The Economics of Transferable Patent Extensions*

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Abstract

Faced with a scarcity of treatments for neglected diseases, experts and governmental organizations have lately proposed to build strong pull incentives around transferable vouchers. Inventors would be granted, and allowed to sell these vouchers to pharmas desiring to extend their exclusive IP rights. However, we know little about how such "Transferable Exclusivity Extensions" fare relative to prizes, who is likely to acquire them and at what cost for society, or how the burden is shared among nations. We shed light on these questions, both from a theoretical perspective and from an empirical analysis of European data.

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1 Introduction

The standard incentive scheme to foster innovation is intellectual property protection (IPP). Patents, trade secrets and copyrights confer monopoly power over a fixed duration, during which the innovator can recoup their investment. IPP however may not ensure the existence of a "business model". Small numbers (orphan diseases), limited ability to pay (drugs for LDCs), and externalities (antibiotics, vaccines) create a significant wedge between the social and private values of the innovation and motivate a different approach. For centuries, this alternative approach has been the granting of cash prizes, or in their modern form advanced market commitments (Kremer, 1998; Berndt et al., 2007; Kremer and Williams, 2010; Kremer et al., 2020).

While reinforced pull mechanisms usually take the form of prizes,[1] it has lately been proposed that inventors of new antibiotics[2] be rewarded with an original currency: transferable exclusivity extensions (TEEs) or "vouchers". The inventor would be given a patent extension right of a given duration, and this right could either be used by the inventor themselves or, more likely, be sold by the inventor to an entity with an existing IP right, that would then enjoy the extra period of exclusivity after the normal expiration date. Although a TEE pull mechanism has yet to be implemented, an early draft of the bipartisan 2018 US REVAMP Act[3] planned for transferable exclusivity vouchers for drugs designated as priority antimicrobial products (Rome and Kesselheim, 2020; Boyer et al., 2022), while a voucher system, similarly designed to support antimicrobial innovation, is currently under consideration in Europe (Årdal et al., 2020). Besides, "priority review vouchers", which were inspired by academic work, have been used in the US since 2007. While they differ economically from TEEs, they share their spirit of rewarding innovation through tradable vouchers.

At first sight, vouchers, which prolong monopoly distortions, would seem to be dominated by prizes, which do not. Hence, prizes would seem in the pole position for financing neglected diseases. This reasoning however ignores two considerations. First, cash transfers must be financed from the general revenue, engendering a shadow cost of taxation. Second, and the novelty of this paper, the benefits of prizes are often overestimated, at least in the absence of a tight intervention into the production and delivery process. The generics experience demonstrates that when the knowledge underlying the branded drug falls into the public domain, prices remain far from competitive for multiple reasons: single supplier of

[1] Together with extended patent lengths and expedited approval processes.

[2] The funding issue is prominent in the case of antibiotics, for which the dearth in the new-antibiotics pipeline raises concerns about impending bacteriological pandemics. The current push and pull mechanisms seem to provide low incentives for innovation in the domain. And there is widespread agreement on the stewardship-based need for delinking rewards from sales.

[3] Re-Valuing Anti-Microbial Products Act (HR6294).

generics or multiple colluding ones, consumer attachment to the branded product, existing regulation.[4] Imperfect generics competition is of particular interest here, as it implies that ending the exclusivity of the branded drug operates a transfer away from the originator,[5] that is detrimental to the incentive to innovate without any corresponding benefit for the consumer. A striking conclusion of our empirical work is that an incentive reward of \$1 through a European voucher system costs less to the consumer/taxpayer than \$1 (and a fortiori less than the cost of a cash award of \$1) in most of the fifteen countries in our data set.

Let us clarify right away what this paper does not do. To this purpose, recall the innovation dilemma, that of rewarding inventors in proportion with their contribution to society while preserving public funds and consumers' access to innovation. This paper is not concerned with the incentive side and simply presumes that society has determined some level of reward for the innovation. Rather, this paper focuses on the second issue, the structure of the reward. Whether the reward is appropriate for the innovation is irrelevant for the structure study, for the cost of providing the reward must be minimized whether the reward is well-picked or off-the-mark.

The contribution of this paper is theoretical and empirical.

Theory. On the theoretical side, this paper offers a model of the costs and benefits associated with a TEE scheme. Assuming that branded molecules are regulated (with an intensity of regulation that depends on the regulator's bargaining power), we compute a cost-over-reward ratio, which captures for each \$1 of additional benefit to the inventor awarded a TEE, how many \$-worth in social surplus are lost for society. If this cost-over-reward ratio is higher than $1 + \lambda$, with $\lambda \geq 0$ the marginal cost of public funds,[6] then a TEE scheme is dominated by an equal-value prize to the inventor. In fact, while to the best of our knowledge, existing analyses of TEEs mainly focus on the length of the exclusivity extension, the relevant measure for a comparison of TEEs with alternative incentive schemes really is the cost-over-reward ratio. Furthermore, we show that the length of the exclusivity extension does not affect the cost-over-reward ratio of a TEE scheme, and is thus irrelevant for its comparison with direct payments to the inventor.[7]

[4] For example, the French regulation secures a price of generics in the year after the exclusivity loss equal to 60% of that of the original brand. Needless to say, French generics prices largely exceed the (often very small) marginal cost.

[5] As we later show, this transfer may or may not have a counterpart in generics' profit, as this profit might be competed away through free entry in the generics market. The important point, though, is that whether generic prices translate into supranormal profits or the dissipation thereof, the opening to competition sacrifices some of the ex-ante incentives for R&D without any benefit for the consumer.

[6] We assume that the planner does not internalize the profits of the developer of the new antibiotic.

[7] Of course, the tailoring of the additional exclusivity length remains necessary to adjust the level of the reward, but such tailoring cannot provide *per se* any argument in favor or against TEEs as opposed to direct payments. We discuss in Section 2.3.2 how the length of a TEE could be optimally adjusted to deliver the

Exclusivity extensions generate a loss of social surplus as they induce higher prices. Yet, in addition to their consumption-distorting impact, we highlight a *redistributive* impact of exclusivity extensions, from generics to the original branded drug company, whenever the generics market is not perfectly competitive. Which of these two effects dominates determines whether the cost-over-reward ratio of a TEE (in a single country) is higher (as is the case when generics are sold at marginal cost) or lower than 1.

Obtaining a simple expression for the cost-over-reward ratio requires some modeling choices. The literature on patents most often assumes that, after patent expiration, the generics industry takes over and charges prices close to marginal cost. However, this assumption is unwarranted. At the very least, fixed costs of entry, production and distribution by themselves prevent marginal cost pricing. Furthermore, generics producers may tacitly collude. The factually incorrect assumption of perfect generics competition implies, as we will see, an important bias in the computation of the cost-over-reward ratio. Yet, accounting for generics' imperfect competition is not straightforward as countries differ in their regulatory institutions. For instance, in some countries such as France, the price of generics is capped (an indirect evidence of the non-competitive nature of the generics market) at a level that depends on the branded molecule price. Even in the absence of such caps, the generics' collusive behavior may depend on the branded molecule price, as we emphasize in Section 2.3.1.

Our model must preserve tractability and cannot account for all subtleties of national regulations or collusive strategies. We thus compute the cost-over-reward ratio under three basic and highly tractable assumptions. The first is that, after patent expiration, the generics and the branded molecules are not substitutes: we capture this in a simple way by assuming that a (country-specific) fraction of consumers are captive of the branded molecule, while generics and the branded molecule are in the consideration set of the remaining fraction. The second assumption is that the price of the branded molecule is determined via Nash bargaining with the regulator.[8] The third assumption is that the regulation of the exclusivity price of the original branded drug does not take into account the impact of that price on the future price of generics after exclusivity loss (i.e. typically more than ten years later).[9]

Coalitions of countries are in general needed to achieve reward levels high enough to incentivize innovation in the absence of viable business models. Within a union (such as

appropriate reward.

[8]While our sample includes only European countries, this framework would accommodate the American absence of regulation by giving no weight to the regulator in the bargaining.

[9]Without this last assumption, if the relation between the two prices were taken into account by the regulator, the Nash bargaining for the branded molecule price would be significantly more complex and it would make our analysis untractable. As a robustness check, Appendix E.3 examines the likely biases that may be created by our independence assumption and shows that our results remain qualitatively valid.

the United States or Europe), decisions are made through majority, supermajority, or even unanimity voting, and to the extent that members can stay out of the financing, cash funding is ripe with free riding.[10] Indeed, the difficulty in reaching a political agreement on a cash transfer was one of the key motivations behind the current European push for an antibiotics voucher scheme. The European Medicines Agency can delay granting licenses to new generics for the molecule that has purchased the voucher, for a time period equal to the length of the voucher, de facto enforcing the IP rights associated with the voucher and making it easier to raise the funds.

It is therefore important to compute the impact of a cash transfer or a voucher scheme on the various polities. This requires making some assumptions on how cash is levied in the case of a prize. For Europe, we assume that contributions to the European budget are proportional to country income. A country tends to prefer a TEE scheme over a cash transfer scheme if its generics prices are high and the market share of generics low (such a country suffers less from a TEE), if its cost of public funds is high (such a country finds cash transfers more costly), and if the drug with extended exclusivity has a relatively small (per inhabitant) market in the country (say, an anti-cholesterol treatment faces less demand in Greece than in Finland).

We conclude the theoretical part with two observations. Firstly, we endogenize the number of generics entrants and the price of generics. We assume that a fraction of consumers are loyal to the originator, while the complementary fraction are fine with generics. Furthermore, generics can collude on a limit price such that the originator is willing to focus on loyal customers. Ending the exclusivity of the branded drug operates a transfer away from the originator, and the concomitant rent may be enjoyed by generics producers or dissipated through the entry mechanism.

Secondly, a pre-specified duration (say, a year) for a voucher creates uncertainty about the exact reward accruing to the antibiotic developer, as well as the overall costs incurred by patients and taxpayers, which raises concerns. The uncertainty can be eliminated by letting the voucher's potential buyers bid in terms of extension length. Namely, fix an arbitrary reward level for the antibiotic developer, and let the buyers announce the minimum length for the voucher that makes them willing to pay this amount of money for the right to extend their patent by this length. The winner of the voucher auction is the buyer who specifies the lowest length.

Empirics. On the empirical side, to the best of our knowledge, our paper is the first to provide an estimation of the costs and benefits associated with a TEE scheme. We use a rich dataset containing all drugs sold in 15 European countries, including the main Euro-

[10] See Dubois et al. (2022).

pean economies, over the period 2002-2012 (see Section 3). We calibrate our model based on this data, providing estimates of demand and market parameters, as well as the values and potential acquirers of one-year vouchers during the period 2002-2012. Crucially, we provide estimates of the cost-over-reward ratios of TEEs in each country, as well as in a (fictitious) union composed of the 15 countries in our data. Relying on estimates from the literature for marginal cost of public funds, we are able to give a first approximation of who in such a union would favor a union-wide TEE, and who would oppose it. According to our model and our data, and subject to the (important) caveats we discuss along the exposition, among the 15 countries in our union, 10 would quite unambiguously prefer a TEE scheme to a direct payment to the antibiotic inventor, 3 would be close to indifferent, while 2 would quite unambiguously prefer a direct payment to a TEE scheme.

Related literature. The literature on transferable exclusivity extensions is still nascent.[11] Rome and Kesselheim (2020) provide an estimation based on US data (2007-2019) of the costs associated with one-year exclusivity extension for fast-track drugs. Their analysis is limited to financial costs and does not consider user welfare. Moreover, while the length of exclusivity extension they consider is motivated by the proposed 2018 REVAMP Act, it could (in theory and possibly in practice) be adjusted to match the amount needed. Hence their analysis falls short of providing a comparison with alternative funding schemes. Relatedly and in the same fashion, a prior literature investigated the costs and benefits from the US FDA Pediatric Exclusivity Extension (started in 1997), which gave pharmaceutical manufacturers 6 additional months of market exclusivity for performing pediatric clinical trials of brand-name drugs widely used in adults.[12] Sinha et al. (2018) thus find that "the costs to consumers have been high, exceeding the estimated costs of investment for conducting the trials", but it is again not clear whether an adjusted (shorter) exclusivity length would have made the exclusivity extensions more efficient than alternative funding schemes. Moreover, the Pediatric Exclusivity Extension featured no voucher market.

Outterson and McDonnell (2016) and Boyer et al. (2022) provide careful discussions of how TEE schemes should be tailored, emphasizing that the length of the exclusivity extension be adapted to the investment need of antibiotic development, as well as what curtains should be set to prevent market abuse – e.g. sufficient advance notice of the exclusivity extension to generic manufacturers. However their discussions remain mostly informal and only consider US patients and markets. Imperfect tailoring and regulation of TEEs may significantly reduce their desirability. Yet, Outterson and McDonnell (2016) and Boyer et al.

[11] See Lakdawalla (2018) for a thorough review of the literature on the economics of the pharmaceutical industry.

[12] The extension was earned if trials were completed, regardless of whether the drug was found to be safe or efficacious in pediatric populations.

(2022) point out that TEEs may be easier to implement, albeit imperfectly, than alternative incentive schemes, such as direct cash transfers, due to budgetary rules and political constraints.

Lastly, another literature, pioneered by Ridley et al. (2006), investigates transferable "priority review vouchers" (PRVs). Gans and Ridley (2013) notably provides a rich analysis of the value of such vouchers depending on their tradability and on the characteristics of medical R&D. Our paper differs from this literature on methodological grounds by providing closed-form formulas to compare vouchers with alternative funding schemes (see in Appendix A how our approach helps derive such formulas in the case of transferable priority review vouchers). On a more conceptual level, while the "transferability" of such vouchers is akin to ours, the impacts and trade-offs involved by priority review vouchers on the one hand, and transferable patent extensions on the other hand differ significantly. We provide in Appendix A an illustration: The cost-over-reward ratio of transferable priority review vouchers decreases with the degree of competition in the generics market, whereas the cost-over-reward ratio of TEEs increases with it. Finally, as Gans and Ridley (2013) point out, the PRV mechanism finds its justification in (is a palliative for) the absence of priority servicing (à la Wilson (1993)) for FDA reviews, in that PRVs re-create an (incomplete) market for priority. Gans and Ridley (2013) discuss political economy reasons why PRVs may be desirable. In contrast, this paper shows that, while political constraints may favor TEEs, the latter can be justified on pure efficiency grounds.

The paper is organized as follows. Section 2 offers a theoretical study of the costs and benefits associated with TEEs, and compares them with those of a direct payment to the inventor, both in the case of a single country and for a union with national pricing regulations. Section 3 develops an empirical analysis on European data, calibrating our model and discussing the likely empirical values of the costs and benefits of a TEE scheme among the 15 European countries in our data, ultimately identifying who in the union would favor, resp. oppose a TEE scheme over a direct payment to the inventor. Section 4 concludes.

