Chapter 3

The Effect of Generic Goods in the Pharmaceutical Industry

3.1 Introduction.

The so-called generic pharmaceuticals are those drugs for which their patents on the active ingredient have expired. Their main characteristic is that they are sold at a cheaper price than the already established, branded, medicine. In all but few cases, and referring to the US, these generics are certified by the FDA (Food and Drug Administration) to be perfect substitutes to the branded good in that their active ingredient is identical. Furthermore, they are bioequivalent in the sense of being statistically indistinguishable from the established product in key aspects of therapeutic use. However, they could vary in characteristics such as shape, colour, packaging and labelling. Taking into account the fact that not all consumers switch immediately to generics gives support to the idea of both goods not being perfect substitutes.

During the 1980s, and especially in the US, there has been a dramatic increase in the spread of generic drugs into markets for pharmaceutical products. For example, the volume of sales of generics in the US accounts for 50% of the total volume of sales of prescribed medicines. The mean in the European Union is around 35%. Both figures are very high compared to the 2% in Spain (NERA 1997). However, Spain has been a peculiar country in this respect, and we will not go into the details of why this has been so. The interested reader will find a description of the Spanish pharmaceutical industry in N.E.R.A. (1997)

and Mestre-Ferrándiz (1999). These figures compared with the figures for 1984 (de Wolf (1988)), as shown in Table 1, reflect the increase in the use of generics. The difference between the US and Europe will be explained throughout the introduction.

Table 1 Total generic sales as % drug sales (1984,1996)

	Year	*Year*
Country	1984	1996
Spain	1.5	2
Total Europe	3	35
USA	15	50

Source: N.E.R.A. (1997) and de Wolf (1988).

The question that arises is why should we be interested in the production of generics and why should they be economically viable? Due to their lower prices with respect to the branded good, their production and use has been promoted by the public administration. In the case of the US, for example, regulation of the pharmaceutical industry has seen different phases. The Kefauver-Harris Act of 1962 enforced the FDA to issue more stringent rules governing new drug testing and approval and reducing the effective patent protection period by delaying the time of approval. This was due to the considerable monopoly power of well-accepted drugs associated with informational failures, physician decision making and third party payment, which reduced the price elasticity of demand to lower level than it otherwise would be. At the same time, the ability of generics to compete was reduced considerably because they had to duplicate the approval tests of the original drug, which are generally very costly. The Waxman-Hatch Act (1984) tried to solve the two problems of the reduced effective patent period and the high degree of difficulty for the generic drug to enter the market once the patent had expired. This was done by extending the life of drug patents and by simplifying the procedures required to approve generic substitutes without patent protection. Generic drugs did not have to duplicate many of the original product

tests to gain approval, but only required a bioequivalence demonstration to the pioneer's brand. This Act had the desired effect of stimulating competition against drugs whose patent protection had expired.

In Europe, in many countries such as Belgium, France, Italy, Spain and the Scandinavian countries, the prescription pattern is influenced by making positive lists, or by placing generics in a superior reimbursement category. Further, availability of generics is encouraged by abbreviated registration procedures in all European countries.

Economic motives other than promoting competition exist for encouraging the use and production of generics both on the part of governments subsidising social health funds as well as the part of consumers who pay for the medicines themselves. For instance, in Spain, even though there is no specific policy to encourage the use of generics, the Ministry of Health has announced the willingness to promote the use of generics in the National Health System as a way of reducing costs. In other countries, such as France, whenever there exist various medicines in the market with the same therapeutic value, general practitioners have to prescribe the cheapest one. Furthermore, the French government has promised, through the Agènce du Médicament, to double the number of generics before the end of 1999 (El Pais, Thursday 19 February, 1998, p. 25).

One of the main factors that could explain generic substitution is the intensified pressure from third party payers to minimise drug prices. In Caves et al. (1991) it is pointed out that the substitution rates from branded to generic goods on Medicaid prescriptions more than doubled prescriptions subject to reimbursement with respect to private insurers. Medicaid, which takes care of US federal medical expenditure for the poor, has imposed reimburse-

ment limits to generic levels, if they exist. Furthermore, the growth of Health Maintenance Organisations (HMOs) has also encouraged the use of generics. HMOs provide health coverage to approximately 11% of the US population and on average, 31% of all HMO pharmacy claims are for generics, compared to the 14% of insurance plans that cover fee-for-service medical practice (Frank and Salkever 1997).

