The Devil's in the details – creating a generic paradox by regulation

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Abstract

Worldwide pharmaceutical markets are heavily regulated. In some countries regulation aims at controlling prices or profits; in others they are limited to ensuring the quality and safety of products.

Sweden is on the regulatory forefront in Europe and in October 2002 Sweden changed the regulatory system to promote generic substitution. The purpose of the reform was to increase competition, and hence lower pharmaceutical prices on off-patent drugs. However, using detailed panel data on prices, we find that in contrast to studies performed under the former regulatory regime, the advent of new competitors increase instead of decrease brand prices. Thus, the regulation may have created a generic paradox. Moreover, we claim this effect to be a result of small details in the regulation, such as storage sales or a dynamic price cap, providing easily exploited contradictory incentives. We therefore conclude that the effects of a basically sound regulation can be spoilt by small details.

Key words: Regulation, Pharmaceuticals, Generic competition

JEL: L59, K23, I18

1. Introduction

Rising health care costs and pharmaceutical spending have caught the attention from the regulators worldwide and generic competition has been identified as a mean to reduce these costs. The overall aim of this paper is to analyze how generic entry into the market affects both prices and competition.

We focus on the Swedish market, since Swedish regulators have been on the forefront and were among the first to introduce a mandatory generic substitution reform (in 2002). We

will go into detail with a few of the specific regulatory features and analyze whether these reinforce or diminish the competition in the market.

According to the literature, the actual effect of generic competition is unclear. The main conclusion seems to be that institutional factors are highly relevant in determining the outcome (Danzon and Chao, 2000). Many studies of pharmaceutical pricing in the US find the puzzling result that brand prices tend increase, instead of decrease, with the number of entrants after the patent expiry (Grabowski and Vernon 1992, Frank and Salkever 1997, Lexchin 2004). This is known as the generic paradox.

Before the introduction of generic substitution in Sweden it was find that entry of both generics (Bergman and Rudholm, 2003) and parallel imports (Ganslandt and Maskus, 2004) reduce brand prices. These both results are confirmed by Kanavos and Costa-Font (2005). The reform was expected to reinforce these effects and Granlund argues, both theoretically (Granlund and Rudholm 2007) and empirically (Granlund 2009), that this was also the case. However, we find that the firms have changed pricing strategies after the reform and that brand prices are not negatively affected by entry. Thus, we now see a generic paradox that was neither present in Sweden prior to the regulation nor found in Granlunds (2009) study. In the second part of the paper we set out to investigate what may have caused this change in pricing behavior. We claim that small details in the regulation have led to unwanted effects on the price setting behavior – and have in fact created (or at least enforced) this generic paradox. We show both theoretically and empirically that the discrete and transparent price mechanism, joint with pharmacies' rights to sell the remainder in their stock and a dynamic price cap, has generated a less functioning market. Thus, the devil of regulation is in the details.

2. Institutional settings (Swedish regulation after the reform)

The change in the Swedish regulatory system in October 2002 contained two main elements. First, the Medical Product Agency was made responsible for defining substitution groups – i.e. groups of products (generics or parallel imports) that should be regarded as interchangeable to the original drug. Those products have the same active substance,

strength, drug formula and package size as the original. Second, all pharmacies[1] became obliged to substitute a subscribed drug to the lowest priced product within the substitution group.

In order to determine which drug is the lowest priced one, the Pharmaceutical Benefits Board has a specific pricing process. Manufacturers hand in applications for price changes on the last day of month (t). The Board approves the application a few days into the next month (t+1) and the prices are in force at the beginning of the subsequent month (t+2). All prices and approved applications are publicly posted on the Board's website. The objective of the discrete and transparent pricing mechanism is to mimic "*the-winner-takes-it-all*"-characteristic of Bertrand competition. Thus, being the lowest priced drug in the substitution group is an important status since that drug should substitute basically all prescriptions in the country for the specific class of pharmaceuticals.

The substitution to the lowest priced drug is limited by a couple of exceptions. First, physicians may prohibit the substitution for medical reasons[2]. Second, patients may substitute to the prescribed product if they pay the price difference out of their own pocket. There are also a variety of fine details in the regulation. We claim that two of these details; a dynamic price cap and storage sales, in combination with the discreteness and transparency in the price mechanism lead to negative effects on competition.

Dynamic price cap: the manufacturers are not allowed to increase price of a product above the highest price among products within the substitution group. In that sense, there is a price ceiling defined by the highest priced product in the market. Any price reduction for the producer of the highest priced drug will lead to an irreversible downward shift in the price level, as prices cannot be increased again. Thus, there are incentives for high priced (brand) producers to be reluctant to reduce prices even though there is entry of generic competitors or parallel importers.