2 The Social Costs and Benefits of a Voucher

In theory, the acquirer of the voucher is the pharmaceutical company with the highest benefit from an extension among the various molecules in its patent portfolio. Let us start with some simple observations. An IP owner's monetary value Υ for an extension Δ of the protection length of a patent due to expire at horizon T is equal to:

$$\Upsilon = (\pi_E - \pi_{NE}) \int_T^{T+\Delta} e^{-r\tau} d\tau$$

where π_E is the profit during the exclusivity period, π_{NE} the profit when exclusivity is lost (the molecule is off-patent), r is the rate of interest and T is the remaining length of time until the patent expires in the absence of a voucher.

Observation 1. *The voucher is more valuable to its acquirer the longer the exclusivity extension (Δ), but also*

- *the shorter the remaining time (T) before the patent expires,*
- *the most profitable the patent (the higher π_E is),*
- *the less profitable the molecule once it is off-patent (the lower π_{NE} is), that is the higher the market share of generics, or the lower the consumers' perception of differentiation between the original branded drug and generics.*

Extending the reasoning, the voucher is particularly valuable for a patent about to expire when a generic company has already invested in a facility and is therefore in the starting blocks to compete with the incumbent. This temporary stranding of the generic, which must incur maintenance costs and interest charges during the exclusivity extension, or even renew its entry investment, is *per se* socially wasteful. We abstract away from such a case in the following, assuming that sufficient prior notice of the identity of the acquirer of the exclusivity extension is given to generics companies.

2.1 Baseline Model: The Case of a Single Country

Let us assume that buyers have no market power in the market for the voucher, that is, the winner of the auction pays her willingness to pay for the patent extension. [We discuss market power in Section 2.3.2.]

The cost of the voucher policy is measured by the loss in social welfare for a given reward level. This loss is, for the molecule that will benefit at horizon T from the patent extension:

$$L \equiv (S_{NE} - S_E) \int_T^{T+\Delta} e^{-r\tau} d\tau,$$

where S_R is the consumer net surplus in regime $R \in \{E, NE\}$. We compute consumer surplus for a given price p as $S(p) = \int_p^{\infty} D(\tilde{p}) d\tilde{p}$ where $D(\cdot)$ is the demand for the molecule.

Therefore, $L = \rho\Upsilon$ where the cost-over-reward ratio ρ is given by:

$$\rho = \frac{S_{NE} - S_E}{\pi_E - \pi_{NE}}.$$

A TEE is preferred to a prize if and only if

$$\rho \leq 1 + \lambda,$$

where $\lambda \geq 0$ is the cost of public funds.

The pharmaceutical company that buys the exclusivity extension faces a demand curve $D(p)$ and a constant marginal cost of production, denoted by $c \geq 0$, for the drug to which it applies the exclusivity extension. We assume that this cost does not depend on the drug being on- or off-patent. Generics face the same constant marginal cost of production c.

Hence, for a given price p and under exclusivity, profit is given by:

$$\pi_E(p) = (p - c)D(p).$$

Regulation. For the sake of tractability (and as discussed in the introduction), we assume that (i) the price of the branded molecule is determined via Nash bargaining with the regulator, and that (ii) during this bargaining, the regulator does not anticipate the relation, if any, between the negotiated exclusivity price of the branded drug and the future price of generics after exclusivity loss.[13]

Namely, the regulator and the pharmaceutical company Nash bargain on the price of the original branded drug p^* under exclusivity and after exclusivity loss.[14] When bargaining, as the regulator does not take into account the impact of the original branded drug price under exclusivity p^* on the generics' price p_g after exclusivity loss, it only considers the impact of p^* on the social surplus due to the consumption of the original branded drug. Letting α denote the regulator's bargaining power, the (Nash-bargained) under-exclusivity and post-exclusivity-loss prices maximize:

$$\left[(p - c)D(p)\right]^{1-\alpha} S(p)^{\alpha}.$$

The (Nash-bargained) regulated price p^* for the original branded drug is thus the same under exclusivity and after exclusivity loss.

Generics partially take over at the end of the exclusivity period. We denote by $p_g \geq c$ the generics' price. If the generics market is perfectly competitive, $p_g = c$. In practice however, the generics' price p_g may be strictly higher than the marginal cost c due to either regulation

[13] As mentioned in the introduction, accounting for a relation between the exclusivity price of the branded drug and the generics price after exclusivity loss, be it due to regulation (reimbursement caps such as in France) or collusive behavior (see Section 2.3.1), makes the Nash bargaining problem formally intractable. We investigate in Appendix E.3 the biases that may be created by our independence assumption, and show the robustness of our insights.

[14] They do not bargain on the length of the (initial) exclusivity period which is fixed by intellectual property law.

guaranteeing a high price to generics,[15] or imperfect competition (see Section 2.3.1). We assume that the generics' price is below the original branded drug price: $p_g \leq p^*$.

Generics meet the demand of a fraction $(1-x)$ of consumers, with $x \in [0,1)$, while the complementary fraction x of consumers remains captive of the original branded drug company (e.g. it does not trust the generics). As a consequence, $\pi_{NE} = x\pi_E$ and $L = (1-x)[S(p_g) - S(p^*)] \int_T^{T+\Delta} e^{-r\tau} d\tau$, and thus

$$\rho = \frac{S(p_g) - S(p^*)}{\pi_E(p^*)},$$

which does not depend on x, the share of captive consumers.

Empirical specification. Our flexible parameterization for demand is inspired from Weyl and Tirole (2012). Namely, the demand for the drug that will benefit from the TEE is given by: for any $p \leq m$,

$$D(p) = \sigma \frac{k+1}{m} \left(1 - \frac{p}{m}\right)^k,$$

where $\sigma(k+1)/m$ is market size, i.e. the size of the population of individuals who potentially benefit from the drug, m a measure of quality (m is the highest WTP in the population, with $m \geq c$ to ensure there is a market for the drug), and $k \geq 0$ a parameter governing the curvature of demand. Our normalization ensures that as k varies, total consumer surplus at price 0 remains constant,[16] equal to σ.

For a given price p and under exclusivity, profit is given by:

$$\pi_E(p) \equiv \sigma \frac{k+1}{m}(p-c)\left(1 - \frac{p}{m}\right)^k.$$

(Exclusivity) profit is locally concave whenever $p < [2m + (k-1)c]/(k+1)$, which holds in particular for any price p below the monopoly price $(m+kc)/(k+1)$.

Consumer surplus is given by

$$S(p) \equiv \int_p^m \sigma \frac{k+1}{m}\left(1 - \frac{\tilde{p}}{m}\right)^k d\tilde{p} = \sigma\left(1 - \frac{p}{m}\right)^{k+1}.$$

[15] In France, generics are guaranteed to receive 60% of the price of the branded molecule in the year after the exclusivity loss.

[16] This normalization as well as market size are irrelevant for the exclusivity price and the cost-over-reward ratio. The parameter k must be weakly below 1 for demand to be globally concave. A lower k implies a more concave demand: the lower k, the larger the share of the population for whom the drug benefits are high/the larger the share of patients who have a high WTP for the drug. In the limit for $k = 0$, all patients have the same WTP equal to m.

The elasticity of demand at a given price p, $kp/(m-p)$ increases with p, decreases with m and increases with k (i.e. decreases the more concave the demand).

The (Nash-bargained) under-exclusivity and post-exclusivity-loss prices maximize:

$$\left[(p-c)\left(1-\frac{p}{m}\right)^k\right]^{1-\alpha}\left[\left(1-\frac{p}{m}\right)^{k+1}\right]^{\alpha},$$

and is thus given by

$$\frac{p^*}{m}=\frac{1-\alpha}{k+1}+\frac{k+\alpha}{k+1}\frac{c}{m}.$$

At the (Nash-bargained) regulated price, the extra profit per unit of time due to the exclusivity extension is given by $(1-x)$ times

$$\pi_E(p^*)=\sigma(1-\alpha)\left(\frac{k+\alpha}{k+1}\right)^k\left(1-\frac{c}{m}\right)^{k+1},$$

while the social cost per unit of time, of buying the original branded drug at the exclusivity price p^* instead of generics at price p_g because of the exclusivity extension, is given by $(1-x)$ times

$$S(p_g)-S(p^*)=\sigma\left[\left(1-\frac{p_g}{m}\right)^{k+1}-\left(\frac{k+\alpha}{k+1}\right)^{k+1}\left(1-\frac{c}{m}\right)^{k+1}\right]$$

Proposition 1. *(i) The cost-over-reward ratio of a TEE scheme with constant marginal cost of production c, generics price p_g is given by:*

$$\rho=\frac{S(p_g)-S(p^*)}{\pi_E(p^*)}.$$

For our flexible specification with demand parameters $\{\sigma,m,k\}$ for the drug benefiting from the exclusivity extension, the above expression writes as:

$$\rho=\frac{\left(1-\frac{p_g}{m}\right)^{k+1}-\left(\frac{k+\alpha}{k+1}\right)^{k+1}\left(1-\frac{c}{m}\right)^{k+1}}{(1-\alpha)\left(\frac{k+\alpha}{k+1}\right)^k\left(1-\frac{c}{m}\right)^{k+1}}.$$

(ii) The cost-over-reward ratio is independent of the share of captive consumers x, decreases with the generics' price p_g and with the regulator's bargaining power α, but increases with the marginal cost of production c. In addition, with our flexible specification, it is independent of the consumers' potential benefit from the drug σ and increases with drug quality m.

(iii) For a perfectly competitive generics market ($p_g = c$), the cost-over-reward ratio of a TEE scheme is greater than 1, strictly so unless $\alpha = 1$ (full bargaining power to the regulator) or demand is inelastic (with our flexible specification, $k = 0$, i.e. all patients have the highest WTP for the drug, m). With our flexible specification, it increases with k.[17]

(iv) More generally, the cost-over-reward ratio of a TEE scheme is greater than 1 if and only if the generics' price p_g is sufficiently low. With our flexible specification,

$$\rho \geq 1 \qquad \Longleftrightarrow \qquad \frac{p_g}{m} \leq 1 - \frac{k+\alpha}{k+1}\left(1 - \frac{c}{m}\right)\left(\frac{k(2-\alpha)+1}{k+\alpha}\right)^{\frac{1}{k+1}}.$$

Proof. The results derive from straightforward computations, except claim (iv), for which we provide details in Appendix D. □

Remark: Distortion vs redistribution. A TEE distorts consumers' demand by maintaining a higher price. Yet, unless the generics' price is equal to the marginal cost, a TEE also induces a redistribution from the generics to the original branded drug (in the limit case where $p_g = p^*$, a TEE is pure redistribution and entails a zero social cost). Which effect dominates determines whether ρ is greater or smaller than 1.

Proposition 1 implies that when the generics market is perfectly competitive ($p_g = c$), the less elastic the demand is, the lower the cost-over-reward ratio.

2.2 Heterogeneous National Impacts of a TEE in a Union

Consider N heterogeneous countries, indexed by i. We maintain our previous assumptions regarding production costs, sales and profits under exclusivity and non-exclusivity, allowing all the parameters except production costs to differ from one country to another.[18] In particular, the exclusivity price in country i is (as is the case in the European Union) Nash-bargained between country i and the pharmaceutical company, with α_i denoting country i's bargaining power.

We first investigate the national costs and benefits of a voucher scheme in the union, depending on national characteristics. We then turn to the comparison between a union-wide voucher scheme and a union-wide cash transfer, from the perspective of each member state.

[17] However, numerical simulations seems to suggest that for p_g sufficiently above c and α sufficiently close to 1, the cost-over-reward ratio decreases with k.

[18] Were the marginal production costs to vary across countries – which should be unlikely in a single market –, the same insights would hold, together with the comparative statics with respect to domestic costs derived in Proposition 1.

Let γ_i denote the ratio of the marginal utility of (national) income y_i for country i over the marginal utility of therapeutical benefit for country i from the drug benefiting from the exclusivity extension (see Appendix C for details).[19] With our flexible specification, demand in country i at a given price p_i is given by

$$D_i(p_i) = \sigma_i \frac{k_i + 1}{m_i} \left(1 - \frac{\gamma_i p_i}{m_i}\right)^{k_i}.$$

Proposition 2. ***(TEE scheme in a union of countries)*** *Suppose that the exclusivity extension associated with a voucher applies to a union of countries, while the regulation of national prices is each country's prerogative. A country tends to prefer a TEE scheme over a cash transfer scheme if its generics prices are high and the market share of generics low, and if its cost of public funds is high. Moreover, with our flexible specification, a country tends to prefer a TEE scheme over a cash transfer scheme if the drug with extended exclusivity has a relatively small (per inhabitant) market in the country.*

Proof. TEE. The pharmaceutical manufacturer's reward at a given price p_i writes as

$$(1 - x_i)(p_i - c) D_i(p_i) \frac{(1 - e^{-r\Delta}) e^{-rT}}{r},$$

and hence for our flexible specification, as

$$(1 - x_i)\sigma_i \frac{k_i + 1}{m_i} (p_i - c) \left(1 - \frac{\gamma_i p_i}{m_i}\right)^{k_i} \frac{(1 - e^{-r\Delta}) e^{-rT}}{r}.$$

The social surplus at price p_i expressed in terms of country i's utility writes as

$$\int_{p_i}^{\infty} D_i(\tilde{p}) d\tilde{p},$$

which yields for our flexible specification,

$$\int_{p_i}^{m_i/\gamma_i} \sigma_i \gamma_i \frac{k_i + 1}{m_i} \left(1 - \frac{\gamma_i \tilde{p}}{m_i}\right)^{k_i} d\tilde{p} = \sigma_i \left(1 - \frac{\gamma_i p_i}{m_i}\right)^{k_i + 1}.$$

The social cost to country i of a price p_i with respect to a price $p_{g,i} \leq p_i$, where $p_{g,i}$ is the generics' price in country i, writes as

$$\frac{(1 - e^{-r\Delta}) e^{-rT}}{r} (1 - x_i) \int_{p_{g,i}}^{p_i} D_i(\tilde{p}) d\tilde{p},$$

[19] We focus on the case in which $\gamma_i c \leq m_i$, since otherwise, the drug benefiting from the extended exclusivity would face a zero demand while on patent in country i.

and thus with our flexible specification,

$$\frac{(1-e^{-r\Delta})e^{-rT}}{r}(1-x_i)\int_{p_{g,i}}^{p_i}\sigma_i\gamma_i\frac{k_i+1}{m_i}\left(1-\frac{\gamma_i\tilde{p}}{m_i}\right)^{k_i}d\tilde{p}$$
$$=\frac{(1-e^{-r\Delta})e^{-rT}}{r}(1-x_i)\sigma_i\left[\left(1-\frac{\gamma_i p_{g,i}}{m_i}\right)^{k_i+1}-\left(1-\frac{\gamma_i p_i}{m_i}\right)^{k_i+1}\right].$$

With our flexible specification, the (Nash-bargained) exclusivity price maximizes

$$\left[(p_i-c)\left(1-\frac{\gamma_i p_i}{m_i}\right)^{k_i}\right]^{1-\alpha_i}\left[\left(1-\frac{\gamma_i p_i}{m_i}\right)^{k_i+1}\right]^{\alpha_i}.$$

Hence, the (Nash-bargained) exclusivity price in country i is given by the first-order condition:

$$\frac{\gamma_i p_i}{m_i}=\frac{1-\alpha_i}{k_i+1}+\frac{k_i+\alpha_i}{k_i+1}\frac{\gamma_i c}{m_i}.$$

As a result, the social cost for country i is given by

$$(1-x_i)\sigma_i\left[\left(1-\frac{\gamma_i p_{g,i}}{m_i}\right)^{k_i+1}-\left(\frac{k_i+\alpha_i}{k_i+1}\right)^{k_i+1}\left(1-\frac{\gamma_i c}{m_i}\right)^{k_i+1}\right]\int_T^{T+\Delta}e^{-r\tau}d\tau,$$

while the total gain for the buyer of the exclusivity extension, and thus in the absence of buyer power on the TEE market, the total reward Υ for the antibiotic developer is:

$$\left[\sum_j(1-\alpha_j)(1-x_j)\frac{\sigma_j}{\gamma_j}\left(\frac{k_j+\alpha_j}{k_j+1}\right)^{k_j}\left(1-\frac{\gamma_j c}{m_j}\right)^{k_j+1}\right]\int_T^{T+\Delta}e^{-r\tau}d\tau.$$

Cash transfer. Let us now consider a cash transfer at the union's level. We assume that the contribution of country i to the developer's reward is proportional to country i's aggregate income. [The model generalizes straightforwardly to any sharing rule among the union members.] Hence, for a total reward Υ, country i contributes $(y_i/\Sigma_j y_j)\Upsilon$ to the union's cash transfer. The cost to country i of such a contribution is given by $\gamma_i(1+\lambda_i)(y_i/\Sigma_j y_j)\Upsilon$, where λ_i is country i's cost of public funds.