With respect to the supply side, it is argued in the literature that there seem to be little or no barriers to entry. This implication is due to the provisions previously mentioned of the Waxman-Hatch Act (Frank and Salkever 1992). Hence, the primary impediments seem to come from the demand side. The first impediment refers to the accumulated goodwill of branded producers, and any concerns about the difference in quality between the two products. This point will be analysed later. The second impediment comes from the role the pharmacist and the consumer play in deciding whether the original brand or the generic is dispensed, once the physician has prescribed the drug and a generic is available. Before 1984, generic substitution was precluded once the physician had dispensed the brand name, although these anti-substitution laws have now been universally rejected and pharmacists are allowed to dispense generics. In Europe, however, generic substitution is not permitted by the pharmacist. This is one of the reasons that could explain the pattern shown in Table 1.

The effect of the introduction of these generics on the price of the already-established branded good has been a source of controversy. Various empirical estimates obtained to measure the price response of branded goods in the face of entry give rise to different conclusions. Frank and Salkever (1992) study a sample of 32 drugs that lost patent protection

during the early to mid-1980s, providing evidence that branded prices have increased after generic entry. Grabowski and Vernon (1992) obtain similar results when estimating the effect of generic entry on prices for 18 high-sales-volume pharmaceutical products when first exposed to generic competition during the mid 1980s. They compared prices before generic entry and prices one year after entry, estimating a negative coefficient for the number of generics on the ratio of generic to branded price, which is of course consistent with brand-name prices rising relative to generic prices after generic entry.

Caves et al. (1991) studied 30 drugs that lost their patent between the years 1976 and 1987. They estimated a 2% reduction in brand name prices after patent loss, while entry by 20 generics caused a 17% price decrease in branded goods. These reductions were viewed as very small price responses to entry.

However, it seems that the most widely accepted view is that brand-name prices have increased after generic entry, rather than observing a two-way price rivalry between branded and generic drug suppliers in order to deter entry. The most common scenario after generic entry is then that the branded good's price is maintained or increased, while losing market share to lower-priced generics. Furthermore, as the number of generics increases, its price is reduced.

This "Generic Competition Paradox", as expressed by Scherer (1993), could be explained by two institutional regularities. First, physicians tend to be reluctant to switch to generics. Not only is the menu of drugs so vast that is virtually impossible for physicians to have full information about all the possible alternatives available, but also the tendency to stick to brand-name pattern of prescription habits as well as the positive attributes ascribed to

branded goods in terms of general reputation makes physicians prescribe more expensive drugs when cheaper ones exist. Pharmaceuticals are usually considered to benefit from first-mover pricing advantages, as Grabowski and Vernon (1992) note:

> "under conditions like those found in pharmaceuticals, first movers have natural product differentiation advantages that permit to charge high prices and retain substantial market shares."

Hence, this strong brand loyalty has made physicians gain experience with the drug under the period of patent exclusivity, making them insensitive to lower price opportunities. A Dutch study (de Wolf 1988) interviewing 200 prescribing physicians shows their reluctance to switch to generics since generic goods were badly represented in the doctor's preferred set of drug names. Secondly, and from the point of view of the consumer purchasing drugs at the retail pharmacy, they usually lack the knowledge to evaluate the alternatives to branded goods. This effect is reinforced with wholesalers and pharmacists who have greater incentives to sell more expensive drugs, specially when pharmacies charge a fixed percentage margin by product sold. This percentage, given a base retail price of 100, ranges from 22.0 in the UK to 28.2 in Spain and 29.0 in France (NERA 1997). This is in contrast to the USA, where Masson and Steiner (1985) provide evidence that generic products usually carry higher gross margins to pharmacists which implies that both the consumer and the pharmacist will be willing to substitute. This difference could be another reason which could explain Table 1.

Hence, when the generic drug is introduced, we could say, without oversimplifying, that drug buyers can be of two different types: those who are price-insensitive to generics and those who are not. With no generics, the problem is standard, but when generics are intro-

duced at a lower price, we have to take into account this market segmentation effect, since we could argue that the branded-good seller prefers to increase price in the price-insensitive market segment and desert the other segments rather than to reduce price to the price sensitive customers. Hence, if we see from empirical results that branded goods have increased in price, then we could reasonably argue that this price discrimination argument yield superior profits. This is the approach taken by Frank and Salkever (1992). They find conditions supporting this empirical fact, and use for this purpose a market segmentation model with one firm producing the branded good and a competitive fringe producing a homogeneous generic drug i.e. they propose a model à la Stackelberg, with a leader - the pioneer firm- and a follower - the competitive fringe.