Storage sales: another feature of the regulation is that pharmacies have the right to sell the remainder in storage from the last month, but at the price level of the new period. In other

[1] All pharmacies belonged to the state owned monopoly and purchase- and retail prices were set nationwide.
[2] This may be the case when substitution will reduce adherence to treatment. Typical such cases are elderly patients having problems recognizing the pharmaceuticals, patients with anxiety that substitution causes more side-effects and mentally ill patients where substitution threatens the trust in medical treatment.

words, the pharmacies are not obliged to substitute to the lowest priced product in the market, but to the lowest priced product available at the specific pharmacy. A recent descriptive study points out that this provision has resulted in a low degree of exclusivity for the lowest priced drug and that the market share received by being lowest persisted several months (TLV, 2009). There are no strong incentives for the pharmacies to purchase the cheapest product from the pharmaceutical companies, in fact, their margin is higher if they buy a more expensive drug and sell it on to the consumers. Selling more expensive generics naturally reduces the price competition between generics and brands. Thus, the storage sales provision may benefit the generics, pharmacies and brands, but not the consumers.

3. Price effects of competition

We are interested in assessing whether increased competition reduces pharmaceutical prices or not. We find that, even though effectively rigged as Bertrand competition, price response to entry is limited. We estimate two pricing models; first using average price as dependent variable which we regard as a rough welfare measure since average prices indicate the actual cost to society. Second, we estimate a model with the average brand price as dependent variable since one of the aims of the regulation was to improve competition between products in the substitution groups.

3.1. Data and descriptive statistics

Our dataset consists of monthly data of prices and quantities on all products in 47 atc-codes[3] during 44 months from January 2005 to August 2005 where we have information of the patent status[4]. This data is complemented with approval date, product name, company name, type of product (e.g. pill or syringe) and dosage from the Medical Product Agency. Out of these 47 substances the patent of 17 expired before January 2005, 17 expired during the period of study and 13 were still protected by patent during our observation period. We further limit our dataset by only studying one-substance drugs (cf. Bergman and Rudholm 2003) and pharmaceuticals whose patents expired (or set to expire) after 1999[5].

[3] Anatomic therapeutic chemical classification system.
[4] Official patent information is opaque and expensive. The information is provided by the National Board of Health and Welfare and from correspondence with pharmaceutical companies.
[5] To avoid distortions from products where the patent since long has been expired.

Additionally, we only include the substitution groups with the highest turnover among identical products with different package size.

3.2. Pricing models

To study the price effects of competition within a substitution group we set up econometric models based on the idea that market price; average price (pbar) or brand price (pbrand), depends on competition, quality and quantity.

Prices are defined per smallest unit (e.g. pill, syringe, ml, etc) within the substitution group. Further, brand prices are calculated as an average over the products sold by the brand manufacturer within the substitution group. Since the market for drugs are suspected to be heterogeneous between substitution groups, we estimate a fixed effect model as

$$LnP_{it} = \beta_0 + \beta_1 NrGen_{it} + \beta_2 NrPar_{it} + \beta_3 MarketMat_{it} + \beta_4 ln\_Q_{i(t-2)} + \lambda_t + \mu_i + u_{it},.$$

Thus, we state that the price is explained by the number of competitors (generic and parallel imports) active in each market, the logarithm of the units sold[6] within the market (*ln_Q)* and the quality (or age) of the product as well as heterogeneous differences between different substitution groups (μ_i). Quality is defined as the number of months elapsed since the product was first introduced in Sweden (*MarketMat*). The idea being that a more novel product is a better product[7]. Our specification bears resemblance to earlier models used to model Scandinavian pharmaceutical markets (Bergman and Rudholm 2003, Ganslandt and Maskus 2004 and Brekke et al 2009). To control for time specific shocks or seasonal demand that may drive pharmaceutical prices, the model is estimated conditional on time specific effects (λ_t).

An obvious concern is that the decision to enter (as generic producer or parallel importer) is endogenous; both the average prices in the market as well as the brand price affect the expected returns, as higher prices will generate entry. We attempt to solve this endogeneity problem by resorting to instrumental variables (IV). Our empirical strategy relies on testing a number of economically appealing variables in search for a model that fit the statistical assumptions of the IV. Thus, the preferred set of instrument is selected based on a series of

[6] Since prices are decided two periods before they are implemented (see the institutional settings) ln_Qi,(t-2) is used in the model.

[7] This is consistent with the regulation that only approves new products if they are cost-effective.

tests[8] verifying these assumptions. Since both the number of generic producers and parallel importers are considered to be endogenous, at least two excluded instruments are needed for the model to be identified.

In the search for valid instruments, we consider four types of information. First, the number of months elapsed since patent expiration is relevant since it is likely that more generics will enter the more time passes after the expiry date. In turn, parallel importers will most likely enter before patent expiry. Second, firms with prior experience within a similar market (ATC-group) are assumed to be more likely to enter. Third, the number of competitors in the Scandinavian markets (Norway and Denmark) is correlated with the endogenous variables, but has no direct on effect on the price in Sweden[9]. Fourth, we consider the lags of the endogenous variables.

We suspect that prices in a substitution group may not be independent from the prices in other substitution groups within the same therapeutic group (ATC-level). We therefore estimate two models with different assumptions regarding the error term[10] (assumed independence or clustered standard errors) to assure robustness over the different assumptions. For efficiency reasons, the models are estimated using GMM. We confirm the endogeneity assumption in both average price models using a heteroskedasticity robust Hausman-like test (cf. Baum et al 2007). In the brand price model non-endogeneity cannot be rejected in the model using clustered standard errors.