As a consequence, for a given reward level Υ, country i favors a TEE over a cash transfer at the union's level if and only if

$$\frac{(1-x_i)\int_{p_{g,i}}^{p_i}D_i(\tilde{p})d\tilde{p}}{\sum_j(1-x_j)(p_j-c)D_j(p_j)}\leq\frac{\gamma_i(1+\lambda_i)y_i}{\sum_j y_j},$$

i.e. with our flexible specification,

$$\frac{(1-x_i)\sigma_i\left[\left(1-\frac{\gamma_i p_{g,i}}{m}\right)^{k_i+1}-\left(\frac{k_i+\alpha_i}{k_i+1}\right)^{k_i+1}\left(1-\frac{\gamma_i c}{m_i}\right)^{k_i+1}\right]}{\sum_j(1-x_j)(1-\alpha_j)\frac{\sigma_j}{\gamma_j}\left(\frac{k_j+\alpha_j}{k_j+1}\right)^{k_j}\left(1-\frac{\gamma_j c}{m_j}\right)^{k_j+1}} \leq \frac{\gamma_i(1+\lambda_i)y_i}{\sum_j y_j}.$$

The rest of the proof involves straightforward computations. □

Remark: National and union-wide TEEs. Let us denote by ρ_i the cost-over-reward ratio of a *national* TEE scheme in country i. Using our analysis in Section 2.1,[20]

$$S_i(p_{g,i}) - S(p_i^*) = \rho_i \pi_E(p_i^*).$$

Hence, rewriting the last inequality in the proof of Proposition 2 yields that country i favors a *union-wide* TEE over a union-wide cash transfer if and only if

$$\left(\frac{(1-x_i)\pi_E(p_i^*)}{\sum_j(1-x_j)\pi_E(p_j^*)}\Big/\frac{y_i}{\sum_j y_j}\right)\rho_i \;\leq\; 1+\lambda_i,$$

while country i favors a *national* TEE over a national cash transfer if and only if $\rho_i \leq 1+\lambda_i$. It is thus possible that a country does not favor a national TEE over a cash transfer but does prefer a union-wide TEE against a union-wide cash transfer (and vice versa), depending on the correlations between national income, the regulator bargaining power (α_i), the policies towards generics substitution (x_i), the demand elasticity (k_i), and the marginal utility of income (γ_i).

Country i 's cost-over-reward ratio in a union is equal to the product of its single-country cost-over-reward ratio and the ratio of the share of the union-level extra profit obtained by the voucher buyer in country i over the share of this country's GDP in the union. Thus, if the share of the union-level extra profit obtained by the voucher buyer in country i is larger than the share of this country's GDP in the union, then the cost-over-reward ratio for a union-level voucher is larger than the cost-over-reward ratio in isolation. This implies that a country is more likely to be favorable to a union-wide TEE if it contributes less (relative to GDP) to the voucher acquirer's extra-profit. Thus if all cost-over-reward ratios ρ_i are less than the cost of public funds $1+\lambda_i$ so that each country is favorable to a voucher over a cash transfer if implemented nationally, then they will all be favorable if the correlation of country specific share of extra profit with country GDP is large enough and they will always be favorable is the correlation is one, meaning that country specific extra-profit shares by country are equal to GDP country shares.

[20] In Section 2.1, we implicitly normalized γ_i to 1.

2.3 Extensions

We briefly discuss two issues affecting the desirability of a TEE scheme: (i) market power in the supply of generics; (ii) market power in the voucher market, and auctioning vouchers.

2.3.1 Market power in the supply of generics

The desirability of a TEE scheme is higher, the less competitive the generics market is. Therefore, setting aside any regulation of the generics' price (e.g. aimed at guaranteeing a continuous, diversified supply), we investigate the outcome of collusion among generics.[21]

As before, a fraction x of consumers are loyal to (or captive of) the originating brand, whereas the generics and the original branded drug are perfect substitutes for the remaining fraction $1-x$ of consumers.[22] We assume that loyalty/captivity is independent of the consumer's willingness to pay for the drug, hence both submarkets have the same demand, up to a factor x or $(1-x)$. [We study in Appendix B a case of correlation.] There are N generics companies (this number will be endogenous). We assume that generics can form a cartel charging the same price p. [We discuss in Appendix B the possibility that the original branded drug company joins the cartel.]

Let δ denote the discount factor. The highest price $p \leq p^*$ (where p^* is the original branded drug's bargained price under exclusivity[23]) that can be sustained by the cartel is given by:

$$x\pi_E(p^*) = (p-c)D(p)$$

This defines a function $p(x)$ with $p'(x) > 0$ (and $p''(x) > 0$ if $p \mapsto (p-c)D(p)$ is concave.)

The ratio of the welfare gain from patent expiration over the profit loss is

$$\rho = \frac{S_{NE} - S_E}{\pi_E - \pi_{NE}} = \frac{(1-x)\int_{p(x)}^{p^*} D(\tilde{p})d\tilde{p}}{(1-x)\pi_E(p^*)} = \frac{\int_{p(x)}^{p^*} D(\tilde{p})d\tilde{p}}{(p^*-c)D(p^*)}$$

At $x = 0$, i.e. for the case of highly effective generics entry/no captive consumers, this ratio is strictly greater than 1. However, this ratio is decreasing in x, and is below 1 for x sufficiently high, converging to 0 as x goes to 1. In other words, when generics form a cartel,

[21] Admittedly, market power in the supply of generics may have other causes – e.g. there could be investments in capacities (Cournot competition), limited awareness of the set of generics available, etc. We focus on collusion as it exhibits a testable relation between the original branded drug's price, generics's price and the share of captive consumers. The relation we derive could be brought to the data to investigate signs of (potential) generics collusion.

[22] We resume the normalization of Section 2.1, and set $\gamma = 1$.

[23] For simplicity, we assume that the regulated price of the original branded drug remains equal to p^* even if generics collude – e.g. because captive consumers would refuse to buy generics even if the original branded drug were missing, or because during the bargaining, the regulator does not foresee the generics' collusion.

the cost-over-reward ratio of a TEE scheme in a single country depends on the share of captive consumers of the original branded drug x, and a TEE is preferred to a cash transfer whenever x is sufficiently high.

In contrast to the conventional wisdom that lower prices increase consumer surplus by an amount greater than the profit loss, here generics entry can be wasteful in that "the bang for the buck" can be small. This brings us to the description of generics entry. Suppose that an entering generics company must sink an investment cost $I > 0$, and that the level of entry is determined by a free-entry condition (ignoring integer problems):

$$(1-x)(p(x)-c)D(p(x)) = NI,$$

as long as $N \leq \bar{N}$, where $\bar{N}$ is the maximum number of firms that allows generics producers to sustain the collusive equilibrium:

$$\bar{N} = \frac{1}{1-\delta}.$$

For a low investment cost, the number of generics entrants is equal to $\bar{N}$. The entry of an N-th generics, $N \geq 2$, is then wasteful as long as $N \leq \bar{N}$ for it does not affect the cartel's existence and price.

Proposition 3. *When generics form a cartel, the cost-over-reward ratio of a TEE is decreasing in the share of captive users x, and a TEE is preferred to a cash transfer whenever x is sufficiently high. [For a single country, the cost-over-reward ratio of a TEE does not depend on x (see Proposition 1).]*

The generics cartel price $p(x)$ is given by $(p(x)-c)D(p(x)) = x\pi_E(p^*)$, and increases with x. If there is free entry and the generics entrants form a cartel, the number of generics active in equilibrium is given by (ignoring integer constraints):

$$N = \min\left\{\frac{x(1-x)\pi_E(p^*)}{I}, \frac{1}{1-\delta}\right\},$$

which is first increasing, then constant, then decreasing in $x \in (0,1)$.

Consistently with our theoretical analysis, in our data the generics' price increases with the share of captive consumers x.[24]

[24] More generally, such correlation may be explained either by collusion among generics (a higher share of captive consumers allowing a higher cartel price as we show), or by reverse causality, the price of generics being high for other reasons (e.g. regulation), more users stick to the original branded drug (which they perceive as higher quality). Maybe less convincingly, such correlation could also be generated by a negative correlation between WTP and captivity, i.e. if the "most captive" users (perceiving the largest quality differential in favor of the original branded drug) are those with the lowest WTP for the drug.

2.3.2 Voucher auctions and market power

a) We assumed that the length of a TEE could be tailored to match the desired reward for the antibiotic developer. However, in practice, for a given reward target, adjusting the length of a TEE requires information on the buyer's profit. While domestic prices and quantities may be observable, production costs and profits abroad are not. At the other extreme, a pre-specified duration for a voucher creates uncertainty about the exact reward accruing to the antibiotic developer, as well as the overall costs incurred by patients and tax-payers, which raises concerns.

To adjust the length of a TEE and eliminate this uncertainty, one can let the voucher buyers bid in terms of extension length.[25] Namely, fix a reward Υ for the antibiotic developer, the same as the one the antibiotic developer would receive under a cash transfer (a monetary prize). For each potential drug j that could benefit from an exclusivity extension, let Δ_j be implicitly defined by

$$\Upsilon = \sum_i [\pi_{E,ij} - \pi_{NE,ij}] \int_{T_j}^{T_j+\Delta_j} e^{-r\tau} d\tau \equiv [\pi_{E,j} - \pi_{NE,j}] \int_{T_j}^{T_j+\Delta_j} e^{-r\tau} d\tau,$$

then the holder of patent j is willing to pay Υ in exchange of any extension of the exclusivity length $\Delta \geq \Delta_j$. The winner of the auction is the one announcing the lowest extension length against cash transfer Υ.

For example, in a Vickrey auction,[26] and for demanded lengths $\Delta_1 \leq \Delta_2 \leq \Delta_3$..., the bidder demanding length Δ_1 obtains a TEE of length Δ_2. Such an auction is optimal under the usual assumptions (symmetric draws of valuations from a distribution with monotone hazard rate, appropriately chosen reserve price).

Observation 2. *To eliminate the uncertainty about the value of a voucher for the inventor, one can set the reward's level and have potential voucher acquirers bid the minimum length of exclusivity extension for which they are willing to pay this reward to the inventor.*

b) In practice, competition in the voucher market may be imperfect because the top-earning drugs may be unequally profitable. As a consequence, the voucher's buyer – e.g. the auction winner – who pays the second-highest bid may pay less than its WTP for the voucher. Hence, while the social cost from the exclusivity extension remains the loss in social surplus from the exclusivity extension of the winning drug, the reward accruing to the antibiotic developer decreases down to the additional profit of an exclusivity extension for

[25] Unlike the least-present-value-of-revenue auction of Engel et al. (2001), which has been used to auction off highway franchises, here the firms would not bid a transfer but a length of exclusivity. But in both cases, the aim is to eliminate risk. In Engel et al, the risk is about future demand and the length of the franchise is adjusted accordingly. Here the uncertainty concerns the value for bidders of exclusivity extensions.

[26] The equivalent of a reserve price in such an auction is a maximum length $\bar{L}$.

the second-highest profitable drug.[27] Therefore, the cost-over-reward ratio of a TEE scheme increases.

Observation 3. *Market power in the voucher market increases the cost-over-reward ratio of TEEs.*

Let us finally mention two important caveats about market power in the voucher market (buyers' side). The first arises when the same firm owns the two molecules that would benefit the most from an extension: The firm would not let the second compete with the first in that case. The second caveat is more interesting: If multiple vouchers are awarded sequentially, buyers may have incentives to wait for being in a market in which they will face little competition from rival buyers. Attrition in that market may occur when some molecules turn off-patent and are replaced by generics or when some molecules have already acquired a TEE – which also depends on the supply of TEEs, i.e. on the supply of new antibiotics, both in terms of quantity and timing. Complex timing and bidding strategies in the successive auctions of TEEs may then arise. As a consequence, TEE schemes may involve in practice a higher uncertainty than in our simple benchmark, which may reduce their desirability.

3 An Empirical Analysis on European Data

We now turn to a calibration of the theoretical model on European data.

3.1 Data Sources

We use IMS (IQVIA) data on sales of all drugs in 15 European countries (Austria, Belgium, Finland, France, Germany, Greece, Ireland, Italy, Norway, Poland, Portugal, Spain, Sweden, Switzerland, UK) from the year 2002 to 2012. These data are available quarterly and include all prescription drugs. Quantities of each drug are measured in terms of standard units (the smallest possible dose available for each molecule). The same source of data was used on an older period by Dubois et al. (2015) to estimate the elasticity of innovation to market size in drugs markets, as well as in many other papers on specific drug markets. The data allow us to observe manufacturer-level sales values in local currencies and sales quantities in standard units. We compute total country level and "European" (15-country) level sales values and volumes by product by year, aggregating the different formats, dosage, strength, packs of a same product and also aggregating the generics of a molecule. We

[27] Admittedly, the buyer's rent (difference between own WTP and second-highest one) may provide an additional incentive to develop an innovation in the first place.

convert local currencies into euros for countries with their own Sovereign currency. Overall, the data allow us to observe the sales of more than 5,000 molecules.

3.2 Estimating the Value of a Voucher

We start by using these data to estimate the value of vouchers had they been implemented during the data period of 2002-2012. Denoting by π_{ijt} the revenue for the original branded drug j in country i during year t, and $T(j)$ the year of exclusivity loss[28] and generics entry for the molecule of drug j, we compute the ratio of post-exclusivity-loss revenue π_{ijt} for $t = T(j) + 1$ and pre-exclusivity-loss revenue for $t = T(j) - 1$ for all drugs with exclusivity loss year $T(j)$.