Several authors have argued that first-mover advantages also exist in the market for generics. In particular, one hypothesis to explain large shares obtained by certain generic firms is that if these introduce the generic several months before their rivals, they will obtain a significant market advantage. Grabowski and Vernon (1992) indicate that for the sample they study, for virtually all products the market leader is an early entrant. Of course, this hypothesis is in line with branded good manufacturers producing their own generic alternative. Lobo (1996) argues that these firms have a natural advantage to produce their own generic version. Furthermore, that can undertake the necessary studies and tests for the certification of the generic good during the patent life of their branded good, so that they are the first in the market, earning higher market shares than their competitors as argued above. If this is so, as Liang (1996) notes, this may lead “late” entrants which are considering en-

try into the market to choose not to enter. The result could be a significant reduction in competition due to the first-mover advantage of the brand-name manufacturer.

Therefore, if we take the US pharmaceutical sector as an example to be used where the generic is well established, we could examine the situation when the generic is already in the market. With this approach, we could have many possible situations, although we will restrict ourselves to the pioneer firm producing its generic alternative, or rather, having a third firm producing it. With this in mind, an interesting question then arises: are there incentives for the pioneer firm to produce the generic itself ? This question could then be extended to include consumer surplus, and hence say under what situation will consumer surplus be greater.

In order to try to answer these questions, we will use a simple market segmentation model with two firms producing a branded good with a different active ingredient. However, and for simplicity, we will assume that both goods are perfect substitutes. As an example, consider two branded drugs; Aspirin, whose active ingredient is acetylsalicylic acid, and Gelocatil whose active ingredient is paracetamol. Some years ago, Bayer's patent on Aspirin expired and a generic is already in the market. The question that is posed in this paper is then under what conditions will Bayer prefer to produce the generic itself, rather than not producing it and letting a third firm produce it, always taking into account that whoever introduces the generic, its price must be lower than the one for Aspirin. Of course, an obvious question following the previous one is under what situation consumers will be better off. Note, that for simplicity, we assume that only the patent for Aspirin has expired and one generic is allowed.

The approach will be as follows. Due to the complexity of obtaining an analytical result with a very general model, we try to restrict ourselves in order for the analysis to be tractable. Hence, we will give functional forms to the demand curves and cost functions, and some “ad hoc” assumptions will be made in order to reduce the number of parameters. The model will be set up in the following way: there exist two branded goods and a generic of the one that has lost its patent. Due to the existence of the generic good, consumers can be divided into two types, those whose demand for the branded good is unaffected by the existence of the generic good (“loyal”consumers), and those whose demand is affected by the generic good (“sensitive” consumers). Therefore, we have the consumers who may buy the generic and whose demand could in principle depend positively on the price of the branded good.

With respect to the technology of producing the branded and the generic good, we will assume that the marginal cost of the generic drug is lower than the marginal cost of the branded good. This is a realistic assumption since due to the characteristics of the two goods, costs of packaging and labelling for the branded good are usually higher, since generics usually come in white boxes without any labelling or colour. With respect to the possibility of access to technology by the third firm, we will assume that technology is freely available. However, if the pioneer firm decides to produce the generic, it does not need to incur any extra fixed costs, since it has the technology required, which we assume is similar to the one used to produce the branded good.

The paper is organised as follows. Section 2 introduces a general market segmentation model. In section 3, we introduce particular functional forms on demand and cost. Also we

solve the model under two alternative scenarios, (i) the firm producing the branded good whose patent has expired also produces its generic alternative; (ii) a third firm produces the generic good. In section 4 we compare the solutions obtained and define the conditions under which the established firm will have incentives to produce the generic itself. Consumer surplus is also compared in this section. Section 5 concludes and provides an agenda for future research.

