

Optimal price regulations in international pharmaceutical markets with generic competition

Difei Geng* and Kamal Saggi†

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Abstract

In a two-country (home and foreign) model in which the home producer of a branded pharmaceutical product faces generic competition in each market, we analyze home's optimal policy choices regarding two major types of price regulations: external reference pricing (ERP) and direct price controls. Home's nationally optimal ERP policy lowers domestic price while maintaining the firm's export incentive. This ERP policy results in a negative international price spillover that the foreign country can (partly) offset via a local price control. Generic competition in either market reduces home's welfare gain from instituting an ERP policy. Weaker competition abroad or a greater weight on firm profits relative to consumer surplus in home's welfare function makes it more likely that home prefers an ERP policy to a price control. While international integration of national generic markets can improve welfare, such is not the case if it causes home to relax its ERP policy.

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*E-mail: dg017@uark.edu.

†E-mail: k.saggi@vanderbilt.edu.

1 Introduction

The high prices charged by some pharmaceutical companies for their branded products are a serious health issue confronting consumers and policy-makers alike.¹ Governments concerned with limiting the adverse impact of such pricing behavior on consumers have a variety of price regulations at their disposal.² In addition to direct price controls, governments can utilize indirect price regulations such as *external reference pricing* (ERP) under which the price that a government permits a seller of a particular product to charge in its local market depends upon the seller's prices for the same product in a well-defined set of foreign markets.³ Not only is such international referencing of prices practiced by a host of European countries, it has also been raised quite recently by President Trump as a possible means for lowering pharmaceutical prices in the United States (US).⁴

Of course, price regulations are not the only means for curtailing the market power of firms selling branded pharmaceuticals. Market competition from generics that possesses the same therapeutic qualities as branded products can potentially help achieve the same objective. The welfare gains resulting from generic competition have induced some countries to take measures aimed at increasing generic penetration rates in their markets. For example, in March 2015 France launched a national plan to promote the use of generics as part of the country's cost containment efforts. Furthermore, there seems to have been a decline in the market exclusivity periods enjoyed by branded drugs in some countries, mainly due to the more aggressive marketing strategies of generic manufacturers – see Dirnagl and Cocoli (2016).

Rules and regulations governing generics differ across countries but, generally speaking, generic producers are allowed to enter the market for a branded pharmaceutical product only after the patent underlying the branded product has expired or been successfully challenged in court. In the US, the Drug Price Competition and Patent Term Restoration

¹For example, see Howard et al. (2015) for a discussion of the rising prices of branded anti-cancer drugs.

²Ekelund and Persson (2003) show that the introductory prices of pharmaceuticals in Sweden have tended to fall over time due to the presence of intensive price regulations whereas they have tended to increase in the United States where such regulations have traditionally been quite weak.

³For example, Canada's ERP policy is based on prices in France, Germany, Italy, Sweden, Switzerland, the UK and the USA while that of France considers prices in Germany, Italy, Spain, and the UK. In a recent report, the World Health Organization (WHO) notes that 24 of 30 OECD countries and approximately 20 of 27 European Union countries use ERP (WHO, 2013).

⁴See "Trump Proposes to Lower Drug Prices by Basing Them on Other Countries' Costs," New York Times, October 25, 2018. See also "How to Cut U.S. Drug Prices: Experts Weigh In" New York Times, December 10, 2018.

Act of 1984, commonly known as the *Hatch-Waxman Act*, establishes the process via which firms can seek approval for producing generic molecules from the United States Food and Drug Administration (Lakdawalla, 2018). Provisions of this Act and analogous regulations in other countries give governments at least some ability to control the intensity of generic competition facing branded products in their markets. The duration of data exclusivity periods – during which generic producers are not permitted to use the safety and efficacy data generated by patent-holders – is one potential policy tool via which regulatory agencies such as the US FDA control the barriers to entry facing generic producers in their markets (Lakdawalla, 2018). For example, the Hatch-Waxman Act roughly provides for a data exclusivity period of 8 years in the US whereas the analogous period in Europe can be up to 11 years.

Our objective in this paper is to shed light on whether and how the presence of generic competition alters the welfare rationale behind two commonly used pricing regulations, i.e., ERP and direct price controls. Our analytical approach generalizes the two-country model of Geng and Saggi (2017) who examine cross-country policy linkages between ERP and price controls for patented products. There are two major modeling innovations of this paper relative to Geng and Saggi (2017). First, unlike Geng and Saggi (2017), the present paper allows for generic competition in each country’s market. Second, this paper also derives the implications of allowing the home government to weigh firm profits differently than consumer surplus thereby providing a more general welfare analysis of ERP policies and price controls than Geng and Saggi (2017).

Incorporating generic competition in each market substantially generalizes the scope of Geng and Saggi (2017) since it makes their model applicable to pharmaceuticals that are under patent protection as well as those that are not (whereas the analysis of Geng and Saggi, 2017 applies only to patented products). This generalization is important since many countries (such as Austria, Portugal, and Slovenia to name a few) also apply ERP policies to branded pharmaceuticals that are no longer protected by patents. Moreover, an attractive feature of our modeling approach is that it captures the idea that the processes for the approval and marketing of generics differ across countries: an independent country-specific parameter measures the degree of therapeutic competition faced by the branded product in each market. This approach allows us to independently vary the intensity of generic competition in each country. For example, we can shut down generic competition in any market by setting the parameter measuring the degree of competition in just that

market equal to zero.

Explicitly incorporating generic competition in the model in this way allows us to explore several real-world questions that are simply beyond the scope of Geng and Saggi (2017). More specifically, we address the following novel questions: How does a country's optimal ERP policy for a branded pharmaceutical depend upon the degree of generic competition faced by it? What type of international spillovers, if any, does local generic competition generate in the presence of an optimally chosen ERP policy? Does stronger generic competition enhance or reduce the welfare efficacy of an ERP policy? Do the welfare effects of generic competition depend upon whether such competition is national or international in scope?

In the model, a single firm produces a branded pharmaceutical product that it sells at home and potentially also in a foreign market. Since home consumers are assumed to value the product relatively more than foreign ones, the firm's optimal price at home is higher than that abroad. While the firm faces local generic competition in each market, it is free to price discriminate internationally since international arbitrage is assumed to be forbidden by the government of the high price market (i.e. home). As Lakdawalla (2018) notes, the international segmentation of markets created by such restrictions gives government some leverage over local pharmaceutical prices and motivates the use of various types of price regulations on their part. Before delving into an analysis of how policy choices of governments interact internationally, we first consider a scenario in which the foreign country is policy inactive and the only policy instrument available to the home country is an ERP policy that stipulates the maximum price ratio (δ) that the firm is permitted to sustain across countries (i.e. the foreign country serves as the reference country for home's ERP policy). We show that, given that the firm sells in both markets, home's ERP policy generates a negative international price spillover: it *raises* the price abroad just as it lowers it at home. Of course, the firm is subject to the ERP pricing constraint *only if it sells in both markets* and can therefore choose to evade this constraint altogether by electing to sell only at home.

When facing an ERP policy in its home market the firm weighs the incremental profit gain that accrues from selling in the foreign market against the adverse impact that charging a lower price abroad has on its profit in the domestic market (due to the presence of an ERP policy at home). The home government, in turn, sets its ERP policy taking the firm's profit incentive into account. We show that, regardless of the degree of generic competition in

each market, under home's optimally chosen ERP policy the firm (just) prefers serving both markets to selling only at home. Furthermore, the effect of generic competition on home's optimal ERP policy is determined by its location. Stronger generic competition at home lowers the firm's domestic profit and makes the foreign market relatively more appealing thereby increasing its incentive to export. This in turn allows the home government to *tighten* its ERP policy. On the other hand, stronger generic competition abroad makes the foreign market less attractive to the firm, which induces the home government to *relax* its ERP policy in order to maintain the firm's export incentive. Although the two types of generic competition have opposing effects on home's optimal ERP policy, the welfare gain enjoyed by the home country from instituting an optimally calculated ERP policy declines in the intensity of generic competition in *either* market. This welfare result implies that the ERP policies and generic competition act as *substitutes* so that the rise of generic competition in global markets should be expected to reduce the incentives that governments have to implement ERP policies and related price regulations.

An important insight of our model is that the presence of an ERP policy at home causes generic competition in one market to spill over to the other market. Moreover, whether this international spillover is positive or negative in nature depends crucially on the responsiveness of home's ERP policy to changes in the degree of generic competition as well as the location of such competition. Specifically, holding constant home's ERP policy, an increase in generic competition in either market lowers prices in both countries. But when home's ERP policy is endogenous, a strengthening of generic competition at home *lowers* the firm's price in the foreign country whereas a strengthening of generic competition in the foreign market *raises* price at home (because it forces the home government to relax its ERP policy to maintain the firm's export incentive). As one might expect, these price adjustments imply that the welfare effects of changes in generic market competition in the two countries are rather different in nature. In particular, while an increase in home generic competition raises welfare in both countries and is therefore Pareto-improving, an increase in foreign generic competition can actually hurt the home country and even lower joint welfare.

We build on our core ERP model by extending it to a three-stage policy game in which the foreign government is also policy active. In the first stage of this policy game, the home government chooses whether to impose a local price control (\bar{p}_H) or an ERP policy (δ) on its pharmaceutical producer. Next, the foreign government sets its local price control

(\bar{p}_F) .⁵ Finally, the firm decides whether to export and then sets its price(s). Analysis of this policy game delivers several novel insights. First, in the presence of an endogenously chosen foreign price control, an increase in foreign generic competition *lowers* global welfare if the home country’s market is relatively large compared to the foreign market. Second, the larger the size of the domestic market relative to the foreign one, the less likely it is that the home government prefers an ERP policy to a price control. This is because an increase in the relative size of the domestic market reduces the importance of safeguarding the firm’s foreign profits (which we find to be the main advantage of an ERP policy over a price control). Third, domestic and foreign generic competition have rather different effects on home’s choice between the two policy instruments: greater generic competition at home tilts the home government’s choice in favor of an ERP policy whereas greater foreign competition has the opposite effect. Fourth, the higher the weight that the home country puts on firm profits relative to consumer surplus, the more likely it is that it prefers an ERP policy to a direct price control.

For the bulk of our analysis we assume that generic competition faced by the branded pharmaceutical product is local in nature. To determine how the scope of generic competition affects our main results, we also analyze the consequences of integrating the two national generic markets into a single global market. There are good practical reasons for addressing this question. For example, the European Union (EU) has been consistently pushing for a more integrated generic market for pharmaceuticals among its member states. There are multiple procedures within the EU through which a generic medicine can be approved simultaneously by more than one member state. Under the *centralized procedure* a generic medicine, once approved by any one member state, is automatically approved for sale in all the EU member states. Another approach relies on the principle of *mutual recognition* under which a generic drug approved by one country (called the “reference member state”) is automatically cleared for sale in all other countries that recognize the first country’s standard (called “concerned member states”). Both approaches can help integrate national generic markets that tend to be segmented due to international differences in regulations pertaining to the approval and sale of generics. We show that while the international integration of national generic markets can improve welfare, such is not the case if it results in a relaxation of home’s ERP policy.

⁵Since the firm’s optimal foreign price is lower by assumption in our model, the foreign government can gain nothing from using an ERP policy and it is sufficient to focus only on its incentive to use a local price control.

While we focus on reference pricing in an international context, reference pricing can also be internal and/or domestic in nature – under such policies drugs are grouped together according to some equivalence criteria (such as therapeutic quality) and a reference price within the same market is set for each group.⁶ Brekke et al. (2007) provide an analysis of such internal reference pricing in a model in which two firms selling horizontally differentiated brand-name drugs compete against each other and a third firm selling a generic version, that like in our model, is perceived to be of lower quality by consumers. They compare the effects of generic and therapeutic reference pricing both with each other and with the complete absence of reference pricing.⁷ One of their important findings is that therapeutic reference pricing generates lower prices than generic reference pricing.⁸ Motivated by the Norwegian experience, Brekke et al. (2011) provide a comparison of price caps and reference pricing and show that whether or not reference pricing is based on market prices or an exogenous benchmark price matters a great deal since generic producers have an incentive to cut prices when facing an endogenous reference pricing policy, which in turn makes the policy preferable from the viewpoint of consumers.⁹ Using a panel data set covering the 24 best selling off-patent molecules, Brekke et al. (2011) also examine the consequences of a 2003 policy experiment where a sub-sample of off-patent molecules was subjected to reference pricing, with the rest remaining under price caps. Their key finding is that prices of both brand names and generics declined due to the introduction of reference pricing while the market share of generics increased.