3.3. The results of the average Price model

Increased generic competition reduces average prices. These results follow from the coefficient on Nrgenfirmg being significantly negative throughout the models. An additional generic competitor decreases the price with 14 - 19%[11]. Thus entry of generic competitors

[8] Since we have to relax the I.I.D. assumption, using cluster standard errors, we use the Kleibergen-Paap LM-statistic and the Kleibergen-Paap F-statistics to test for Underidentification and Weak identification, respectively. The latter is compared with the Stock-Yogo critical values (Stock and Yogo 2005) Further, the Hansens J statistics are used to test for underidentification.

[9] Due to data limitations, the number of competitors in Norway is defined on ATC-level.

[10] We solve the dependence problem by clustering the standard errors on ATC-level. This substantially reduces the degrees of freedom and reduces variation in both the first and the second stage. As a consequence, the strength of the instruments and the significance level of the coefficients decrease. To address the problem of weak instruments we include lags of the endogenous variables as excluded instruments. However, this forces us to assume no serial correlation.

[11] Estimations using an off-patent sample confirm the results.

significantly reduces the costs of pharmaceuticals and the size of the effect is significantly larger than those found by Bergman and Rudholm (2003). The effect of parallel imports is less clear, although there seems to be a positive association between higher prices and more parallel importers. Compared to generics parallel imported products are relatively expensive to buy since they often are patent protected[12]. By large our results are consistent over the different models, which is an indication of robustness.

Table I: Average Prices

Variables	FE-IV	FE-IV	FE-OLS	FE-OLS
Nrgenfirm	-.142***	-.186***	-.159***	-.159***
	(0.000)	(0.000)	(0.000)	(0.000)
Nrparfirm	.0564**	.00664	.0111***	.0111
	(0.013)	(0.630)	(0.001)	(0.314)
L2.ln_Q	-.0819***	-.0732***	-.0798***	-.0798***
	(0.000)	(0.000)	(0.000)	(0.000)
Markmatgroup	-.0000248	-2.85e-06	-4.14e-06	-4.14e-06
	(0.257)	(0.965)	(0.830)	(0.949)
Observations	7178	7178	7178	7178
Cluster S.E	No	ATC-level	No	ATC-level
R^2	0.326	0.327	0.336	0.336

3.4. The results of the Brand Price model

The effect of more competitors on the brand prices is an interesting story. It turns out that the effect of generic entry is either positive or insignificant. In the IV-model without clusters an additional generic competitor would increase brand prices by 4%. In the other models the effect on brand prices of generic entry is statistically or/and economically insignificant. These results[13] implies that the brands do not respond to generic entry by reducing prices, but may instead increase prices, which is an illustration of the generic paradox.

An additional parallel importer affects brand prices either positively or insignificantly. We believe that this result may be driven by a reverse causality problem, i.e. high prices before patent expiry attract parallel importers, which the instrumental variables fail to solve. Statistically, our set of possible instruments has problems explaining the entry of parallel importers, which could be explained by the spot market characteristics of the parallel imports. Potentially, there are strategic differences in the behavior of the parallel importers

[12] When the analysis is carried out on a on-patent sample only, we find that an additional parallel importer reduces the price by 1-4%.
[13] These results are confirmed using a off-patent sample only.

before and after patent expires. If the estimations instead are performed using a reduced sample, either on- or off-patent drugs only, the effect is negative (but small). The low impact on prices may be due to the fact that most parallel imported products are directed to UK, while the Swedish market is considered a residual market.

Table II: Brand Prices

Variables	FE-IV	FE-IV	FE-OLS	FE-OLS
Nrgenfirm	.037***	.000286	-.00596*	-.00596
	(0.000)	(0.974)	(0.060)	(0.627)
Nrparfirm	.0698**	.00215	.00161	.00161
	(0.0122)	(0.479)	(0.550)	(0.841)
L2.ln_Q	-.0196***	-.00103	-.0145***	-.0145
	(0.000)	(0.902)	(0.001)	(0.398)
Markmatgroup	-.000101***	-.0000259*	-.0000495**	-.0000495
	(0.000)	(0.091)	(0.018)	(0.118)
Observations	6024	6024	6024	6024
Cluster S.E	No	ATC-level	No	ATC-level
R^2	-0.087	0.001	0.004	0.004

4. Creating a Generic Paradox

The empirical findings in the pricing models show that generic competition decreases average prices but has either positive or no effect on brand prices. This paradox of generic entry is well-known from other markets (Grabowski and Vernon 1992, Frank and Salkever 1997, Lexchin 2004) and is often explained as a result of increased market segmentation. Additionally, it follows the findings of Kanavos et al (2008) where brand prices (in a cross-national study[14]) do not respond to increased generic competition in countries with free pricing. They argue that the reference price system often used in Europe, forces brand prices down, which is not the case in the US. Nevertheless, as discussed in the introduction, this behavior was not apparent in Sweden before the generic substitution reform.