3.2 The Model.

3.2.1 General Set-up.

Consider a situation where to cure a certain illness (say “headache”) there exist two alternative drugs. For illustrative purposes, call them Aspirin, produced by Bayer, and denoted as firm A, and Gelocatil produced by Gelos and denoted as firm B. However, for simplicity, we will consider the case for these two goods to be perfect substitutes. Bayer has lost its patent over acetylsalicylic acid several years ago and a generic substitute exists for Aspirin, with the condition that its price has to be lower than the price of the branded good. This generic can be produced only by one firm, either by the already established, pioneer, firm or by a third firm which only produces the generic.

Market demand for branded medicines can be thought of as composed of two elements. There are consumers insensitive to the generic, together with consumers whose decision depend both on the prices of the branded good as well as the price of the generic.

Finally, demand for the generic drug depends on its own price as well as the price of the branded alternatives.

To be precise, demand functions for branded goods are

$$q_i(p_i, p_j, p_G) = q_{i1}(p_i,p_j) + q_{i2}(p_i, p_j, p_G), \tag{77}$$

where $i = A, B; \qquad j \neq i; \qquad p_G = price\ of\ the\ generic,$

and

$$\frac{\partial q_{i1}(p_i,p_j)}{\partial p_i} \leq 0, \qquad \frac{\partial q_{i1}(p_i,p_j)}{\partial p_j} \geq 0,$$

$$\frac{\partial q_{i2}(p_i,p_j)}{\partial p_i} \leq 0, \ \frac{\partial q_{i2}(p_i,p_j)}{\partial p_j} \geq 0, \ \frac{\partial q_{i2}(p_i,p_j)}{\partial p_G} \geq 0.$$

Demand for the generic drug is:

$$q_G(p_i, p_j, p_G), \tag{78}$$

where

$$\frac{\partial q_G(p_i, p_j, p_G)}{\partial p_G} \leq 0, \ \frac{\partial q_G(p_i, p_j, p_G)}{\partial p_i} \geq 0, \ \frac{\partial q_G(p_i, p_j, p_G)}{\partial p_j} \geq 0.$$

As mentioned above, we present two alternative configurations of the supply side of the market. In the first one, firm A produces both the branded good and its generic, while the alternative scenario consists of three single-product firms.

3.2.2 Two firms (A, B) producing the branded goods; firm A produces the generic.

The profit function for firm A is given by

$$\begin{aligned}\pi_A(p_A, p_B, p_G) = p_A\left[q_{A1}(p_A, p_B) + q_{A2}(p_A, p_B, p_G)\right] \\ +p_G\left[q_G(p_A, p_B, p_G)\right] \\ -C_A\left[q_{A1}(p_A, p_B) + q_{A2}(p_A, p_B, p_G), q_G(p_A, p_B, p_G)\right].\end{aligned} \tag{79}$$

The profit function for firm B, which does not produce the generic, is given by

$$\begin{aligned}\pi_B(p_A, p_B, p_G) = p_B\left[q_{B1}(p_A, p_B) + q_{B2}(p_A, p_B, p_G)\right] \\ -C_B\left[q_{B1}(p_A, p_B) + q_{B2}(p_A, p_B, p_G)\right].\end{aligned} \tag{80}$$

We will consider the Nash (non-cooperative) equilibrium concept, where each firm chooses the strategy that maximises its own profit, given the strategy of its rival. Formally, and referring to our case, we have the following definition:

Definition 1 *A vector of prices* $p^* = (p_A^*, p_B^*, p_G^*)$ *is said to form a Nash equilibrium if and only if* p_A^*, $p_G^* = \arg p_A, p_G \max\, \pi_A(p_A, p_B, p_G)$ *s.t.* $p_B = p_B^*$ *and* $p_B^* = \arg p_B \max\, \pi_B(p_A, p_B, p_G)$ $s.t.$ $p_A = p_A^*$ *and* $p_G = p_G^*$.

Notice that firm A's strategy will be to choose (simultaneously) two prices p_A, p_G, subject to the constraint that $p_G \leq \alpha p_A$, with $0 < \alpha < 1$. Recall that this constraint is introduced

to take into account the regulation procedures whereby the price of the generic good has to be lower than the price of the branded good.