Our paper also contributes to the literature on the economics of exhaustion policies

⁶See Danzon and Ketcham (2004) for a description of the key prototypical systems of therapeutic reference pricing.

⁷As Brekke et al. (2007) note, under generic reference pricing the cluster includes products that have the same active chemical ingredients whereas under therapeutic reference pricing the cluster includes products with chemically related active ingredients that are pharmacologically equivalent or have similar therapeutic effects. While generic reference pricing applies only to off-patent drugs, therapeutic reference pricing can also include on-patent drugs.

⁸Brekke et al. (2009) estimate the effects of a reform in Norwegian price regulation systems that replaced the price cap (PC) regulation with an internal reference pricing (RP) system. The authors find that RP is more effective than PC in lowering both branded and generic drug prices, with the effects being larger for branded drugs. Miraldo (2009) compares two different types of endogenous reference pricing policies in a two-period model of horizontal differentiation: one where the reference price is the minimum of the observed prices and another where it is a linear combination of them. In the model, the reference pricing policy is chosen in response to first period prices set by firms. The key result is that, in equilibrium, price competition between firms is less aggressive under the latter type of reference pricing policy.

⁹The Norwegian price cap regulation is an ERP policy where the reference basket is the following set of “comparable” countries: Austria, Belgium, Denmark, Finland, Germany, Ireland, the Netherlands, Sweden, and the UK. Unlike us, Brekke et al. (2011) focus on the domestic market and take foreign prices to be exogenously determined.

which determine whether or not holders of intellectual property rights (IPRs) are subject to competition from parallel imports which in turn determines their ability to engage in international price discrimination.¹⁰ We add value to this literature in two important aspects. First, we focus on how ERP policies and price controls are possible means for controlling prices as opposed to potential competition from parallel imports. Second, while this literature focuses almost exclusively on patented products, our analysis focuses on branded products that face competition from generic producers.

2 How an ERP policy affects prices

Consider a world comprising two countries: home (H) and foreign (F). A single home firm sells a branded pharmaceutical product (x) whose quality is normalized to 1. The branded pharmaceutical product faces therapeutic competition from locally sold generics in each market.¹¹ For expositional ease, the unit production cost of both the branded product and the generic version are normalized to zero. Each country's generic market is assumed to be perfectly competitive so that, in equilibrium, the price of each generic equals marginal cost.¹² Let γ_i be the quality/effectiveness of country i 's generic product as perceived by consumers, where $i = H, F$. We assume $0 \leq \gamma_i < 1$ so that, all else equal, consumers value generic products less than the branded version. This could either be because consumers are more loyal to the branded product or because they perceive the branded product to have higher quality than generics even though it may be no more effective in therapeutic terms than generics.¹³

Observe that the parameter γ_i also indirectly captures the intensity of competition faced by the branded product in market i : an increase in γ_i implies stiffer product market

¹⁰See for example Malueg and Schwartz (1994), Maskus (2000), Richardson (2002), Li and Maskus (2006), Valletti (2006), Grossman and Lai (2008), and Roy and Saggi (2012).

¹¹In the benchmark model we assume generic competition is *local*, i.e. each generic product is only sold in the domestic market. Later, in section 5.1, we consider the case where generic products can be traded internationally.

¹²As Berndt and Newhouse (2012) note, it is indeed appropriate to model generic drug producers as price-takers operating in a perfectly competitive markets.

¹³One potential reason consumers may value the branded product more is because in many countries a person's ability to sue a drug manufacturer is limited to the branded company who created the label (i.e. generic producers do not face the same degree of product liability as firms producing branded products). For example, the US Supreme Court has ruled that people cannot bring design-defect claims against generic drug producers because such producers cannot redesign safer products while also complying with existing FDA regulations: redesigning a drug to make it safer effectively renders it a "new" drug as opposed to being a generic version of an existing branded product.

competition between the two types of products since, from the consumers' perspective, the two products become closer substitutes for one another. We let γ_i be a country-specific parameter because the perceived quality of generics can differ across countries, as can regulatory exclusivity due to differences in the scope of patent protection, the nature of procedures used for approving generics, and other types of market regulations that impact the ability of generic producers to compete with the branded product.

A consumer in country i buys at most 1 unit of the product regardless of its version. Let n_i denote the number of consumers in country i . If a consumer buys the original version her utility is given by $u_i = t - p_i$, where p_i is the price of the product and t measures the consumer's taste for quality. If a consumer buys the generic version her utility is given by $u_i = \gamma_i t$. Utility under no purchase equals zero. For simplicity, t is assumed to be uniformly distributed over the interval $[0, \mu_i]$ where $\mu_i \geq 1$. Given this preference structure, it is straightforward that consumers are partitioned into two groups depending on the taste parameter t : consumers in $[\tilde{t}_i, \mu_i]$ have a greater taste for quality and therefore buy the branded product whereas those in $[0, \tilde{t}_i]$ buy the generic where $\tilde{t}_i = p_i/(1 - \gamma_i)$.

The two countries differ in three key aspects.¹⁴ First, home consumers value quality relatively more, that is, $\mu_H = \mu \geq 1 = \mu_F$. Second, the home market is larger (i.e. has more consumers): $n_H = n \geq 1 = n_F$. Third, the degree of competition faced by the branded product can vary across countries i.e. γ_H needs not equal γ_F .

The firm faces an external reference pricing (ERP) policy set by its home government which stipulates the maximum price ratio (δ) it can sustain across countries. Provided the firm sells in both markets, home's ERP policy imposes the following pricing constraint on the firm

$$p_H \leq \delta p_F, \tag{1}$$

where $\delta \geq 1$ represents the rigor of home's ERP policy; p_H and p_F are the firm's prices at home and abroad. Hence the firm's foreign price serves as a *reference* for its home price. A lower δ obviously implies a more stringent ERP policy because it gives the firm less room to price discriminate internationally. Note also that when $\delta = 1$ the firm does not have *any* room to price discriminate across markets. Since the general motivation behind ERP is to

¹⁴We later extend the model to allow for a foreign price control. As noted in the Introduction, price controls are highly prevalent in the pharmaceutical industry, which is where ERP policies occur most commonly.

lower domestic prices, we focus on the case where $p_F \leq p_H$, that is, the home price of the branded product exceeds the foreign price.¹⁵

It is straightforward to show that (see appendix for details) the firm's optimal prices in the two markets when facing the ERP constraint given in (1) equal

$$p_H(\delta) = \frac{\mu\delta(n\delta + 1)(1 - \gamma_H)(1 - \gamma_F)}{2[\mu(1 - \gamma_H) + n\delta^2(1 - \gamma_F)]} \text{ and } p_F(\delta) = p_H(\delta)/\delta \quad (2)$$

which can be used to calculate the firm's optimal global profit under the ERP policy δ :

$$\pi(\delta) \equiv \pi(p_H(\delta), p_F(\delta)) = \frac{\mu(n\delta + 1)^2(1 - \gamma_H)(1 - \gamma_F)}{4[\mu(1 - \gamma_H) + n\delta^2(1 - \gamma_F)]}. \quad (3)$$

As one might expect, $\partial\pi(\delta)/\partial\delta > 0$, i.e. the firm's maximized global profit increases as home's ERP policy becomes less stringent:

It is useful to note that the firm's optimal market specific prices (in the absence of any ERP constraint) are given by

$$p_H^d = \frac{\mu}{2}(1 - \gamma_H) \text{ and } p_F^d = \frac{1}{2}(1 - \gamma_F). \quad (4)$$

As is clear, the use of an ERP policy can be an effective means for lowering the price at home only when $p_H^d > p_F^d$. Note that

$$p_H^d \geq p_F^d \Leftrightarrow \mu \geq \frac{1 - \gamma_F}{1 - \gamma_H}. \quad (5)$$

The above inequality shows that whether the domestic price exceeds the foreign price in the absence of an ERP policy depends on the degree of demand asymmetry across countries (as captured by μ) as well as differences in the intensity of generic competition in the two markets (captured by the ratio $(1 - \gamma_F)/(1 - \gamma_H)$). The higher is γ_F relative to γ_H , the stronger is the relative intensity of foreign generic competition and the higher is the relative price at home. Since $\mu \geq 1$, if generic competition at home is weaker (i.e. $\gamma_H \leq \gamma_F$), then the home price p_H^d necessarily exceeds the foreign price p_F^d . Condition (5) says that if $\gamma_H > \gamma_F$, for the home price to exceed the foreign price ($p_H^d \geq p_F^d$) we need the relatively higher demand pressure at home (captured by μ) on local price to dominate the relative downward pressure on prices exerted by generic competition in each market (captured by

¹⁵For example, drug prices in the UK tend to be lower than those in other EU countries and the UK does not use any ERP policy perhaps because higher foreign reference prices cannot help lower domestic prices.

γ_i). In what follows, we will see that condition (5) is necessarily satisfied under all scenarios that are relevant for addressing the questions motivating our analysis.

We can show the following:

Proposition 1: *If the firm sells in both markets when facing the ERP policy δ at home, the following hold:*

(i) *The tighter the home's ERP policy (i.e. the smaller is δ), the lower the firm's home price and the higher its foreign price: i.e. $\partial p_H(\delta)/\partial\delta > 0$ and $\partial p_F(\delta)/\partial\delta < 0$.*

(ii) *Holding constant home's ERP policy, prices in both markets decrease with an increase in the intensity of generic competition in either market i.e. $\partial p_i(\delta)/\partial\gamma_i < 0$ and $\partial p_i(\delta)/\partial\gamma_j < 0$ where $i, j = H, F$, and $i \neq j$.*

Part (i) of Proposition 1 says that a tighter ERP policy at home lowers the domestic price while simultaneously *raising* the foreign price. There is strong empirical support for these dual and opposing price effects of a country's ERP policy on local prices relative to foreign ones. For example, in their study of ERP policies in seven European countries for eleven pharmaceutical products, Kanavos et al. (2010) found that such policies lowered prices in those countries that based local prices on either the lowest (or the average) prices in their reference baskets. In our two-country model, owing to differences in demand across countries, the firm's foreign optimal price is lower than its home price but the basic idea is the same: a country instituting an ERP policy can lower the local price only if foreign prices are lower than the domestic price.

Kanavos et al. (2017) note that when Croatia started to use the Czech Republic as a reference for its local pharmaceutical prices (as opposed to France where prices were relatively higher), local pharmaceutical prices in Croatia fell. In similar vein, Slovakia too experienced price reductions in 2009 when it started to base local pharmaceutical prices on average prices in the six lowest priced countries in Europe (Kaló et al., 2008 and Leopold et al., 2012). Conversely, in the US – a country that does not use ERP policies or price controls of any type on pharmaceuticals – consumers find themselves paying significantly higher prices for branded pharmaceuticals relative to other parts of the world. For example, in their study of 79 drugs that accounted for 40% of all Medicare part D spending in the US, Kang et al. (2019) found that there was a wide gap between the US and international prices: the ratio of US to foreign price for their sample of drugs ranged between 1.3 to 70.1.

The authors conclude that the US could use ERP to significantly lower prices and improve local access to branded pharmaceuticals.

Consider now the slightly more subtle result that the domestic ERP policy causes a negative international spillover by raising the foreign price. As one might imagine, empirically identifying such international price spillovers is a rather challenging task. Yet, there is fairly convincing indirect evidence that such spillover effects indeed exist and are particularly worrisome for low and middle income countries who might find themselves at the receiving end of ERP policies implemented by richer countries (Goldberg, 2010). For example, in their study of orphan drugs spanning thirteen European countries, Young et al. (2017) note that while the use of ERP policies may have caused the absolute prices of such drugs to converge across countries, it also likely had the perverse effect of increasing net prices in poorer European countries that would have faced lower prices if ERP policies were not widely prevalent in Europe. The authors report that once buying power (via per capita national income) is taken into account, consumer access to such drugs in the lower income European countries such as Bulgaria, Romania, and Hungary was much worse than that in high income countries such as Norway, Sweden, France, and Germany because roughly similar prices of orphan drugs across these economically disparate countries implied a higher economic burden for consumers in countries with lower per capita incomes.

