. Note that the first condition is likely to be satisfied by patented drug prices, especially when a drug also enjoys market exclusivity linked to an orphan drug status. The second condition is also satisfied, at least in the Netherlands, as there is no sector-specific regulator for drug prices.[29]

Writing from a US perspective, Abbott (2016) notes that "the arguments against application of excessive pricing doctrine [in the field of patented drugs, added] are essentially arguments against government interference in the free market. But, no market is "less free" than the pharmaceutical market. It is regulated every step of the way, except in the United States with respect to prices. And it is somewhat odd to argue that patent owners protected by legislative monopolies are pricing in a freely competitive market. It is obvious that they are not."[30] We think that Abbott (2016) can be interpreted in a way that allows competition authorities to *potentially* improve market outcomes by (when appropriate) showing high prices of patented drugs are excessive. Finally, Fonteijn, Akker, and Sauter (2018) explore the compatibility of competition law and intellectual property law from a legal perspective.[31] They conclude that both bodies of law are compatible or even complementary, and that competition law should be applied taking the goal of intellectual property law into account. In the following sub-section we propose a way to do this.

4.2 Feasibility

The landmark case on excessive pricing in the EU is *United Brands*.[32] The European Commission found that United Brands Company had abused its dominant position in the market for bananas by charging excessive prices for the sale of Chiquita bananas to customers in Belgium-Luxembourg, Denmark and Germany. In its ruling in this case the European Court of Justice explained what an excessive price is and how it can be proved:

> 249. It is advisable therefore to ascertain whether the dominant undertaking has made use of the opportunities arising out of its dominant position in such a way to reap trading benefits which it would not have reaped if there had been normal and sufficiently effective competition.
> 250. In this case charging a price which is excessive because it has no reasonable relation to the economic value of the product supplied would be such an abuse.
> 251. This excess could, *inter alia*, be determined objectively if it were possible for it to be calculated by making a comparison between the selling price of the product in question and its costs of production, which would disclose the amount of the profit margin; […]
> 252. The questions therefore to be determined are whether the difference between the costs

[29] Note that the ACP only advises the Minister on whether or not a drug should be admitted to the basic benefit package. Maybe there should be sector-specific regulation, but that is a different matter.
[30] Abbott (2016) at 302.
[31] Chris Fonteijn, Ilan Akker and Wolf Sauter, *Reconciling Competition and IP Law: the Case of Patented Pharmaceuticals and Dominance Abuse*, 2018 ACM Working Paper
[32] Case 27/76 *United Brands and United Brands Continentaal v Commission* EU:C:1978:22.

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actually incurred and the price actually charged is excessive, and, if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products.

253. Other ways may be devised – and economic theorists have not failed to think up several - of selecting the rules for determining whether the price of a product is unfair.

Most commentators interpret *United Brands* in such a way that a two-legged test must be satisfied to establish an abusive price.[33] It must first be shown that the price is excessive, that is, price 'has no reasonable relation to the economic value of the product'. If so, it must subsequently be shown that the price is unfair, either in itself or in relation to other competing products. Importantly, the Court does not precisely pin down how excessiveness and unfairness can be proved. This is made evident by the excerpts 'inter alia' (251) and 'other ways may be devised' (253).[34] The Court, however, does provide the calculation of a profit margin as an example of how excessiveness may be shown. We consider ourselves 'economic theorists' in the sense of *United Brands* (253) and therefore take the liberty to propose two possible lines of thought for applying the *United Brands* test to prices of patented drugs. In doing so, we closely stick to the method we proposed for identifying inefficient innovation incentives. Our proposals are not meant as the only appropriate means to establish excessiveness and unfairness of drug prices. Rather, they should be seen as a possible way to apply the *United Brands* test in the particular area of patented drug prices. Moreover, it should be noted that the method we devise below is proposed specifically for the case of patented drugs. We do not consider the method relevant when a drug is no longer protected by patent or orphan drug status. The reason is that for such drugs providing innovation incentives is no longer necessary.

Regarding excessiveness we offer the following discussion points. A price that is above the QALY reference value (or, within the Dutch context, is negatively advised on by the ACP) might be considered excessive, for two reasons. First, when $s_i > 1$, the price is higher than the true willingness to pay by society. One can argue this implies that the price has no reasonable relation to the economic value of the product. When $s_i > 1$, the payer does not just realise a small surplus but actually lose surplus, both in terms of static efficiency (price) and dynamic efficiency (innovation). This is an unusual and remarkable outcome, but it can arise within the political context of national health care plans where central decision makers are in a weak negotiating position to buy drugs on behalf of the population.

Second, as we have shown, investment incentives improve if prices implying $s_i > 1$ are lowered.

[33] Amongst others Pinar Akman and Luke Garrod, "When are Excessive Price Unfair?" (2011) 7 *Journal of Competition Law & Economics* 403-426; Liyang Hou, "Excessive Prices Within EU Competition Law" (2011) 7 *European Competition Journal* 47-70; Robert O'Donoghue and Jorge Padilla, *The Law and Economics of Article 102 TFEU* (Hart Publishing, second edition, 2013); Marcus Glader and Ioannis Kokkoris, "Excessive Pricing" in Francisco Enrique González-Díaz and Robbert Snelders (eds.), *EU Competition Law, vol V, Abuse of Dominance Under Article 102 TFEU* (Claeys and Casteels, 2013) 615-666. An exception is Massimo Motta and Alexandre de Streel, "Excessive Pricing and Price Squeeze under EU Law" in Claus-Dieter Ehlermann and Isabela Anastasiu (eds.), *European Competition Law Annual 2003: What Is an Abuse of a Dominant Position?* (Hart Publishing, 2006) 91-126 by arguing there is only one test, namely whether "the price is significantly above the competitive level".