The brands still make up over 40% of the off-patent market (one year after patent expiration). Therefore the generic paradox is not only interesting in an academic perspective; it also hinders substantial savings of drug costs. Naturally we are interested in finding out the cause of this change in pricing behavior; Does the generics substitution per see enhance competition such that it enforce market segmentation or is the generic paradox caused (or strengthened) by specific provisions in the regulation? We proceed by

[14] US, UK, France, Italy, Spain, Canada, Germany.

investigating the effects of the price cap, first theoretically, then empirically. We then turn to the storage sales and look for empirical evidence of it.

4.1. Theoretical framework

In this section we will develop a general theoretical framework based on the characteristics of the competition and regulation in the market. Following Brekke et al (2009) and Königbauer (2006), we propose that pharmaceuticals are vertically differentiated and in similarity with Frank and Salkever (1992) our model use the notion that some consumers are price sensitive whereas others are not. However, the pricing is different from previous models due to the regulatory setting and we introduce a dynamic setting with reputation building. Further, a dynamic price cap introduces new dynamics into the model that captures the idea of credible commitment discussed by Bergman and Rudholm (2003). In contrast to models by Granlund (2007) and Frank and Salkever (1992) we use a simultaneous move game instead of a Stackelberg game, since the regulation is based on simultaneous price setting.

In each market there is price competition between two firms i=B,K where B denotes a branded product and K a competitor (generic or parallel trade). We assume that consumers are heterogeneous with respect to the willingness to pay (θ) for a specific treatment and that they are uniformly distributed on the interval $\theta \in [0,1]$.

Each firm produces a product with quality s_i and without loss of generality we assume $s_B > s_K$. This may be caused by the fact that consumers are familiar with the brand names or due to advertising. All consumers prefer more quality to less:

$$s_B > s_K \rightarrow u(s_B, \theta) > u(s_K, \theta).$$

Most pharmaceutical markets include some kind of copayment scheme governed by either public health institutions, private insurances or a mix of the two. We denote the part paid by consumers with α, the rest is covered by public or private insurance systems. Total consumer payment will be denoted c_i and is designed after the conditions in the Swedish regulation. As described in the regulatory setting, the payment depends on which drug the consumers buy and on the price of the cheapest drug within each substitution group. We also include a fixed cost $f>0$ in the payment, thus consumer expenditure are determined by a two part tariff. The

fixed cost can be interpreted as the non-monetary cost of attending a physician (Brekke, et al 2009). Total consumer prices are:

$$c_i = \begin{cases} \mathrm{f} + \alpha \mathrm{p_i} & \text{if i is the low priced drug} \\ \mathrm{f} + \mathrm{p_j} - (1-\alpha)\mathrm{p_i} & \text{if i is the high priced drug} \end{cases}$$

where $\alpha \in [0,1]$ is the copayment rate.

To simplify the analysis we will in the remainder assume that the branded product is the highly priced product and the competitor is low price. In the special case where the physician decides that substitution cannot take place the branded product is reimbursed as the low cost product. This occurs for proportion (*1-x*) and these consumers are assumed not to be price sensitive. For the rest of the market, proportion (*x*) there is price competition.

Consumers will buy one product at most (since a product often is a complete treatment) and will refuse to buy if prices are higher than the consumer's valuation. The consumer utility from purchasing a product is $U_{\theta i}(s) = \theta s_i - c$, and consumers buy the product offering the largest utility. The utility for not buying is normalized to zero and the total number of consumers is normalized to 1.

The consumer is indifferent to buying the branded product B and the competing product K when $\theta s_B - c_B = \theta s_K - c_K$, and the indifferent consumer is hence located at $\hat{\theta} = \frac{P_B - P_K}{S_B - S_K}$. Consumers with a $\theta < \hat{\theta}$ will buy the competing product, those with $\theta > \hat{\theta}$ will buy the brand product. Without loss of generality we define the quality advantage for the brand manufacturer to be $S = S_B - S_K$. This gives us the following demand system

$$D_B(P_B, P_K) = (1-x) + x\left[1 - \frac{P_B - P_K}{S}\right]$$

$$D_K(P_B, P_K) = x\left[\frac{P_B - P_K}{S} - (f + \alpha p_K)\right]$$

if both firms are active in equilibrium, i.e. if the market is covered. In order to ensure market coverage we set equilibrium demand for the low quality firm to zero and solve for this condition. The market coverage condition is $f \leq \frac{1}{2x}$. Throughout the paper we assume this condition to hold. The production costs are assumed to be constant, common for the two firms and are normalized to zero. Thus profits are given by $\pi_i = p_i D_i$.

We use the theoretical model outlined above to determine the effects that the regulation will have on pricing behavior. When the incumbent brand manufacturer faces entry it can decide to fight the entrant by pricing below equilibrium prices or to accommodate the competition. Due to subgame imperfection, fighting is never a credible threat in a one-shot game as should the entrant enter then the brand manufacturer will always find it better to accommodate. However, it is well known that in a repeated game the incumbent may build a reputation for fighting and may therefore deter entry.