In a recent paper, Dubois et al. (2019) estimate a structural model of demand and supply for pharmaceuticals in the US and Canada to assess the potential role of ERP policies in the US. Their model accommodates the fact that Canadian prices are set via a bargaining process between firms and the Canadian government whereas US prices are unconstrained. The authors find that although the enactment of an ERP policy in the US would result in slightly lower prices locally, it would also impose large welfare losses on Canadian consumers because of the substantial increases in Canadian prices that would accompany such a policy change in the US. Thus, their study finds support for both local and international price effects highlighted by our analysis.

In our model, the reduction in domestic price of the branded product caused by the ERP policy lowers the market share of generics at home. Thus, the tighter the ERP policy enforced by the home country, the lower the market share of home generic producers. This result on the effect of home's ERP policy on the market share of generics fits well with the analysis of Danzon and Chao (2000) who note that market shares of generic producers competing with off-patent products are significantly higher in countries that

permit (relatively) free pricing, such as the US, the United Kingdom, and Germany, relative to countries that have strict price or reimbursement regulations, such as France, Italy, and Japan. In their recent and detailed empirical study of generic drug markets in Europe and the US based on 2013 data on 200 off-patent active ingredients, Wouters et al. (2017) report a wide variation in the proportion of prescriptions filled with generics, from a low of 17% in Switzerland to a high of 83% in the US. No doubt this cross-country variation in the share of generics across countries partly reflects international differences in the processes by which generics are approved for sale. But it also stands to reason that by lowering prices of branded products price regulations of various types make it harder for generics to capture market share. This perspective suggests that price regulations and generic competition substitute for one another to some degree, an issue we formally explore in section 3.3 of the paper.

Part (ii) of Proposition 1 says that for any given ERP policy δ , an increase in generic competition in either market lowers prices in both markets. Thus, by linking prices across markets, home's ERP policy becomes a conduit for transmitting market conditions across countries. To the best of our knowledge, existing empirical studies have not (yet) examined how ERP policies can transmit market competition conditions across countries. However, the available evidence indicates that ERP policies do transmit price conditions internationally and whether price variations across countries are caused by market competition conditions or differences in demand owing to income differences is an interesting question for future empirical research to address.

3 Optimal ERP policy

The home government chooses its ERP policy to maximize national welfare. Provided the firm serves both markets, consumer surplus under the ERP policy in market i where $i = H, F$ is given by

$$cs_i(\delta) = \frac{n_i}{\mu_i} \int_0^{\tilde{t}_i(p_i(\delta))} \gamma_i t dt + \frac{n_i}{\mu_i} \int_{\tilde{t}_i(p_i(\delta))}^{\mu_i} (t - p_i(\delta)) dt \quad (6)$$

where the first term captures the surplus enjoyed by consumers that buy the generic product while the second term measures the consumer surplus of those that buy the branded product. Total home welfare equals

$$w_H(\delta) = cs_H(\delta) + \pi(\delta) \quad (7)$$

whereas $w_F(\delta) = cs_F(\delta)$ and global welfare is defined as $w(\delta) \equiv w_H(\delta) + w_F(\delta)$. It is straightforward to show that

$$\frac{\partial w_H(\delta)}{\partial \delta} < 0 \quad (8)$$

i.e., domestic welfare declines as the ERP policy becomes less stringent. This happens because domestic price increases with δ and part of the increase in global profit experienced by the firm because of a greater ability to price discriminate internationally comes at the expense of local consumers. While the firm cares only about its aggregate global profit, the home government takes into account the adverse effect of increasing local price on domestic consumers.

3.1 Nature of optimal ERP policy

In what follows, we first state our main result and then build intuition for it.

Proposition 2: (i) *The firm prefers serving both markets to selling only at home iff home's ERP policy is sufficiently lax: i.e. $\pi(\delta) \geq \pi_H^d$ iff $\delta \geq \delta^*$ where*

$$\delta^* = \frac{1}{2} \left[\frac{\mu(1 - \gamma_H)}{1 - \gamma_F} - \frac{1}{n} \right]. \quad (9)$$

(ii) *Home welfare $w_H(\delta)$ is maximized by implementing the export-inducing ERP policy δ^* .*

(iii) *Home's optimal ERP policy δ^* is decreasing in the intensity of domestic generic competition ($\partial \delta^* / \partial \gamma_H < 0$) whereas it is increasing in the intensity of foreign generic competition ($\partial \delta^* / \partial \gamma_F > 0$).*

(iv) *Equilibrium prices in the two markets under this ERP policy are given by*

$$p_F^* \equiv p_F(\delta = \delta^*) = \frac{n\mu(1 - \gamma_H)(1 - \gamma_F)}{1 - \gamma_F + n\mu(1 - \gamma_H)}$$

and

$$p_H^* \equiv \delta^* p_F^* = \frac{\mu(1 - \gamma_H)(n\mu(1 - \gamma_H) - (1 - \gamma_F))}{2(1 - \gamma_F + n\mu(1 - \gamma_H))},$$

where $p_F^* > p_F^d$ whereas $p_H^* < p_H^d$.

Since the firm's maximized profit under the ERP constraint $\pi(\delta)$ when it sells in both markets is monotonically increasing in δ whereas its maximal domestic profit π_H^d is independent of it, there exists a unique ERP policy δ^* that solves $\pi(\delta) = \pi_H^d$. We call δ^* the

export-inducing ERP policy since at $\delta = \delta^*$ the firm is indifferent between selling only at home and selling in both markets when facing the pricing constraint imposed by the ERP policy.¹⁶ When $\delta > \delta^*$ we have $\pi(\delta) > \pi_H^d$ and the firm strictly prefers selling in both markets, whereas when $\delta < \delta^*$ we have $\pi(\delta) < \pi_H^d$ and the firm is better-off selling only at home. While setting its ERP policy, the government takes into account that the firm can escape the ERP constraint altogether by choosing to simply not sell in the foreign market and collecting π_H^d in the domestic market.

To understand the intuition behind why δ^* maximizes home welfare, suppose $\delta = \delta^*$ and consider how a reduction in δ affects domestic welfare. We know that for all $\delta < \delta^*$, the firm prefers to sell only at home at its optimal domestic price p_H^d . This implies that an ERP policy tighter than δ^* fails to exert *any* influence on the firm's price since under such a policy the firm does not export so that there is no foreign price it has to take into account while setting its home price (making home's ERP policy irrelevant). Given that the firm charges p_H^d at home, for all $\delta < \delta^*$, domestic consumer surplus under the ERP policy δ exactly equals the level which obtains in the complete absence of an ERP policy (i.e. $cs_H(\delta) = cs_H^d$). However, since the firm does not export for all ERP policies tighter than δ^* and therefore earns no export profit, domestic welfare for all $\delta < \delta^*$ is *strictly lower* than w_H^d . Thus, an ERP policy tighter than δ^* can never be optimal from home's perspective: *home is better off eliminating the ERP policy altogether when $\delta < \delta^*$.*

Now consider why the home government has no incentive to raise δ above δ^* . We know that the firm continues to export if δ is raised above δ^* and in fact, its global profit strictly increases in δ (Proposition 1, part *iii*). However, total domestic welfare $w_H(\delta)$ is strictly declining in δ for all $\delta > \delta^*$. As a result, for all $\delta > \delta^*$, it is optimal for the home government to tighten its ERP policy all the way down to δ^* . Thus, the export inducing ERP policy δ^* maximizes home welfare.

As is clear, the firm's tendency to eschew the foreign market when it faces too strong an ERP policy at home is a crucial driver of our model. Considerable empirical evidence indicates that the presence of price regulations does induce firms to significantly delay (or completely avoid) the introduction of their products into new markets when they expect such foreign entry to have an adverse effect on their prices (and hence profitability) in their existing markets. For example, using launch data in 25 major markets, including 14 EU

¹⁶We break such indifference on the part of the firm in favor of exporting.

countries, of 85 new chemical entities (NCEs) launched between 1994 and 1998, Danzon et al. (2005) find that, controlling for per capita income and other country and firm characteristics, countries with lower expected prices or smaller expected market size have fewer launches and longer launch delays. They also note that these delays are noteworthy since companies have a strong financial incentive to launch early since patents have a limited duration. However, the risk of price spillovers makes companies more willing to delay launch or forego launch entirely in low-priced countries, particularly in countries with small markets.¹⁷

Using data from drug launches in 68 countries between 1982 and 2002, Lanjouw (2005) shows that price regulations and the use of ERP by industrialized countries contributes to launch delay in developing countries.¹⁸ In similar vein, using data on 1444 drugs produced by 278 firms in 134 therapeutic classes from 1980-1999, Kyle (2007) finds that drugs invented by firms that have headquarters in countries that use price regulations are sold in fewer markets internationally and with longer delays than products that originate in countries that do not have such regulations. Danzon and Epstein (2012) uncover similar effects in their analysis of drug launches in 15 European countries over 12 different therapeutic classes during 1992-2003, i.e., the delay following a prior launch in a high-price EU country on a subsequent launch in a low-price EU country is stronger than the corresponding effect of a prior launch in a low-price EU country. Goldberg (2010) provides an insightful discussion of much of this evidence.

Our analysis suggests that optimally designed ERP policies should take export incentives of pharmaceutical companies into account. Of course, some degree of launch delay might simply be inevitable since governments cannot really fine tune ERP policies at the product level so that, when facing a common ERP policy that applies to a range of pharmaceutical products, only some producers are likely to find it optimal to forego foreign markets in order to preserve optimal prices in their relatively more important markets.

¹⁷In a recent paper, Maini and Pammolli (2019) develop and estimate a dynamic structural model to analyze the impact of ERP on launch delays using data on drug sales from Europe. They estimate that if ERP policies were removed then launch delays in eight low-income European countries would decline by as much as one year per drug.

¹⁸Lanjouw (2005) also reports a rather telling interview with a Bayer executive who states that Bayer chose not to introduce a patented antibiotic ciprofloxacin in India during the late 1980s because it was negotiating prices with several developed country markets at that time and it did not want those prices to be affected by its launch in India.

Observe from (9) that $\delta^* \geq 1$ iff $\mu \geq \mu^*$ where

$$\mu^* \equiv \frac{2n+1}{n} \frac{1-\gamma_F}{1-\gamma_H}. \quad (10)$$

In other words, the home government picks an interior ERP policy that gives the firm some room to price discriminate internationally (i.e. for $\delta^* > 1$) only when the domestic market is sufficiently larger than the foreign one (i.e. $\mu > \mu^*$). When the two markets are fairly similar, i.e. $\mu \leq \mu^*$, the firm is willing to sell abroad even under the strictest possible ERP policy (i.e. $\delta^* = 1$). Intuitively, when $\mu \leq \mu^*$ the foreign market is attractive enough to the firm that it is willing to sell there even when it has *no* room to price discriminate internationally. Thus, our model suggests that the ERP policies of countries with smaller markets are likely to be more stringent relative to those of larger countries.