Hence, the problem for firm A becomes

$$\underset{p_A,p_G}{Max}\ \pi_A(p_A,p_B,p_G)\ s.t.\ p_G \leq \alpha p_A. \tag{81}$$

Solving the problem amounts to formulate the following auxiliary Lagrangean function:

$$\begin{aligned}\pounds\ (p_A,p_G,\lambda) = p_A\left[q_{A1}(p_A,p_B)+q_{A2}(p_A,p_B,p_G)\right]+p_G\left[q_G(p_A,p_B,p_G)\right]\\ -C_A\left[q_{A1}(p_A,p_B)+q_{A2}(p_A,p_B,p_G),q_G(p_A,p_B,p_G)\right]\\ +\lambda(\alpha p_A-p_G),\end{aligned} \tag{82}$$

whose Khun-Tucker conditions are

$$\begin{aligned}\frac{\partial \pounds\ (p_A,p_G,\lambda)}{\partial p_A} = q_{A1}+q_{A2}+\left(p_A-\frac{\partial C_A}{\partial q_A}\right)\left(\frac{\partial q_{A1}}{\partial p_A}+\frac{\partial q_{A2}}{\partial p_A}+\frac{\partial q_{A2}}{\partial p_G}\frac{\partial p_G}{\partial p_A}\right)\\ +\left(p_G-\frac{\partial C_A}{\partial q_G}\right)\left(\frac{\partial q_G}{\partial p_A}+\frac{\partial q_G}{\partial p_G}\frac{\partial p_G}{\partial p_A}\right)+\lambda\alpha\leq 0,\end{aligned} \tag{83}$$

$$p_A\left(\frac{\partial \pounds\ (p_A,p_G,\lambda)}{\partial p_A}\right)=0, \tag{84}$$

$$\begin{aligned}\frac{\partial \pounds\ (p_A,p_G,\lambda)}{\partial p_G} = q_G+\left(p_A-\frac{\partial C_A}{\partial q_A}\right)\left(\frac{\partial q_{A1}}{\partial p_A}\frac{\partial p_A}{\partial p_G}+\frac{\partial q_{A2}}{\partial p_G}+\frac{\partial q_{A2}}{\partial p_A}\frac{\partial p_A}{\partial p_G}\right)\\ +\left(p_G-\frac{\partial C_A}{\partial q_G}\right)\left(\frac{\partial q_G}{\partial p_G}+\frac{\partial q_G}{\partial p_A}\frac{\partial p_A}{\partial p_G}\right)-\lambda\leq 0\end{aligned} \tag{85}$$

$$p_G\left(\frac{\partial \pounds\left(p_A, p_G, \lambda\right)}{\partial p_G}\right) = 0, \tag{86}$$

$$\frac{\partial \pounds\left(p_A, p_G, \lambda\right)}{\partial \lambda} = \alpha p_A - p_G \geq 0, \tag{87}$$

$$\lambda\left(\frac{\partial \pounds\left(p_A, p_G, \lambda\right)}{\partial \lambda}\right) = 0, \tag{88}$$

$$p_A \geq 0, p_G \geq 0, \lambda \geq 0. \tag{89}$$

Before going into the details, notice that from (3.83),

$$\begin{aligned} q_{A1} + q_{A2} + \left(p_A - \frac{\partial C_A}{\partial q_A}\right)\left(\frac{\partial q_{A1}}{\partial p_A} + \frac{\partial q_{A2}}{\partial p_A} + \frac{\partial q_{A2}}{\partial p_G}\frac{\partial p_G}{\partial p_A}\right) \\ + \left(p_G - \frac{\partial C_A}{\partial q_G}\right)\left(\frac{\partial q_G}{\partial p_A} + \frac{\partial q_G}{\partial p_G}\frac{\partial p_G}{\partial p_A}\right) + \lambda\alpha \leq 0 \end{aligned}$$

and given that $\lambda\alpha$ and $q_{A1}+q_{A2}$ are non-negative, as well as $\left(p_A - \frac{\partial C_A}{\partial q_A}\right)$ and $\left(p_G - \frac{\partial C_A}{\partial q_G}\right)$, which are the mark-ups of price over marginal cost, then the response of q_A and/or q_G to a change in p_A has to be negative for the first order condition to be satisfied. This price response consists of a direct effect, which works through q_A and q_G, the latter being non-negative while the former being non-positive, and an indirect effect, working through p_G's reaction function in terms of p_A. From the assumption of the signs of the derivatives on the demand functions, it implies that if $\dfrac{\partial p_G}{\partial p_A} > 0,$ the reduced form demand curve, which is the one that only takes into account the direct effects, will be less own-price elastic than

the ordinary demand curve, which takes into account both the direct and the indirect effect, for the branded good for firm A.