We thus compute the ratios $\frac{\pi_{ijT(j)+1}}{\pi_{ijT(j)-1}}$ across products j whose exclusivity loss year $T(j)$ is between 2003 and 2012. We denote by μ_i the median of these ratios within country i. This ratio varies across countries depending on the regulation of prices when generics enter, the regulatory rule concerning generic substitution and the specific price drop and revenue decrease that firms experience after loss of exclusivity. We assume that this proportional revenue loss is anticipated by firms who consider purchasing an exclusivity extension to avoid this loss.

The value of an extension by one year of the exclusivity period in country i for drug j whose exclusivity expires at the end of year t is the value of profits with exclusivity, minus the expected counterfactual value of profits in case of exclusivity loss: $\pi_{ijt} - \mu_i \pi_{ijt}$.[29] If the voucher is used at year t for extending the exclusivity of a drug j expiring at year $T(j) \geq t+1$, this value needs to be discounted and it is given at t by

$$V_{jt} \equiv \delta^{T(j)-t-1} \sum_{i=1}^{I} \pi_{ijT(j)}(1 - \mu_i) = \delta^{T(j)-t-1} V_{jT(j)}$$

where $\{1, .., I\}$ is the set of countries where it would apply and δ is the yearly discount factor. We can then define the largest potential benefit at time t from an exclusivity extension as

$$V_t^1 \equiv \max_{\{j|T(j)\geq t+1\}} V_{jt}$$

and the drug with this highest value $j^1(t) \equiv \arg\{\max_{\{j|T(j)\geq t+1\}} V_{jt}\}$, as well as the second highest value V_t^2 and iteratively, the n-th highest value V_t^n. The buyer of a transfer exclusivity extension at year t is then likely to be the one with the highest value among all drugs

[28] With our previous notation, the time T before patent expiration for j, at year t is thus given by: $T = T(j) - t$.

[29] As the length of exclusivity extension is irrelevant for the cost-over-reward ratio of TEEs, henceforth we focus on the value of a one-year extension.

expiring in the future, i.e. V_t^1, if that buyer has not already purchased a voucher for the same drug (more on this shortly).

In the data however, we observe revenues and not profits. To compute the value of a voucher, i.e. a buyer's additional profit, we thus build an upper bound estimate of the marginal cost of each molecule. This upper bound is obtained using the minimum price for this molecule observed in any of the 15 countries in our data set over all time periods, hence assuming zero markups.[30] For older molecules, this upper bound is typically a generic price (we observe a generic version for 1,428 molecules of the 5,352 molecules in our sample). For recent molecules, we do not observe generics yet, and this upper bound may seem extreme. However, some of the countries in our data set have strong regulatory powers that enable them to negotiate prices close to marginal cost, so that the minimum (on-patent) price remains a reasonable estimate of cost.

Using our estimated upper bound on marginal costs, our estimates of a voucher's value and cost-over-reward ratio ρ are conservative (resp. a lower bound on the voucher's true value, and an upper bound on the true cost-over-reward ratio). At the other extreme, we take zero as a lower bound on marginal costs, hence using revenue as an upper bound on the true profits (thereby deriving a lower bound on the cost-over-reward ratio ρ). We denote by $\underline{V}_t^n$ and $\bar{V}_t^n$ the lower and upper bounds on the true profits, i.e. on the value of a one-year exclusivity extension to its buyer.

Table 1 reports the estimates of μ_i, i.e. the median of the ratios of the patent-holder's revenue one year after generic entry over the one the year before. These values depend on each country's regulation of generic prices, generic substitution policy and branded drug prices after generic entry. We assume that firms take these values as the anticipated relative decline of revenue after exclusivity loss in each country. Table 1 shows that companies can expect roughly to lose more than 60% of their revenue in Norway and Sweden when exclusivity ends, 50% in Germany, 40% in Italy, the UK and Belgium, 33% in France and 25% in Spain. Table 1 also documents the number of exclusivity losses observed during 2002-2012, the variation across countries stemming from differences in available products. We also report the share of captive consumers x_i for country i, which we will use to compute the cost-over-reward ratio. These shares are estimated via the quantity share of a molecule sold in generic form one year after the branded drug's exclusivity loss.[31]

Table 2 reports the five largest values $\bar{V}_t^n$ from a one-year exclusivity extension delivered at the European (15-country) level in any year between 2002 and 2011. It also reports to

[30] We implicitly assume that country-specific drivers of marginal costs of products within a molecule are negligible.

[31] To avoid timing issues when a generic entry enters at the end of a year, we consider generics have entered once they reach at least 10% market share of sales quantities of a molecule, which usually happens quickly in all European countries.

Table 1: Relative Loss of Revenue and Share of Captive Users after Generic Entry by Country

Country	Number of exclusivity losses	Preservation revenue μ_i	Share captive x_i
AUSTRIA	20	0.603	0.511
BELGIUM	19	0.597	0.563
FINLAND	18	0.451	0.400
FRANCE	29	0.663	0.329
GERMANY	141	0.473	0.394
GREECE	20	0.950	0.454
IRELAND	14	0.880	0.437
ITALY	40	0.585	0.473
NORWAY	32	0.391	0.379
POLAND	34	0.869	0.148
PORTUGAL	23	0.821	0.408
SPAIN	26	0.740	0.483
SWEDEN	54	0.340	0.460
SWITZERLAND	15	0.613	0.459
UK	20	0.564	0.313

Notes: Second column is the number of drugs on patent that lost exclusivity during 2003-2012 and the third column is the median μ_i of ratios $\frac{\pi_{ijT(j)+1}}{\pi_{ijT(j)-1}}$ across products j whose exclusivity loss year $T(j)$ is between 2003 and 2012.

which drug corresponds each value, and its year of exclusivity expiration (absent any extension). The values are discounted – e.g. Sanofi's willingness-to-pay for a one-year exclusivity extension for its Plavix patent expiring in 2008, thus reaches its maximum in the year of the patent expiration (2008), and decreases the further away the patent expiration. Table 2 shows that the additional profits that a one-year exclusivity extension generates for its buyer vary substantially depending on the buyer and the year of purchase. Moreover, these additional profits exhibit a strong path-dependence as the identity of the buyer in a given year depends on the history of past vouchers sold, which itself depends on the realized innovations awarded TEEs, as well as on the strategic behaviors by potential buyers. As an illustration, if a voucher had been granted in 2002 and bought by Sanofi for Plavix, Sanofi may not have competed for another voucher in the following year, which could then have been purchased by Pfizer for Lipitor (the second largest value in 2003). Suppose for the sake of illustration that each drugmaker buys at most one voucher per drug. Then, Table 2 indicates that if a one-year voucher had been awarded each year between 2002 and 2006 and bought by the firm with the highest value for it in that given year, the value of such vouchers to their buyers would have varied substantially, from 473 million euros down to 298 million euros.[32] Hence,

[32]Taken literally, Table 2 further suggests that whether or not any additional one-year vouchers had been

Table 2: Value of One-Year Voucher by Year (in k€)

Year	$\bar{V}_t^1$	$\bar{V}_t^2$	$\bar{V}_t^3$	$\bar{V}_t^4$	$\bar{V}_t^5$
2002	PLAVIX (2008)	ZOCOR (2002)	LIPITOR (2011)	NORVASC (2003)	PANTOZOL (2008)
	468,221	463,005	459,136	348,136	285,430
2003	PLAVIX (2008)	LIPITOR (2011)	NORVASC (2003)	PANTOZOL (2008)	ZYPREXA (2010)
	482,702	473,337	358,904	294,257	280,059
2004	PLAVIX (2008)	LIPITOR (2011)	PANTOZOL (2008)	ZYPREXA (2010)	SEROQUEL (2011)
	497,631	487,976	303,358	288,720	280,623
2005	PLAVIX (2008)	LIPITOR (2011)	PANTOZOL (2008)	ZYPREXA (2010)	SEROQUEL (2011)
	513,021	503,068	312,740	297,650	289,302
2006	PLAVIX (2008)	LIPITOR (2011)	PANTOZOL (2008)	ZYPREXA (2010)	SEROQUEL (2011)
	528,888	518,627	322,413	306,855	298,250
2007	PLAVIX (2008)	LIPITOR (2011)	PANTOZOL (2008)	ZYPREXA (2010)	SEROQUEL (2011)
	545,245	534,667	332,384	316,346	307,474
2008	PLAVIX (2008)	LIPITOR (2011)	PANTOZOL (2008)	ZYPREXA (2010)	SEROQUEL (2011)
	562,109	551,203	342,664	326,130	316,984
2009	LIPITOR (2011)	ZYPREXA (2010)	SEROQUEL (2011)	NEXIUM (2010)	TAXOTERE (2010)
	568,250	336,216	326,787	295,677	287,107
2010	LIPITOR (2011)	ZYPREXA (2010)	SEROQUEL (2011)	NEXIUM (2010)	TAXOTERE (2010)
	585,825	346,615	336,894	304,821	295,986
2011	LIPITOR (2011)	SEROQUEL (2011)	ZOMETA (2012)	SINGULAIR (2012)	VIAGRA (2012)
	603,943	347,313	149,702	147,214	128,432

Notes: Voucher values $\bar{V}_t$ for one year TEE, in 1000 Euros, with yearly discount factor $\delta = 0.97$ for vouchers purchased in a given year for extending the exclusivity several years ahead. The values for the end of sample, particularly 2010 and 2011 are not reliable because our sample stops in 2012 and we thus lack observations for drugs whose exclusivity stops in or after 2012.

not only would fixed extension lengths almost always miss any pre-specified reward target, they would also generate substantial uncertainty. Our suggestion that the regulator set a reward level and that potential buyers bid the extension length for which they are ready to pay the reward, with the shortest extension length winning the auction, would address both issues (see Section 2.3.2).[33]

Lastly, to avoid the temporary stranding of generics, the regulator may for instance forbid a drugmaker from buying a voucher for a drug with patent expiration the next year. Table 2 then suggests that such a regulation may not always prevent the drugmaker with the highest value for a voucher from buying it.

As a robustness check, Table 5 in Appendix E.1 reports the same quantities as Table 2 using the lower-bound estimates $\underline{V}_t^n$. Notably, these lower-bound estimates turn out to be close to the upper-bound estimates in Table 2, and to yield the same ranking for the five highest values each year as the upper-bound estimates.

awarded in 2007 and 2010, a one-year voucher awarded in 2011 and bought by the firm with the highest value for it in that given year would have had a value of only 150 million euros to its buyer (owner of Zometa). However, this may be an artifact of our data sample as we do not observe sales after 2012, and we thereby understate the value of future discounted profits from drugs with patent expiration in 2013 or later.

[33]The high volatility evidenced in Table 2 suggests that the extension lengths of winning bids may vary substantially across years, from at least a factor 1 to 3.

3.3 An Empirical Calibration of the Cost-Over-Reward Ratio of a TEE

We are interested in the costs and benefits of a TEE scheme, were the 15 European countries in our data set to form a union and implement a union-wide TEE scheme. In order to estimate the social cost of such a TEE scheme, we need to evaluate the shape of the demand function for a molecule in each country. To do so, we use our data to perform a calibration using the variation over time of prices and quantities per molecule. Following our theoretical model, for each country i, we assume that the demand in year t for each molecule j is given by:

$$D_{ijt}(p_{ijt}) = \sigma_{ijt}\frac{k_{ijt}+1}{m_{ijt}}\left(1-\frac{\gamma_i p_{ijt}}{m_{ijt}}\right)^{k_{ijt}}$$

where $\sigma_{ijt} = \sigma_{ij}\exp(\epsilon_{ijt})$ is the aggregate demand shock, and m_{ijt} the maximum willingness-to-pay for drug j in country i at time t, and k_{ijt} a parameter that affects the shape of demand. To filter out some noise in the data and avoid excessive variations in the estimated shape of demand functions, we approximate the maximum willingness-to-pay m_{ijt} by $m_i \equiv \max_{j,t}\{p_{ijt}\}$ and the demand parameter k_{ijt} by k_i, which are country-specific, but drug- and time-independent. Put differently, we assume that the shape of demand (as a function of price) is determined by country-specific effects – e.g. related to population characteristics, lifestyle, environment, etc. –, up to a multiplying factor which is drug- and time-specific. We further assume that $\sigma_{ij} = \sigma_i$ for all j and report in Appendix E.4 the case where we allow σ_{ij} to be heterogenous across molecules. When $\sigma_{ij} = \sigma_i$ for all j, we obtain the following demand function in country i for drug j at time t:

$$D_{ijt}(p_{ijt}) = \sigma_i\exp(\epsilon_{ijt})\frac{k_i+1}{m_i}\left(1-\frac{\gamma_i p_{ijt}}{m_i}\right)^{k_i}$$

Taking logs and a linear approximation when $\frac{\gamma_i p_{ijt}}{m_i} \ll 1$, we identify $(k_i\gamma_i)$ using the price coefficient $\widehat{(k_i\gamma_i)}$ of the following simple linear regression assuming that ϵ_{ijt} is uncorrelated with p_{ijt}:

$$\log D_{ijt} \approx \log(\sigma_i\frac{k_i+1}{m_i}) - (k_i\gamma_i)\frac{p_{ijt}}{m_i} + \epsilon_{ijt} \tag{1}$$

We then use the relationship derived in Section 2 between the regulated prices, marginal cost, maximum willingness to pay and bargaining parameters: averaging over all drugs j yields that

$$\frac{\gamma_i\bar{p}_i}{m_i} = \frac{1-\alpha_i}{k_i+1} + \frac{k_i+\alpha_i}{k_i+1}\frac{\gamma_i\bar{c}_i}{m_i} \tag{2}$$

where $\bar{p}_i = \frac{1}{J(i)\overline{T}}\sum_{j,t} p_{ijt}$ is the mean price per molecule in country i and $\bar{c}_i = \frac{1}{J(i)}\sum_{j\in i} c_j$

is the mean cost per molecule for drugs in country i ($J(i)$ being the total number of drugs present in country i, and $\overline{T}$ the length of the data time period).

We search for parameters $\gamma_i > 0, k_i \in (0,1), \alpha_i \in (0,1)$ solution of equations (1) and (2) and such that $0 \leq \gamma_i \leq m_i/c_j$ for all j in country i (meaning that demand should be positive when price is equal to marginal cost). However, due to measurement errors and approximations, the set of parameters satisfying these constraints for all drugs is empty.[34] We thus search for the parameters that satisfy all constraints at country level and that maximize the set of drugs for which the constraints $\gamma_i \leq m_i/c_j$ are satisfied. Hence, we solve the following problem:

$$\max_{\alpha_i \in (0,1), k_i \in (0,1), \gamma_i} \quad \sum\nolimits_j 1_{\{0 \leq \gamma_i c_j \leq m_i\}}$$
$$s.t. \quad (1), (2)$$

where (1) means that $\widehat{k_i \gamma_i}$ is obtained by equation (1).

Table 3 reports the estimated values for α_i, k_i, γ_i as well as the market size parameter $\dfrac{\sigma_i(k_i+1)}{m_i}$ in relative terms among the countries which allows us to compare these estimates to the share of total pharmaceutical expenditures or total GDP that each country represents. For the largest countries, these relative market size estimates are in general smaller than their share of GDP (except for Spain).