While real-world ERP policies are more nuanced and complex than our analytical formulation, several pieces of indirect evidence indicate that the nature of observed ERP policies is quite consistent with our model. First, the *range* of pharmaceutical products subject to ERP policies seems to be larger in smaller countries in the sense that they are more likely to impose such policies on pharmaceuticals even when they are no longer protected by patents. For example, Rémuzat et al. (2015) and Kanavos et al (2017b) note that it is more common for smaller countries to apply ERP to both on and off-patent drugs.¹⁹ Similarly, it is more common for smaller countries (such as Belgium, Romania, Egypt, Jordan, UAE, and Turkey) to apply ERP to all drugs regardless of whether they are included in the national positive list (Kanavos et al., 2017). Yet another piece of corroborating evidence is found in the *specification of the external price* that is used as a reference price by various European countries: Rémuzat et al. (2015) report that richer countries (such as Austria, Denmark, the Netherlands, and Switzerland) are more likely to use the mean price of their reference basket whereas poorer countries (such as Bulgaria, Romania, Hungary, and Slovenia) tend to use the lowest price. Clearly, basing the local price on the lowest price in the reference basket is a more stringent ERP policy. Evidence from outside Europe is also broadly consistent. For example, rich countries like Japan and Canada tend to use the average price in their reference baskets as the reference price whereas Turkey tends to use the lowest price in its reference basket. The final bit of evidence concerns the *composition* of the reference basket itself. It is well known that when setting their ERP policies, many countries typically tend to include only foreign countries with similar market sizes and per

¹⁹These countries include Austria, Bulgaria, Czech, Latvia, Poland, Portugal, Romania, Slovakia, Slovenia, Jordan, and Lebanon.

capita incomes. For example, EU countries do not set ERP policies on the basis of prices in Asian or African developing countries. If lowering local prices were the sole motivation of ERP policies, European governments should be using the lowest available foreign prices while setting their ERP policies. The insight provided by our analysis is that setting too stringent an ERP policy can be counterproductive for a rich country since it can cause firms to forsake low-price markets abroad just so that they can sustain high prices in their relatively lucrative markets.

The intuition for part (iii) of Proposition 2 is as follows. More intense generic competition at home reduces the firm's local profit thereby making it more willing to export which in turn increases its tolerance for a tighter ERP policy at home. On the other hand, higher foreign competition renders the firm less willing to export so that the ERP policy needs to be looser to maintain the firm's incentive to export. As a result, home and foreign generic competition affect the export inducing ERP policy δ^* in opposite directions. Also, note that if $\gamma_H = \gamma_F$ then $\delta^* = \frac{1}{2}(\mu - \frac{1}{n})$ which is the same as the export inducing ERP policy in the *absence* of generic competition in either market. In other words, when generic competition is equally strong in both markets, although it lowers the absolute value of the firm's profit in each market, it does not affect its incentive to export since that depends upon its global profit under exporting *relative* to its domestic profit from selling only at home.

Since the corner case of $\delta^* = 1$ is relatively uninteresting, through-out the rest of the paper, we assume that the following inequality holds:

Assumption 1: $\mu \geq \mu^* \Leftrightarrow \delta^* \geq 1$.

Note that when Assumption 1 holds Condition (5) is automatically satisfied, i.e. $\mu \geq \mu^* \Rightarrow \mu \geq (1 - \gamma_F)/(1 - \gamma_H)$.

3.2 Price and welfare effects of generic competition

We now examine how generic competition affects prices when home's ERP policy adjusts endogenously in response to changes in market conditions:

Lemma 1: (i) $\partial p_H^*/\partial \gamma_H < 0$; (ii) $\partial p_F^*/\partial \gamma_H < 0$; (iii) $\partial p_H^*/\partial \gamma_F > 0$ and (iv) $\partial p_F^*/\partial \gamma_F < 0$.

As expected, an increase in home generic competition lowers domestic price. It is worth noting that this happens due to two reasons in our model. First, holding constant the ERP policy, competition directly lowers the market power of the firm. Second, the reduction in domestic profits makes exporting more attractive to the firm which in turn allows the home government to tighten its ERP policy. Both of these factors reinforce each other, leading to a decline in the firm's domestic price.

The second part of Lemma 1 shows that changes in competition in the home market are transmitted abroad via home's ERP policy. On the one hand, an increase in generic competition at home pushes down the domestic price, which lowers the foreign price for a given level of ERP policy (since home price is simply a multiple of the foreign price, i.e. $p_H^* \equiv \delta^* p_F^*$). On the other, an increase in domestic generic competition induces the home government to tighten its ERP policy (i.e. lower δ^*) and this tends to increase the foreign price (since $\partial p_F / \partial \delta < 0$). It turns out that the direct effect of an increase in local generic competition dominates the spillover effect created by the adjustment in home's ERP policy so that, on net, an increase in domestic generic competition lowers the foreign price.

Part (iii) of Lemma 1 reports a counter-intuitive result: *a strengthening of generic competition in the foreign market raises the home price*. As is clear, competition from foreign generics makes exporting less attractive to the firm. As a result, home government has to relax its ERP policy to maintain the firm's export incentive and this tends to drive up the home price. On the other hand, foreign generic competition puts a downward pressure on the foreign price and this tends to lower the home price through the international price linkage created by home's ERP policy. Nevertheless, it turns out that the local effect created by the relaxation of home's ERP policy dominates the international spillover generated by the reduction in the foreign price so that the home price ends up increasing with a strengthening of foreign generic competition.

The last part of Lemma 1 says that foreign generic competition serves to reduce price in the foreign market. For one thing, such competition lowers the firm's market power in the foreign market and forces it to lower its local price. For another, home's ERP policy *relaxes* in response to foreign competition and this further reduces the foreign price.

Let $w_i^* = w_i(\delta = \delta^*)$ be country i 's welfare under the equilibrium ERP policy δ^* so that $w^* = w_H^* + w_F^*$ denotes global welfare under δ^* . We can now describe the equilibrium welfare effects of changes in generic competition in the two markets:

Proposition 3: *In the presence of an optimally chosen ERP policy at home, an increase in generic competition at home raises welfare in both countries (i.e. $\partial w_H^*/\partial\gamma_H > 0$, $\partial w_F^*/\partial\gamma_H > 0$ and $\partial w^*/\partial\gamma_H > 0$), whereas an increase in generic competition abroad lowers home welfare, increases foreign welfare, and has no effect on global welfare (i.e. $\partial w_H^*/\partial\gamma_F < 0$, $\partial w_F^*/\partial\gamma_F > 0$ and $\partial w^*/\partial\gamma_F = 0$).*

Proposition 3 indicates that the welfare impacts of changes in the degree of generic competition in the two markets can be very different in nature due to the endogenous adjustment in home’s ERP policy that accompanies such changes. As already shown, home generic competition lowers prices and raises consumer surplus in both markets. The associated reductions in the deadweight loss in both markets ensure that the welfare gains generated by increased competition dominate the loss in firm’s global profit, so that global welfare increases. On the other hand, foreign competition lowers the foreign price (and therefore raises its welfare) whereas it raises home price (and therefore reduces home welfare). These two conflicting welfare effects end up perfectly offsetting each other so that changes in foreign generic competition do not affect aggregate global welfare. This perfect offsetting is surely an artifact of the specific structure of our model. However, the important point to note here is that changes in generic market competition that induce the firm to reduce its international price differential (due to a tightening of the ERP constraint faced by it) are necessarily welfare improving whereas increases in market competition that cause it to engage in a greater degree of international price discrimination generate a negative welfare effect that undermines the direct benefits of increased competition.

3.3 Generic competition and the welfare rationale for ERP

Since all government regulations are costly to implement in the real world, it is worth asking how the welfare gain delivered by an optimally chosen ERP policy depends upon the degree and scope of generic competition faced by the firm.²⁰ In other words, how does the marginal benefit of introducing an ERP policy at home depend upon the intensity of generic competition? Home’s welfare gain from implementing an optimal ERP policy is measured by

$$\Delta w_H^* = w_H^* - w_H^d.$$

We can show the following:

²⁰For example, Espin et al. (2011) point out that the implementation of an ERP policy for pharmaceutical products requires considerable resources for the collection and analysis of price data from different countries.

Proposition 4: *An increase in generic competition in either market reduces home’s welfare gain from implementing an ERP policy: $\partial\Delta w_H^*/\partial\gamma_i < 0$ for $i = H, F$.*

The intuition behind Proposition 4 is the following. Home generic competition lowers the potential gains for the home country from using an ERP policy because it helps reduce the domestic price of the branded product and makes further price containment less valuable. On the other hand, an increase in foreign generic competition reduces the effectiveness of home’s ERP policy since it causes the home price to increase by inducing a relaxation in home’s ERP policy, which in turn reduces home’s welfare gain from introducing such a policy in the first place.

Proposition 4 has clear empirical implications: *all else equal, ERP policies should be more likely to be used by governments when generic competition is weaker.* This implication is consistent with the existing real-world evidence on the use of ERP policies: it is well known that developed countries use ERP policies to regulate prices of patented products much more frequently than they do for off-patent products (WHO, 2013). The insight provided by our model is that the presence of generic competition reduces the marginal benefit of instituting an ERP policy since part of the objective of lowering local prices via an ERP policy is already provided to some degree by generic competition. ERP policies provide a greater welfare kick when applied to patented products since such products typically do not face generic competition.

There is little empirical evidence on the role of ERP in the presence of generic competition, perhaps because this connection has not even been explored yet in any theoretical study. To the best of our knowledge, the only empirical paper that explores the joint impact of reference pricing and generic competition on prices is Koskinen et al. (2014). This study assesses the effects of reference pricing and the extension of generic substitution (a policy which essentially encourages generic production) on the market for antipsychotic drugs in Finland. An important aspect of this study is that it can identify the marginal impact of reference pricing in a market that already has generic competition because of the fact that reference pricing and generic substitution were implemented with a six year time gap between them. Thus, the results of the paper speak to the question addressed by Proposition 4. Koskinen et al. (2014) report three important findings, all of which are consistent with our analysis. First, reference pricing led to a substantial reduction in the daily cost of antipsychotic medication in Finland although the impact was not equally strong for all pharmaceuticals. Second, the additional cost reductions achieved due to the

introduction of reference pricing after the adoption of generic substitution were comparatively minor since greater generic competition had already helped reduce prices – a finding that indicates that the two types of policies end up acting as substitutes for one another insofar as the goal is to lower prices. Third, the authors report that the drug for which the time gap between reference pricing and generic substitution was the smallest (so that the degree of generic competition was relatively weak when reference pricing was first introduced), reference pricing had the strongest effect on local prices. While Koskinen et al. (2014) focus on internal reference pricing based on close substitutes, as opposed to external reference pricing, their results are useful for understanding our analytical findings since both types of price regulations essentially serve to lower the prices of branded drugs.

4 ERP versus price controls

In our model, while only the home country can benefit from an ERP policy (since the firm's unconstrained price at home is higher, i.e., $p_H^d > p_F^d$), both countries have an incentive to impose a local price control on the firm since its price in each market exceeds marginal cost. Furthermore, as Proposition 1 notes, home's ERP policy raises the foreign price *above* that which prevails in its absence (i.e. $p_F^* > p_F^d$). This negative price spillover provides the foreign government an additional incentive to counter home's ERP policy via a local price control. Accordingly, we now build on our basic model by studying the following game:

Stage 1: Home government chooses between a local price control (\bar{p}_H) and an ERP policy (δ).

Stage 2: Foreign government sets its local price control \bar{p}_F .

Stage 3: Firm decides whether to export and sets its price(s).

Before proceeding further, we make two important observations. First, the home government cannot freely set both its local price \bar{p}_H and its ERP policy δ since the latter indirectly determines the firm's local price (as a multiple δ of its foreign price). Thus, at the first stage of the game, it is sufficient to examine the home country's choice between the two policy instruments. Second, as noted earlier, the foreign government has nothing to gain from using an ERP policy since the firm's optimal foreign price is lower than the home price (i.e. $p_F^d < p_H^d$). Thus, allowing the foreign government to choose between a price control and an ERP policy would add nothing to our analysis and it is sufficient to consider only the foreign government's price control decision.

4.1 Firm's pricing and export decision

First note that the pricing and export decision of the firm when it faces price controls in both markets is trivial: it is willing to sell in country i so long as the price control \bar{p}_i set by the local government is greater than or equal to its marginal cost.

Suppose now that at stage three of the game, the firm faces the ERP policy δ at home and the price control \bar{p}_F abroad. When facing these policies, the firm is always free to collect maximal domestic profit π_H^d by choosing to sell only at home at its optimal home price p_H^d . To determine whether doing so is optimal, consider the firm's pricing decision if it sells in both markets. Since the ERP constraint $p_H \leq \delta\bar{p}_F$ binds in equilibrium, the firm's home price equals $p_H = \delta\bar{p}_F$ so that its total global profit is given by

$$\pi(\delta, \bar{p}_F) = \frac{n\delta\bar{p}_F}{\mu} \left(\mu - \frac{\delta\bar{p}_F}{1 - \gamma_H} \right) + \bar{p}_F \left(1 - \frac{\bar{p}_F}{1 - \gamma_F} \right). \quad (11)$$

Thus, when the firm faces an ERP policy at home and a price control abroad, it essentially has no freedom to set prices if it chooses to export: it charges \bar{p}_F abroad and $\delta\bar{p}_F$ at home.