From (3.85), we can say something similar with respect to the demand curve for the generic good. When $\lambda = 0,$ since

$$q_G + \left(p_A - \frac{\partial C_A}{\partial q_A}\right)\left(\frac{\partial q_{A1}}{\partial p_A}\frac{\partial p_A}{\partial p_G} + \frac{\partial q_{A2}}{\partial p_G} + \frac{\partial q_{A2}}{\partial p_A}\frac{\partial p_A}{\partial p_G}\right) + \\ + \left(p_G - \frac{\partial C_A}{\partial q_G}\right)\left(\frac{\partial q_G}{\partial p_G} + \frac{\partial q_G}{\partial p_A}\frac{\partial p_A}{\partial p_G}\right) \leq 0,$$

and given that $q_G,$ $\left(p_A - \frac{\partial C_A}{\partial q_A}\right)$ and $\left(p_G - \frac{\partial C_A}{\partial q_G}\right)$ are all non-negative, in addition to the signs of the derivative of the demand functions, the effect of a change in the price of the generic on the demand for the branded good of firm A and/or on the demand for the generic must be negative for the first order condition to be satisfied. Again, we have two effects, direct plus indirect, the indirect working through the price reaction function of p_A in terms of p_G. Hence, if $\frac{\partial p_A}{\partial p_G} > 0,$ then the reduced form demand for the generic will be less own-price elastic than the ordinary demand curve.

Firm B, however, does not have to maximise profits subject to any constraint since it does not produce the generic, and will have the following program:

$$\underset{p_B}{Max}\ \pi_B(p_A, p_B, p_G). \tag{90}$$

The first order condition (FOC) is given by

$$\frac{\partial\, \pi_B(p_A, p_B, p_G)}{\partial p_B} = q_{B1} + q_{B2} + \left(p_B - \frac{\partial C_B}{\partial q_B}\right)\left(\frac{\partial\, q_{B1}}{\partial p_B} + \frac{\partial\, q_{B2}}{\partial p_B}\right) = 0. \qquad (91)$$

The set of FOCs allows us to obtain a candidate equilibrium price vector $p^{1*} = (p_A^{1*}, p_B^{1*}, p_G^{1*})$ up to satisfaction of the second order condition (SOC). Note that the 1 in the superscript stands for scenario 1.

3.2.3 Two firms (A, B) producing the branded goods; firm C produces the generic.

In this case, a third firm, C, produces the generic drug, again taking into account that the price of the generic is lower than the price of the pioneer good. Now, we need to solve the profit maximisation program for three firms, in order to obtain a Nash (noncooperative) equilibrium, which can be defined formally in this scenario as:

Definition 2 *A vector of prices $p^* = (p_A^*, p_B^*, p_G^*)$ is said to form a Nash equilibrium if, for every firm i=A,B,C, p_i* maximises firm i' s profit, given that the other firms play the strategy specified by p^*_{-i}.*

The profit function for firm A will then be:

$$\pi_A(p_A, p_B, p_G) = p_A\left[q_{A1}(p_A, p_B) + q_{A2}(p_A, p_B, p_G)\right] \qquad (92)$$
$$-C_A\left[q_{A1}(p_A, p_B) + q_{A2}(p_A, p_B, p_G)\right].$$

with the following program:

$$\underset{p_A}{Max}\ \pi_A(p_A, p_B, p_G). \tag{93}$$

The first order condition that results is

$$\frac{\partial \pi_A(p_A, p_B, p_G)}{\partial p_A} = q_{A1} + q_{A2} + \left(p_A - \frac{\partial C_A}{\partial q_A}\right)\left(\frac{\partial q_{A1}}{\partial p_A} + \frac{\partial q_{A2}}{\partial p_A}\right) = 0. \tag{94}$$

Note that firm B's program will be symmetric to A's and the FOC is the same as (3.91). When firm C chooses p_G in order to maximise its profit, he does so subject to the constraint that $p_G \leq \alpha p_A$. Hence, we have to set up a Lagrangean for firm C, and solve using Kuhn-Tucker conditions again. The program for firm C is then,

$$\underset{p_G}{Max}\ \pi_C(p_A, p_B, p_G) = p_G\left[q_G(p_A, p_B, p_G)\right] - C_C\left[q_G(p_A, p_B, p_G)\right] \tag{95}$$
$$s.t.\ p_G \leq \alpha p_A,$$

resulting in the following Lagrangean function

$$\pounds\left(p_G, \mu\right) = p_G\left[q_G(p_A, p_B, p_G)\right] - C_C\left[q_G(p_A, p_B, p_G)\right] + \mu(\alpha p_A - p_G). \tag{96}$$

