ENTRY AND COMPETITION IN A REGULATED PHARMACEUTICAL MARKET*

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November, 2009

Abstract

Controlling the price of an expensive off-patent branded drug is often done through price comparisons with the existing price of reference of a cheaper therapy in the market. However, under the expectation of such regulation equilibrium expected prices and profitability could be driven down ex-ante. In fact some recent empirical studies have found that Reference Pricing (RP) may discourage entry in the relevant market of close therapies. We present an oligopoly model of vertical differentiation in the context of consumer preferences for varieties à la Hotelling and show that indeed RP regulation reduces the likelihood of entry in that it reduces the entrant’s profit. Market size improves entry profits whereas a cost advantage for the provision of quality on the side of the incumbent reduces them. Nevertheless when the size of the market is small RP can increase entry profits, with respect to the unregulated benchmark, for a sufficiently high efficiency advantage of the incumbent. Some policy recommendations are: i) RP reduces entry profits when the incumbent firm has little or no efficiency advantage for any market size, therefore it could be designed at intermediate levels between no regulation and full reference pricing (FRP). ii) RP is expected to increase entry profits when the size of the market is small and the efficiency advantage relatively high, therefore FRP can both reduce prices and promote entry, iii) As market size increases, the efficiency advantage required for the positive effect of FRP becomes larger so that it is expected that the regime most likely reduces entry profits.

JEL Classification: L11, L13, L65, I18

Keywords: Pharmaceutical prices, Reference Pricing, Price Regulation, Product Differentiation

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*This study was supported by the Research Project ECO2008-06395-C05-01 sponsored by the Ministerio de Ciencia e Innovación of Spain. I am indebted to my advisors Sergi Jiménez-Martín and Antonio Cabrales for their continuous support and guidance. The helpful suggestions of Jaume Puig, Fran Ruiz-Aliseda, Joel Shapiro and Karl Schlag are gratefully acknowledged. I am also grateful to Joan Ramon Borrell who discussed an early version of this paper. This work also benefited tremendously by discussions with participants to the Microeconomics Seminar Series and CRES Seminar Series at UPF as well as the research group of FEDEA-”La Caixa”. Any remaining errors and omissions are of my entire reponsibility.
1 Introduction

1.1 Motivation

In this article we present the findings of a study on how entry of a generic competitor in prescription off-patent pharmaceutical markets may be discouraged by a simple reference pricing (RP) regulatory regime. Reference pricing compares the price of an expensive branded originator drug with a price of reference. The idea of the device is to make the consumer cost conscious by introducing an avoidable out-of-pocket co-payment in the event of purchasing an expensive treatment. The consumer is therefore forced to pay the difference of the price of the expensive drug with respect to a reference price, which is usually a function of a set of alternative cheaper products. These products can be generic bio-equivalent versions of the branded originator drug or substitute therapies based on other active ingredients.\(^1\)

The distinctive feature of our model is that we introduce two important structural elements of pharmaceutical markets interacting with price regulation, market size and the length of previous patent protection. The model is able to predict correctly most of the observed and expected effects of RP and moreover can be used as a device to simulate regulatory regime changes that can be designed to promote entry of generic products into the regulated market.

According to a number of studies (c.f. Caves et al. (1991), Regan (2008)), price competition between branded and generic products is imperfect mainly because of persuasive advertisement as a mean to produce perceived quality differentiation.\(^2\) In addition, it is also thought that demand price elasticity is low because of the presence of a third party that pays for treatments (public or private insurance coverage). Finally, it has been been also noted that given some lack of information on available products to treat a certain medical condition and their relative costs, physicians are not aware of the overall cost of treatment when they prescribe a therapy and, in any case, they have no incentives to prescribe cheaper varieties of a product.\(^3\) It is not surprising then, that RP is better understood as a demand side instrument in that it ultimately seeks to increase the elasticity of demand and increase price competition between branded originator products and generic or close substitute therapies. Firms under RP are free to select their price strategies however introducing this regime is expected to make them closer price competitors. Puig-Junoy (2005) has pointed out that the European Commission has suggested to State Members of the Union to adopt this regime, because according to this institution the RP system

\(^{1}\)Still a third version is applied in which given no availability of local cheaper alternative product exists, authorities use as reference the price of the same product in a different country. Implications of these type of alternative scheme are not considered in our paper, nonetheless Danzon and Epstein (2008) provides an interesting analysis of this scheme on entry on prescription drug markets and international diffusion of innovative products.

\(^{2}\)This feature has promoted the assessment of product differentiation in a vertical fashion in the theoretical literature. This is not a trivial question because it is well known that marketing or detailing investments by brand-name producers is known to surpass the level of investments in R&D.

\(^{3}\)For instance in a recent survey conducted by the OFT in the UK to around 1,000 general practitioners, the most relevant conclusion is that doctors prescribe with very little knowledge of the cost of treatment, making it reasonable to negotiate price caps and price cuttings for some prescription medicines For a complete analysis of prescriptions refer to "The Pharmaceutical Price Regulation Scheme", Office of Fair Traiding, 2007.
delivers price reductions with little market distortions. In fact, as compulsory price comparisons make the consumer aware of a cheaper variety of the treatment, RP is expected to increase the consumption of these products and therefore induce higher expected profits for potential entrants to the generic segment of the market.

In OECD pharmaceutical industries, price regulation of off-patent markets aims basically at keeping public financed health expenditures in line with projected budgets and delivery also improved levels of value for money. Agencies in charge of such policies are concerned with the security and efficacy of treatments, however as noted in Puig-Junoy (2005) a major point of interest is to contain the growth of third party payments for pharmaceutical products by increasing the consumption of a generic available therapy. According to OECD health statistics, for example, in Germany, pharmaceutical products explained 13.6% of national health expenditures in 2000, while in 2007 the figure increase to 15.1%. In Spain, pharmaceutical products explained consistently around 21% of national health expenditures between 2000 and 2007. On average, OECD countries spend almost 17% of health services in consuming pharmaceutical products, with most countries increasing in real terms the costs of treatment per capita (e.g. Germany and Spain had per capita pharmaceutical expenditures in 2007 50% above the observed figures in 2000).

Upon these arguments, the RP policy design might not deliver the expected results if price regulation aims only at short run price cuts. The reason is that ex-ante, price regulation might reduce the expected entry pay-offs of a substitute therapy making it less likely that the RP mechanism will actually produce the expected price reductions. In fact, according to a small set of empirical econometric studies by Kyle (2007), Moreno-Torres et al. (2009) and Danzon and Chao (2000) RP is, in general, expected to lag or reduce entry of generic products and other substitute therapies. In other words, the findings of these works suggest that RP may be inconsistent with its own objectives. The scheme and more precisely the agencies adopting the scheme assume that prices will be adjusted downwards by competitive pressures because cheaper products will enter the market after patent expiration, making the price of reference more competitive. As it is evident, if entry is lagged or even discouraged, those expected price reductions will not be realized neither in the short run nor possibly in the medium term. This small set of empirical works though provide a number of interesting regularities:

- First, entry is more feasible whenever the market of the specific product is larger, however there is not a clear-cut conclusion on how this effect can be identified in real data and how might price regulation interact with market size. Market size is often estimated with a measure of revenues or profits which makes it endogenous to the observed equilibrium prices and number of firms.

- Second, entry of generic products is less likely whenever the period of patent protection of the originator drug is longer. It has been suggested that this

\[4\text{See the database at www.oecd.org}\]

\[5\text{Nevertheless there has been also at least one empirical work that contrary to the list of papers cited has found the opposite result. This is the case of Strom and Haabeth (2006) in which the Norwegian market for pharmaceutical products is analyzed.}\]
result is due to the fact that branded drug producers can better invest in forming an important base of loyal consumers.

- Third, and related to the first finding, generic market shares are larger in markets with larger sizes, however this does not mean necessarily that expected profits are larger due to the interactions between price regulation and the expected price of entry.

In this paper we describe a theoretical model to study in a systematic way the interactions of the RP regime with the structural parameters of interest of pharmaceutical markets that are thought to explain generic entry: market size and the length of patent protection enjoyed by the incumbent branded producer. The latter is modeled as an efficiency advantage of the incumbent in terms of providing marketing investment to produce perceived quality differentiation.

The model is one of a duopoly where firms can select the amount to invest in an attribute of quality so that we introduce differentiation of branded to generic or alternative substitute products. After selecting the amount of "quality" to provide firms compete à la Bertrand in prices. The incumbent originator drug producer has an strategic advantage in that he moves first in the quality game. Likewise the incumbent is endowed with an efficiency advantage to invest so as to model the way in which the length of patent protection ease his capabilities of attracting a loyal base of clients.

The competing products are also exogenously differentiated in a linear space of physical characteristics to bring some flexibility in the analysis regarding generic entry or not to close substitutes entry. The model is based on of Shaked and Sutton (1987) and Economides (1993) analysis. The horizontal differentiation space also allows to introduce as a parameter the size of the market in a way that is fundamentally different from the notorious endogenous way it is analyzed in the empirical literature. Here the size of the market refers to the size of the population in terms of the length of different medical conditions that have to be treated with the existing drugs.

We show that most empirical regularities observed in the relevant empirical literature can be simulated with the model but more interestingly, it provides a number of testable hypothesis on the interactions of markets size, efficiency advantages and other parameters with the regulatory policy. This model then suggests a number of ways to better identify how price regulation affects entry controlling for market size effects, for example.