As before, the firm is indifferent between selling in both markets and selling only at home if and only if

$$\pi(\delta, \bar{p}_F) = \pi_H^d \quad (12)$$

The above equation implicitly defines the locus of policy pairs (δ, \bar{p}_F) along which the firm is indifferent between selling only at home and selling in both markets. Explicitly solving this equation for δ as a function of \bar{p}_F yields a formula for the *export-inducing ERP policy* given any foreign price control \bar{p}_F :

$$\bar{\delta}(\bar{p}_F) = \frac{\mu(1 - \gamma_H)}{2\bar{p}_F} - \frac{\sqrt{n\mu\bar{p}_F(1 - \gamma_H)(1 - \gamma_F)(1 - \gamma_F - \bar{p}_F)}}{n\bar{p}_F(1 - \gamma_F)}. \quad (13)$$

Figure 1 illustrates the $\bar{\delta}(\bar{p}_F)$ function in the (\bar{p}_F, δ) space.

— Figure 1 here —

Note from Figure 1 that as the foreign price control tightens (i.e. \bar{p}_F falls), the firm becomes less willing to export and home's ERP policy has to be relaxed to maintain its export incentive (i.e. to ensure that $\pi(\delta, \bar{p}_F) = \pi_H^d$ continues to hold). Conversely, if the

foreign price control becomes more lax, the home country can implement a more stringent ERP policy without compromising the firm's export incentive. Note also that $\bar{\delta}(\bar{p}_F)$ is convex in \bar{p}_F , which implies that as the foreign price control gets tighter, home's ERP policy needs to adjust to an increasingly larger extent to keep the firm just willing to export.

An increase in generic competition at home shifts the $\bar{\delta}(\bar{p}_F)$ curve down. Since home generic competition reduces the firm's profitability in the domestic market, for any given foreign price control \bar{p}_F , an increase in domestic generic competition requires a tighter ERP policy to keep the firm indifferent to exporting. Furthermore, an increase in generic competition abroad shifts the $\bar{\delta}(\bar{p}_F)$ curve up. This occurs since foreign generic competition lowers the firm's willingness to export. As a result, for a given level of foreign price control \bar{p}_F , the home country's ERP policy needs to be looser to hold the firm's export incentive constant.

Next, consider the second stage of the game.

4.2 Foreign government's best response

Suppose home opts for a price control \bar{p}_H at the first stage of the game and consider the foreign government's best response.

4.2.1 If home opts for a price control

Given the home price control \bar{p}_H , in the second stage, foreign simply chooses the lowest price at which the firm is willing to sell in its market. Thus, it sets $\bar{p}_F = 0$ to maximize local welfare. Given that, at the first stage of the game, home too finds its optimal to set its price control equal to the marginal cost of production (i.e. it sets $\bar{p}_H = 0$) since its price control has no bearing on the foreign price control and the export decision of the firm. Thus, when home chooses a price control as opposed to an ERP policy, equilibrium price in each market simply equals the firm's marginal cost and the firm makes zero profits in both markets.

Now consider the subgame starting at stage two given that the home country opts for an ERP policy at the first stage.

4.2.2 If home opts for an ERP policy

At the second stage of the game, given home's ERP policy δ , the foreign government chooses the level of its price control \bar{p}_F taking into account the firm's pricing behavior as well as its export incentive. It is easy to see that it is optimal for the foreign country to pick the lowest price that just induces the firm to export. This is because, conditional on the firm exporting, foreign welfare is inversely related to local price. But if the firm does not export, then foreign consumers lose complete access to the good and foreign welfare drops to zero.

For $\bar{p}_F \in [0, p_F^*]$ since the $\bar{\delta}(\bar{p}_F)$ function is monotonically decreasing in \bar{p}_F , its inverse yields the best response of the foreign country to a given ERP policy of the home country. For $\bar{p}_F \in [p_F^*, 1]$ since the $\bar{\delta}(\bar{p}_F)$ function is increasing in \bar{p}_F , there exist two possible price controls that yield the firm the same level of global profit for any given ERP policy. However, since it is optimal for the foreign country to pick the lower of these two price controls, the best response of the foreign country can never exceed p_F^* . Thus, foreign's best response as a function of the ERP policy implemented by home is simply the downward sloping part of the $\bar{\delta}(\bar{p}_F)$ curve in Figure 1.

4.3 Home's policy choice

To determine the home government's optimal choice between the two policy instruments (i.e. δ and \bar{p}_H) at the first stage of the game, we need to compare home welfare under its optimal ERP policy with that under an optimally chosen price control. Proposition 5 below states the key result of this analysis.

4.3.1 Nature of home's optimal ERP policy

Deriving the welfare-maximizing ERP policy chosen by home taking into account the best response of the foreign government at stage two and the decisions of the firm at stage three yields:

Proposition 5:

(i) *The home country's welfare-maximizing ERP policy is given by:*

$$\delta^d = \frac{1}{n(1-\gamma_F)} \left[n\mu(1-\gamma_H) - \sqrt{n\mu(1-\gamma_F)(1-\gamma_H)} \right].$$

(ii) This ERP policy is Pareto-efficient and the price control chosen in response by the foreign country equals the firm's optimal price p_F^d for the foreign market.

(iii) $\partial\delta^d/\partial\mu > 0$ and $\partial\delta^d/\partial n > 0$.

(iv) $\partial\delta^d/\partial\gamma_H < 0 < \partial\delta^d/\partial\gamma_F$.

The equilibrium policy pair (δ^d, p_F^d) is denoted by point \mathbf{H}_0 on Figure 1. Since the firm has the strongest incentive to export when it can charge its optimal price p_F^d abroad, by choosing to implement the policy δ^d home can ensure that foreign indeed sets its local price exactly equal to p_F^d : if foreign were to set a tighter price control, the firm would not sell in its market and foreign welfare would drop to zero. It is worth noting that in the absence of a foreign price control, point \mathbf{H}_0 is unattainable for home since if it were to choose the policy δ^d the firm would export and its price abroad would equal $p_F(\delta = \delta^d) > p_F^d$ and its total profit would exceed π_H^d . But because of the foreign price control, home can implement δ^d knowing that foreign will impose the lowest price consistent with the firm selling in its market, which at the policy δ^d equals p_F^d . It is worth noting that, from the foreign country's perspective, although this outcome coincides with the complete absence of an ERP policy at home, its price control policy is still beneficial for local consumers since the foreign price under home's optimal ERP policy δ^* in the absence of a foreign price control is actually higher than that under δ^d (i.e. $p_F^* > p_F^d$).

The key to understanding why δ^d is Pareto-efficient is to note that for all $\bar{p}_F \in (p_F^d, p_F^*]$ a reduction in \bar{p}_F benefits both home and foreign since prices fall in both countries without a change in the firm's global profits (which equal π_H^d) whereas for $\bar{p}_F \in (0, p_F^d]$, a reduction in \bar{p}_F makes the foreign country better off at the expense of home. Over the latter range, since $\partial^2\delta/\partial^2\bar{p}_F \geq 0$ reductions in the foreign price control \bar{p}_F necessitate a relatively sharp increase in the home's ERP policy in order to preserve the firm's export incentive. As a result for $\bar{p}_F \in (0, p_F^d]$, a tightening of the foreign price control *increases* price at home (due to the relatively sharp adjustment in its ERP policy) so that home loses while foreign gains from a reduction in \bar{p}_F .

The intuition for why the equilibrium ERP policy δ^d increases in n and μ is the same as before: these changes make the home market more attractive to the firm who therefore needs to be granted greater leeway in international price discrimination in order for it to be willing to sell abroad.

Part (iv) shows that the effects of generic competition on the ERP policy chosen by the home country as described in Proposition 2 are robust to the presence of a foreign price

control. The intuition is also the same as before: generic competition at home makes the firm more willing to export whereas generic competition abroad makes it less willing to do so.

We are now ready to address the welfare effects of generic competition when home's ERP policy and the foreign price control are in place and adjust endogenously to any changes in such competition. We can show:

Proposition 6:

(i) *An increase in the degree of generic competition at home raises domestic welfare while it does not affect foreign welfare: (i.e. $\partial w_H/\partial\gamma_H > 0$, $\partial w_F/\partial\gamma_H = 0$ and $\partial w/\partial\gamma_H > 0$).*

(ii) *An increase in foreign generic competition lowers home's welfare ($\partial w_H/\partial\gamma_F < 0$) whereas it raises foreign welfare ($\partial w_F/\partial\gamma_F > 0$). It increases joint welfare ($\partial w/\partial\gamma_F > 0$) iff the following inequality holds:*

$$n\mu(1 - \gamma_H) < 4(1 - \gamma_F). \tag{14}$$

It is useful to contrast Proposition 6 with Proposition 2, which reports the effects of generic competition in the two markets in the absence of a foreign price control. While domestic generic competition benefits the foreign country when it does not implement a price control, it has no bearing on foreign welfare when the foreign country imposes an optimal price control in response to home's ERP policy. The intuition for this is simply that the equilibrium price control is set at the firm's optimal price for the foreign market (p_F^d) which is independent of the degree of domestic generic competition. A comparison of Propositions 3 and 6 indicates that an increase in domestic generic competition is Pareto-improving whether or not a foreign price control is in existence.

Part (ii) of Proposition 6 obtains because an increase in foreign generic competition directly lowers p_F^d and therefore increases foreign welfare. Domestic welfare declines with γ_F because home is forced to relax its ERP policy when γ_F increases ($\partial\delta^d/\partial\gamma_F > 0$) and this raises the domestic price without affecting firm's global profit (which equals π_H^d in equilibrium). The question of how an increase in foreign generic competition affects global welfare turns on a comparison of its opposing welfare effects on the two countries. Inequality (14) indicates that the larger are n or μ , the less likely it is that global welfare increases due to an increase in γ_F : an increase in either parameter implies a larger welfare loss at home both due to the scale of the home market and due to the larger relaxation in

its ERP policy necessitated by more intense foreign generic competition. Note also that an increase in γ_H makes it more likely that inequality (14) is satisfied whereas an increase in γ_F has the opposite effect. This tells us that when foreign generic competition is intense to begin with, the foreign welfare gain that results from a further increase in γ_F is fairly small.

4.3.2 Home's optimal price control

When the home country uses a price control, its welfare is maximized by setting the home price equal to marginal cost since this minimizes domestic deadweight loss without having any effect on the firm's export incentive which is determined completely by the foreign price control. The foreign country also sets the local price control equal to marginal cost while (just) maintaining the firm's incentive to export to its market. As a result, the firm makes zero profit in each market when both countries use price controls. Let $w_H(\bar{p}_i = 0)$ denote the home's equilibrium welfare when both countries use price controls.

4.3.3 Equilibrium policy choice: ERP versus price control

We are now ready to examine the home country's choice between an ERP policy and a price control at the first stage of the game. Recall that home's optimal ERP policy δ^d is such that it induces the foreign country to choose a price control equal to p_F^d . Thus the firm earns optimal monopoly profit in the foreign market. By contrast, when the home country opts for a price control, the firm makes zero profit abroad since the foreign government sets its price control equal to marginal cost. While implementing an ERP policy helps the home government preserve the firm's export profits, it also yields lower home consumer surplus than a price control since it does not push down domestic price all the way to marginal cost. Therefore, when choosing between the two types of price regulations, the home country essentially faces a trade-off between higher foreign profit earned by its firm (under its ERP policy) and greater domestic consumer surplus (delivered by the price control).