For it to be profitable for the brand manufacturer to accommodate the following relation is required to hold;

$$\frac{1}{1-\delta}\pi_B^A \geq \pi_B^F + \frac{\delta}{1-\delta}\pi_B^M$$

where $\delta \in (0,1)$ is the discount factor,$\pi_B^A, \pi_B^F \; and \; \pi_B^M$ are the accommodation, fighting, and monopoly profits for the brand manufacturer. This implies that the discounted profit from accommodating, today and in the future, needs to exceed the profits from fighting to exclude the rival plus the following period of monopoly pricing. Rearranging the above we find that accommodation is only profitable for the brand manufacturer if it does not value the future too highly. The restriction on the discount factor is;

$$\delta \leq \hat{\delta} = \frac{\pi_B^A - \pi_B^F}{\pi_B^M - \pi_B^F}$$

where $\hat{\delta}$ is the maximum discount rate for accommodation to be better. The reason that the discount factor is bound from above is that future monopoly sales generates higher per period profits than accommodation. For the brand to prefer accommodation the future has to be discounted, i.e. δ<1.

Discount factors are normally interpreted as a measure of how stable a firm is and firms with a high risk of exiting the market have low discount factors. Our model tells us that weaker brands should accommodate to a higher extent, whereas strong brands should fight the entry. In order to find out under what conditions the brand manufacturer will fight or accommodate, we need to determine the profits for the brand manufacturer's different strategies.

We begin by deriving the equilibrium when the brand manufacturer decides to accommodate entry. Since prices are strategic complements, increasing its own price will

induce the competitor to increase its price. Assuming that both firms are active in equilibrium and that each firm sets price to maximize its profits, given the competitors reactions, the equilibrium profits are given by

$$\pi_B^A = \frac{S(2 + 2S\alpha - fx)^2}{x(3 + 4S\alpha)^2}$$

$$\pi_K^A = \frac{S(2fx)^2(S\alpha + 1)}{x(3 + 4S\alpha)^2}$$

We find that the effects on both firms profits from changes in degree of copayment, competitive part of the market and quality difference, have the same signs. Increasing copayment (α) naturally has a negative impact on profits since consumers have to pay more themselves and hence may decide not to buy the products. Increasing the portion of the market subjet to competition (x) also has a negative effect on the firms profits since the brand manufacturer will lower prices to capture more of the competitive market and the competitor will resond by also lowering prices. Increasing quality difference will naturally increase both prices and profits of the brand manufacturer. However, more interesting is that also the competitor will increase price and proficts when the difference increases. This is caused by the increased differentiation and the fact that prices are strategic complements.
The other option for the brand manufacturer is to fight the entry. As the brand is perceived to be of higher quality it can force the entrant to exit the market and still make a positive profit itself, i.e. engage in limit pricing. We find the price that the brand manufacturer would need to set in order to force the competitor out of the market, by setting the competitor's demand function to zero, inserting the competitor's reaction function and solving the equation for p_B. The price that would force the competitor to exit is

$$p_B = fS$$

Naturally these prices increase with the quality differences. Profits in this limit-pricing equilibrium are

$$\pi_B^F = fs(1 - fx)$$

$$\pi_K^F = 0$$

It is easy to see that the degree of copayment has no effects on prices in this equilibrium since prices are set to exclude the competitor. When the competitive part of the market increases, profits for the brand manufacturer are reduced since the protected market becomes smaller. Increased quality difference would enable the brand manufacturer to

charge a higher price while still forcing the competitor out and therefore also increase profits.

When the brand manufacturer has fought and deterred all entrants and is the only firm active, a monopolist. The size of the market is then given by the consumer who is indifferent between purchasing the product or not. As consumers pay $f+\alpha p_B$ for the product the indifferent consumer is located at $\theta = \frac{f+\alpha p_B}{S_B}$. Due to monopoly pricing, there will be more consumers not purchasing the branded product under the monopoly regime. However, in line with the solidarity principle, the consumers with high valuation (likely to be those with severe problems) will still get the product and enjoy a positive utility. The brand manufacturer chooses prices to maximize profits and monopoly profits are given by $\pi_B^M = \frac{\left(\frac{s_B - fx}{2x\alpha}\right)^2}{4x\alpha s_B}$

Unlike the two previous equilibria (accommodation and fighting) the effect of copayment, size of competitive market and quality on profit are not monotone but depends on the quality of the brand manufacturer is above or below ½. For $s_B > ½$ increases in copayment and competitive market size have a negative effect on profit whereas increased quality has a positive effect on profit. The opposite is true if $s_B < ½$.