In addition, with the model it is possible to assess how RP can be designed in such a way so as to alleviate the effects of the length of patent protection over entry profits. In terms of this model, the latter circumstance is studied in a context of structural blockaded entry. The existing literature on the analysis of competition of branded and generic products in the context of price regulation lacks a clear link with the empirical observations of pharmaceutical markets. In this sense this work is the first in closing the gap between empirical findings and a systematic approach for understanding how such regularities might be produced and how they can be better identified using real data.
1.2 Modeling a pharmaceutical market

We aim at modeling an off-patent pharmaceutical market in which three basic structural ingredients are of paramount relevance: i) The presence of an incumbent producer that commercializes an original branded drug and a close substitute therapy which is a generic copy of the original, these two products are produced separately by independent firms, ii) a continuum of consumers distributed along a horizontal line in which each position will be interpreted as an individual specific medical history, the size of the line will be interpreted as a measure of the size of the market, iii) a technological advantage for the incumbent in spending more efficiently in marketing to create a persuasive quality characteristic.

With respect to the first point, there are important elements to consider. First, according to industry information, generic products are not identical to branded originator drugs. Authorities, however, require that a generic proves bio-equivalence with respect to the existing branded drug in the sense that the main active ingredient (molecule) of the product has to be the same and, more importantly, in the same dosage. However, it is well known that products are differentiated mainly in its inactive ingredients such as the main excipient. An excipient is an inactive ingredient that helps the body to absorb the active ingredient. In addition, products are differentiated in that the other components to give it its size, form, resistance, texture and taste are usually distinguishable. Inactive ingredients are known to produce different side effects to different consumers and so the physician has to be aware of the medical history of the patient to prescribe the available variety that better suits her. For instance, bisulfites that are used as preservatives for many drugs are known to cause allergic episodes to asthmatic patients, these allergies can have different levels of severity. We will assume that the generic product has proven bio-equivalence in the sense that it provides the same amount of the active ingredient in the body at fairly the same speed as the branded product. Nonetheless, as it is in reality, it has relevant active ingredients that makes interchangeability with the branded drug a relevant issue that the physician is aware off. This does not mean that the generic is not a safety drug, however as in the branded case, it may produce side effects that makes the patient worse off depending on her specific medical history. In this sense, our model will allow for at least some horizontal product differentiation in the spirit of Hotelling (1929) and D’aspremont et al. (1979) This model then can also be used to analyze more general cases in which the available substitute therapy to the branded drug is less interchangeable.

The second point introduces in the model the possibility that consumers in the market are ordered according to their most preferred drug variety in terms of the expected side effects. Physicians are assumed to know perfectly the specific characteristics and medical history of their patients so that they will always prescribe according to this information.

The third element is introduced in the model as a mean to study how the length of previous patent protection enjoyed by the incumbent may affect the way in which the RP regime is expected to determine profits and entry. The assumption of the model is that the larger the patent protection the larger the ability of the incum-
bent to provide more efficiently the optimal amount of marketing expenditures for creating perceived differences in drug qualities.

1.3 Related literature

Price competition in the context of price regulation has been studied before for pharmaceutical markets. Cabrales (2003) developed a model of vertical product differentiation to study how price caps on the price of a high perceived quality drug may affect the penetration of a generic product. He shows, accordingly to Danzon and Chao (2000) that stronger price regulation explains lower market shares for generic products. This work also introduces a technological advantage for the incumbent much in the way we propose in our model and as in our model, he assumes this advantage is positively correlated to the length of previous patent protection enjoyed by the branded drug. In the same model, Merino-Castelló (2003) studied a simple Reference Pricing scheme where she introduced strategic issues in that price and quantity competition could be assessed. Merino’s work showed that the RP regime can be expected to be successful in reducing average prices. However, the price of the generic product remains constant and its market share is expected to reduce. Hence, RP cannot be expected to increase the consumption of generic products. In that model, the RP system is modeled as an average of the branded drug price and the generic substitute price which is not commonly observed in reality.

Königbauer (2007) studies how persuasive advertising from the incumbent can induce vertical product differentiation and generic entry by setting the price of the incumbent at a considerably high level. Konigbauers’ work also suggests that, contrary to empirical observations, price regulation may further induce vertical product differentiation and so creates larger opportunities for profitable entry. More recently, Brekke et al. (2007) studied a model of oligopolistic competition to study how Reference Pricing may distort the incentives to entry of a branded therapeutic close substitute in a market where there the branded originator drug already competes in prices with a generic producer. The model uses a set up with horizontal product differentiation à la Hotelling and given levels of vertical product differentiation, therefore quality differentiation is not studied into a strategically context. Finally, Miraldo (2009) studies different versions of the Reference Pricing scheme in a model of horizontal product differentiation. She shows that when the price of reference is a linear combination of the price of brand drug of a given high quality level, the scheme provides a mechanism for price coordination and leads to higher prices in respect to a rule which sets the price of reference as the minimum of the observed prices. She does not provide for an analysis of entry, however her work is interesting in that she is the first in analyzing a context in which the demand is not fully satisfied. Yet, her work is not intended to parallel observed features of Reference Pricing in reality.

The model we present and analyze in the next sections has many elements that makes it different from previous theoretical exercises. The fundamental one is that market size and cost advantages from the part of the incumbent branded drug producer are introduced as key drivers for the incidence of Reference Pricing over the equilibrium outcomes. The second one is that vertical product differentiation is
made also dependent on horizontal product characteristics, therefore it provides a
general approach to assess Reference Pricing by allowing the potential entrant to be
a close substitute (generic producer) or a substitute therapy.

The paper evolves in the following manner, Section 2 develops the model and the
equilibrium for the case in which there is no price regulation, the results are therefore
identified as the NPR case. Section 3 provides an analysis of the expected effects of
introducing the RP regime, those results are identified as the full reference pricing
regime or FRP, referring to the typical case in which the authority establishes the
avoidable additional co-payment to be the full price differential between the price of
the branded drug and the price of reference. Section 4 summarizes the results and
suggests ways in which those results can be identified in quasi-experiments (regime
changes) or with a sample of product markets that are already under the RP regu-
lation.

2 The Model

2.1 Set up

This model features many characteristics of the one designed by Economides (1993).
It has been changed in a number of ways to better fit it to the case of a pharmaceu-
tical market as mentioned in section 1.2. We have an incumbent firm (originator)
with label 1 and a potential entrant known as 2. Firms (products) are both ver-
tically and horizontally differentiated. We denote by $z_j, j = \{1, 2\}$ a firm specific
"quality" attribute which in principle satisfies $z_1 \geq z_2$ and $z_j$ will be selected from
an interval $[0, z]$. Although this approach has been used before to study pharmaceu-
tical markets [See Cabrales (2003) and Merino-Castelló (2003)] the interpretation
is somehow different from the traditional view suggested in the seminal work of
Shaked and Sutton (1987), for example. In this setting, the idea is that the incum-
bent provides a branded product which is supposed to "capture" an important share
of the preferences of heterogeneous physicians prescribing drugs. In the literature
mentioned above, it is sustained that vertical product differentiation is an adequate
way to model brand loyalty, however it could also have different interpretations, for
instance as investing in the perception of safeness of the drug.

If both firms participate in the market they will be in addition, an in principle, sym-
metrically (and exogenously) located in a line segment $[0, S]$ of physical attributes.
We will assume that $S \geq 1$, where $S = 1$ is the initial size of the market. The
reference firm will be at position $a < \frac{S}{2}$ whereas the incumbent will be at $S - a$. An
originator drug and a corresponding generic copy will be close to each other in terms
of their characteristics, for instance in terms of their efficacy and side effects. We
allow, however, for some horizontal differentiation to model the fact that these two
drugs are not identical. Therefore, there are relevant characteristics (e.g. inactive
ingredients) that cause differentiated side effects. In this sense, horizontal product
differentiation is not strategic but exogenous and due to the form in which each
producer prepares its own treatment. Hence, a firm will be "located" in a point of
the space $[0, z] \times [0, S]$. 

7
Since the relevant exercise implies studying entry conditions for a sufficiently close substitute for the incumbent’s product, and in particular a generic variety of the originator drug, we will always study the equilibrium of the model for \( a \) close to \( S_2 \). That is, for a small and positive scalar \( \varepsilon > 0, a \in \left[ \frac{S_2}{2} - \varepsilon, \frac{S_2}{2} \right) \).

Consumers are uniformly distributed along the interval \([0, S]\) of preferred characteristics, where the position is labeled \( x \) and \( S \) indicates the size of the heterogeneity of preferences for drug physical characteristics. The density at each location is then \( f_x = \frac{1}{S} \) and its cumulative distribution function (c.d.f) is \( F_x = \frac{x}{S} \). A consumer whose preferred treatment is \( x \) but is offered a variety located at \( l \) will face a disutility for the mismatch which is quadratic: \( t (x - l)^2 \) where \( t \) is a parameter of the substitution of competing varieties which in what follows we normalize to \( t = 1 \). Other papers have used this type of formulation which is intended to model the fact that varieties produce different side effects and the intensity of those side effects are modeled as a distance of the characteristics of the patient and the treatment. Although the horizontal dimension has limited intuitive interpretations, one might think of a larger size of heterogeneity as an index of the complexity of the disease on the population of patients. Some medical conditions could affect a larger size of the population than others, making it more difficult for one drug to match the multiple individual conditions that must be treated. For example, drugs that are used to treat the flu have often very different intensities of side effects as a larger size of the population is usually affected by this disease.