Straightforward calculations establish the following key result:

Proposition 7: *Home welfare under an ERP policy is higher than that under a local price control (i.e. $w_H(\delta^d, p_F^d) \geq w_H(\bar{p}_i = 0)$) if and only if the following inequality holds:*

$$n\mu \leq \tilde{n}\tilde{\mu} \text{ where } \tilde{n}\tilde{\mu} \equiv \frac{(1 - \gamma_F)(2\sqrt{2} + 3)}{(1 - \gamma_H)}. \quad (15)$$

Thus, whether the home country opts for an ERP policy over a price control is determined by inequality (15). This simple inequality provides important insights into factors that determine a country's choice between an ERP policy and a price control. It indicates that the larger the relative size of the domestic market (i.e. the higher are n or μ), the less likely it is that the home government prefers an ERP policy to a price control. Intuitively, an increase in the relative size of the domestic market reduces the importance of maintaining the firm's foreign profits (which is the main advantage of the ERP policy over a price control). Although our model abstracts from innovation, it is worth noting that incentives for innovation typically respond positively to product market profits post innovation. This suggests that ERP policies might have an additional advantage over direct price controls to the extent that they do more to encourage innovation.²¹

Inequality (15) also clarifies that local and foreign generic competition have opposite effects on home's choice between the two policy instruments: greater local competition (i.e. higher γ_H) makes it more likely that home prefers an ERP policy to a price control whereas greater foreign competition (i.e. higher γ_F) makes it less likely that it does so.²² Home competition increases the attractiveness of an ERP policy relative to a price control since it allows the home government to implement a tighter ERP policy (which is desirable from a welfare perspective) whereas an increase in foreign competition makes an ERP policy less attractive relative to a price control since such competition makes the optimal ERP policy more lax in nature.

5 Further analysis

In this section, we address two additional issues. First, we investigate the effects of integrating the two national generic markets into a single world market in which consumers are free to buy the generic product of either country. Second, we consider a situation where the welfare function of the home country does not weigh firm profits and consumer surplus equally. The latter analysis sheds light on how the presence of political economy motives – wherein the firm is more effective at lobbying the government than consumers – or considerations related to innovation – since innovation incentives can be driven by profitability

²¹We thank an anonymous referee for raising this point. The innovation effects of ERP policies relative to other types of price controls is surely a topic worthy of further research.

²²It is important to be careful here: in an absolute sense, the presence of generic competition at home reduces the marginal benefit of both types of price regulations but its *relative* impact is larger for the case of a direct price control so that an ERP policy becomes *relatively more attractive* than a price control when domestic competition is stronger.

– affect the nature of home’s optimal ERP policy as well as its choice between an ERP policy and a direct control.

5.1 Integration of generic markets

As we noted earlier in the paper, regulatory divergences regarding national requirements for the approval and sale of generics tend to segment national markets and can have the effect of limiting international competition in generics (IGBA, 2015). Thus, it is reasonable to assume, as we do in our core model, that generic markets are segmented internationally (i.e. generic producers in each country can only sell their product in the local market). But international trade in generic products surely exists and has been growing, with India and China emerging as major international suppliers of generic products in world markets. Indeed, the Food and Drug Administration (FDA) of the United States has publicly argued in favor of lifting barriers to generic competition by implementing a single drug development program and utilizing common aspects of applications to facilitate filing for approval in multiple countries. Since the idea of facilitating international trade in generics has obvious intellectual and practical appeal, it is worth asking how the integration of national generic markets into a single world market affects the firm producing the branded product and consumers in both countries. We now address this issue.

When the perceived quality of generics differs across countries, an obvious argument in favor of such integration is that it makes it possible for consumers in both markets to purchase the higher quality generic. For example, if the home generic is seen by consumers as being superior to the foreign one (i.e. $\gamma_H > \gamma_F$) then integration of the generic market benefits foreign consumers who switch from buying their local generic to the one imported from the home country. However, the home firm loses from this switch on the part of foreign consumers since it ends up facing more intense competition in the foreign market. Such increased competition in the foreign market makes the firm more reluctant to export which in turn induces the home government to relax its ERP policy (Lemma 1). Furthermore, from Proposition 5 it immediately follows that this change in home’s ERP policy reduces home welfare as well as global welfare when $n\mu(1-\gamma_H) \geq 4(1-\gamma_F)$. As we noted earlier, this inequality implies that if foreign generic competition is already quite intense (i.e. γ_F is high but smaller than γ_H), integrating the two generic markets can *lower* world welfare because integration does not substantially improve the quality of the generic product available to foreign consumers while it causes the home price to increase due to the relaxation in home’s ERP policy caused by integration.

It should be clear from the above discussion that if consumers view the foreign generic to be superior to the home one ($\gamma_F > \gamma_H$), integration induces the home government to tighten its ERP policy and raises global welfare by lowering prices in both countries while also bringing them closer to each other. Finally, note from Proposition 7 that if the generic markets are globally integrated then the home country prefers ERP over a price control if and only if the two markets are of similar size, that is, $n\mu < 2\sqrt{2} + 3$. Note that when generic markets are globally integrated, the intensity of generic competition has no effect on home's ERP policy (and therefore on its choice between ERP and a price control) since the firm faces the same competition in each market. Under such a situation, an increase in generic competition in either market necessarily benefits consumers in both countries and increases aggregate welfare even as it hurts the firm.

5.2 A more general welfare function

Suppose the home country's welfare function takes the following form:

$$w_H(\delta; \alpha) = cs_H(\delta) + \alpha\pi(\delta) \tag{16}$$

where $\alpha \geq 0$. Obviously, the larger is α the greater the weight that the home country puts on profits relative to consumer surplus while making its policy choices. There are two important considerations that could induce the home government to weigh consumer surplus and firm profits unequally. The first perspective is that since we are considering pharmaceutical products, in certain markets (say HIV drugs) consumer interests maybe so dominant (in the sense that lack of adequate access can have catastrophic health consequences) that a government might be willing to discount firm profits heavily relative to consumer welfare – a scenario in which α would be much smaller than 1. The second perspective takes a more long-run view: since innovation is likely to be responsive to firm profits, a government might put greater weight on profits than consumer surplus since greater innovation is in the interest of both firms and consumers.²³ Both perspectives have a compelling argument so that, in what follows, we discuss both scenarios.

The main question we address is: how does the relative weight on profits (α) affect home's policy choices? To this end we analyze the three-stage game developed in section 4 where home chooses between ERP and a price control taking into account the fact that the foreign government institutes a local price control to maximize local welfare. First note

²³We thank two external referees for raising these points.

that when home implements an ERP policy, the value of α does not affect the equilibrium outcome (i.e. its optimal policy remains δ^d). This is because, in equilibrium, under the optimal ERP policy the firm's global profit is equal to its domestic monopoly profit π_H^d . Furthermore, the foreign country is better off by tightening its price control to extract any of the firm's profit beyond π_H^d without undermining the firm's incentive for selling in its market. It follows that the contribution of the firm's profit to home's welfare equals $\alpha\pi_H^d$. Since home cannot use ERP to increase its firm's equilibrium profit beyond π_H^d , it essentially chooses its optimal ERP policy to maximize local consumer surplus. This optimal level of ERP is exactly what we obtained under $\alpha = 1$.

Let us now consider home's choice of a price control when the government values consumer surplus more than firm profits so that $\alpha \in [0, 1)$. Since the foreign country chooses the tightest price control for which the firm is willing to serve its market, it sets the local price equal to marginal cost so that the firm's foreign profit equals zero. Home chooses its price control \bar{p}_H to solve:

$$\max_{\bar{p}_H} w_H(\delta; \alpha) = \max_{\bar{p}_H} cs_H(\bar{p}_H) + \alpha\pi_H^d(\bar{p}_H) \quad (17)$$

Since we already know from previous analysis that home's optimal price control is zero for $\alpha = 1$, it must also be zero for all $\alpha < 1$ where home cares even more about consumer surplus.²⁴ Thus, the optimal foreign price control $\bar{p}_H^* = 0$ for all $\alpha \in [0, 1)$.

Proposition 8. *Suppose home welfare equals $w_H(\delta; \alpha) = cs_H(\delta) + \alpha\pi(\delta)$, where $\alpha \in [0, 1)$. Then, home prefers the optimal ERP policy δ^d to the optimal price control $\bar{p}_H^* = 0$ if and only if $\mu n \leq \widetilde{\mu n}(\alpha)$ where*

$$\widetilde{\mu n}(\alpha) = \frac{(1 - \gamma_F)(2\sqrt{2(2 - \alpha)} - 2\alpha + 5)}{(1 - \gamma_H)(2\alpha - 3)^2} \quad (18)$$

Furthermore, we have $\frac{\partial \widetilde{\mu n}}{\partial \alpha} > 0$; $\frac{\partial \widetilde{\mu n}}{\partial \gamma_H} > 0$; and $\frac{\partial \widetilde{\mu n}}{\partial \gamma_F} < 0$.

Proposition 8 implies that the message of Proposition 7 remains qualitatively unchanged when home has the more general welfare objective $w_H(\delta; \alpha)$. That is, home still prefers ERP to a price control provided market size is sufficiently similar across countries, i.e. $\mu n \leq \widetilde{\mu n}(\alpha)$. The critical threshold $\widetilde{\mu n}(\alpha)$, defined in (18), is increasing in α so that the higher the weight that home puts on firm profits relative to consumer surplus, the more

²⁴Of course, we rule out the uninteresting case where home can set a negative price control.

likely it is to prefer an ERP policy to a price control. The comparative statics of the threshold $\widetilde{\mu n}$ reported in Proposition 8 are similar to those reported in Proposition 7 so that the qualitative effects of generic competition on home's choice between ERP and price controls do not depend upon α : given any α , an increase in home generic competition makes ERP more attractive to the home country than a price control, while the opposite holds for generic competition in the foreign country.

Next suppose $\alpha \geq 1$. As noted above, this case is worth discussing since a government might value firm profits quite highly in order to incentivize innovation, something that we do not explicitly model in this paper. When $\alpha \geq 1$, we can solve the maximization problem in (17) for home's optimal price control $\bar{p}_H^*(\alpha)$:

$$\bar{p}_H^*(\alpha) = \frac{\mu(\alpha - 1)(1 - \gamma_H)}{2\alpha - 1} \quad (19)$$

Several observations about the optimal price control $\bar{p}_H^*(\alpha)$ are worth noting. First, it can be readily seen from (19) that $\bar{p}_H^*(\alpha)$ is positive whenever $\alpha > 1$ – i.e. if the home government values firm profits more than consumer surplus, it allows the firm to charge a positive mark-up. Second, it is easily checked that $\frac{\partial \bar{p}_H^*(\alpha)}{\partial \alpha} > 0$, implying that home's optimal price control increases with the weight attached to firm profits in the government's welfare function. Third, $\bar{p}_H^*(\alpha)$ converges to the monopoly price p_H^d from below as α gets larger – intuitively, the firm's domestic profit is maximized by at $\bar{p}_H^*(\alpha) = p_H^d$ and the more the government cares about profits, the closer it sets the price control to the firm's optimal monopoly price. In general, home's optimal price control is always weakly lower than p_H^d and it equals p_H^d only when the relative weight on local consumer surplus is essentially zero (which is the case when α is arbitrarily large).

Plugging $\bar{p}_H^*(\alpha)$ into (17) we obtain home's optimal welfare under the price control. Denote this maximized welfare under the optimal price control $\bar{p}_H^*(\alpha)$ by $\bar{w}_H^*(\alpha)$. Then, comparing home's welfare under its optimal ERP policy with that under the optimal price control yields the following result for $\alpha \geq 1$:

$$w_H(\delta^d) \geq \bar{w}_H^*(\alpha) \text{ iff } \mu n \leq \widehat{\mu n}(\alpha)$$

where

$$\widehat{\mu n}(\alpha) \equiv \frac{(1 - \gamma_F)(2\alpha - 1)(2\sqrt{2\alpha(\alpha - 1)} + 4\alpha - 1)}{1 - \gamma_H}.$$

Thus, Proposition 8 continues to hold when $\alpha \geq 1$ with a minor modification: we simply need to replace $\widetilde{\mu n}(\alpha)$ by $\widehat{\mu n}(\alpha)$. Finally, it is easy to show that $\frac{\partial \widehat{\mu n}}{\partial \alpha} > 0$; $\frac{\partial \widehat{\mu n}}{\partial \gamma_H} > 0$; and $\frac{\partial \widehat{\mu n}}{\partial \gamma_F} < 0$.