Table 3 exhibits the cost-over-reward ratio of a country-level (and not union-wide) TEE scheme which, accounting for the marginal utility of income, γ_i, writes as[35]:

$$\rho_i^{gen} = \frac{\left(1 - \dfrac{\gamma_i \bar{p}_{ig}}{m_i}\right)^{k_i+1} - \left(\dfrac{k_i+\alpha_i}{k_i+1}\right)^{k_i+1}\left(1 - \dfrac{\gamma_i \bar{c}_i}{m_i}\right)^{k_i+1}}{(1-\alpha_i)\left(\dfrac{k_i+\alpha_i}{k_i+1}\right)^{k_i}\left(1 - \dfrac{\gamma_i \bar{c}_i}{m_i}\right)^{k_i+1}}$$

where $\bar{p}_{ig}$ is the average generic price level for country i. Table 3 also reports the mean price elasticity $\mathcal{E}_i = -k_i \dfrac{\gamma_i}{m_i} \bar{p}_i$ where $\bar{p}_i$ is the mean price. Interestingly, we find that if the generics price were equal to marginal cost, the cost-over-reward ratios, denoted by ρ_i^{comp}, would exceed 1 (as the theory predicts), and therefore a cash transfer would be preferable

[34] This happens because k_i must be weakly below 1, thus γ_i must be larger than the price coefficient in regression (1). But, there is always a drug in each country whose estimated cost c_j is so high that m_i/c_j is lower than the price coefficient of (1). This happens because we do not observe real cost but use the minimum price of a molecule as an upper bound of the cost.

[35] Were the generics price equal to marginal cost, country i's cost-over-reward ratio would be equal to

$$\rho_i = \frac{1 - \left(\dfrac{k_i+\alpha_i}{k_i+1}\right)^{k_i+1}}{(1-\alpha_i)\left(\dfrac{k_i+\alpha_i}{k_i+1}\right)^{k_i}} \equiv \rho_i^{comp}.$$

to a country-wide voucher for sufficiently low costs of public funds. However, for standard estimations of marginal costs of public funds (which are usually estimated above 1.3, as in Barrios et al. (2013)), a voucher is preferred to a cash transfer. (The comparison is in fact much stronger: for any marginal cost of public funds above 1, all countries in our sample prefer TEEs over a cash transfers.) Further strengthening this result, as the prices of generics are in practice above marginal costs, a more accurate estimation of the cost-over-reward ratio is ρ_i^{gen}. It is lower than 1 in all countries in our data. Hence, for any marginal cost of public funds above 1, all countries in our sample prefer TEEs over a cash transfers.

This preference is robust to molecule fixed effects, as shown in Table 11 in Appendix E.4. In fact, adding molecule fixed effects induces a less elastic demand and cost-over-reward ratios even more favorable to vouchers.

Table 3: Demand and bargaining parameters, and cost-over-reward ratio by country for a country-level TEE

Country	(1) α_i	(2) k_i	(3) γ_i	(4) $\mathcal{E}_i$	(5) $\frac{y_i^{ph}}{\sum_j y_j^{ph}}$	(6) $\frac{y_i^{gdp}}{\sum_j y_j^{gdp}}$	(7) $\frac{\frac{\sigma_i(k_i+1)}{m_i}}{\sum_j \frac{\sigma_j(k_j+1)}{m_j}}$	(8) ρ_i^{comp}	(9) ρ_i^{gen}
AUSTRIA	0.7529	0.9645	32.00	-0.167	0.022	0.058	0.035	1.0693	0.5658
BELGIUM	0.7916	0.9581	28.00	-0.150	0.030	0.027	0.051	1.0570	0.8099
FINLAND	0.7016	0.9530	21.00	-0.201	0.013	0.013	0.033	1.0857	0.6767
FRANCE	0.8018	0.9615	36.00	-0.146	0.202	0.149	0.121	1.0539	0.8410
GERMANY	0.8558	0.9789	39.00	-0.112	0.203	0.209	0.102	1.0385	0.8213
GREECE	0.8413	0.9679	25.00	-0.125	0.026	0.020	0.066	1.0424	0.8689
IRELAND	0.7892	0.8999	14.00	-0.148	0.011	0.013	0.030	1.0559	0.6719
ITALY	0.8625	0.9502	33.00	-0.116	0.143	0.135	0.119	1.0360	0.8780
NORWAY	0.8472	0.9316	16.00	-0.119	0.009	0.018	0.014	1.0399	0.7631
POLAND	0.8007	0.9748	23.00	-0.165	0.027	0.047	0.064	1.0547	0.4719
PORTUGAL	0.8664	0.9566	17.00	-0.101	0.021	0.018	0.074	1.0350	0.8087
SPAIN	0.8154	0.9388	25.00	-0.152	0.115	0.093	0.133	1.0493	0.8088
SWEDEN	0.7038	0.9588	19.00	-0.204	0.023	0.025	0.035	1.0852	0.7567
SWITZERLAND	0.8281	0.9536	17.00	-0.124	0.021	0.026	0.029	1.0459	0.7149
UK	0.8851	0.9858	55.00	-0.095	0.133	0.149	0.093	1.0303	0.7666

Notes: ρ_i^{comp} denotes the cost-over-reward ratio were generics sold at our estimate of the marginal cost (perfect competition). We also report each country's share of union pharmaceutical expenses, share of union GDP, and share of union market size.

Table 4 reports the values of the cost-over-reward ratio for a *union-wide* TEE scheme. From our theoretical model, country i favors a TEE over a cash transfer given marginal cost

Table 4: Union-wide TEE cost-over-reward ratio by country

Country	(1) $\tilde{\rho}_i$	(2) $\tilde{\rho}_i^{gen}$	(3) $\frac{\gamma_i y_i^{gdp}}{\sum_j y_j^{gdp}}$	(4) $\frac{(1)}{(3)}$	(5) $\frac{(2)}{(3)}$
AUSTRIA	0.924	0.489	1.841	0.50	0.27
BELGIUM	1.270	0.973	0.763	1.66	1.28
FINLAND	0.775	0.483	0.279	2.78	1.73
FRANCE	7.857	6.270	5.351	1.47	1.17
GERMANY	6.378	5.044	8.140	0.78	0.62
GREECE	0.749	0.624	0.511	1.47	1.22
IRELAND	0.286	0.182	0.179	1.60	1.02
ITALY	3.557	3.014	4.453	0.80	0.68
NORWAY	0.139	0.102	0.285	0.49	0.36
POLAND	0.769	0.344	1.073	0.72	0.32
PORTUGAL	0.565	0.442	0.307	1.84	1.44
SPAIN	2.860	2.204	2.330	1.23	0.95
SWEDEN	0.862	0.601	0.476	1.81	1.26
SWITZERLAND	0.308	0.211	0.448	0.69	0.47
UK	7.885	5.868	8.212	0.96	0.71

Note: Columns (1) and (4) report the same information as respectively columns (2) and (5) assuming perfect competition in the generics market.

of public funds $1+\lambda_i$, if and only if[36]

$$\tilde{\rho}_i^{gen} \equiv \frac{(1-x_i)\sigma_i\left[\left(1-\frac{\gamma_i p_{g,i}}{m}\right)^{k_i+1} - \left(\frac{k_i+\alpha_i}{k_i+1}\right)^{k_i+1}\left(1-\frac{\gamma_i c}{m_i}\right)^{k_i+1}\right]}{\sum_j (1-\alpha_j)(1-x_j)\frac{\sigma_j}{\gamma_j}\left(\frac{k_j+\alpha_j}{k_j+1}\right)^{k_j}\left(1-\frac{\gamma_j c}{m_j}\right)^{k_j+1}} \leq \frac{\gamma_i(1+\lambda_i)y_i}{\sum_j y_j}.$$

where x_i is the share of country i's consumers who remain captive of the original branded drug company, and y_i the country i GDP.

Country i prefers a union-wide TEE over a direct payment (cash transfer) if and only if its value in column (5) is below its marginal cost of public funds $1+\lambda_i$. Comparing the values in column (5) to standard estimates of marginal costs of public funds (typically 1.3), Table 4 thus suggests that, according to our model and our data, among the 15 countries in our union, 10 would quite unambiguously prefer a (union-wide) TEE scheme to a (union-wide) cash transfer. By contrast, two countries, namely Portugal and Finland, would be unambiguously

[36] When generics are priced at their marginal cost ($p_g = c$), the condition becomes:

$$\tilde{\rho}_i \equiv \frac{(1-x_i)\sigma_i\left[1-\left(\frac{k_i+\alpha_i}{k_i+1}\right)^{k_i+1}\right]\left(1-\frac{\gamma_i \bar{c}_i}{m_i}\right)^{k_i+1}}{\sum_j (1-\alpha_j)(1-x_j)\frac{\sigma_j}{\gamma_j}\left(\frac{k_j+\alpha_j}{k_j+1}\right)^{k_j}\left(1-\frac{\gamma_j \bar{c}_j}{m_j}\right)^{k_j+1}} \leq \frac{\gamma_i(1+\lambda_i)y_i}{\sum_j y_j}.$$

against a TEE scheme with respect to a cash transfer, while the three remaining countries, namely Belgium, Greece and Sweden, would be close to indifferent between the two schemes. Admittedly, higher estimates of marginal costs of public funds, such as those in Barrios et al. (2013),[37] would make all countries in our sample but one prefer TEEs over cash transfers, with only Finland preferring cash transfers over TEEs. Nonetheless, we keep the standard estimate of 1.3 for marginal cost of public funds as our main benchmark. Lastly, the relative preferences of Finland and Portugal for (union-wide) cash transfers fit our model's predictions as both have relatively high drug demands with respect to their shares in the union's budget (see columns (6) and (7) in Table 3).[38] Lastly, we provide in Appendix E.2 the values of cost-over-reward ratios for a 13-country-union TEE without the unwilling countries (Finland and Portugal), and show that among these 13 countries, 9 would still be in favor of a TEE scheme, while 4 (Belgium, France, Greece and Sweden) would be close to indifferent between a TEE scheme and a direct payment.

4 Conclusion

The introduction covered the main insights of our analysis. As this paper is a first attempt at comparing TEEs and prizes, we repeat some of the caveats regarding policy implications. On the one hand, free-riding within the union may hinder the prize mechanism, providing an additional argument in favor of TEEs. On the other hand, market power and strategic intertemporal bidding in the vouchers market may well increase the cost-over-reward ratio. We need to improve our understanding of these issues.

This paper is, to the best of our knowledge, the first to provide a conceptual framework to study TEEs, as well as the first to provide estimates of their impacts. Given the likely addition of this new approach to the innovation policy toolbox, we hope that it will motivate future research and policy reflexions.

[37] Barrios et al. (2013) estimates in particular the marginal cost of public funds of Portugal and Finland as respectively 1.82 and 1.61.

[38] So do Belgium and Greece, who are indeed close to indifference. While Ireland too has a relatively high demand with respect to its budget share, it also has little competition in the generics market (ρ_i^{gen} much lower than ρ_i^{comp} in Table 3), which makes a TEE scheme relatively less costly, as our theoretical analysis shows.

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A Comparing "Priority Review Vouchers" to cash transfers

We sketch a model of "priority review vouchers (PRV)" (Ridley et al., 2006) in order to emphasize the malleability of our methodological approach.

Let T denote the patent length, T_R the standard review time, and $\Delta \in (0, T_R)$ the reduction induced by a priority review. Letting p^* and p_g denote, respectively, the original branded drug regulated price and the generics price, the value of a priority review voucher to the buyer is thus equal to

$$(e^{-r(T_R-\Delta)} - e^{-rT_R})\left(\frac{1-e^{-rT}}{r}\pi_E + \frac{e^{-rT}}{r}\pi_{NE}\right),$$

where, under the maintained assumptions of the TEE model, $\pi_E = \pi(p^*)$ and $\pi_{NE} = x\pi(p^*)$. The additional social surplus brought by a priority review is equal to

$$(e^{-r(T_R-\Delta)} - e^{-rT_R})\left(\frac{1-e^{-rT}}{r}S(p^*) + \frac{e^{-rT}}{r}\left[xS(p^*) + (1-x)S(p_g)\right]\right).$$

Suppose that the authority incurs the additional cost $(1+\lambda)\phi(\Delta)$ of expediting the review. Let us compare a PRV to a prize. A prize Υ costs $(1+\lambda)\Upsilon$ to the government. Under a PRV, to achieve a reward Υ, the reduction of review time must satisfy:

$$(e^{-r(T_R-\Delta)} - e^{-rT_R})\left(\frac{1-e^{-rT}}{r}\pi(p^*) + \frac{e^{-rT}}{r}x\pi(p^*)\right) = \Upsilon.$$

This defines a function $\Delta(p^*, x)$, decreasing in both arguments (as long as $\Delta(p^*, x) \leq T_R$, otherwise a PRV cannot yield reward Υ). Hence, a PRV is preferred to a prize if and only if

$$\rho^{PRV} \leq 1 + \lambda,$$

where

$$\rho^{PRV} \equiv \frac{(1+\lambda)\phi(\Delta(p^*,x)) - (e^{-r(T_R-\Delta(p^*,x))} - e^{-rT_R})\left(\frac{1-e^{-rT}}{r}S(p^*) + \frac{e^{-rT}}{r}\left[xS(p^*) + (1-x)S(p_g)\right]\right)}{(e^{-r(T_R-\Delta(p^*,x))} - e^{-rT_R})\left(\frac{1-e^{-rT}}{r}\pi(p^*) + \frac{e^{-rT}}{r}x\pi(p^*)\right)}.$$

Observation 4. *As opposed to TEEs, the cost-over-reward ratio of priority review vouchers increases with the generics' price (for the drug benefiting from the voucher, keeping x constant). Put differently, priority review vouchers are more desirable the more competitive the generics market, whereas TEEs are more desirable the less competitive the generics market.*

All else being equal, this observation suggests reversed preferences for countries with respect to both schemes (against cash transfers): the strongest supporters of TEEs (against

cash transfers) would be the strongest opponents of PRV (against cash transfers), and vice versa. [Depending on parameter values, the strongest opponents of PRV may still favor PRV over cash transfers, and the strongest supporters of TEEs may still prefer cash transfers.]

B Market power in the supply of generics

We investigate in more details the generics' optimal cartel. Let us first take generics entry as given, and denoted by N the number of generics who enter the market once the exclusivity expires. The N generics face two options:

(i) collude among themselves, leaving the original branded drug company set the monopoly price for its captive consumers;

(ii) include the original branded drug company in the cartel.

We first assume (as in the text) that a consumer's captivity (or lack thereof) to the original branded drug is independent of her WTP, hence both the demand of captive and non-captive consumers is given by $D(\cdot)$, up to a size factor. We study below a polar case of correlation.

Collusion among generics only. The no-deviation condition for generics writes as $N \leq 1/(1-\delta)$ with δ the firms' (common) discount factor. The original branded drug company is unwilling to undercut the cartel's price $p \leq p^*$ if and only if

$$x\pi^* \geq (p-c)D(p),$$

where $\pi^* \equiv \pi_E(p^*)$ is the regulated monopoly profit given demand q.