Although branded and generic drugs are taken in practice as perfect substitutes from the perspective of their therapeutic characteristics: main active ingredient (molecule), dosage, etc., it is the case that branded drugs have different non-trivial characteristics than those of generic products. Hence, we will always allow for at least some degree of differentiation through the horizontal dimension as described in section 1.2.

At each point of the segment there is a distribution of tastes for quality attributes \( \theta \) belonging, for simplicity, to the interval \([0, 1]\) with density \( dG = 1 \), hence the mean valuation parameter is \( \bar{\theta} = \frac{1}{2} \). Seemingly controversial, the quality dimension of pharmaceutical products have been used in the literature specially to model and explain price changes for branded drugs in response to entry of other varieties. This type of interpretation would make sense in the U.S. where patients are heterogeneous on their insurance coverage bringing about a sense of vertical differentiation due to differences in income levels as a source of market segmentation. In Europe, in general, this type of interpretation is misleading as most patients are insured at the same level by National Health Systems (NHS). Hence, a more sensible interpretation would be the existence of heterogeneity of perceptions on the safeness of a drug. Branded drugs, due to its previous existence and continuous marketing are supposed to have the best reputation of safeness with respect to an unknown variety or non-branded variety.

Nevertheless the discussion in the lines above calls for a specific terminology of the vertical dimension, we will follow the literature and simply refer to it as a "perceived quality" dimension as in Cabrales (2003).
2.1.1 Reference pricing and co-payments

There exists a compulsory co-payment, or initial co-payment, that consumers have to make out-of-pocket. This is assumed to be fixed across products at $0 < \alpha \leq 1$. Hence any patient consuming product $j$ has to pay at least $\alpha p_j$ for $j = 1, 2$. The national health authority introduces also an additional co-payment based on the cost differential of the treatment chosen and a price of reference $\tilde{p}$ for the treatment. This additional co-payment takes the following form: $\beta (p_j - \tilde{p})$ whenever it is verified that $p_j > \tilde{p}$ and where $0 \leq \beta \leq 1 - \alpha$. The upper limit of the regulatory parameter implies that the most stringent regulatory decision is to force the patient to bear the entire cost differential between the cost of the preferred available treatment and the cost of reference. We will refer to the case where $\beta = 1 - \alpha$ as the case of full reference pricing or FRP. Nonetheless, the model may allow for different degrees of incidence of the reference price system by modeling the regulatory decision as a continuous parameter, $\beta$ however, it is most usual that the regulatory decision, in reality, is discrete so that either there is no reference system or there is such a system forcing the patient to bear an out-of-pocket payment of $(p_j - \tilde{p})$ on top of the initial co-payment based on the price of reference, $\alpha \tilde{p}$.

The patient, possibly advised by a pharmacist, can lessen or avoid the additional co-payment if she switches to a cheaper treatment. We assume that the alternative cheaper treatment is always available and the pharmacist has full incentives to inform the patient about the existence in the first place. In principle, both drugs are available for the patient at her local pharmacy.

As a matter of comparison with previous papers (cf. Merino-Castelló (2003)) we will set the value of $\alpha$ to $0.4 = \frac{2}{5}$ as it is supposed to be the usual level of initial co-payment for example in Spain.

2.1.2 Consumers’ choice and internal RP

Assume consumers have the same valuation for successfully treating a disease $v$ and this is large enough such that all consumers are treated in equilibrium. A consumer $i$ whose most preferred treatment is $x_i$, is assumed to enjoy the following utility from consuming a product $j$:

\[
V_{j,i} = \begin{cases} 
\theta_i z_j - (x_i - l_j)^2 - \frac{2}{3}p_j - \beta(p_j - \tilde{p}) & \text{if } p_j > \tilde{p} \\
\theta_i z_j - (x_i - l_j)^2 - \frac{2}{3}p_j & \text{if } p_j \leq \tilde{p}
\end{cases}
\]  

For $j = 1, 2$ and $l_1 = S - a$ and $l_2 = a$.

Consumers are assumed to buy only one unit of the desired treatment so that the choice is made over a discrete space. In some sense consumers select a complete treatment rather than a quantity of tablets, therefore competing drugs are assumed to deliver also similar lengths of treatment. To obtain the demand for each drug we first find the indifferent consumer in terms of the preference for varieties. As it is the case of interest, we will assume that $p_1 > \tilde{p} \geq p_2$ and we will also assume or impose that if firm 2 decides to enter it does so with a lower but positive level of
quality such that we observe $z_1 > z_2 > 0$.\footnote{It will be shown later that, in equilibrium, indeed setting $z_2 = 0$ for the potential entrant is equivalent to stay out of the market.}

In order to construct more easily the demand system we also impose a condition so that $(\frac{2}{5} + \beta)(p_1 - p_2) + \frac{S(S-2a)}{(z_1-z_2)} \geq 1$. Under the set of assumptions adopted so far the demand system is given by:

$$Q_1(p, z) = \frac{S(S - 2a) + \bar{\theta}(z_1 - z_2) - \gamma(p_1 - p) - \beta(p_1 - \bar{p})}{2(S - 2a)} \tag{2}$$

$$Q_2(p, z) = \frac{S(S - 2a) - \bar{\theta}(z_1 - z_2) + \gamma(p_1 - p) + \beta(p_1 - \bar{p})}{2(S - 2a)} \tag{3}$$

Where, $Q_j$ is the quantity sold by firm $j = 1, 2$. In this paper we will study a circumstance in which the regulator will always design beforehand the RP regime considering that a cheaper substitute of the original drug will always enter the market. In the regulator’s plan, once patent expires it will expect to set $\bar{p} = p_2$. This assumption is motivated by our interest on studying the strategic effects of the regulation over the decisions of undertakings that internalize that with certainty regulation will take this form. In this setting, firm 2 is the firm of reference. This version of the RP scheme is sometimes called internal reference pricing as opposed to a version in which the price of reference is taken from a foreign market. Define the price and quality differentials as following, $\Delta z = z_1 - z_2$ and $\Delta p = p_1 - p_2$. Under the internal RP assumptions the demand system reduces to:

$$Q_1(\Delta p, \Delta z) = \frac{S(S - 2a) + \bar{\theta}\Delta z - \gamma\Delta p}{2(S - 2a)} \tag{4}$$

$$Q_2(\Delta p, \Delta z) = \frac{S(S - 2a) - \bar{\theta}\Delta z + \gamma\Delta p}{2(S - 2a)} \tag{5}$$

Where $0 < \gamma = \frac{2}{5} + \beta \leq 1$. Note that $\gamma$ cannot be equal to zero, otherwise prices will have no importance and most possibly profits will be not-concave in which case we lose some regularity characteristics of the functions that are desirable to ease the analysis. This means that necessarily the initial compulsory co-payment $\alpha$ needs to be bounded away from zero which is the case in reality. For future reference, and for simplicity (as it does not change anything), we will say that there is no price regulation, NPR, whenever $\gamma = \frac{2}{5}$, and we will say that there is a full price regulation regime, FRP, whenever $\gamma = 1$

A complete derivation of the demand system can be found in the Appendix A at the end of this document.
2.1.3 Profit functions and technology

We assume constant marginal costs of production for both types of firms and these are set to be zero for simplicity. Most of the empirical exercises in the literature basically make this assumption based on specific industry data. For instance some empirical works have calculated that marginal costs are around 5% of the final price (See Caves et. al. (1992)).

We further assume that any level \( z_j \) of quality has a convex cost, however the incumbent may have a technology advantage modeled through a parameter \( c \geq 2 \), so that \( z_j^2 \geq \frac{z_2^2}{2} \) whenever \( z_1 = z_2 \). As noted before, the incumbent is endowed a technology advantage that is correlated with the previous length of patent protection much in the spirit of Cabrales (2003). However, in Cabrales’ model the cost advantage is linear with respect to the cost parameter of the potential generic entrant. In contrast, in our model the cost advantage function is \( 1/c \) for the incumbent which delivers lower relative advantage increases the higher is \( c \).

In general, we will look for an equilibrium in which \( p_1 > p_2 \), then the incumbent profit function is given by:

\[
\pi_1(\Delta p, \Delta z) = \begin{cases} 
  p_1 \frac{S(S-2a+\theta \Delta z - \gamma \Delta p)}{2(S-2a)} - \frac{z_2^2}{c} & p_1 > p_2 \\
  p_1 \frac{S(S-2a+\theta \Delta z - \alpha \Delta p)}{2(S-2a)} - \frac{z_1^2}{c} & p_1 \leq p_2 
\end{cases}
\]  

(6)

For the reference firm we assume, although not crucial, that apart from any expenses on a selected level of quality, it has to face a set-up or entry fixed cost of \( F \). This setup cost can be interpreted as the cost associated with proving bio-equivalence and safeness to the standards of the national health authority. therefore, its profit function is given by:

\[
\pi_2(\Delta p, \Delta z) = p_2 \frac{S(S-2a) - \theta \Delta z + \gamma \Delta p}{2(S-2a)} - \frac{z_2^2}{2} - F
\]

(7)

As we will see in the next section, firms are assumed to play a two-stage game in which firm 2, the firm of reference will decide to enter only if its expected profit levels given the incumbent’s decision on its level of quality investment, is at least enough to cover the entry fixed cost \( F \geq 0 \). Otherwise the potential entrant is assumed the stay out of the market with \( z_2 = 0 \).