6 Conclusion

The market power of firms selling patented pharmaceutical products declines with the expiration of patents (after which generic competition becomes viable) but brand names can endow pharmaceutical companies with market power even in the absence of patents. This is presumably why governments attempt to lower prices of branded pharmaceutical products that are no longer protected by patents by using a variety of price regulations. In addition to such regulations, governments also have the ability to affect the degree of generic competition in their markets via the process by which they allow generic entry after the expiration of patents. Motivated by these observations, in this paper we have analyzed the effect that price regulations such as ERP and price controls have on consumers as well as firms that make pricing decisions taking such policies into account.

Our simple two-country model captures the trade-offs facing firms subject to price regulations as well as the incentives of the governments setting them. We show that generic competition has rather subtle effects on an optimally chosen ERP policy. When such competition is present in the market of the government setting the ERP policy, it allows the government to set a tighter ERP policy (i.e. one that restricts international price discrimination to a greater extent). However, a strengthening of generic competition in the foreign market induces the home government to relax its ERP policy, thereby leading to greater international price discrimination on the part of the firm. Such endogenous adjustment in home's ERP policy undermines the positive welfare effects of increased generic competition in the foreign market.

Since home's ERP policy imposes a negative price spillover on the foreign country, we allow the foreign government to impose a local price control in response to an ERP policy at home that can help limit its impact on foreign consumers. When both governments are policy active, we show that the equilibrium ERP policy of the home government is Pareto-efficient and it results in the foreign government allowing the home firm to charge its optimal price (p_F^d) in the foreign market. Though the foreign country is unable to lower the local price all the way to marginal cost, it still benefits from being able to use a price control since the price in its market when only the home government is policy active is actually higher than the firm's optimal foreign price (p_F^d).

We also examine the home government's choice between an ERP policy and a price control when the foreign government can respond to its policy decision by enacting a price

control of its own. An important result here is that an ERP policy is more effective at preserving the firm's foreign profit than a price control so that the home country prefers to use an ERP policy when the foreign market is not too small relative to the domestic one. While our model abstracts from innovation, our analysis suggests that governments might have an incentive to prefer ERP policies to direct price controls if they expect innovation to respond positively to product market profits. We also show that stronger generic competition at home tilts the choice in favor of an ERP policy whereas stronger foreign generic competition has the opposite effect. Furthermore, due to the endogenous adjustment in home's ERP policy, global integration of the generic market does not necessarily improve welfare when home generics are superior in quality than foreign ones. Finally, we show that the greater the weight a government puts on firm profits relative to consumer surplus, the more likely it is to prefer an ERP policy to a price control.

In closing, we discuss the implications of our findings for the ongoing debate over the introduction of an ERP policy in the US. Overall, our theoretical findings coupled with existing evidence suggest that the implementation of an ERP policy by the US is likely to help curb local pharmaceutical prices but to be effective, the policy would need to be designed and implemented carefully. First, care must be taken when choosing the appropriate reference basket for the US. Our model indicates that the reference basket of the US should include countries that have relatively similar market demand conditions to it. This is because if the US reference basket were to include countries with very low market prices, US firms could simply choose to not sell in such markets thereby making its ERP policy rather ineffective. Second, to operationalize its ERP policy, the US would need to choose the appropriate prices to compare within its reference basket. In this regard, we suggest that an effective strategy for the US might be to operationalize its ERP policy via local ex-factory prices (i.e. prices listed by manufacturers) in its reference countries since these prices are controlled by manufacturers and are more likely to reflect their incentives to price discriminate internationally, something an ERP policy is designed to limit. Since ex-factory prices do not typically include markups charged by downstream sellers, taxes, or rebates/discounts they are relatively easy to observe and compare internationally thereby making them a useful benchmark for implementing ERP policies. Indeed, this is one potential reason that many countries base their ERP policies on ex-factory prices (WHO, 2013). Furthermore, since supply-chains of pharmaceuticals and channels of retail vary substantially across countries, prices set by manufacturers are more directly comparable

across countries relative to retail prices.²⁵ The third major policy implication of our analysis is that generic competition acts as a substitute for ERP in containing the prices of branded drugs. As a result, the optimal ERP policy for the US would need to take account of the fact that local generic competition in the US is decidedly more robust than in other countries. Indeed, the gains from implementing an ERP policy for off-patent drugs in the US would appear rather limited and it would make eminent practical sense for the policy to be focused on only patented drugs. Finally, note that given that the US has a significant capacity for pharmaceutical innovation, it is crucial that its ERP policy should attempt to balance the objective of lowering domestic prices against maintaining the innovation incentives of firms. In the context of our model, this implies that it would be desirable for the US to put a relatively large weight on firm profits, something that would lead to a relatively lax ERP policy. To the extent the benefits of innovation spill across national boundaries, the rest of the world also has a substantial stake in how an ERP policy in the US affects incentives for innovation.

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7 Appendix

For all of the proofs below, we maintain Assumption 1 which ensures that optimal ERP policy of the home country is an interior solution (i.e. $\delta^* > 1$).

Optimal pricing and profit maximization with and without ERP

If the firm faces no ERP constraint, it is free to charge its optimal local price in each market thereby extracting the maximum possible profit while facing local generic competition. More specifically, the firm solves

$$\max_{p_H, p_F} \pi(p_H, p_F; \gamma_H, \gamma_F) \equiv \frac{n}{\mu} p_H \left(\mu - \frac{p_H}{1 - \gamma_H} \right) + p_F \left(1 - \frac{p_F}{1 - \gamma_F} \right). \quad (20)$$

The solution to the above problem is given by

$$p_H^d = \frac{\mu}{2}(1 - \gamma_H) \text{ and } p_F^d = \frac{1}{2}(1 - \gamma_F)$$

As expected, p_i^d is decreasing in γ_i indicating that an increase in generic competition in market i lowers the firm’s optimal price for that market. Sales in each market under international price discrimination equal $x_H^d = n/2$ and $x_F^d = 1/2$ while global sales equal $x^d = x_H^d + x_F^d = (n + 1)/2$. Let the firm’s global profit under optimal market specific prices be denoted by $\pi^d = \pi_H^d + \pi_F^d$, where $\pi_i^d = p_i^d x_i^d = n_i \mu_i (1 - \gamma_i)/4$ and $i = H, F$.

Now suppose the home country implements the ERP constraint $p_H \leq \delta p_F$. If the firm sells in both markets when facing this constraint its profit maximization problem is

$$\max \pi(p_i; \gamma_i) \text{ subject to } p_H \leq \delta p_F.$$

Given that the ERP constraint is binding, we can solve for firm's optimal prices in the two markets as

$$p_H(\delta) = \frac{\mu\delta(n\delta + 1)(1 - \gamma_H)(1 - \gamma_F)}{2[\mu(1 - \gamma_H) + n\delta^2(1 - \gamma_F)]} \text{ and } p_F(\delta) = p_H(\delta)/\delta. \quad (21)$$

The sales associated with these prices can be recovered from the respective demand curves in the two markets and these equal

$$x_H(\delta) = \frac{n[2\mu(1 - \gamma_H) + \delta(n\delta - 1)(1 - \gamma_F)]}{2[\mu(1 - \gamma_H) + n\delta^2(1 - \gamma_F)]} \text{ and } x_F(\delta) = \frac{\mu(1 - n\delta)(1 - \gamma_H) + 2n\delta^2(1 - \gamma_F)}{2[\mu(1 - \gamma_H) + n\delta^2(1 - \gamma_F)]}. \quad (22)$$

Global sales under the ERP constraint equal $x(\delta) = x_H(\delta) + x_F(\delta)$.²⁶ The firm's optimal global profit under ERP policy δ can be calculated by substituting $p_H(\delta)$ and $p_F(\delta)$ into $\pi(p_H, p_F)$. We have

$$\pi(\delta) \equiv \pi(p_H(\delta), p_F(\delta)) = \frac{\mu(n\delta + 1)^2(1 - \gamma_H)(1 - \gamma_F)}{4[\mu(1 - \gamma_H) + n\delta^2(1 - \gamma_F)]}. \quad (23)$$

Proof of Proposition 1

(i) We have

$$\frac{\partial p_H(\delta)}{\partial \delta} = A \cdot B_1$$

where

$$A = \frac{\mu(1 - \gamma_H)(1 - \gamma_F)}{2[\mu(1 - \gamma_H) + n\delta^2(1 - \gamma_F)]^2} \text{ and } B_1 = [(2\delta\mu n + \mu)(1 - \gamma_H) - n\delta^2(1 - \gamma_F)]$$

Since $A > 0$, we only need to show that $B_1 > 0$ for $\delta^* < \delta < \frac{\mu(1 - \gamma_H)}{1 - \gamma_F}$. It is easy to show that

$$\frac{\partial B_1}{\partial \delta} = 2n[\mu(1 - \gamma_H) - \delta(1 - \gamma_F)] > 0$$

for $\delta^* < \delta < \frac{\mu(1 - \gamma_H)}{1 - \gamma_F}$, so B_1 is increasing in δ for all relevant values of δ . Moreover, we have

$$B_1|_{\delta=\delta^*} = \frac{[\mu n(1 - \gamma_H) + (1 - \gamma_F)][3\mu n(1 - \gamma_H) - (1 - \gamma_F)]}{4n(1 - \gamma_F)} > 0$$

²⁶It can be calculated that $x(\delta) < x^d$, that is, global sales are lower under ERP than under discrimination for any levels of generic competition. However, as was shown earlier, joint welfare is higher under ERP. This is consistent with Schmalensee (1981) and Varian (1985) who establish that raising global output is only a necessary (but not sufficient) condition for price discrimination to yield higher welfare. In our model, the welfare enhancement from larger global output under discrimination is dominated by that from reducing the international price differential induced via ERP. As a result, joint welfare ends up being higher under ERP.

It follows that $B_1 > 0$ for all $\delta^* < \delta < \frac{\mu(1-\gamma_H)}{1-\gamma_F}$.

Next, we have

$$\frac{\partial p_F(\delta)}{\partial \delta} = A \cdot B_2$$

where

$$B_2 = [\mu(1 - \gamma_H) - \delta(n\delta + 2)(1 - \gamma_F)].$$

It can be shown that

$$\frac{\partial B_2}{\partial \delta} = -2(n\delta + 1)(1 - \gamma_F) < 0$$

so that B_2 is decreasing in δ for $\delta^* < \delta < \frac{\mu(1-\gamma_H)}{1-\gamma_F}$. Moreover, one can show that

$$B_2|_{\delta=\delta^*} = -\frac{[\mu n(1 - \gamma_H) + (1 - \gamma_F)][\mu n(1 - \gamma_H) - 3(1 - \gamma_F)]}{4n(1 - \gamma_F)} < 0$$

for $\delta^* < \delta < \frac{\mu(1-\gamma_H)}{1-\gamma_F}$, which implies that $B_2 < 0$ for all relevant values of δ . Since $A > 0$, we have $\frac{\partial p_F(\delta)}{\partial \delta} < 0$ for all $\delta^* < \delta < \frac{\mu(1-\gamma_H)}{1-\gamma_F}$.

(ii) Direct calculations show that

$$\frac{\partial p_H(\delta)}{\partial \gamma_H} = -\frac{\mu n \delta^3 (n\delta + 1)(1 - \gamma_F)^2}{2[\mu(1 - \gamma_H) + n\delta^2(1 - \gamma_F)]^2} < 0;$$

$$\frac{\partial p_F(\delta)}{\partial \gamma_F} = -\frac{\mu^2 (n\delta + 1)(1 - \gamma_H)^2}{2[\mu(1 - \gamma_H) + n\delta^2(1 - \gamma_F)]^2} < 0;$$

$$\frac{\partial p_H(\delta)}{\partial \gamma_F} = -\frac{\mu^2 \delta (n\delta + 1)(1 - \gamma_H)^2}{2[\mu(1 - \gamma_H) + n\delta^2(1 - \gamma_F)]^2} < 0$$

and

$$\frac{\partial p_F(\delta)}{\partial \gamma_H} = -\frac{\mu n \delta^2 (n\delta + 1)(1 - \gamma_F)^2}{2[\mu(1 - \gamma_H) + n\delta^2(1 - \gamma_F)]^2} < 0.$$

Proof of Lemma 1

(i) We have

$$\frac{\partial p_H^*}{\partial \gamma_H} = -\frac{\mu B_3}{2[\mu n(1 - \gamma_H) + (1 - \gamma_F)]^2}$$

where

$$B_3 = \mu^2 n^2 (1 - \gamma_H)^2 + 2\mu n(1 - \gamma_H)(1 - \gamma_F) - (1 - \gamma_F)^2.$$

Note that

$$\frac{\partial B_3}{\partial(\mu n)} = 2(1 - \gamma_H)[\mu n(1 - \gamma_H) + (1 - \gamma_F)] > 0$$

so that B_3 is increasing in μn . Moreover, for $\mu > \frac{2n+1}{n} \frac{1-\gamma_F}{1-\gamma_H}$ we have $\mu n > (2n+1) \frac{1-\gamma_F}{1-\gamma_H} \geq \frac{3(1-\gamma_F)}{1-\gamma_H}$ as $n \geq 1$. But direct calculations show that

$$B_3 \Big|_{\mu n = \frac{3(1-\gamma_F)}{1-\gamma_H}} = 14(1-\gamma_F)^2 > 0.$$

This implies that $B_3 > 0$ and therefore $\partial p_H^* / \partial \gamma_H < 0$ for all $\mu > \frac{2n+1}{n} \frac{1-\gamma_F}{1-\gamma_H}$.