As a consequence, the generics-only cartel is described by two constraints:

$$\begin{cases} N \leq 1/(1-\delta) \\ (p-c)D(p) \leq x\pi^* \end{cases}$$

Each cartel member makes a profit given by

$$\frac{x(1-x)\pi^*}{N},$$

which, interestingly, is non-monotonic in x.

Collusion including the original branded drug company. Can all producers collude on some price p? The no-deviation condition for generics writes as $N+1 \leq 1/(1-\delta)$. The

no-deviation condition for the original branded drug company writes as

$$\left(x + \frac{1-x}{N+1}\right)(p-c)D(p) \geq (1-\delta)(p-c)D(p) + \delta x \pi^*.$$

Hence for the largest feasible cartel, $N + 1 = 1/(1-\delta)$, and the original branded drug company' no-deviation condition writes as

$$(p-c)D(p) \geq \pi^*.$$

Together with $p \leq p^*$, this implies that $p = p^*$ (the cartel sustains the regulated monopoly price!). Each generic, resp. the original branded drug company, then makes a profit

$$\frac{(1-x)\pi^*}{N+1}, \qquad \text{resp.} \qquad \left(x + \frac{1-x}{N+1}\right)\pi^*,$$

which decreases, resp. increases, with x.

Do generics coopt the original branded drug company in their cartel?[39] The original branded drug company always prefer to be on board. Generics prefer the original branded drug company to be on board if and only if

$$\frac{(1-x)\pi^*}{N+1} \geq \frac{x(1-x)\pi^*}{N}, \qquad \text{i.e.} \qquad N \geq \frac{x}{1-x}.$$

This condition holds in particular for any $N \geq 1$ whenever $x \leq 1/2$. [An intuition is as follows: Generics cartel members trade off a share of the non-captive consumers (from $1/N$ to $1/(N+1)$, i.e. a loss proportional to $1/(N(N+1))$, in exchange of a higher price (from p to p^*, with p independent of N) on their remaining share (thus a gain proportional to $1/N$). Hence, for N sufficiently high, the gain more than compensates the loss.]

Generics entry in equilibrium. Let us now consider generics entry in equilibrium, i.e. endogenize the number of generics N.[40] (We ignore integer constraints on N for the sake of exposition.) Let $I > 0$ denote the entry cost.

- Case (I): $I \leq (1-\delta)x(1-x)\pi^*$. Then, a member of a generics-only cartel with size $1/(1-\delta)$ covers its entry cost. As a consequence, $N = 1/(1-\delta)$ generics enter. Therefore, as $N > \delta/1-\delta)$, the generics cartel does not include the original branded drug.

[39] More precisely, we consider the following timing. Upon patent expiration, generics simultaneously decide whether to enter the market. Then, the generics who have entered decide whether to collude, and how. As a consequence, the number of generics N is fixed during the collusive stage.

[40] Our timing is thus as follows: (1) The regulator sets a regulated price p^*, (2) generics decide whether to enter (we denote by N the number of generics who do enter), (3) generics who have entered collude and coordinate on the most profitable equilibrium for them.

- Case (II): $(1-\delta)x(1-x)\pi^* < I \leq (1-\delta)(1-x)\pi^*$. Then, a member of a generics-only cartel with size $1/(1-\delta)$ does not cover the entry cost, whereas a member of a cartel including $\delta/(1-\delta)$ generics and the original branded drug covers it. (No cartel can have strictly more than $\delta/(1-\delta)$ generics and include the original branded drug.) Hence, the number of generics who enter is equal to

$$N = \max\left\{\frac{\delta}{1-\delta}, \frac{x(1-x)\pi^*}{I}\right\}.$$

  Whether their cartel includes the original branded drug depends on the following inequality:

  (II.a) If $\delta/(1-\delta) < x(1-x)\pi^*/I$, i.e. if $I < (1-\delta)x(1-x)\pi^*/\delta$, then the generics cartel does not include the original branded drug.

  (II.b) If $I \geq (1-\delta)x(1-x)\pi^*/\delta$ (which thus requires $x \leq \delta$), then the generics cartel includes the original branded drug.

- Case (III): $(1-\delta)(1-x)\pi^* < I$. Then the number of generics who enter is equal to

$$N = \max\left\{\frac{x(1-x)\pi^*}{I}, \frac{(1-x)\pi^*}{I} - 1\right\}$$

  Whether their cartel includes the original branded drug depends on the following inequality:

  (III.a) If $x(1-x)\pi^*/I \leq (1-x)\pi^*/I - 1$, i.e. $I \leq (1-x)^2\pi^*$ (which thus requires $x \leq \delta$), the generics cartel includes the original branded drug (indifference if equality).

  (III.b) If $I > (1-x)^2\pi^*$, the generics cartel does not include the original branded drug.

Correlation between captivity and WTP. To alleviate the expressions, suppose the marginal cost of production c is equal to zero. For simplicity, we omit regulation (in the form of Nash-bargaining on prices), and hence we consider unregulated profit maximization by the firms. Suppose N generics have entered the market.[41] Suppose captive consumers have the highest WTPs. Let θ_x be given by $1 - F(\theta_x) = x$ (captive consumers are exactly the consumers with WTP $\theta \geq \theta_x$), where F is the c.d.f. of therapeutical needs for drug j.

[41] For the sake of brevity, we do not endogenize N later on, as this paragraph is only meant to illustrate how correlation between captivity and WTP affects the generics' incentive to include the original branded drug in their cartel.

As an illustration, with our flexible specification for demand,

$$F \ : \ \begin{cases} [0,m] \longrightarrow [0,1], \\ \theta \longmapsto 1 - \left(1 - \dfrac{\theta}{m}\right)^k. \end{cases}$$

We focus on parameter values such that $p \mapsto p[1 - F(p)]$ is concave.

For collusion among generics only, the two conditions become:

$$\begin{cases} N \leq 1/(1-\delta) \\ p[x + F(\theta_x) - F(p)] \leq \max\limits_{p' \geq \theta_x} p'[1 - F(p')] \end{cases}$$

For collusion including the original branded drug company, the two conditions are

$$\begin{cases} N + 1 \leq 1/(1-\delta) \\ p\left(x + \dfrac{[F(\theta_x) - F(p)]}{N+1}\right) \geq (1-\delta) \max\left(\max\limits_{p \geq \theta_x} p[1 - F(p)],\ \max\limits_{p \leq \theta_x} p\big(x + [F(\theta_x) - F(p)]\big)\right) \\ \qquad\qquad\qquad\qquad\qquad\qquad\qquad\qquad + \delta \max\limits_{p \geq \theta_x} p[1 - F(p)] \end{cases}$$

Henceforth, we focus on the case in which x is sufficiently small that a monopolist sets a price strictly below θ_x. As an illustration, for our flexible specification, this case arises if and only if[42]

$$x \leq \left(\frac{k}{k+1}\right)^k$$

The second condition above then writes for $N + 1 = 1/(1-\delta)$ as

$$\Big(x + (1-\delta)[F(\theta_x) - F(p)]\Big)p \geq (1-\delta) \max_{p' \leq \theta_x} p'\Big(x + [F(\theta_x) - F(p')]\Big) + \delta\theta_x[1 - F(\theta_x)]$$

Letting p_x^m be the price that solves the maximum on the RHS, i.e. $p_x^m[1 - F(p_x^m)] = \max\limits_{p' \leq \theta_x} p'(x + [F(\theta_x) - F(p')])$, the inequality rewrites as

$$0 \geq (1-\delta)\Big(p_x^m[1 - F(p_x^m)] - p[1 - F(p)]\Big) + \delta x(\theta_x - p),$$

which is a contradiction by definition of p_x^m and as $p \leq \theta_x$. Therefore, whenever x is sufficiently low, the generics cartel does not include the original branded drug company.

[42] The RHS strictly decreases with $k \in (0,1)$, down from 1 for $k = 0$ to 1/2 for $k = 1$.

The generics-only cartel price $p_g < \theta_x$ is then given by:

$$p_g[1 - F(p^g)] = \theta_x[1 - F(\theta_x)],$$

while the original branded drug's price is given by θ_x.

C Heterogeneous national welfare functions

Let us denote by j the drug that may benefit from the exclusivity extension. Let y_i be country i's aggregate income, p_{ij} the price of drug j in country i, and h_i aggregate "health" of country i's inhabitants absent drug j. We write country i's objective as:

$$u(y_i, p_{ij}) = \phi\Big(y_i - p_{ij}D_{ij}(y_i, p_{ij}),\ h_i + \omega(y_i, p_{ij})\Big),$$

where $\phi : \mathbb{R}^3 \to \mathbb{R}$ is a function of:

- disposable aggregate income after expenditures on drug j, $y_i - p_{ij}D_{ij}(y_i, p_{ij})$, i.e. for our flexible specification, $y_i - p_{ij}\sigma_{ij}\dfrac{k_{ij}+1}{m_{ij}}[1 - F_{ij}(\underline{\theta}(y_i, p_{ij}))]$ where $\underline{\theta}(y_i, p_{ij})$ is the lowest therapeutical benefit from drug j that country i decides to cover when national revenue is y_i and drug price p_{ij} (more on this below), and F_{ij} is the c.d.f. of individuals' therapeutical benefits from drug j.[43]

- aggregate health of country i's inhabitants including the therapeutical benefits brought by usage of drug j, $h_i + \omega(y_i, p_{ij})$, i.e. with our flexible specification, $\displaystyle\int_{\underline{\theta}(y_i,p_{ij})}^{m_{ij}} \theta dF_{ij}(\theta)$ times patients' population size, $\sigma_{ij}(k_{ij}+1)/m_{ij}$,

Hence, for our flexible specification:

$$u(y_i, p_{ij}) = \phi\Big(y_i - p_{ij}\sigma_{ij}\frac{k_{ij}+1}{m_{ij}}[1 - F_{ij}(\underline{\theta}(y_i, p_{ij}))],\ h_i + \sigma_{ij}\frac{k_{ij}+1}{m_{ij}}\int_{\underline{\theta}(y_i,p_{ij})}^{m_{ij}} \theta dF_{ij}(\theta)\Big).$$

We assume that ϕ strictly increases with each of its arguments, and is continuously differentiable.

We assume that expenditures on drug j are sufficiently low with respect to aggregate income, and the therapeutical benefits brought by drug j sufficiently low with respect to aggregate health that a first-order approximations are valid. Country i thus decides to buy

[43] With our flexible specification, the c.d.f. of therapeutical needs for drug d is given (as before) by

$$F_{ij} \ : \ \begin{cases} [0, m_{ij}] \longrightarrow [0,1], \\ \theta \longmapsto 1 - \left(1 - \dfrac{\theta}{m_{ij}}\right)^{k_{ij}} \end{cases}$$

the drug at price p_{ij} to give it to all its inhabitants with therapeutical need $\theta \in [\theta, \theta + d\theta]$ if and only if

$$\theta \geq \frac{\phi_y(y_i, h_i)}{\phi_h(y_i, h_i)} p_{ij} \equiv \underline{\theta}(y_i, p_{ij}).$$

where ϕ_y and ϕ_h denote the partial derivatives of ϕ with respect to its first and second arguments (we omit the arguments to alleviate the expressions).

Let $\gamma_i \equiv \phi_y/\phi_h$ be the ratio of *marginal utility of income* y_i for country i over the *marginal utility of therapeutical benefit* for country i from the drug benefiting from the exclusivity extension. Using a first-order approximation, country i's objective as a function of drug price p_{ij} thus writes as

$$\sigma_{ij} \frac{k_{ij}+1}{m_{ij}} \int_{\gamma_i p_{ij}}^{m_{ij}} (\theta - \gamma_i p_{ij}) dF_{ij}(\theta) = \gamma_i \sigma_{ij} \frac{k_{ij}+1}{m_{ij}} \int_{p}^{m_{ij}/\gamma_i} \left(1 - \frac{\gamma_i \tilde{p}}{m_{ij}}\right)^{k_{ij}} d\tilde{p}$$

using an integration by parts. Therefore, the social surplus at price p_{ij} writes as

$$\gamma_i \sigma_{ij} \frac{k_{ij}+1}{m_{ij}} \int_{p_{ij}}^{m_{ij}/\gamma_i} \left(1 - \frac{\gamma_i \tilde{p}}{m_{ij}}\right)^{k_{ij}} d\tilde{p} = \sigma_{ij} \left(1 - \frac{\gamma_i p_{ij}}{m_{ij}}\right)^{k_{ij}+1}$$

D Proof of Proposition 1

We show claim (iv) of Proposition 1, i.e. the monotonicity of the cost-over-reward ratio with respect to k for $p_g = c$.

For $p_g = c$, the cost-over-reward ratio writes as the following function on $[0, 1]$:

$$\rho(k) = \frac{1 - \left(\frac{k+\alpha}{k+1}\right)^{k+1}}{(1-\alpha)\left(\frac{k+\alpha}{k+1}\right)^{k}}$$

We will show that the derivative with respect to k is positive on $(0, 1)$ (reminding that we always have $0 \leq \alpha < 1$).

Using automatic differentiation tools, we get:

$$\rho'(k) = \frac{\left(\frac{k+1}{k+\alpha}\right)^{k} \cdot \left[(k+1)^2(\alpha+k)\ln\left(\frac{k+\alpha}{k+1}\right) + (1-\alpha)\left(a\left(\frac{k+\alpha}{k+1}\right)^{k} + k\left(\frac{k+\alpha}{k+1}\right)^{k} + k + k^2\right)\right]}{(k+\alpha)(\alpha-1)(k+1)^2}$$

Let's define:

$$g(k) \equiv (k+\alpha)(\alpha-1)(k+1)^2 < 0$$

$$h(k) \equiv \left(\frac{k+\alpha}{k+1}\right)^{k} > 0$$

$$p(k) \equiv (k+1)^2(\alpha+k)\ln\left(\frac{k+\alpha}{k+1}\right)$$

$$l(k) \equiv \alpha\left(\frac{k+\alpha}{k+1}\right)^k + k\left(\frac{k+\alpha}{k+1}\right)^k + k + k^2$$

$$m(k) \equiv p(k) + (1-\alpha)l(k)$$

$$\hat{k}(k) \equiv \frac{p(k)}{1-\alpha}\ ; \qquad m(k) = (1-\alpha)\left[\hat{k}(k) + l(k)\right]$$

So that $\rho'(k) = \dfrac{p(k)+(1-\alpha)l(k)}{h(k)g(k)} = \dfrac{m(k)}{h(k)g(k)}$ and we know that $h(k)g(k) < 0$.

D.1 Case $0 \leq \alpha \leq 0.5$

D.1.1 Summand $l(k)$

We claim that (on the interval $[0,1]$) $h(k) = \left(\dfrac{k+\alpha}{k+1}\right)^k \leq 1 - \dfrac{1}{2}(1-\alpha)k$. We will show that the right and left sides match for $k=0$ and $k=1$, and that the left side is convex, while the right side is linear. Hence, by property of convexity, the inequation will be proved.