The Kuhn-Tucker conditions that come out from this maximisation program are

$$\frac{\partial \pounds\left(p_G, \mu\right)}{\partial p_G} = q_G + \left(p_G - \frac{\partial C_C}{\partial q_G}\right)\left(\frac{\partial q_G}{\partial p_G}\right) - \mu \leq 0, \tag{97}$$

$$p_G\left(\frac{\partial \pounds\left(p_G,\mu\right)}{\partial p_G}\right)=0, \tag{98}$$

$$\frac{\partial \pounds\left(p_G,\mu\right)}{\partial \mu}=\alpha p_A-p_G\geq 0, \tag{99}$$

$$\mu\left(\frac{\partial \pounds\left(p_G,\mu\right)}{\partial \mu}\right)=0, \tag{100}$$

$$p_G\geq 0,\mu\geq 0. \tag{101}$$

With this set of FOCs, we can find equilibrium prices $p^{2*}=(p_A^{2*},p_B^{2*},p_G^{2*})$ up to satisfying the SOCs. Note again that the 2 in the superscript refers to scenario 2.

3.2.4 Comparing the two scenarios.

Once we have solved for the equilibrium prices for the two different cases, and profits are evaluated, we would like to compare the level of profits for firm A in order to see under what conditions it has incentives to produce the generic itself. Another interesting comparison would be to compute total consumer surplus for both situations, and compare welfare levels. Recall that consumer surplus is the area under some individuals's demand curve. For example, for the individuals whose demand function is given by $q_{A1}(p_A,p_B)$, we get that the consumer surplus for those individuals between price p and an arbitrary price $\tilde{p}$ is given by

$$CS^{A1} = \int_{p}^{\tilde{p}} q_{A1}(\xi, p_B) d\xi. \tag{102}$$

Of course, we will be interested in comparing consumer surplus in equilibrium, so we would like to evaluate them given equilibrium prices. Hence, and again using $q_{A1}(p_A, p_B)$ as an example, we would like to find the consumer surplus for that segment at p_B^* i.e. we are interested in

$$CS^{A1} = \int_{p^*}^{\tilde{p}} q_{A1}(\xi, p_B^*) d\xi. \tag{103}$$

In order to find total consumer surplus, we need to sum up the consumer surplus for all the demand curves for each scenario, so that we are able to compare them.

3.3 A Specific Set-up.

In order to obtain specific expressions for equilibrium prices and hence be able to compare between the two scenarios proposed, we will give particular functional forms to the demand and cost functions.

3.3.1 Two firms (A, B); firm A produces the generic.

The demand functions for the branded good for each firm will be, for firm A and firm B respectively, as follows:

$$q_{A1}(p_{A,}p_B) = a_{11} - a_{12}p_A + a_{13}p_B, \tag{3.104}$$

$$q_{A2}(p_A, p_B, p_G) = a_{21} - a_{22}p_A + a_{23}p_B + a_{24}p_G, \tag{3.105}$$

$$q_{B1}(p_{A,}p_B) = b_{11} - b_{12}p_B + b_{13}p_A, \tag{3.106}$$

$$q_{B2}(p_A, p_B, p_G) = b_{21} - b_{22}p_B + b_{23}p_A + b_{24}p_G. \tag{3.107}$$

The demand function that firm A will face for the generic is

$$q_G(p_A, p_B, p_G) = g_1 - g_2p_G + g_3p_A + g_4p_B. \tag{108}$$

Notice that, by construction, all price coefficients have to be positive. With respect to the cost function faced by firm A, it will be as follows:

$$C_A(q_{A1} + q_{A2,}q_G) = K_A + c_A\left(q_{A1} + q_{A2}\right) + c_Gq_G, \tag{109}$$

where, by assumption, $c_G \leq c_A$. Notice that implicitly, with this cost function, we are making the assumption that the costs for the branded and the generic good are independent. However, we could have dependent costs, which could give rise to economies of scope. Hence, the profit function for firm A becomes

$$\pi_A(p_A, p_B, p_G) = (p_A - c_A)\left[q_{A1}(p_A, p_B) + q_{A2}(p_A, p_B, p_G)\right] \tag{110}$$

$$+ (p_G - c_G)\left[q_G(p_A, p_B, p_G)\right] - K_A.$$

Full derivations of the FOCs for firm A and B are available from the author. These are used to find the equilibrium prices. However, and due to the large number of parameters involved, the following assumptions are made.