(ii) We have

$$\frac{\partial p_F^*}{\partial \gamma_H} = -\frac{\mu n(1-\gamma_F)^2}{[\mu n(1-\gamma_H) + (1-\gamma_F)]^2} < 0.$$

(iii) We have

$$\frac{\partial p_H^*}{\partial \gamma_F} = \frac{\mu^2 n(1-\gamma_H)^2}{[\mu n(1-\gamma_H) + (1-\gamma_F)]^2} > 0.$$

(iv) We have

$$\frac{\partial p_F^*}{\partial \gamma_F} = -\frac{\mu^2 n^2(1-\gamma_H)^2}{[\mu n(1-\gamma_H) + (1-\gamma_F)]^2} < 0.$$

Proof of Proposition 3

We first prove the effects of a change in γ_H . For home welfare we have

$$\frac{\partial w_H^*}{\partial \gamma_H} = \frac{\mu n[\mu n(1-\gamma_H) - (1-\gamma_F)]}{8[\mu n(1-\gamma_H) + (1-\gamma_F)]^3} B_4$$

where

$$B_4 = \mu^2 n^2(1-\gamma_H)^2 + 4\mu n(1-\gamma_H)(1-\gamma_F) + 7(1-\gamma_F)^2.$$

It is easy to check that $B_4 > B_3 > 0$ so that $\partial w_H^* / \partial \gamma_H > 0$. For foreign welfare, we have

$$\frac{\partial w_F^*}{\partial \gamma_H} = \frac{\mu n(1-\gamma_F)^3}{[\mu n(1-\gamma_H) + (1-\gamma_F)]^3} > 0.$$

Finally, direct calculations show that $\partial w^* / \partial \gamma_H = \frac{1}{8}\mu n > 0$.

Next we prove the effects of a change in γ_F . For home welfare it is easy to see that

$$\frac{\partial w_H^*}{\partial \gamma_F} = -\frac{\mu^2 n^2(1-\gamma_H)^2[\mu n(1-\gamma_H) + 3(1-\gamma_F)]}{2[\mu n(1-\gamma_H) + (1-\gamma_F)]^3} < 0.$$

Moreover, for foreign welfare we have

$$\frac{\partial w_F^*}{\partial \gamma_F} = \frac{\mu^2 n^2(1-\gamma_H)^2[\mu n(1-\gamma_H) + 3(1-\gamma_F)]}{2[\mu n(1-\gamma_H) + (1-\gamma_F)]^3} > 0.$$

It follows that

$$\frac{\partial w^*}{\partial \gamma_F} = \frac{\partial w_H^*}{\partial \gamma_F} + \frac{\partial w_F^*}{\partial \gamma_F} = 0.$$

Proof of Proposition 4

Direct calculations show that

$$\frac{\partial \Delta w_H^*}{\partial \gamma_H} = -\frac{\mu n(1 - \gamma_F)^3}{[\mu n(1 - \gamma_H) + (1 - \gamma_F)]^3} < 0.$$

Next, we have

$$\frac{\partial \Delta w_H^*}{\partial \gamma_F} = -\frac{\mu n(1 - \gamma_H) - (1 - \gamma_F)}{4[\mu n(1 - \gamma_H) + (1 - \gamma_F)]^3} B_5$$

where

$$B_5 = \mu^2 n^2 (1 - \gamma_H)^2 + 4\mu n(1 - \gamma_H)(1 - \gamma_F) + (1 - \gamma_F)^2.$$

It is easy to check that $B_5 > B_3 > 0$ and thus $\partial \Delta w_H^* / \partial \gamma_F < 0$.

Proof of Proposition 5

(i) Home country's welfare maximizing ERP induces the foreign country to choose its local price at p_F^d . Thus δ^d is obtained by setting $\bar{p}_F = p_F^d$ in $\bar{\delta}(\bar{p}_F)$.

(ii) See the text.

(iii) We can calculate that

$$\frac{\partial \delta^d}{\partial \mu} = \frac{(1 - \gamma_H)[2\sqrt{\mu n(1 - \gamma_H)(1 - \gamma_F)} - (1 - \gamma_F)]}{2(1 - \gamma_F)\sqrt{\mu n(1 - \gamma_H)(1 - \gamma_F)}}.$$

It can be checked that $2\sqrt{\mu n(1 - \gamma_H)(1 - \gamma_F)} - (1 - \gamma_F) > 0$, which implies that $\partial \delta^d / \partial \mu > 0$. Besides, we have $\partial \delta^d / \partial n = \frac{\mu(1 - \gamma_H)}{2n\sqrt{\mu n(1 - \gamma_H)(1 - \gamma_F)}} > 0$.

(iv) One can calculate that

$$\frac{\partial \delta^d}{\partial \gamma_H} = -\frac{\mu[2\sqrt{\mu n(1 - \gamma_H)(1 - \gamma_F)} - (1 - \gamma_F)]}{2(1 - \gamma_F)\sqrt{\mu n(1 - \gamma_H)(1 - \gamma_F)}} < 0$$

and

$$\frac{\partial \delta^d}{\partial \gamma_F} = \frac{\mu(1 - \gamma_H)[2\sqrt{\mu n(1 - \gamma_H)(1 - \gamma_F)} - (1 - \gamma_F)]}{2(1 - \gamma_F)^3\sqrt{\mu n(1 - \gamma_H)(1 - \gamma_F)}} > 0.$$

Proof of Proposition 6

(i) First note that foreign welfare depends on the foreign price p_F only. In Nash equilibrium we have $p_F = p_F^d = \frac{1}{2}(1 - \gamma_F)$ which does not depend on home's generic competition γ_H . Hence an increase in generic competition at home does not change foreign price and welfare. Next, one can show that

$$\frac{\partial w^d}{\partial \gamma_H} = \frac{\mu n [\sqrt{\mu n (1 - \gamma_H)(1 - \gamma_F)} - (1 - \gamma_F)]}{8\sqrt{\mu n (1 - \gamma_H)(1 - \gamma_F)}} > 0,$$

implying higher generic competition at home raises world welfare. It follows that an increase in generic competition at home must raise domestic welfare.

(ii) Since in Nash equilibrium $p_F = p_F^d = \frac{1}{2}(1 - \gamma_F)$, a higher γ_F lowers p_F and raises foreign welfare. Also one can show that

$$\frac{\partial p_H}{\partial \gamma_F} = \frac{\mu(1 - \gamma_H)}{4\sqrt{\mu n (1 - \gamma_H)(1 - \gamma_F)}} > 0,$$

i.e. foreign generic competition raises domestic price and lowers domestic consumer surplus. Since the firm's equilibrium profit equals its domestic monopoly profit which does not change with γ_F , we know domestic welfare must fall. As for world welfare, we have

$$\frac{\partial w}{\partial \gamma_F} = \frac{2\sqrt{\mu n (1 - \gamma_H)(1 - \gamma_F)} - \mu n (1 - \gamma_H)}{8\sqrt{\mu n (1 - \gamma_H)(1 - \gamma_F)}} > 0 \text{ iff } \mu n > \frac{4(1 - \gamma_F)}{(1 - \gamma_H)}.$$

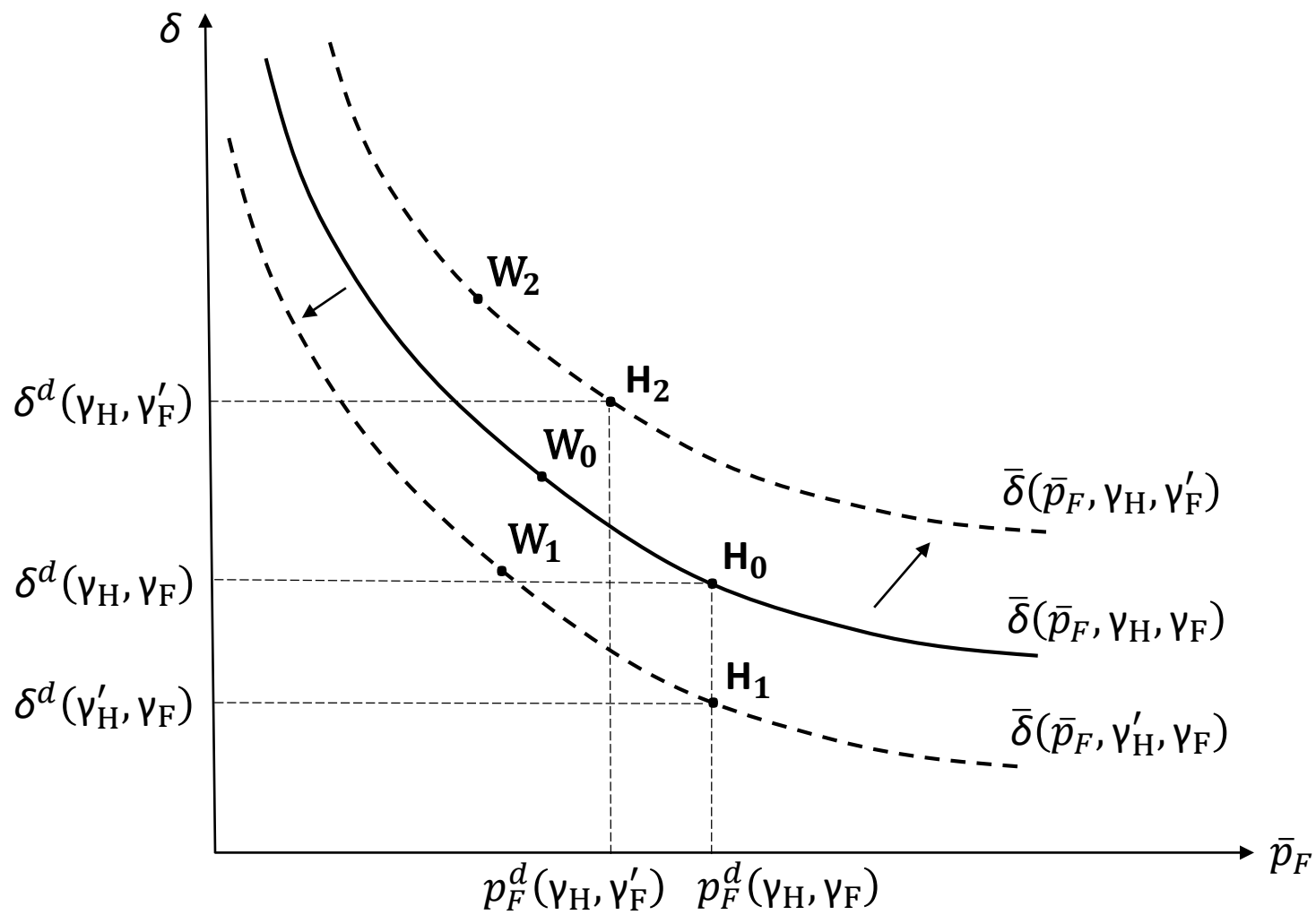


Figure 1: Equilibrium policies ($\gamma'_H > \gamma_H$ and $\gamma'_F > \gamma_F$)