Let us define LHS $= \left(\dfrac{k+\alpha}{k+1}\right)^k$ and RHS $= 1 - \dfrac{1}{2}(1-\alpha)k$.

Matching at both ends: For $k=0$, we clearly get LHS $= 1$ and RHS $= 1$. For $k=1$, we clearly get LHS $= \dfrac{\alpha+1}{2}$ and RHS $= \dfrac{1}{2} + \dfrac{\alpha}{2}$.

Convexity of $h(k)$ (LHS) We remember $h(k) = \left(\dfrac{k+\alpha}{k+1}\right)^k$ (the LHS above, also factor of ρ'). To show h is convex, we will show its second derivative is positive ($h''(k) > 0$ on $(0,1)$).

Using automatic differentiation tools, we get:

$$h'(k) = h(k)\cdot\left[\frac{(1-\alpha)x}{(k+\alpha)(k+1)} + \ln\left(\frac{k+\alpha}{k+1}\right)\right]$$

Let $\psi = \dfrac{(1-\alpha)x}{(k+\alpha)(k+1)} + \ln\left(\dfrac{k+\alpha}{k+1}\right)$, so that $h'(k) = h(k)\cdot\psi(k)$.

Now, $h''(k) = h(k)\cdot\psi'(k) + h'(k)\cdot\psi(k) = h(k)\cdot\left[\psi'(k) + \psi(k)^2\right]$. Using (again) automatic differentiation tools, we get: $\psi'(k) = \dfrac{(1-\alpha)\left[k(1+\alpha)+2\alpha\right]}{(k+\alpha)^2(k+1)^2}$. When $\alpha, k \in \,]0,1[$, it is trivial that $\psi'(k) > 0$; and, of course, $\psi(k)^2 \geq 0$.

Thus, we finally get $h''(k) > 0$, i.e. h is convex.

Final estimate for $l(k)$ Using $h(k) \leq 1 - \dfrac{1}{2}(1-\alpha)k$, we get:

$$l(k) < (\alpha+k)\left(1 - \frac{k}{2} + \frac{\alpha k}{2}\right) + k + k^2$$

D.1.2 Summand $p(k)$

We remark that $\left(\frac{k+\alpha}{k+1}\right) - 1 = \frac{\alpha-1}{k+1}$; And $0 \leq \left(\frac{k+\alpha}{k+1}\right) \leq 1$. Thus, using the four terms Taylor expansion of $\ln(u)$ at $u = 1$, and the fact that all remaining terms of the Taylor expansion are negative (if $u \in [0,1]$), we have:

$$\ln(u) \leq (u-1) - \frac{(u-1)^2}{2} + \frac{(u-1)^3}{3} - \frac{(u-1)^4}{4}$$

$$\text{i.e.} \quad \ln\left(\frac{k+\alpha}{k+1}\right) \leq -\left(\frac{1-\alpha}{k+1}\right) - \frac{1}{2}\left(\frac{1-\alpha}{k+1}\right)^2 - \frac{1}{3}\left(\frac{1-\alpha}{k+1}\right)^3 - \frac{1}{4}\left(\frac{1-\alpha}{k+1}\right)^4$$

multiplying by $(k+1)^2(\alpha+k)$ and dividing by $(1-\alpha)$:

$$\hat{k}(k) \leq (k+\alpha)\left[-(k+1) - \frac{1}{2}(1-\alpha)^2 - \frac{1}{3}\frac{(1-\alpha)^3}{k+1} - \frac{1}{4}\frac{(1-\alpha)^4}{(k+1)^2}\right]$$

now, we use the following lower bounds:

$$(1-\alpha)^2 \geq 1 - 2\alpha$$

$$(1-\alpha)^3 \geq 1 - 3\alpha$$

$$\frac{1}{k+1} \geq 1 - k + k^2 - k^3$$

$$\frac{1}{k+1} \geq 1 - k \text{ so } \frac{1}{(k+1)^2} \geq (1-k)^2$$

to obtain:

$$\hat{k}(k) \leq (k+\alpha)\left[-(k+1) - \frac{1}{2}(1-\alpha) - \frac{1}{3}(1-2\alpha)(1-k+k^2-k^3) - \frac{1}{4}(1-3a)(1-2k+k^2)\right]$$

D.1.3 Factor $m(k)$

We have $m(k) = (1-\alpha)\left(\hat{k}(k) + l(k)\right)$, so letting $\hat{m}(k) = \frac{m(k)}{1-\alpha}$ and using the estimates above:

$$\hat{m}(k) \leq (k+\alpha)\left(-(k+1) - \frac{1}{2}(1-\alpha) - \frac{1}{3}(1-2\alpha)(1-k+k^2-k^3) - \frac{1}{4}(1-3\alpha)(1-2k+k^2)\right) + (\alpha+k)\left(1 - \frac{k}{2} + \frac{\alpha k}{2}\right) + k + k^2$$

after expanding, simplifying[44]:

$$12 \cdot \hat{m}(k) \leq -8\alpha^2k^3 + 17\alpha^2k^2 - 20\alpha^2k + 23\alpha^2 - 8\alpha k^4 + 21\alpha k^3 - 27\alpha k^2 + 15\alpha k - 13\alpha + 4k^4 - 7k^3 + 4k^2 - k$$

[44] We used SymPy to avoid errors and multiplied by 12 to avoid having fractions in coefficients.

Now, we let:

$$p_1(k) = -k + 4k^2 - 7k^3 + 4k^4$$

$$p_2(k) = -1 + 15k - 27k^2 + 21k^3 - 8k^4$$

$$p_3(k) = -20k + 17k^2 - 8k^3$$

so that $12 \cdot \hat{m}(k) \leq -12\alpha + 23\alpha^2 + p_1(k) + \alpha p_2(k) + \alpha^2 p_3(k)$. One may check that $p_1(k) < 0$ for $x < 1$, $p_2(k) < 0$ and $p_3(k) < 0$. When $\alpha \leq 0.5$, we also have $-11\alpha + 23\alpha^2 < 0$. Therefore, we finally have $m(k) < 0$, which implies $\rho'(k) > 0$ in the case $\alpha \leq 0.5$.

D.2 Case $0.5 \leq \alpha < 1$

D.2.1 Summand $l(k)$

Since we proved (on the interval $[0, 1]$) $h(k) = \left(\frac{k+\alpha}{k+1}\right)^k \leq 1 - \frac{1}{2}(1-\alpha)k$, so we in fact have $h(k) \geq \frac{1}{2}$ on this interval. Thus, $l(k) \leq \frac{\alpha}{2} + \frac{k}{2} + k + k^2$.

D.2.2 Summand $p(k)$

We proceed similarly as above, using only the first term of the expansion ($\ln(u) \leq 1 - u$ if $u \in]0, 1]$):

$$\ln\left(\frac{k+\alpha}{k+1}\right) \leq \left(\frac{\alpha - 1}{k+1}\right)$$

This leads to:

$$p(k) \leq (k+1)(\alpha+k)(\alpha-1)$$

$$\text{so } \hat{k}(k) \leq -(k+1)(\alpha+k)$$

D.2.3 Factor $m(k)$

We have $m(k) = (1-\alpha)\left(\hat{k}(k) + l(k)\right)$, so:

$$m(k) \leq (1-\alpha) \cdot \left(-\alpha - \alpha k + \frac{\alpha}{2} + \frac{k}{2}\right)$$

Now, if $\alpha \geq \frac{1}{2}$, clearly $m(k) < 0$; this again implies $\rho'(k) > 0$.

E Data Appendix

E.1 Lower Bound Values of one year voucher by year

Table 5: Lower Bound Values of one year voucher by year (in 1000 €)

Year	$\underline{V}_t^1$	$\underline{V}_t^2$	$\underline{V}_t^3$	$\underline{V}_t^4$	$\underline{V}_t^5$
2002	PLAVIX (2008)	ZOCOR (2002)	LIPITOR (2011)	NORVASC (2003)	PANTOZOL (2008)
	440,359	452,902	424,550	345,259	270,056
2003	PLAVIX (2008)	LIPITOR (2011)	NORVASC (2003)	PANTOZOL (2008)	ZYPREXA (2010)
	453,979	437,681	355,937	278,409	274,375
2004	PLAVIX (2008)	LIPITOR (2011)	PANTOZOL (2008)	ZYPREXA (2010)	SEROQUEL (2011)
	468,019	451,217	287,019	282,861	257,219
2005	PLAVIX (2008)	LIPITOR (2011)	PANTOZOL (2008)	ZYPREXA (2010)	SEROQUEL (2011)
	482,494	465,172	295,896	291,609	265,174
2006	PLAVIX (2008)	LIPITOR (2011)	PANTOZOL (2008)	ZYPREXA (2010)	SEROQUEL (2011)
	497,417	479,559	305,048	300,628	273,376
2007	PLAVIX (2008)	LIPITOR (2011)	PANTOZOL (2008)	ZYPREXA (2010)	SEROQUEL (2011)
	512,801	494,391	314,482	309,926	281,830
2008	PLAVIX (2008)	LIPITOR (2011)	PANTOZOL (2008)	ZYPREXA (2010)	SEROQUEL (2011)
	528,661	509,681	324,208	319,511	290,547
2009	LIPITOR (2011)	ZYPREXA (2010)	SEROQUEL (2011)	NEXIUM (2010)	TAXOTERE (2010)
	525,445	329,393	299,533	244,140	274,358
2010	LIPITOR (2011)	ZYPREXA (2010)	SEROQUEL (2011)	NEXIUM (2010)	TAXOTERE (2010)
	541,695	339,580	308,797	251,691	282,843
2011	LIPITOR (2011)	SEROQUEL (2011)	ZOMETA (2012)	SINGULAIR (2012)	VIAGRA (2012)
	558,449	318,347	89,707	131,425	114,167

Notes: Voucher values $\underline{V}_t$ for one year TEE, in 1000 Euros, with yearly discount factor $\delta = 0.97$ for vouchers purchased in a given year for extending the exclusivity several years ahead. As we rank values using the upper bound $\bar{V}_t$, it can happen that $\underline{V}_t^m < \underline{V}_t^n$ for $m < n$ while upper bounds are ordered. The values for the end of sample, particularly 2010 and 2011 are not reliable because our sample stops in 2012 and thus once we lack observation of other drugs whose exclusivity stops in or after 2012.

E.2 Calibration removing unwilling countries

Table 6: Union level TEE cost-over-reward ratio by country - removing unwilling country

Country	(1) $\tilde{\rho}_i$	(2) $\tilde{\rho}_i^{gen}$	(3) $\frac{\gamma_i y_i^{gdp}}{\sum_j y_j^{gdp}}$	(4) $\frac{(1)}{(3)}$	(5) $\frac{(2)}{(3)}$
AUSTRIA	0.989	0.524	1.900	0.52	0.28
BELGIUM	1.360	1.042	0.787	1.73	1.32
FRANCE	8.413	6.714	5.524	1.52	1.22
GERMANY	6.829	5.401	8.404	0.81	0.64
GREECE	0.802	0.669	0.528	1.52	1.27
IRELAND	0.306	0.195	0.185	1.66	1.05
ITALY	3.808	3.228	4.597	0.83	0.70
NORWAY	0.149	0.109	0.294	0.51	0.37
POLAND	0.823	0.368	1.108	0.74	0.33
SPAIN	3.062	2.360	2.406	1.27	0.98
SWEDEN	0.923	0.644	0.491	1.88	1.31
SWITZERLAND	0.330	0.226	0.463	0.71	0.49
UK	8.443	6.283	8.478	1.00	0.74

Notes: We also report the share of each country population, pharmaceutical manufactures revenue as well as the share of GDP.

E.3 Regulation of the branded drug's exclusivity price: Robustness checks

Our main analysis assumed that, during its bargaining with the branded drug, the regulator does not anticipate that the generics' price (after exclusivity) may depend on the exclusivity price of the branded drug – and in particular increase with the latter – either due to regulation on the reimbursement of generics, or collusive behavior by generics suppliers. As a consequence, our analysis overestimates the bargaining power α of the regulator. Therefore, as a robustness check, we perform a counterfactual with an exogenously given α (set to 0.5), lower than the one we estimate in our main analysis. We then derive estimates for k based on the exogenous α, and compute the cost-over-reward ratios using the exogenously fixed α and the estimated k (which give us the profit and demand functions), together with the prices of the original branded drug and the generics observed in the data.

Because in our main estimation, countries' bargaining powers varied, we perform a second robustness check in which we set a country's bargaining power α to 75% of its value in our main estimation, and proceed as in our first robustness check.

Results are reported in the following Tables. Importantly, validating our main estimation, TEEs remain preferred to cash transfers for a strong majority of countries in our sample.

Table 7: Demand, Bargaining parameters and cost-over-reward ratio by country ($\alpha = 0.5$)

Country	α_i	k_i	γ_i	$\mathcal{E}_i$	$\frac{y_i^{ph}}{\sum_j y_j^{ph}}$	$\frac{y_i^{gdp}}{\sum_j y_j^{gdp}}$	$\frac{\frac{\sigma_i(k_i+1)}{m_i}}{\sum_j \frac{\sigma_j(k_j+1)}{m_j}}$	ρ_i	ρ_i^{gen}
AUSTRIA	0.5000	0.9645	32.00	-0.167	0.022	0.058	0.035	1.1640	0.8740
BELGIUM	0.5000	0.9581	28.00	-0.150	0.030	0.027	0.051	1.1635	1.0409
FINLAND	0.5000	0.9530	21.00	-0.201	0.013	0.013	0.033	1.1632	0.8869
FRANCE	0.5000	0.9615	36.00	-0.146	0.202	0.149	0.121	1.1638	1.0627
GERMANY	0.5000	0.9789	39.00	-0.112	0.203	0.209	0.102	1.1651	1.0878
GREECE	0.5000	0.9679	25.00	-0.125	0.026	0.020	0.066	1.1643	1.0968
IRELAND	0.5000	0.8999	14.00	-0.148	0.011	0.013	0.030	1.1590	0.9672
ITALY	0.5000	0.9502	33.00	-0.116	0.143	0.135	0.119	1.1629	1.1092
NORWAY	0.5000	0.9316	16.00	-0.119	0.009	0.018	0.014	1.1615	1.0579
POLAND	0.5000	0.9748	23.00	-0.165	0.027	0.047	0.064	1.1648	0.8865
PORTUGAL	0.5000	0.9566	17.00	-0.101	0.021	0.018	0.074	1.1634	1.0885
SPAIN	0.5000	0.9388	25.00	-0.152	0.115	0.093	0.133	1.1621	1.0551
SWEDEN	0.5000	0.9588	19.00	-0.204	0.023	0.025	0.035	1.1636	0.9430
SWITZERLAND	0.5000	0.9536	17.00	-0.124	0.021	0.026	0.029	1.1632	1.0250
UK	0.5000	0.9858	55.00	-0.095	0.133	0.149	0.093	1.1656	1.0896

Notes: Compared to Table 3, we fix $\alpha = 0.5$. We also report each country's share of union pharmaceutical expenses, share of union GDP, and share of union market size.