We set out to find an expression of when the brand manufacturer would rather accommodate than fight and derived the requirement $\delta \leq \hat{\delta}$ where $\hat{\delta} = \frac{\pi_B^A - \pi_B^F}{\pi_B^M - \pi_B^F}$. For any δ larger than $\hat{\delta}$ the best response for the brand manufacturer will be to fight and hence brand prices will fall as a response to entry. Inserting the profit functions we get the somewhat messy expression of the minimum discount factor required for accommodation being profitable.

$$\hat{\delta} = 4S\alpha s_B(fx-1)\frac{fx(5+12S\alpha)+(S\alpha)^2(8fx-4)-8S\alpha-4}{(4S\alpha+3)^2(s_B^2+(fx)^2-2fxs_B+4S\alpha s_B((fx)^2-fx))}$$

The maximum discount factor is zero when the market coverage criterion f is at its maximum and positive at f=0. Within this range there is a positive maximum discount factor that allows for accommodation when $s_B \leq \frac{1}{2} + S\alpha$. That is, for accommodation to be preferred the brand quality and quality difference to competitor cannot be too large since a large quality difference will make fighting less costly. Looking at the partial derivatives on the effect of

increased copayment on the different profit functions we find that increasing the copayment will increase the maximum discount factor, therefore accommodation is the best strategy also for more patient brands.

The effect of increased share of the competitive market on the required discount rate is slightly more complicated. Following the requirement derived above that $s_B \leq \frac{1}{2} + S\alpha$, then an increase in x will increase the maximum δ. The reason for this is that monopoly prices are higher than accommodation prices, reducing the protected price insensitive market (1-x) is therefore more costly in the monopoly periods.

4.2. Dynamic price cap

The dynamic price cap makes any price cut by the brand irreversible and must therefore be considered carefully when deciding to fight or accommodate the competitor. Entry deterrence models with prices as strategic variable are often criticised for leading to non-credible threats. This is specifically the case with the limit-pricing theorem that in many context has been criticised as fighting is not a subgame perfect equilibrium since fighting would be less profitable than accommodation if entry occurred. The dynamic price cap in the Swedish regulation however provides a formidable device for committing to future prices since they cannot be adjusted upwards.

With the price cap the strategies for the brand is either to fight forever or to accommodate forever. Accommodation will be the preferred outcome as long as $\pi_B^A \geq \pi_B^F$. Inserting the profit expressions and re-arranging we find that the relation holds if

$$S(2fx - 1)\frac{fx(5 + 4S\alpha(2S\alpha + 3))}{x(4S\alpha + 3)^2} \geq 0$$

It is no surprise that it can be shown that the above always hold (for all $f<f_{max}$). Thus with a price cap, the brand will not fight the entry but accommodate as fighting is too costly. Hence the dynamic price cap removes the aggressive pricing behaviour by the brands. Increased copayment and a larger size of the market open to competition will reduce the difference between accommodation and fighting. Increased quality differences will instead increase the differences.

The strategic behaviour of the brand depends on the regulatory setting. With a dynamic price cap accommodation will always be the best response to entry, whereas without a price cap the reaction of a brand will depend on the brands' discount factor(δ) and the maximum discount factor making accommodation the profitable strategy ($\hat{\delta}$). Hence, the highest priced product, which effectively sets the price cap, would have a lower propensity to reduce the prices. We test this hypothesis empirically using the pharmaceutical product as the unit of analysis instead of the substitution group. Since the effects of the dynamic price cap are strongly connected to generic substitution, the sample is restricted to off-patent drugs[15] only. To examine the dynamic price cap feature, we estimate the probability of a price reduction (Y=1) of a product as

$$\text{Prob}(\text{Y} = 1|\text{x}) = \gamma MaxP_{it} + \beta X_{it} + \omega Z_i + \lambda_t + \mu_i + \varepsilon_{it}$$

To evaluate the effect of having the highest price within the substitution group (*MaxP*), the model is estimated conditional on time varying market characteristics X_{it}, time invariant product characteristics, Z_i, (substance and the type of producer) and time specific effects. In an attempt to address the problems of unobserved heterogeneity and dependence between products within the same substitution group or ATC-level, we estimate two separate models using different assumptions of the error terms[16]. As market characteristics, X_{it}, we include the month elapsed since the patent expiry[17] as well as the second lags of both the size of the market and the Herfindahl-Hirschman Index (HHI) in the two models.

All variables reveal similar effects in the two models. As suspected, the highest priced products are significantly less likely to reduce prices. Overall, the results are as predicted. The time elapsed since patent expiry increases, at a diminishing rate, the probability of price reductions. In comparison to the baseline group, branded products, the probability of a price reduction is substantially higher for generic or parallel imported products.

[15] Substances where generic substitution is restricted by other means than by patents are also excluded. For example products not defined as substitutable by the MPA (e.g. Lamotragin and Alfuzosin).

[16] First we assume μ_i+ε_it=u_it~(N,0) but not I.I.D, applying Quasi Maximum Likelihood and estimating a pooled probit clustering on ATC-level. Secondly we assume both μ_i and ε_it being I.I.D with a normal distribution and estimate the model using a Random Effect Probit. Due to the reduced number of degrees of freedom, ATC-dummies cannot be included in Zi, when estimating the pooled probit. Of the same reason the time specific effects are reduced to seasonal dummies.

[17] And it's square.