2.2 Timing and equilibrium

We model the strategic interactions between the incumbent and the potential entrant in an oligopoly model of price competition, however firms are expected to invest in a quality attribute.
Firms are assumed to play a two-stage game, in the first stage firms play a sequential quality game. In the first period, firm 1 chooses its quality level considering the optimal strategies of firm 2, that is it enjoys a leader’s advantage. Firm 2 will decide to enter and its quality entry level if it is capable of covering the entry cost. In the second stage, firms decide simultaneously their prices.

Figure 1 shows how the game unfolds. We will solve for a sub-game perfect Nash Equilibrium by means of a backward induction exercise. Quasi-concavity of the game secures the existence of a sub-game perfect Nash Equilibrium in pure strategies, hence we can safely solve it by backward induction solving first the pricing stage game using the Nash Bertrand price equilibrium concept:

2.2.1 Equilibrium in the pricing stage game

We first obtain the reaction functions for the pricing sub-game for both firms by taking their corresponding first order conditions:

$$p_1 = \frac{1}{2\gamma} \left(S(S - 2a) + \bar{\theta}\Delta z\right) + \frac{1}{2} p_2$$  \hspace{1cm} (8)

$$p_2 = \frac{1}{2\gamma} \left(S(S - 2a) - \bar{\theta}\Delta z\right) + \frac{1}{2} p_1$$  \hspace{1cm} (9)

As a regular result, prices are strategic complements. The Nash equilibrium of the pricing stage game is given by:
Where the function \( s_0 \) is defined as follows:

\[
s_0 = 3S(S - 2a)
\]

This function \( s_0 \) can be understood as an index of symmetric market power that will increase with \( S \), as firms can better profit from their corresponding "back yards" and decreases with \( a \) as firms become closer substitutes in their physical relevant characteristics. As it can be seen following the price equilibrium \( \{p^*_1, p^*_2\} \) that any positive quality differential implies a positive price differential.

2.2.2 A digression on horizontally homogeneous drugs

From the equilibrium prices, (10) and (11), it can be seen that if firms produce identical products, meaning \( a = \frac{S}{2} \) and so \( s_0 = 0 \). Then the potential entrant will never have an incentive to enter the market because in general it will have to charge negative prices, as it is always the case that \( \Delta z > 0 \), which is not possible. Remember that the incumbent can produce the same amount of marketing as the potential entrant more efficiently. The incumbent will have to serve the entire demand \( S \). In this case, one might expect the incumbent to provide at least some marketing investments to profit from a positive price, in fact in this case the amount invested will be: i) increasing in the parameter of efficiency advantage, \( c \) and ii) increasing in the parameter of the market size, \( S \).

Note also that this result depends on the assumption that marginal costs of production are constant and equal to zero. With positive marginal costs prices will depend positively also on this and it can be shown that the potential entrant might enter the market as long as the quality differentials does not offset the marginal cost of production. This will mean that an inefficient entrant, possibly a generic producer, might enter the market. We do not further discuss this case as products are considered to be exogenously horizontally differentiated.

2.2.3 Statics of regulation on the pricing game

As a preliminary inspection we are interested in the sensibility of the second period strategic choices to the regulatory ambience. In our model we have parameterized in a very simple way the regulatory design. In fact, increasing regulation is translated into an increase in \( \gamma \) up to its natural limit 1.

Assume that the quality is exogenously given and is always non-negative. As a preliminary result, this model predicts that increasing the stringiness of price regulation will reduce both the incumbent and the reference firm prices. This is true for positive prices in equilibrium. As noted in the following price derivative:
\[ \frac{\partial p_1}{\partial \gamma} = -\frac{1}{3\gamma^2} (s_0 + \bar{\theta} \Delta z) \]

\[ \frac{\partial p_2}{\partial \gamma} = -\frac{1}{3\gamma^2} (s_0 - \bar{\theta} \Delta z) \]

For an equilibrium in which \( p_1^*, p_2^* > 0 \), prices will be reduced but the price of the incumbent will be hurt more than that of the potential entrant. In fact, the higher the expected price differential without pricing regulation, that is the higher \( \Delta p|_{\beta=0} = \frac{1}{\alpha} \Delta z \), the higher the initial effect of a positive level of regulation over the incumbent. Price differentials will go down depending on the regulatory effects over quality differentials.

Intuitively, as price competition is fostered by the introduction of price regulation, then firms may find it optimal to further soften this competition by increasing the degree of product differentiation, in this case their degree of vertical product differentiation. However, thinking twice the problem it also follows that when investing in quality is a costly activity it could be the case that the incumbent would find it optimal to lower its investments in quality. A discussion on this type of result can be found in Noh and Moschini (2006).

2.2.4 Equilibrium in the attribute sub-game

We now solve the first period quality game given the solution for the stage pricing game obtained in the last sub-section. We collect the reduced form equations for the prices in \( p(\Delta z) = [p_1(\Delta z), p_2(\Delta z)] \). We define the reduced form profit function from the pricing game for the entrant as follows:

\[
\pi_2(\Delta z) = \frac{1}{18(S - 2a)\gamma} (s_0 - \bar{\theta} \Delta z)^2 - \frac{z_2^2}{2} - F
\]

The corresponding reaction function of the entrant for the quality sub-game is obtained by taking the first order condition of the above reduced form profit function with respect to \( z_2 \) taken as given the quality level of the incumbent:

\[ z_2 = \frac{s_0}{s_1} \bar{\theta} - \frac{\bar{\theta}^2}{s_1} z_1 \]  

(13)

where:

\[ s_1 = 9\gamma (S - 2a) - \bar{\theta}^2 \]

As a regularity condition we will impose that \( s_1 > \bar{\theta}^2 \). Whenever the optimal \( z_1 \) is greater than \( \frac{s_0}{\bar{\theta}} \) we assume that the best response from the potential entrant is to set \( z_2 = 0 \). Note however that from equation (11), this implies a price of zero so that in this case \( z_2 = 0 \) is equivalent to set \( \pi_2 < 0 \) for \( F > 0 \), meaning that the firm will not enter the market. Note also that even with \( F = 0 \) the potential entrant will not enter the market. In fact with \( F > 0 \), the value of \( z_1 \) that makes entry unprofitable is in general lower than \( \frac{s_0}{\bar{\theta}} \). In Appendix B, we show the function \( x_i_1 \) which is the
threshold, as a function of $F$, that makes entry unprofitable. There it is shown that when $F > 0$, the value of $z_1$ that makes entry unprofitable is lower than $\frac{s_0}{\theta}$.

The best response for the firm of reference is, in general, a decreasing function in the level of the quality attribute of the incumbent firm. Attributes are then strategic substitute actions from the point of view of the potential entrant. The reaction function changes both its intercept and slope negatively with the stringiness of price regulation. It can be shown that $s_1$ is an increasing function on the regulatory parameter. The higher the level of $\gamma$ the lower the best response of the potential entrant for any level of $z_1$ provided a positive level of quality investment of the potential entrant.

The latter expected result means that as price competition becomes tougher due to the regulatory intervention, the best response of the potential entrant prescribes a lower margin of vertical product differentiation with respect to the case in which there is no price regulation.

The profit function for the incumbent is:

$$\pi_1(\Delta z) = \frac{1}{18(S-2a)\gamma} \left(s_0 + \tilde{q} \Delta z \right)^2 - \frac{z_1^2}{c}$$  \hspace{1cm} (14)$$

The reduced form profit function for the incumbent should consider then the best reaction of the potential entrant to any level of its own investment. The profit function for $z_1 < \frac{s_0}{\theta}$ is, therefore:

$$\pi_1(z_1) = \frac{1}{18\gamma(S-2a)s_1^2} \left(s_1 s_0 - s_0 \tilde{q}^2 + \tilde{q} \gamma (S-2a) z_1 \right)^2 - \frac{z_1^2}{c}$$  \hspace{1cm} (15)$$

We will assume that this function is strictly concave on $z_1$. Taking the first order condition with respect to $z_1$, the optimal level of quality follows for the incumbent firm:

$$z_1^* = \left( \frac{s_1 - \tilde{q}^2}{\frac{2}{s_1^2} - (s_1 + \tilde{q}^2) \theta^2} \right) \tilde{q} s_0$$  \hspace{1cm} (16)$$

We will assume this function is strictly positive which is in general true. This is indeed the case as for the numerator $s_1 > \tilde{q}^2$. For the denominator it can be shown that for $c = 2$ (no efficiency advantage) solving for $s_1$ such that the denominator is zero gives the solution $\frac{\tilde{q}^2}{2}(1 - \sqrt{5})$, since $s_1$ is assumed to be greater than $\tilde{q}^2$ and the numerator is increasing in $s_1$ then, for $c = 2$ the numerator is positive. However as $c$ increases $z_1^*$ increases but at some point $z_1^*$ will be negative which is not possible by assumption. Therefore $z_1^*$ is positive as long as $c$ is not to big. 7

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7There is also a solution for the denominator $\frac{\tilde{q}^2}{2}(1 + \sqrt{5})$ for which some numerical simulations show that still $z_1^*$ is positive.
2.2.5 Equilibrium with no RP: $\gamma = \frac{2}{5}$

As a benchmark case we first show the equilibrium an its characteristics for the case in which there is no RP regulation meaning that the authority sets $\gamma = \frac{2}{5}$, there is no entry cost $F = 0$ and the incumbent has no efficiency advantage $c = 2$.