[34] In the recent *AKKA/LAA* case, the Court of Justice reaffirms this approach. Case 177/16 *Biedrība "Autortiesību un komunicēšanās konsultāciju aģentūra - Latvijas Autoru apvienība" Konkurences padome* EU:C:2017:689 at 36 and 37.

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This alone also implies excessiveness. One may counter here that a price such that $s_i > 1$ need not be far from the most efficient investment incentive ($s_i = 1$), and therefore $s_i > 1$ is not sufficient to conclude that the price is excessive. This ignores the trade-off between efficiency and distribution. For any price such that $s_i < 1$, more innovation incentives go at the expense of consumer surplus. In our model, investment incentives are optimal when consumer surplus is zero (and so the company extracts all the value of the drugs). When price is increased further, there is no longer a trade-off between distribution and efficiency. As consumer surplus is already zero at $s_i = 1$, both dimensions simply deteriorate.

The reasoning that a price such that $s_i > 1$ is unfair closely resembles the reasoning for excessiveness. We claim that a price that implies $s_i > 1$ is unfair. First, a price such that $s_i > 1$ yields a negative consumer surplus. Second, patents (and, if applicable, orphan drug designations) grant market power to firms that have a successful innovation. This benefit is granted to the firm in order to promote efficient innovation incentives (which would be significantly lower or reduced if competing firms could simply copy the product). As long as a higher price improves innovation incentives, a price increase may be considered fair since this is precisely the goal of patent protection (even though it goes at the expense of consumer surplus). However, in case firms use their dominant position that results from patent protection to extract prices that overshoot the goal of patent protection, this is no longer fair. Put differently, the firm takes more than it needs to fulfil the very purpose why it was granted the dominant position (i.e., spurring innovation).

A further observation relates to United Brands (249) which stipulates that prices can be deemed excessive if a firm reaps benefits which it would not have reaped if there had been normal and sufficiently effective competition. Clearly in the context of our model no 'normal and sufficiently effective competition' would allow prices such that $s_i > 1$. In contrast, normal competition would drive prices down to a level where profits can be made and innovation is stimulated. Those prices cannot be such that $s_i > 1$.

Finally, we do realize that referring to willingness to pay by a society is unusual in the context of excessive prices. Yet, there are at least four reasons for regarding society's WTP in the case of pharmaceutical drugs. First, there are often no consumers who pay directly, so that unfairness does not relate directly to consumers but to the group of payers. Second, and related to this, given that we spend (directly or indirectly) public money on innovative drugs, the payer is legitimized in asking the question whether he gets value for his money. Third, society's WTP in the context of pharma can be measured adequately. Finally, society's WTP allows us to relate excessiveness to the efficiency of innovation incentives, which is a crucial component of efficiency in this market.

Concluding, assume a country, for one reason or the other, pays more for a drug under patent protection than the proper WTP to society. In such cases competition authorities can use this feature not only to counteract the argument that such prices are needed for innovation (sections 2 and 3) but also as one way to operationalize the United Brands test for excessive prices.

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5. Concluding remarks and discussion

This paper makes three contributions. First, not every price of a patented drug provides efficient investment incentives. In particular, prices can be higher than the value of the drug to society which leads to inefficient innovation decisions. Second, at least in the Dutch context (but presumably applicable to many other countries too), prices that are higher than the value to society can be identified by comparing the price to the QALY reference value used for assessing the cost-effectiveness of drugs (possibly corrected for a variety of ethical and other considerations). Third, we explored how these results can play a role in assessing excessiveness and unfairness of patented drugs prices within the confines of the landmark competition case on excessive prices in the EU, *United Brands*.

For the first two contributions to hold one needs to make a number of assumptions, some more controversial than others. We have underpinned our assumptions in detail, but there is room for discussion regarding the following assumptions. The first key assumption is that it is acceptable to analyse innovation incentives from the perspective of an individual country. The second key assumption is that the QALY benchmark (possibly corrected for relevant ethical considerations) is a proper way to assess the value of a drug to society. Whilst there can be plenty of discussion about using QALY values, the way this is done in the Netherlands makes us confident that the assessments are based on a full set of considerations, including input from all stakeholders and ethical and distributional issues. The third key assumption we need is that a Minister's decision (to pay more) is a less accurate reflection of the benefit of the drug to society than the advice of the Dutch independent commission. We have argued in detail why we think this assumption is reasonable, but one could also defend the position that political arguments are part of society and therefore also reflect value to society. The final key assumption is that we disregard possible profits once protective measures have expired.

Our third contribution, the application of the *United Brands* test in the area of patented drugs, may also be deemed controversial. First, because our proposed approach has never been applied before (or even suggested, to the best of our knowledge). Second, because it differs from the more traditional way of calculating profit margins. Third, because one can defend the position that in the presence of an institutional setup that handles drug prices (even though there is no specific drug price regulator in the Netherlands), the institutional framework should be improved rather than the competition authority stepping in. Despite these counterarguments, we don't see a principled reason to avoid this avenue as a way to operationalize United Brands test in the area of patented drugs and we welcome a broad discussion on this topic.

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