Table 8: Union level TEE cost-over-reward ratio by country ($\alpha = 0.5$)

Country	(1) $\tilde{\rho}_i$	(2) $\tilde{\rho}_i^{gen}$	(3) $\frac{\gamma_i y_i^{gdp}}{\sum_j y_j^{gdp}}$	(4) $\frac{(1)}{(3)}$	(5) $\frac{(2)}{(3)}$
AUSTRIA	0.699	0.525	1.841	0.38	0.29
BELGIUM	1.127	1.009	0.763	1.48	1.32
FINLAND	0.492	0.375	0.279	1.76	1.34
FRANCE	7.317	6.682	5.351	1.37	1.25
GERMANY	8.042	7.508	8.140	0.99	0.92
GREECE	0.862	0.812	0.511	1.69	1.59
IRELAND	0.251	0.210	0.179	1.41	1.17
ITALY	4.703	4.485	4.453	1.06	1.01
NORWAY	0.166	0.151	0.285	0.58	0.53
POLAND	0.712	0.542	1.073	0.66	0.50
PORTUGAL	0.768	0.719	0.307	2.50	2.34
SPAIN	2.852	2.589	2.330	1.22	1.11
SWEDEN	0.551	0.447	0.476	1.16	0.94
SWITZERLAND	0.329	0.290	0.448	0.73	0.65
UK	12.382	11.574	8.212	1.51	1.41

Notes: Compared to Table 4, we fix $\alpha = 0.5$. We also report the share of each country population, pharmaceutical manufactures revenue as well as the share of GDP.

Table 9: Demand, Bargaining parameters and cost-over-reward ratio by country ($\alpha = 0.75\hat{\alpha}$)

Country	α_i	k_i	γ_i	$\mathcal{E}_i$	$\frac{y_i^{ph}}{\sum_j y_j^{ph}}$	$\frac{y_i^{gdp}}{\sum_j y_j^{gdp}}$	$\frac{\frac{\sigma_i(k_i+1)}{m_i}}{\sum_j \frac{\sigma_j(k_j+1)}{m_j}}$	ρ_i	ρ_i^{gen}
AUSTRIA	0.5647	0.9645	32.00	-0.167	0.022	0.058	0.035	1.1368	0.8173
BELGIUM	0.5937	0.9581	28.00	-0.150	0.030	0.027	0.051	1.1250	0.9828
FINLAND	0.5262	0.9530	21.00	-0.201	0.013	0.013	0.033	1.1519	0.8653
FRANCE	0.6014	0.9615	36.00	-0.146	0.202	0.149	0.121	1.1222	1.0034
GERMANY	0.6418	0.9789	39.00	-0.112	0.203	0.209	0.102	1.1080	1.0093
GREECE	0.6310	0.9679	25.00	-0.125	0.026	0.020	0.066	1.1114	1.0273
IRELAND	0.5919	0.8999	14.00	-0.148	0.011	0.013	0.030	1.1221	0.9002
ITALY	0.6469	0.9502	33.00	-0.116	0.143	0.135	0.119	1.1047	1.0353
NORWAY	0.6354	0.9316	16.00	-0.119	0.009	0.018	0.014	1.1078	0.9772
POLAND	0.6005	0.9748	23.00	-0.165	0.027	0.047	0.064	1.1233	0.7967
PORTUGAL	0.6498	0.9566	17.00	-0.101	0.021	0.018	0.074	1.1039	1.0065
SPAIN	0.6116	0.9388	25.00	-0.152	0.115	0.093	0.133	1.1170	0.9887
SWEDEN	0.5278	0.9588	19.00	-0.204	0.023	0.025	0.035	1.1516	0.9223
SWITZERLAND	0.6211	0.9536	17.00	-0.124	0.021	0.026	0.029	1.1143	0.9454
UK	0.6638	0.9858	55.00	-0.095	0.133	0.149	0.093	1.1004	0.9983

Notes: Compared to Table 3, we fix $\alpha = 0.75\hat{\alpha}$. We also report each country's share of union pharmaceutical expenses, share of union GDP, and share of union market size.

Table 10: Union level TEE cost-over-reward ratio by country ($\alpha = 0.75\hat{\alpha}$)

Country	(1) $\tilde{\rho}_i$	(2) $\tilde{\rho}_i^{gen}$	(3) $\frac{\gamma_i y_i^{gdp}}{\sum_j y_j^{gdp}}$	(4) $\frac{(1)}{(3)}$	(5) $\frac{(2)}{(3)}$
AUSTRIA	0.766	0.551	1.841	0.42	0.30
BELGIUM	1.163	1.016	0.763	1.53	1.33
FINLAND	0.581	0.436	0.279	2.08	1.56
FRANCE	7.422	6.636	5.351	1.39	1.24
GERMANY	7.413	6.752	8.140	0.91	0.83
GREECE	0.816	0.754	0.511	1.60	1.48
IRELAND	0.260	0.209	0.179	1.46	1.17
ITALY	4.277	4.009	4.453	0.96	0.90
NORWAY	0.155	0.137	0.285	0.54	0.48
POLAND	0.723	0.513	1.073	0.67	0.48
PORTUGAL	0.694	0.632	0.307	2.26	2.06
SPAIN	2.826	2.501	2.330	1.21	1.07
SWEDEN	0.649	0.520	0.476	1.36	1.09
SWITZERLAND	0.319	0.270	0.448	0.71	0.60
UK	10.778	9.779	8.212	1.31	1.19

Notes: Compared to Table 4, we fix $\alpha = 0.75\hat{\alpha}$. We also report the share of each country population, pharmaceutical manufactures revenue as well as the share of GDP.

E.4 Alternative calibration

Table 11 shows the estimated parameters when we add a molecule fixed effect in the demand equation (1) in which case we estimate

$$\log q_{ijt} \approx \log(\sigma_{ij}\frac{k_i+1}{m_i}) - k_i\gamma_i\frac{p_{ijt}}{m_i} + \epsilon_{ijt}$$

where the parameter σ_i reported is $\sigma_i \equiv \frac{1}{J(i)}\sum_j \sigma_{ij}$.

Table 11: Demand, Bargaining parameters and cost-over-reward ratio by country

Country	α_i	k_i	γ_i	$\mathcal{E}_i$	$\frac{y_i^{ph}}{\sum_j y_j^{ph}}$	$\frac{y_i^{gdp}}{\sum_j y_j^{gdp}}$	$\frac{\frac{\sigma_i(k_i+1)}{m_i}}{\sum_j \frac{\sigma_j(k_j+1)}{m_j}}$	ρ_i	ρ_i^{gen}
AUSTRIA	0.9140	0.8898	12.00	-0.058	0.022	0.058	0.034	1.0212	0.5366
BELGIUM	0.9725	0.9030	4.00	-0.020	0.030	0.027	0.049	1.0066	0.7687
FINLAND	0.9474	0.9147	4.00	-0.037	0.013	0.013	0.031	1.0129	0.6271
FRANCE	0.9450	0.8559	11.00	-0.040	0.202	0.149	0.120	1.0130	0.8066
GERMANY	0.9783	0.7244	7.00	-0.015	0.203	0.209	0.102	1.0046	0.7924
GREECE	0.9360	0.8604	11.00	-0.049	0.026	0.020	0.068	1.0153	0.8448
IRELAND	0.9291	0.8633	5.00	-0.051	0.011	0.013	0.030	1.0171	0.6414
ITALY	0.9776	0.8283	6.00	-0.018	0.143	0.135	0.120	1.0051	0.8490
NORWAY	0.9554	0.8716	5.00	-0.035	0.009	0.018	0.014	1.0106	0.7381
POLAND	0.9116	0.9112	11.00	-0.074	0.027	0.047	0.065	1.0221	0.4433
PORTUGAL	0.9487	0.8701	7.00	-0.038	0.021	0.018	0.077	1.0123	0.7897
SPAIN	0.9515	0.9251	7.00	-0.042	0.115	0.093	0.132	1.0120	0.7737
SWEDEN	0.8978	0.9243	7.00	-0.072	0.023	0.025	0.034	1.0259	0.7124
SWITZERLAND	0.9215	0.9435	8.00	-0.058	0.021	0.026	0.030	1.0198	0.6947
UK	0.9852	0.8174	8.00	-0.011	0.133	0.149	0.094	1.0033	0.7427

Notes: Adding molecule fixed effect in demand. We also report each country's share of union pharmaceutical expenses, share of union GDP, and share of union market size.

E.5 Alternative fixing bargaining parameter

Table 12: Union level TEE cost-over-reward ratio by country

Country	(1) $\tilde{\rho}_i$	(2) $\tilde{\rho}_i^{gen}$	(3) $\frac{\gamma_i y_i^{gdp}}{\sum_j y_j^{gdp}}$	(4) $\frac{(1)}{(3)}$	(5) $\frac{(2)}{(3)}$
AUSTRIA	0.338	0.177	0.690	0.49	0.26
BELGIUM	0.171	0.130	0.109	1.57	1.20
FINLAND	0.136	0.084	0.053	2.56	1.59
FRANCE	2.313	1.841	1.635	1.41	1.13
GERMANY	1.111	0.876	1.461	0.76	0.60
GREECE	0.326	0.271	0.225	1.45	1.21
IRELAND	0.099	0.062	0.064	1.55	0.98
ITALY	0.621	0.525	0.810	0.77	0.65
NORWAY	0.043	0.031	0.089	0.48	0.35
POLAND	0.357	0.155	0.513	0.70	0.30
PORTUGAL	0.234	0.183	0.126	1.85	1.45
SPAIN	0.755	0.577	0.652	1.16	0.88
SWEDEN	0.300	0.208	0.175	1.71	1.19
SWITZERLAND	0.145	0.099	0.211	0.69	0.47
UK	1.122	0.830	1.195	0.94	0.70

Notes: Adding molecule fixed effect in demand. We also report the share of each country population, pharmaceutical manufactures revenue as well as the share of GDP.

Table 13: Union level TEE cost-over-reward ratio by country - removing unwilling country

Country	(1) $\tilde{\rho}_i$	(2) $\tilde{\rho}_i^{gen}$	(3) $\frac{\gamma_i y_i^{gdp}}{\sum_j y_j^{gdp}}$	(4) $\frac{(1)}{(3)}$	(5) $\frac{(2)}{(3)}$
AUSTRIA	0.362	0.190	0.713	0.51	0.27
BELGIUM	0.183	0.140	0.112	1.63	1.24
FRANCE	2.478	1.973	1.688	1.47	1.17
GERMANY	1.190	0.939	1.508	0.79	0.62
GREECE	0.349	0.291	0.232	1.50	1.25
IRELAND	0.106	0.067	0.066	1.61	1.01
ITALY	0.666	0.562	0.836	0.80	0.67
NORWAY	0.046	0.033	0.092	0.50	0.36
POLAND	0.383	0.166	0.530	0.72	0.31
SPAIN	0.809	0.618	0.674	1.20	0.92
SWEDEN	0.322	0.223	0.181	1.78	1.23
SWITZERLAND	0.156	0.106	0.218	0.72	0.49
UK	1.202	0.890	1.233	0.97	0.72

Notes: Adding molecule fixed effect in demand. We also report the share of each country population, pharmaceutical manufactures revenue as well as the share of GDP.

Table 14: Demand, Bargaining parameters and cost-over-reward ratio by country ($\alpha = 0.5$)

Country	α_i	k_i	γ_i	$\mathcal{E}_i$	$\frac{y_i^{ph}}{\sum_j y_j^{ph}}$	$\frac{y_i^{gdp}}{\sum_j y_j^{gdp}}$	$\frac{\frac{\sigma_i(k_i+1)}{m_i}}{\sum_j \frac{\sigma_j(k_j+1)}{m_j}}$	ρ_i	ρ_i^{gen}
AUSTRIA	0.5000	0.8898	12.00	-0.058	0.022	0.058	0.034	1.1581	1.0530
BELGIUM	0.5000	0.9030	4.00	-0.020	0.030	0.027	0.049	1.1592	1.1422
FINLAND	0.5000	0.9147	4.00	-0.037	0.013	0.013	0.031	1.1602	1.1080
FRANCE	0.5000	0.8559	11.00	-0.040	0.202	0.149	0.120	1.1553	1.1263
GERMANY	0.5000	0.7244	7.00	-0.015	0.203	0.209	0.102	1.1430	1.1313
GREECE	0.5000	0.8604	11.00	-0.049	0.026	0.020	0.068	1.1557	1.1279
IRELAND	0.5000	0.8633	5.00	-0.051	0.011	0.013	0.030	1.1559	1.0884
ITALY	0.5000	0.8283	6.00	-0.018	0.143	0.135	0.120	1.1529	1.1438
NORWAY	0.5000	0.8716	5.00	-0.035	0.009	0.018	0.014	1.1566	1.1254
POLAND	0.5000	0.9112	11.00	-0.074	0.027	0.047	0.065	1.1599	1.0306
PORTUGAL	0.5000	0.8701	7.00	-0.038	0.021	0.018	0.077	1.1565	1.1273
SPAIN	0.5000	0.9251	7.00	-0.042	0.115	0.093	0.132	1.1610	1.1312
SWEDEN	0.5000	0.9243	7.00	-0.072	0.023	0.025	0.034	1.1609	1.0805
SWITZERLAND	0.5000	0.9435	8.00	-0.058	0.021	0.026	0.030	1.1624	1.0975
UK	0.5000	0.8174	8.00	-0.011	0.133	0.149	0.094	1.1519	1.1419

Notes: Compared to Table 11, we fix $\alpha = 0.5$. Adding molecule fixed effect in demand. We also report each country's share of union pharmaceutical expenses, share of union GDP, and share of union market size.

Table 15: Union level TEE cost-over-reward ratio by country ($\alpha = 0.5$)

Country	(1) $\tilde{\rho}_i$	(2) $\tilde{\rho}_i^{gen}$	(3) $\frac{\gamma_i y_i^{gdp}}{\sum_j y_j^{gdp}}$	(4) $\frac{(1)}{(3)}$	(5) $\frac{(2)}{(3)}$
AUSTRIA	0.140	0.127	0.690	0.20	0.18
BELGIUM	0.218	0.214	0.109	2.00	1.97
FINLAND	0.091	0.087	0.053	1.72	1.64
FRANCE	1.490	1.453	1.635	0.91	0.89
GERMANY	1.815	1.797	1.461	1.24	1.23
GREECE	0.181	0.176	0.225	0.80	0.78
IRELAND	0.050	0.047	0.064	0.78	0.73
ITALY	0.979	0.971	0.810	1.21	1.20
NORWAY	0.034	0.033	0.089	0.38	0.37
POLAND	0.144	0.128	0.513	0.28	0.25
PORTUGAL	0.161	0.157	0.126	1.28	1.25
SPAIN	0.548	0.534	0.652	0.84	0.82
SWEDEN	0.105	0.098	0.175	0.60	0.56
SWITZERLAND	0.066	0.062	0.211	0.31	0.29
UK	2.676	2.653	1.195	2.24	2.22

Notes: Compared to Table 12, we fix $\alpha = 0.5$. Adding molecule fixed effect in demand. We also report the share of each country population, pharmaceutical manufactures revenue as well as the share of GDP.