Proposition 1 Assume there is no RP, hence $\gamma = \frac{2}{5}$. Assume also $s_1 > \bar{\theta}^2$ and $c = 2$ so that there is no cost advantage for the incumbent and $F = 0$. Then there exist a Sub-game Perfect Nash Equilibrium (SPE) for the quality-entry-price game. Denote equilibrium variables with $NPR$, from no price regulation. The equilibrium is such that $z_{1NPR} > z_{2NPR} > 0$, $p_{1NPR} > p_{2NPR} > 0$, $Q_{1NPR} > Q_{2NPR} > 0$, $\pi_{1NPR} > \pi_{2NPR}$.

Proof: Under the assumption that $s_1 > \bar{\theta}^2$, $\frac{\partial \pi_2}{\partial z_2} < 0$ and $\pi_2$ is a concave function, therefore the potential entrant has no incentives to leapfrog the incumbent therefore the equilibrium obtained by the first order conditions is a SPE. It is relatively easy to see that with this conditions, $z_{1NPR} < \frac{s_0}{\bar{\theta}}$ hence under the reaction function for the potential entrant prescribes $z_{2NPR} > 0$. More over, from the reaction function for firm 2, $z^*_{2}$ the value of $z_1$ which makes both quality investments equal is $s_0 \bar{\theta} \frac{s_1}{s_1 + \bar{\theta}^2}$ comparing $z^*_1$ with the former indicates that the latter is greater if $s_1 \bar{\theta}^2 > 0$ which always holds true provided some level of horizontal differentiation. Then it is the case that $z_{1NPR} > z_{2NPR}$. From the equilibrium of the pricing sub-game, and the fact that $z_{1NPR} < \frac{s_0}{\bar{\theta}}$, it is straightforward that $p_{1NPR} > p_{2NPR} > 0$.

Showing that $\pi_{1NPR} > \pi_{2NPR}$ is a bit cumbersome. This is true whenever $\frac{\pi_{1NPR}}{\pi_{2NPR}} > 1$.

Using $z^*_2$ the profit ratio is greater than one if $8\bar{\theta}s_0s_1 - (s_1 - \bar{\theta}^2)z^*_1 - s_0\bar{\theta} > 0$. This condition is more difficult to observe whenever $z^*_1$ is greater since, by assumption $s_1 > \bar{\theta}^2$. Assume $z^*_1 = \frac{s_0}{\bar{\theta}}$, the level that makes entry unprofitable. At this level, the condition is shown to be $s_0s_1(8\bar{\theta}^2 - 1) > 0$ which is always true. Therefore, since we have shown before that $z_{1NPR} < \frac{s_0}{m}$ then $\frac{\pi_{1NPR}}{\pi_{2NPR}} > 1$, therefore $\pi_{1NPR} > \pi_{2NPR}$.

end of proof.

Proposition 1 tells us that from the most favorable conditions for entry, meaning $c = 2$ and $F = 0$, the model predicts an intuitive equilibrium in which the entrant enters with a lower marketing investment with respect to the incumbent, lower price, lower market share and lower profit. In this case the incumbent has the advantage to anticipate the reaction of the entrant which gives it incentives to invest in marketing so that products are vertically differentiated and the difference in marketing investments delivers all the results.

Now, we can study the predictions of the model under more difficult circumstances for entry. Although the strategic advantage of the incumbent in the quality investment sub-game already describes an equilibrium consistent with empirical regularities, it has been suggested that the length of patent protection gives the incumbent an advantage that makes entry more difficult. In our model this implies increasing
c from 2, since it has been suggested that the advantage of patent protection is related to the efficiency of the incumbent to invest in marketing so as to obtain some consumer loyalty. We propose the following lemma:

**Lemma 1** Consider the equilibrium in Proposition 1. Then as c increases from 2, meaning an efficiency advantage for the incumbent, the entry profits follow $\frac{\partial \pi_{NPR}}{\partial c} < 0$. Therefore, there exists a value of c that makes entry unprofitable.

**Proof:** Substitute $z_{1}^{*}$ in $\pi_{2}(\Delta z)$ for $F = 0$ and consider the optimal level of investment of the incumbent, $z_{1}^{*}$:

$$\pi_{2}(z_{1}^{*}) = (s_{0} - \theta z_{1}^{*})^{2} \left( \frac{1}{2s_{1}} \right)$$

From the equation of $z_{1}^{*}$ and as long this is positive, this quality investment increases as c increases, therefore, the entrant’s profit will always decrease with the efficiency advantage of the incumbent. Furthermore, since the level of investment that makes entry unprofitable is $z_{1} = \frac{s_{0}}{\theta}$ then c that makes entry unprofitable is:

$$\tilde{c} = \frac{s_{1}}{m^{2}}$$

**end of proof.**

From the above Lemma and its corresponding proof it is straightforward to see that the efficiency level that makes entry unfeasible is increasing in the size of the market through the function $s_{1}$. Hence this model predicts three of the observations in un-regulated markets: First, the potential entrant, if enters, it does so at a lower price and market share than the incumbent. Second, the longer the period of patent protection (in this model, the larger the efficiency advantage for the incumbent) the lower the expected profits for the potential entrant. Third, expected entrant’s profits are higher in size the larger the size of the market.

Whenever the structure of the market prescribes that the incumbent’s optimal investment is greater or equal than $\frac{s_{0}}{\theta}$ then we can say that entry is *blockaded* in the usual sense, for example, explained in Tirole (1988). The natural way of analyzing blockaded entry is through the efficiency advantage of the incumbent. Entry will most likely be blocked in markets where the incumbent producer has enjoyed a longer period of patent protection and the size of the market is relatively small.

More over, for any given efficiency advantage, the size of the market always increases the expected profits of the potential entrant. Figure 1 shows the expected evolution of profits for the potential entrant as c increases. The figure is shown for three different levels of the size of the market, where $S' = 1 < S'' < S'''$. 

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The intuition of this result is straightforward. As the incumbent increases its level of investments, because it is cheaper for greater \( c \), the best reaction of the potential entrant is to reduce its own investment and concentrate in the low quality individuals. Therefore quality differential increases, which reduces the price of the incumbent (it will concentrate in providing a low quality low price product) but not enough so as to compensate for the quality differential so that its expected demand is smaller, therefore its expected profits will always be lower.

### 2.2.6 Numerical example

We clarify the predictions of the market by showing a numerical example for the findings discussed in the previous section. In the following table we show the expected profits for the entrant as a function of the efficiency advantage from the incumbent, \( c \), which increases from no efficiency advantage \( c = 2 \). The table also show variations of the result for different market sizes from the smallest \( S = 1 \) specified in the model.

As it is shown, for the smallest market size, entry is only feasible as long as \( c \leq 3 \), that is fifty percent above the level where the incumbent has no advantage. For higher values, then entry is not profitable. The result changes when the size of the market increases to \( S = 1, 25 \), the expected profit increases with respect to the initial market size until the efficiency advantage takes a value of \( c = 5 \). For a much larger market size, fifty percent above the initial level, entry is profitable for every level of the efficiency advantage.

For the non regulatory case, the model then delivers sensible results in that as
Table 1: Expected entry profits \( \pi_s^* \) for the NRP for different \( c \) and \( S \)

<table>
<thead>
<tr>
<th>( c )</th>
<th>( S=1 )</th>
<th>( S=1,25 )</th>
<th>( S = 1,5 )</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>0.148</td>
<td>0.352</td>
<td>0.665</td>
</tr>
<tr>
<td>2.5</td>
<td>0.090</td>
<td>0.278</td>
<td>0.570</td>
</tr>
<tr>
<td>3.0</td>
<td>0.033</td>
<td>0.199</td>
<td>0.471</td>
</tr>
<tr>
<td>3.5</td>
<td>-</td>
<td>0.120</td>
<td>0.367</td>
</tr>
<tr>
<td>4.0</td>
<td>-</td>
<td>0.048</td>
<td>0.262</td>
</tr>
<tr>
<td>4.5</td>
<td>-</td>
<td>0.002</td>
<td>0.160</td>
</tr>
<tr>
<td>5.0</td>
<td>-</td>
<td>-</td>
<td>0.070</td>
</tr>
</tbody>
</table>

efficiency increases for the incumbent, most possibly because of a larger period of previous patent protection, the expected profits decreases. However, as market size increases the expected profits are in general greater, meaning that even with a large efficiency advantage from the incumbent, the size of the market can give room to entry.

2.2.7 Horizontally differentiated products

The model, moreover, is robust in its predictions whenever we explore the situation in which the potential entrant’s product and the incumbent’s are more differentiated in its, say, physical characteristics. We have claimed that the analysis so far is valid for products that, although, not identical are close enough so as to suggest that they are interchangeable for consumers whenever perceived quality differentials are large enough. When products are more differentiated in terms of the horizontal dimension of the model, then this can be interpreted as situation in which the incumbent originator producer faces the entry of an alternative therapeutically equivalent product, as in Brekke et al. (2007) or Miraldo (2009). In this case, products are supposed to be differentiated more significantly, say, in its main active ingredient. Then the extreme case is that in which \( l_1 = S \) and \( l_2 = 0 \), that is firms are located in the edges of the line segment \([0, S]\)

Therefore, the expected result when products are far apart from each other in its characteristics are the following: i) As products are more imperfect substitutes from the demand point of view, price competition is softened, ii) the latter translates in lower investments in perceived quality from the incumbent as its relative return decreases, iii) However, the potential entrant has incentives to increase its marketing expenditures as it its best response to the optimal decision of the incumbent. Then quality differentiation is much lower than when products are closer substitutes.