Table III: Probability of a price reduction

	Pooled Probit	RE-Probit
MaxPdum	-0.317**	-0.151**
	(0.014)	(0.027)
Parallel	1.04***	1.29***
	(0.000)	(0.000)
Generics	1.26***	1.71***
	(0.000)	(0.000)
Patexpmon	0.005	0.0174**
	(0.303)	(0.020)
Patexpmon2	-0.00004	-0.00007***
	(0.487)	(0.007)
L2.ln_Q	0.12***	0.12***
	(0.000)	(0.000)
L2.HHI	-0.015***	-0.023***
	(0.007)	(0.000)
Constant	-2.93***	-3.56***
	(0.000)	(0.000)
Observations	18080	18080
ATC-dummies	No	Yes
Time dummies	Seasons	Yes
Cluster S.E.	ATC-level	No

We acknowledge that without an exogenous chock, or another identifying strategy, we cannot have any claims on causality. Still, using panel data, there is a strong correlation between having the highest price and not reducing the price. The probability of a price reduction is at average four percentage points lower for the highest priced product in the market, even when holding constant for the substance, type of producer, level of competition, and the market size. Thus, the results cannot reject the hypothesis that this feature of the regulation has a negative effect on the competition.

4.3. The effect of storage sales

The second detail we set out to study is the storage sales. We suspect that the pharmacies storage sales handling alleviates the strong competition encouraged by substitution to the cheapest drug. When the generic producers price their products lower than their competitors, i.e. winning the Bertrand game, the pharmacies will stock up on the cheap products. In the next period there are incentives for the generic producers to increase prices since pharmacies may order the same products out of habit (or mistake). As mentioned above, there are no incentives for the pharmacies to sell cheaper products to the consumers. Thus, the hypothesis is that firms can reap the benefits from having the lowest

price, several months after that occurred, as pharmacies stock up and keep selling from their stocks even if the product increase prices.

To study this feature, we model the quantity sold of a specific product as a function of its own price and a dummy for having the lowest price. By also including a dummy of being the lowest in the preceding period we attempt to test if there is an additional effect on sales in period t+1 of having the lowest price in t. Consequently, we specify a two-way fixed effect model as

$$ln(q_{it}) = \beta_1 \, ln \, p_{it} + \beta_2 minP_{it} + \beta_3 minP_{i(t-1)} + \mu_i + \vartheta_t + \varepsilon_{it}$$

where $ln(q_{it})$ and $ln(p_{it})$, respectively, is the quantity sold of the smallest unit (e.g. pills or syringes) and the unit price of a specific product. The minimum price dummies $minP_{it}$ and $minP_{i(t-1)}$ takes the value one if the product has the lowest price within the substitution group. According to the national reimbursement regulation, patients who recurrently collect the same prescription are not compensated by the reimbursement program if they collect a prescription before two thirds of the last dose is estimated to be consumed. Since most drugs are prescribed in intervals of three months there are incentives not to collect the same drug within 60 days. Thus, the lagged dummy shall not capture any habit persistence among the recurrent consumers.

To solve the possible endogeneity problem of $ln(p_{it})$, we again resort to instrumental variable techniques. As excluded instrument for price, we sort Danish pharmaceuticals into the Swedish substitution groups and calculate an average price for the substitution group. We assume that it is primarily the generic firms that exploit the possibilities in the storage sales provision[18] but we also test for the full sample. Being conservative, we again estimate the models using cluster standard errors on the ATC-level.

As expected, the effect of being the winner in the Bertrand game has as predicted a positive effect on the quantity. Further, in line with our hypothesis, there is – primarily among the generic products – an additional positive effect in period t of the lowest price in period t-1. Even if we relax the endogeneity assumption, relying on the FE-OLS model, the interpretation of the results remain the same. The fact that the effect from having lowest

[18] This since parallel importers may not have sufficient quantities to exploit this feature and reducing prices for the brands would lead to an irrevocable price decrease.

price last period (storage sales effect) is larger than the effect of being the lowest priced in the current period shall not necessarily be interpreted as the former effect being larger. Statistically, the effect of having the lowest price in the current period may be reduced by the price variable which also has a negative sign.

The analysis of the sales patterns reveals that the sales boost from winning the Bertrand game is not constrained to the period in which the product is lowest priced. Instead the effect lasts much longer. This significantly reduces the exclusivity introduced by generic substitution and makes price competition less strong. This tells us that the storage sales provision significantly reduces the price competition from the generic products introduced by the reform.

Table IV: Quantity Model

	FE-OLS	FE-IV	FE-IV
LnP	-0.707***	-0.651***	-1.26
	(0.000)	(0.033)	(0.147)
DumMinP	0.46***	0.484**	0.178
	(0.000)	(0.015)	(0.564)
DumMinP_lag	0.923***	0.925***	0.811***
	(0.000)	(0.000)	(0.000)
Sample	Generics	Generics	Full
Observations	13254	13254	19629
Cluster S.E.	ATC-level	ATC-level	ATC-level
R^2	0.132	0.131	0.076

5. Discussion and policy considerations

The generic substitution reform in 2002 has been praised for lowering pharmaceutical costs. We find that the regulation has an overall positive effect as it encourage generic substitution, which reduces average prices. However, we also discover that the regulation is not efficient since it includes several features that hinder the regulation from realising the full potential from competition induced by the generic substitution. We find evidence of a generic paradox, i.e. that brand prices do not decrease as generics enter. This result contradicts the studies conducted during the earlier regulatory regime, which indicates that the generic paradox may be caused by the regulation.