Prices are overall greater than in the case of Proposition 1, profits are also greater, and therefore entry is much more feasible. Therefore, the model predicts that it is easier for a potential entrant to profit from the market if it does so with a new therapeutically equivalent product provided, of course, that the expected profits are enough to cover the sunk costs of the investments required to produce the innovation. This, for example, will be the case of a large laboratory seeking to enter a market with a new product that has already been developed.
3 Analysis of the Price Regime

In this section we perform the analysis and review the predictions of the model in terms of the price regime designed so as to promote price competition. To begin with, let us recall that the price regime is supposed to deliver up to three important results for policy makers: i) As it promotes price competition by increasing the price elasticity of demand, then overall costs of treatment are reduced (average prices reduces), ii) the usage of the potential entrant increases, provided it enters the market, iii) the regime is supposed to increase the likelihood of entry of the potential generic producer.

3.1 Internal RP regime with no efficiency advantage

As described in section 2, the RP regime implies for the consumer of the expensive originator drug that, on top of paying the initial copayment corresponding to the product of reference she will have to pay the entire difference differential \( p_1 - p_2 \). Note that the full price regulation regime implies \( \gamma = 1 \) as \( \beta = 1 - \alpha \).

Considering the result of Proposition 1, introducing the full price regulation regime implies decreasing \( z_1^* \) as increased price competition reduces the incentives to invest in the marketing. However, note that from the reaction function of the potential entrant \( z_2^* \) it is not clear whether the best reaction will be to increase its marketing effort or reduce them, basically because increasing \( \gamma \) towards 1 implies increasing the function \( s_1 \) which reduced both the intercept and the slope (in absolute value) of the reaction function.

In fact, the quality differential reduces but reducing also the marketing investment of the potential entrant. Hence this is a positive effect for the entrant as its equilibrium price depends negatively in the quality differential. However, there is a direct effect of price regulation over its equilibrium price because price regulation makes price competition more profound (as prices are strategic complements). This direct effect prevails and the equilibrium price of the potential entrant is reduced by the regulatory regime.

The following Proposition shows the result in which the essential assumption is that the size of the market is relatively small, in terms of \( S \) this happens when \( S = 1 \).

**Proposition 2** Consider Proposition 1 and additionally assume \( S = 1 \), that is the market is relatively small. The full reference pricing regime \( \gamma = 1 \) makes the expected profit of the potential entrant under this regime \( \pi_2^{FRP} \) (full reference pricing) to satisfy \( \pi_2^{NPR} > \pi_2^{FRP} \).

**Proof:** Consider first the optimal investment in quality for the incumbent, \( z_1^* \) when there is no efficiency advantage, \( c = 2 \), \( z_1^*(c = 2) \). This optimal investment is
decreasing in the regulatory regime $\gamma$, since:

$$ \frac{\partial z^*_1(c = 2)}{\partial \gamma} = - \left( \frac{(s_1 - \bar{\theta}^2)(1 - \bar{\theta}^2) + \bar{\theta}^4}{(s_1 - (s_1 + \bar{\theta}^2)\bar{\theta}^2)^2} \right) s_0 \theta \frac{\partial s_1}{\partial \gamma} = H(s_1)s_0\theta \frac{\partial s_1}{\partial \gamma} $$

is decreasing because $\frac{\partial s_1}{\partial \gamma} > 0$ and $H(s_1) < 0$. Now recall the expected profit function for the potential entrant as a function of the optimal investment of the incumbent:

$$ \pi_2(z^*_1) = (s_0 - \theta z^*_1)^2 \left( \frac{1}{2s_1} \right) $$

Taking the first order condition with respect to $\gamma$ follows the expression:

$$ \frac{\partial \pi_2(z^*_1)}{\partial \gamma} = H(s_1)s_0\theta \frac{\partial s_1}{\partial \gamma} - \frac{(s_0 - \theta z^*_1) \partial s_1}{2s_1^2} \frac{\partial s_1}{\partial \gamma} $$

Since $\frac{\partial s_1}{\partial \gamma} > 0$ for this partial derivative to be negative it suffices to show that:

$$ z^*_1 < \frac{s_0}{\theta} - 4s_1^2 H(s_1)s_0 $$

From Proposition 1 we know that $z^*_1 < \frac{s_0}{\theta}$ when $c = 2$. Therefore since $H(s_1) < 0$, then the latter condition is always satisfied.

**end of proof.**

The full implications of the introduction of the regulatory regime can be better shown with the numerical solution for $\gamma = \frac{2}{5}$, the NRP case, and $\gamma = 1$, the full regulatory regime. In the Table 2 it is shown that the regulatory regime succeeds in reducing the price of the incumbent, however it also reduces the price of the potential entrant. It is also successful in increasing the consumption of the generic variety, as $Q_2$ increases however, the price effect offsets the grow in the market share of the entrant to the point that the expected profit of the entrant decreases.

<table>
<thead>
<tr>
<th>$\gamma$</th>
<th>$z^*_1$</th>
<th>$z^*_2$</th>
<th>$\frac{z^<em>_2}{z^</em>_1}$</th>
<th>$p^*_1$</th>
<th>$p^*_2$</th>
<th>$Q^*_2$</th>
<th>$\pi^*_2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>$\frac{2}{5}$</td>
<td>0,484</td>
<td>0,290</td>
<td>0,732</td>
<td>0,565</td>
<td>0,435</td>
<td>0,435</td>
<td>0,148</td>
</tr>
<tr>
<td>$1$</td>
<td>0,148</td>
<td>0,132</td>
<td>0,978</td>
<td>0,202</td>
<td>0,198</td>
<td>0,494</td>
<td>0,089</td>
</tr>
</tbody>
</table>

Therefore, whenever there is no efficiency advantage, or in other words, whenever this advantage is not relevant, introducing the full RP regime will always reduce the expected profits of the entrant, hence RP might explain a reduced likelihood of entry in this case.
3.2 Internal RP regime with an efficiency advantage

Now, let us show the most relevant result of the paper. We have shown that for no efficiency advantage, the model suggests that introducing the RP regime although successful in reducing prices and increasing the consumption of the generic entrant might actually induce less entry as entry profits are driven down.

Recall that from equation (16), which showed the level of quality investment from the incumbent, that \( z^*_1 \) is an increasing function on the efficiency advantage \( c \). In fact we also showed that for small market size, say \( S = 1 \), expected profits for the entrant are much lower whenever \( c \) increases from \( c = 2 \). Therefore we might think of a circumstance in which the initial level of efficiency advantage is high enough so that with no regulation the initial expected profit for the entrant is low enough so that the effect of price regulation, by which the quality investment of the incumbent is severely reduced, does so to the point that this effect prevails to the direct effect of such regulation over the price of the entrant. Hence, it is possible to find a market configuration in which the RP actually increases the expected profits of the entrant.

The following proposition suggests this result:

**Proposition 3** There exists a level of efficiency advantage, that is sufficiently long period of previous patent protection, \( c^{RP} \) for which the full RP regime \( \gamma = 1 \) implies that \( \pi^{NPR}_2(c = c^{RP}) < \pi^{FPR}_2(c = c^{RP}) \)

**Proof:** (Sketch) Imagine that for no price regulation, that is the NPR case seen before, \( \pi^{NPR}_2 = 0 \). This is so whenever \( z^*_1 > \frac{s_0}{\theta} \) which is true, as seen before in Lemma 1 whenever \( c > \tilde{c} = \frac{s_1}{\theta^2} \). It is relatively easy to see that for \( S = 1 \) and sufficient horizontal product differentiation, meaning \( a < \frac{1}{2} \) that \( c > \tilde{c} = \frac{a}{m^2} > 2 \) which has to be true otherwise we would be contradicting Proposition 1 which has been proven.

Now, it is necessarily true that since \( z^*_1 \) always decreases with \( \gamma \) irrespective of the value of \( c \), the efficiency advantage, therefore for this extreme case \( \pi^{FPR}_2 > \pi^{NPR}_2 = 0 \). Then by continuity of the profit function of the potential entrant, it will always be possible to find a value of \( c \), call it, \( \tilde{c}^{RP} \) below \( \tilde{c} \) but arbitrarily close so as to observe \( \pi^{FPR}_2 > \pi^{NPR}_2 > 0 \) under such \( c^{RP} \)

**end of proof (Sketch)**

So far we have not been able to show the exact closed form solution for the problem by which with small \( S = 1 \), the values of the efficiency advantage can be divided so that below an specific threshold \( c^{RP} \), the full reference pricing always delivers lower profits for the entrant than with NPR, and above that threshold the full regulatory regime actually increases entry profits with respect to the NPR case. We so far have shown, first, in Proposition 2, that with no efficiency advantage passing from NPR to full RP always reduces the profits of the entrant. We have also shown, at least in a sketch proof, that must exist some \( \tilde{c}^{RP} \) which intuitively satisfies \( c^{RP} < \tilde{c}^{RP} \) in which price regulation has a positive effect over the expected profits of entry.
However we have found the solution by a numerical algorithm in MATLAB, assuming, as noted before the market size $S = 1$ and different values of $a < \frac{1}{2}$, starting from $a = 0, 45$. The algorithm solves for the solution of the following expression:

$$
\pi_2^*(c|\gamma = 1, a, S = 1, m = \frac{1}{2}) - \pi_2^*(c|\gamma = \frac{2}{5}, a, S = 1, m = \frac{1}{2}) = 0
$$

The following table summarizes the results for different values of $a$. For the first value, it shown that $c_{RP} = 2$ (it actually is $c_{RP} < 2$ but it cannot be) meaning that for such close substitutes, introducing the RP regime by setting $\gamma = 1$ always reduces the expected profit of the entrant. For the next value of $a = 0, 40$, whenever the efficiency advantage is lower than $c_{RP} = 2, 55$, the RP regime reduces the expected profits of entry whereas if the efficiency advantage is higher than this threshold the the RP regime can promote entry.

Table 3: Value of the threshold $c_{RP}$ for some $a$

<table>
<thead>
<tr>
<th>$a$</th>
<th>$c_{RP}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.45</td>
<td>2.00</td>
</tr>
<tr>
<td>0.40</td>
<td>2.55</td>
</tr>
<tr>
<td>0.35</td>
<td>3.08</td>
</tr>
<tr>
<td>0.30</td>
<td>4.20</td>
</tr>
<tr>
<td>0.00</td>
<td>10.90</td>
</tr>
</tbody>
</table>

As the most interesting case is that in which RP is set to a generic substitute, meaning sufficiently close to the branded producer, the numerical solution suggests that, for example, if the generic is located at $l_2 = 0, 4$ (conversely the incumbent at $l_1 = 0, 6$), the price regulation can have a positive role in promoting entry as long as the efficiency advantage for the incumbent is large enough. Translated into policy making, this results suggest the important Corollary that RP can deliver price reductions as well as improved expectations of entry (as entry profits increases) as long as the regime is put in practice in a relatively small product market in which an incumbent has enjoyed a relatively long patent protection period.

This result might be contrasted for instance for a recent case in Portugal. In a case study, Portela (2009), studied markets before and after the introduction of the RP system and found that generic entry increased which suggests that economic expectations on the market were improved.

Now in the next section we propose an analysis of the results extending it to study the conclusions with respect to market size.

### 3.3 Market size and the efficiency advantage

Note that intuitively, with growing market size, both the incumbent and the potential entrant can take advantage of an increased backyard in the sense that there will be a larger set of consumers to the left of $l_2 = a$ and to the right of $l_1 = S - a$. In this sense, market power will be symmetrically increased for both firms, making it easier to profit from market. In section 2.2.5 we have already shown that for the NPR case,
the expected profits for the potential entrant increases with the size of the market, irrespective of the level of efficiency advantage of the incumbent. Market size will not in general change the results for RP, however the profit levels will in general be greater for a larger size.

The effects on the relation between \( c \) and FRP that were shown schematically in the last section may be altered though by the size of the market. To recall, FRP was shown to be entry improving for a sufficiently large efficiency advantage of the incumbent. Therefore there was a role for FRP in promoting entry as the expected profits for the potential entrant were shown to be greater under the reference pricing scheme with respect to NPR. Market size, however, will increase the level of efficiency that makes entry unprofitable, that is \( \tilde{c} = \frac{s'}{m^2} < \frac{s''}{m^2} \) (FRP), for \( S' < S'' \) (FRP), profits for the entrant as a function of \( c \) will be in general flatter for FRP than for NPR. Therefore the level of the efficiency advantage for which FRP has the entry promoting effect will also be increased.

Hence, the model suggests that it will be more difficult to observe the positive effect over entry for the FRP whenever market size is bigger. Notwithstanding, market size always delivers greater profits in equilibrium when comparing two markets with FRP.

Figure 3: *Optimal expected entrant’s profit as a function of \( c \) for different market sizes \( S, S'' > S' \): NPR vs FRP*

![Figure 3](image_url)

Figure 3, shows the scheme of the interactions of the size of the market with the efficiency advantage and FPR. The bold lines, as in Figure 2, show the expected entrant’s profit for two different levels of market size for the NPR case and the corresponding efficiency advantage that makes entry unprofitable. The dotted lines
present the corresponding optimal expected profits for the entrant for each of the market sizes for the FPR case. The intersection of each bold line with the corresponding dotted line defines the efficiency value $c^{RP}$ discussed in the previous section. As it can be seen, for the larger market size that intersection occurs at a much higher $c$, hence FPR cannot deliver the positive result of promoting entry with respect to the NPR case unless the efficiency advantage is very large.

This result suggests that FRP might be designed in a way that consider the entry discouraging effect for small levels of advantage. For small levels of efficiency advantage, RP could be, for instance, designed at an intermediate level so that $\alpha < \gamma < 1$. For product markets where it is reasonable expected the the incumbent enjoys a high efficiency advantage that can easily make it to invest in marketing for create the perceived quality differential with respect to the potential entrant, then FPR can put in place in the expectation of delivering the entry promoting effect.

4 Summary of the results and concluding remarks

In this paper we have presented a model of a pharmaceutical market to study the effects of a reference pricing system (RP) over the likelihood of entry of a generic substitute to the branded originator drug producer. We have shown that the model predicts that under no price regulation, the NPR, case, the likelihood of entry, measured as the expected profits for the generic entrant always reduces with the efficiency of the incumbent firm in providing for perceived quality. At a certain level of the incumbent’s efficiency, entry is blocked as this advantage give incentives to the incumbent to increase its efforts in investing in quality differentials. The entrant cannot profit from the market. Market size increases the entrant’s profit, as market size implies increased market power. The size of the market also alleviates the problem of blockaded entry as the efficiency advantage required to make entry unprofitable grows larger with this parameter. The efficiency advantage from the incumbent and market size have the expected effects over entry for markets with no price regulation, the NPR case.

In regards to the effects of full price regulation, the FRP case, we divide the results and discussion in two groups, one that refers to the findings of the model and other referring to suitable hypothesis testing suggested by the model and that can enrich the empirical discussion that is gaining attractiveness.

4.1 The effects of RP over entry

In this model we have shown that RP always reduces entry profits when efficiency advantage of the incumbent, either because it has enjoyed before a period patent protection or because it is a large multinational firm, is low. Reduced entry profits are compared to the NPR in which firms compete in a situation in which the only source for direct price elasticity comes from the existence of the initial co-payment $\gamma = \frac{2}{5}$. There are two effects over entry, one positive due to the reduction of quality differentials, and one negative due to the increased price competition that
drives down the expected entrant’s price. However relatively high efficiency of the incumbent, FPR may alleviate the problem of blockaded entry.

Table 4: Summary of the effects of FRP on the entrant’s profit

<table>
<thead>
<tr>
<th></th>
<th>$S = 1$ (Low)</th>
<th>$S = 1, 2, 5$ (High)</th>
<th>$S = 1, 5$ (Very High)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$c = 2$ (Low)</td>
<td>$\pi_{2}^{NPR} &gt; \pi_{2}^{FRP}$</td>
<td>$\pi_{2}^{NPR} &gt; \pi_{2}^{FRP}$</td>
<td>$\pi_{2}^{NPR} &gt; \pi_{2}^{FRP}$</td>
</tr>
<tr>
<td>$c = 3$ (High)</td>
<td>$\pi_{2}^{NPR} = 0 &lt; \pi_{2}^{FRP}$</td>
<td>$\pi_{2}^{NPR} &gt; \pi_{2}^{FRP}$</td>
<td>$\pi_{2}^{NPR} &gt; \pi_{2}^{FRP}$</td>
</tr>
<tr>
<td>$c = 5$ (Very High)</td>
<td>$\pi_{2}^{NPR} = 0 &lt; \pi_{2}^{FRP}$</td>
<td>$\pi_{2}^{NPR} = 0 &lt; \pi_{2}^{FRP}$</td>
<td>$\pi_{2}^{NPR} &lt; \pi_{2}^{FRP}$</td>
</tr>
</tbody>
</table>

Table 4 summarizes the results of the effect of FPR over the entrant’s profit with respect to the NPR case. As it is shown, for the extreme case of no efficiency advantage, when $c = 2$, FPR always reduces the entrant’s profits with respect to the NPR equilibrium irrespective of the size of the market. For a high $c$, in the table $c = 3$, FPR can actually alleviate the problem of blockaded entry for a small market size, as shown in the table, the expected entrant’s profit is positive whereas for the NPR case there will be no profitable entry. As market size increases the effect disappears and FPR reduce the incentives to entry.

For the case of a very high efficiency advantage, $c$, FPR can actually explain entry, which has important policy implication as it is suggesting a role for FPR, not only as a device to deliver short run price reduction but as a driver to entry as even for a high market size it could alleviate the problem of blockaded entry. Even for a very high market size, FRP explains higher profits for the entrant, however at this point as market size is big enough still the NPR profits are positive.

4.2 Testable hypotheses

As for the testable hypotheses that can be studied in an empirical context, we first make a caution comment in that recent empirical studies have used both the length of the previous patent protection and the size of the market as control variables, for example in Moreno-Torres et al. (2009) for the Spanish case. Indeed, our model suggests that controlling for the market size, RP always reduce entry profits. However, controlling for the length of the previous patent protection enjoyed by the incumbent, which we claimed is positively correlated to its ability to deliver more efficiently perceived quality investments, might not be enough to identify the effect of FPR. There appears to be a non-linear interaction between FRP and the length of patent protection, or in our model, the level of the incumbent’s efficiency.