The promotion of generic substitution may in itself induce market segmentation and cause the generic paradox. However, we point out small details in the regulation that have at least strengthened the effect. Although we cannot discriminate between these hypotheses, our

theoretical model and empirical findings support the hypothesis that the devil is in the details.

The transparency and discreteness of the price mechanism (prices are set once a month and are posted publicly) provides a possibility to exploit the contradictory incentives in the regulation induced by small details as the dynamic price cap and the storage sales. The transparency guarantees that all the players in the game know the price-bid of the others, and the discreteness prevents continuous undercutting. Our empirically findings show that pharmaceutical firms in fact exploit these incentives, and thus these details in the regulation cause, or at least enforce, the generic paradox.

The price cap affects the brand price directly and is the number one suspect for the cause of the generic paradox. However, the storage sales feature reduces the competitive forces among the generics, indirectly contributing to the generic paradox. A lower competition among the generic producers implies a lower competitive pressure on the brands products. Since the competition among generic products as well as between generics and brands are distorted by the provisions of the regulation, these details causes larger problem than a generic paradox.

The direct policy implications from these results are clear; change the dynamic price cap model and prohibit storage sales. The Dental and Pharmaceutical Benefits Agency has recently decided to revise some of the provisions in the regulation. Among the provisions to change are the ones analyzed in this report. The agency has decided that the pharmaceutical with lowest price on the market shall be delivered by the pharmacy. Thus the storage maintenance at the pharmacies is going to change which will get rid of the storage sales effect. Further it has proposed to change the dynamic price cap to a price cap based on a relation to the lowest priced generic substitute, i.e. in practice reverting to the old reference price system. This may reduce the magnitude of the generic paradox.

The indirect point this paper makes is more general, the effect of the regulation is at large decided by the details. Even though a regulation may have an overall good structure, without a full understanding of the details the outcome may be inefficient.

References

Baum, M., M. Schaffer and S. Stillman (2007), "Enhanced routines for instrumental variables/GMM estimation and testing", Boston College Economics, Working paper no. 667.

Bergman, M. and N. Rudholm (2003), "The Relative Importance of Actual and Potential Competition: Empirical Evidence from the Pharmaceuticals Market," *The Journal of Industrial Economics*, Vol. 51, No. 4, pp. 455-467

Brekke, K., T. H. Holmås, And O.R. Straume (2009), "Regulation, generic competition and pharmaceutical prices: theory and evidence from a natural experiment", Working Paper, Norwegian School of Economics and Business Administration.

Chen, J. and J.A. Rizzo (2007), "Entry Pricing and Product Quality: The Case of Antidepressant Drugs", Working paper, Stony Brook University

Danzon, P. and L-W. Chao (2000), "Does regulation drive out competition in pharmaceutical markets?", *Journal of Law & Economics*, vol. 43:2 311-357

Frank, R.G and D.S. Salkever (1992), "Pricing, patent loss and the market for pharmaceuticals", *Southern Economic Journal* 59, 165–179.

Frank. R. and D. Salkever (1997), "Generic Entry and the Pricing of Pharmaceuticals" *Journal of Economics & Management Strategy*, : 1, 75–90

Ganslandt, M. and K.E. Maskus (2004), "Parallel imports and the pricing of pharmaceutical products: evidence from the European Union," *Journal of Health Economics* 23, 1035–1057

Grabowski, H. and J. Vernon (1992), "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act", *Journal of Law and Economics*, 35:2 2, pp. 331-350

Granlund, D. (2009), "Price and welfare effects of a pharmaceutical substitution reform", Working Paper, The Swedish Retail Institute (HUI).

Granlund, D. and N. Rudholm (2007), "Consumer Information and Pharmaceutical Prices: Theory and Evidence", Working paper, Department of Economics, Umeå University

Kanavos, P. and J. Costa-Font (2005), "Pharmaceutical parallel trade in Europe: stakeholder and competition effects", *Economic Policy October* 2005 pp. 751–798

Kanavos, P., Costa-Font, J. and E. Seeley (2008), "Competition in off-patent drug markets: Issues, regulation and evidence", *Economic Policy,* 23:55, pp. 499-544,

Königbauer, I. (2007), Advertising and generic market entry. *Journal of Health Economics*, 26, 286-305.

Lexchin J. (2004), "The effect of generic competition on the price of brand name drugs". *Health Policy*, 68(1), 47-54.

Stock, J.H. and M. Yogo (2005), Testing for Weak Instruments in Linear IV Regression. In D.W.K. Andrews and J.H. Stock, eds. Identification and Inference for Econometric Models: Essays in Honor of Thomas Rothenberg. Cambridge: Cambridge University Press, 2005, pp. 80–108. Working paper version: *NBER Technical Working Paper* 284.

TLV (2009), *Tillägg till uppdrag angående förberedande åtgärder med anledning av omregleringen av apoteksmarknaden,* Tandvård-och Läkemedelsförmånsverket (The Dental and Pharmaceutical Benefits Board)