In fact, an important question is whether the positive role of FRP can be identified in data. Note that for this it is not necessary to have a policy change from NPR to FRP. With a sample of product markets already working at a FRP regime it could be possible to test whether the entry rates can be explained by a positive role of the FRP regime, interacting the regime with information on the length of
patent protection enjoyed by the incumbent before entry was a potential event.

Additionally, the model suggests that the size of the market might not explain entry at very high levels of this parameter unless the efficiency advantage is very large. The key identification assumption requires the regime change from NPR to FPR. This is radically different with respect to the empirical strategies that has been discussed in the first section of this paper. In these empirical papers, market size is a control variable but it could have some interesting interaction with FPR that might be identified in data as long as the policy change can be observed in data.

In this paper we have not play with the level of horizontal product differentiation. This means that all the results requires controlling for the attribute differences in the competing drugs. These attributes have to be introduced in an empirical model in regards to relevant effects as side effects, for instance. Hence, a large set of information might be needed that could be difficult to find and implement in practice.
References


Danzon, P. and Epstein, A.: 2008, Effects of regulation on drug launch and pricing in interdependent markets. MIMEO.


A Demand derivation

Consider first the demand for firm 2, the firm of reference. A consumer $x_i$ will consume from firm 2 as long as:

$$V_{i2} > V_{i1} \quad (17)$$

Considering the assumptions

$$\theta_i z_2 - t(x_i - a)^2 - \alpha p_2 > \theta_i z_1 - t((S - a) - x_i)^2 - \alpha p_1 - \beta(p_1 - \tilde{p}) \quad (18)$$

Solving this equation for the position of the consumer on the horizontal segment we obtain:

$$\frac{S(S - 2a)t - \theta_i (z_1 - z_2) + \alpha(p_1 - p_2) + \beta(p_1 - \tilde{p})}{2(S - 2a)t} > x_i \quad (19)$$

We first integrate over the density of $x_i$ conditional on the preference for the quality attribute so that the expected length of the horizontal segment that corresponds to firm 2 is the following:

$$q_2 = \frac{S(S - 2a)t - \theta_i (z_1 - z_2) + \alpha(p_1 - p_2) + \beta(p_1 - \tilde{p})}{2(S - 2a)t} \quad (20)$$

The next step is to simplify the density for the distribution of preferences for the quality attribute so that $dF(\theta_i) = \frac{1}{\theta_H - \theta_L}$ which implies that at any point of the horizontal segment, the mean preference for any level of quality is given by $m = \frac{\theta_H + \theta_L}{2}$. In addition we have imposed an upper bound to $\theta_H$ so that $(\alpha + \beta)(p_1 - p_2) + \frac{S(S - 2a)}{(z_1 - z_2)t} \geq \theta_H$. Therefore, integrating over the space of the distribution of $\theta_i$ we obtain the demand function for the firm 2:

$$Q_2(p, z) = \frac{S(S - 2a)t - m(z_1 - z_2) + \alpha(p_1 - p_2) + \beta(p_1 - \tilde{p})}{2(S - 2a)t} \quad (21)$$

where $p$ and $z$ are the corresponding vectors of prices and qualities.

Given our assumption of full coverage of the population and the assumption that $\theta_H - \theta_L = 1$, then $m(\theta_L) = \frac{1}{2} + \theta L$ and the total demand for firm 1 is:

$$Q_1(p, z) = \frac{S(S - 2a)t + m(z_1 - z_2) - \alpha(p_1 - p_2) - \beta(p_1 - \tilde{p})}{2(S - 2a)t} \quad (22)$$

As noted in the corresponding section, the internal reference pricing implies $\tilde{p} = p_2$ because it is expected that the generic entrant if it enters it does so providing a low
quality product. Denote $\Delta z = z_1 - z_2$ and $\Delta p = p_1 - p_2$, and also $\gamma = \alpha + \beta$ then the demand system is:

$$Q_1(\Delta p, \Delta z) = \frac{S(S - 2a)t + m\Delta z - \gamma \Delta p}{2(S - 2a)t}$$ \quad (23)

$$Q_2(\Delta p, \Delta z) = \frac{S(S - 2a)t - m\Delta z + \gamma \Delta p}{2(S - 2a)t}$$ \quad (24)

**B Derivation of the level of investment of the incumbent that makes entry unprofitable for a general $F$**

we can use (13) to find a reduced form profit function for firm 2 as a function of the strategic decisions of the incumbent:

$$\pi_2(z_1) = \frac{1}{18(S - 2a)\gamma s_1^2} \left( (s_1 - m^2)(s_0 - mz_1) \right)^2 - \frac{m^2(s_0 - mz_1)^2}{2s_1^2} - F$$ \quad (25)

Consider the expression this expression and equalize $\pi_2(z_1) = 0$. From the definition of $s_1$ we may rewrite this equation in the following way:

$$\frac{1}{(s_1 + m^2)s_1^2}(s_1 - m^2)^2(s_0 - mz_1)^2 - \frac{m^2(s_0 - mz_1)^2}{s_1^2} = 2F$$ \quad (26)

Next factorize $(s_0 - mz_1)^2$ and rewrite the latter equation:
\[(s_0 - mz_1)^2 \left(\frac{(s_1 - m^2)^2}{(s_1 + m^2)^2} - m^2\right) = s_1^2 F \tag{27}\]

Now, the latter equation may be solved for \(z_1\):

\[z_1 = \xi_1 = \frac{s_0}{m} - \frac{1}{m} 2^{\frac{1}{2}} \left(\frac{(s_1 + m^2)s_1}{s_1 - 3m^2}\right)^{\frac{1}{2}} F^{\frac{1}{2}} \tag{28}\]

Therefore whenever \(F > 0\) the level of marketing investment of the incumbent that makes entry unprofitable is lower than \(\frac{s_0}{m}\).

**C Predictions with no RP and fully horizontally differentiated products**

In this appendix we briefly study the case in Proposition 1 under the circumstance that products are fully horizontally differentiated, that is when firms are located at the corresponding edges of the line segment \([0, S]\), \(l_1 = S\) and \(l_2 = 0\). To this aim we show the numerical solutions of Proposition 1 for the case in which products are close the center of the line segment, specifically we will show the case for \(a' = 0.4S\) and the case for which \(a'' = 0\) and an intermediate level of horizontal product differentiation.

The following table shows the market equilibriums for the corresponding levels of horizontal product differentiation, and additional how the results changes when the efficiency advantage changes from \(c = 2\) to \(c = 3\) so as to provide some robustness check. As it can be seen, when product differentiation is greater quality differentials reduces as the quality investment from the incumbent reduces and the potential entrant’s quality investment increases as it has incentives to profit from higher quality consumers that are now much far away from its competitor. This implies a negative effect for the incumbent’s price and a positive effect for the entrant’s price, however from the corresponding equilibrium price equations (10) and (11), more horizontal product differentiation implies higher market power so that the price of the incumbent always increases.

The potential entrant is able to capture a relatively larger proportion of the market, therefore its expected profit increases. This result observed is irrespective of the size of the efficiency of the incumbent, however as more efficiency implies higher quality investments, all the levels are changed.

As noted before in the main body text of this paper, the case of full horizontal differentiation can be put in terms of a situation in which the potential entrant is a large laboratory that has already developed an alternative drug based on an alternative active ingredient and is seeking to profit from a market in which the incumbent has already been present with its product for some time. Price competition is softened by the horizontal dimension of the model. Note also that the model predicts that the differences between an equilibrium where the incumbent has no efficiency, or the previous length of patent protection was not relevant in explaining is ability
to invest in marketing, and an equilibrium in which the incumbent has an efficiency advantage are smaller whenever the horizontal differentiation is extreme.

Table 5: Market equilibrium for different degrees of product differentiation

<table>
<thead>
<tr>
<th>c = 2</th>
<th>$z_1^*$</th>
<th>$z_2^*$</th>
<th>$z_1^* - z_2^*$</th>
<th>$p_1^*$</th>
<th>$p_2^*$</th>
<th>$Q_2^*$</th>
<th>$\pi_2^*$</th>
</tr>
</thead>
<tbody>
<tr>
<td>a=0.4</td>
<td>0.484</td>
<td>0.290</td>
<td>0.194</td>
<td>0.565</td>
<td>0.435</td>
<td>0.435</td>
<td>0.148</td>
</tr>
<tr>
<td>a=0.2</td>
<td>0.363</td>
<td>0.331</td>
<td>0.032</td>
<td>1.511</td>
<td>1.489</td>
<td>0.496</td>
<td>0.685</td>
</tr>
<tr>
<td>a=0</td>
<td>0.350</td>
<td>0.333</td>
<td>0.017</td>
<td>2.506</td>
<td>2.494</td>
<td>0.499</td>
<td>1.189</td>
</tr>
<tr>
<td>c = 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a=0.4</td>
<td>1.023</td>
<td>0.136</td>
<td>0.886</td>
<td>0.795</td>
<td>0.205</td>
<td>0.205</td>
<td>0.033</td>
</tr>
<tr>
<td>a=0.2</td>
<td>0.571</td>
<td>0.314</td>
<td>0.256</td>
<td>1.585</td>
<td>1.415</td>
<td>0.472</td>
<td>0.618</td>
</tr>
<tr>
<td>a=0</td>
<td>0.538</td>
<td>0.324</td>
<td>0.214</td>
<td>2.571</td>
<td>2.429</td>
<td>0.486</td>
<td>1.127</td>
</tr>
</tbody>
</table>