Assumptions

- Due to the demand barriers to entry discussed in the introduction, we will assume that the size of the market for branded goods is twice the size of the generic. Hence, we have that $a_{11} = a_{21} = b_{11} = b_{21} = 1$ and therefore $g_1 = 2$.

- There exists symmetry between the consumers buying either of the branded goods, which implies having the same parameters on the demand functions faced by firm A and B. The two branded goods are considered to be perfect substitutes, which imposes further restrictions on the parameters. These assumptions imply that, for the demand-insensitive segments, we have $a_{12} = a_{13} = b_{12} = b_{13} = d_1$. However, we will assume that branded goods and the generic are not perfect substitutes, but rather, there exists a degree of differentiation between them. Hence, in order to take into account this, we require that $a_{22} = a_{23} = b_{22} = b_{23} = g_2 = d_2$ and $a_{24} = b_{24} = g_3 = g_4 = d_3$.

Therefore, we can reduce the system of demand equations as follows:

$$
\begin{aligned}
q_{A1}(p_A,p_B) &= 1 - d_1\left(p_A - p_B\right), \\
q_{A2}(p_A, p_B, p_G) &= 1 - d_2\left(p_A - p_B\right) + d_3 p_G, \\
q_{B1}(p_A,p_B) &= 1 - d_1\left(p_B - p_A\right), \\
q_{B2}(p_A, p_B, p_G) &= 1 - d_2\left(p_B - p_A\right) + d_3 p_G, \\
q_G(p_A, p_B, p_G) &= 2 - d_2 p_G + d_3(p_A + p_B).
\end{aligned}
$$

- With respect to the technology, as stated before, the marginal cost of the generic will be less than the marginal cost of the branded good. Firm A and B will have identical costs with respect to the branded good each produces, so $c_A = c_B$ and $K_A = K_B = K$. For simplicity, we will set $K = 2$. Again, for illustrative purposes, we will assume that $c_A = c_B = 1$, and $c_G = 0.8$.

- The parameter α measures how low the price of the generic should be compared to the price of the pioneer good. We will consider as an example the case for Spain, where the price of the generic has to be, at least, 20% less than the original brand. Hence, we fix $\alpha = 0.8$ for illustrative purposes.

Once we have imposed these assumptions, the Kuhn-Tucker conditions for firm A and first order conditions for firm B respectively are shown in Appendix 1.

Consider first the case $\lambda = 0$, which implies that the constraint is non-binding. Equilibrium prices then depend on $d_1, d_2,$ and d_3. Under this situation, for prices and quantities to be nonnegative, we need some coefficient to be negative, which is ruled out by assumption.

Hence, let us consider $\lambda > 0$, which implies $p_G = 0.8p_A$ i.e. the constraint is totally satiated. When solving for the equilibrium prices, we obtain the following:

$$
\begin{aligned}
p_A^{1*} &= \frac{230(d_1+d_2)+40d_3-60d_3(d_1+d_2)+182d_2d_1+107d_2^2+75d_1^2}{214d_2d_1-200d_3(d_2+d_1)-16d_3^2+139d_2^2+75d_1^2},\\
p_B^{1*} &= \frac{375d_1^2+950d_1+990d_2d_1-500d_3d_1-160d_3^2+1270d_2+615d_2^2-440d_3-436d_3d_2}{5\left(214d_2d_1-200d_3(d_2+d_1)-16d_3^2+139d_2^2+75d_1^2\right)},\\
p_G^{1*} &= \frac{4\left(230\left(d_1+d_2\right)+40d_3-60d_3(d_2+d_1)+182d_2d_1+107d_2^2+75d_1^2\right)}{5\left(214d_2d_1-200d_3(d_2+d_1)-16d_3^2+139d_2^2+75d_1^2\right)}.
\end{aligned}
$$

These prices need to satisfy the non-negativity constraint. If this is so, the equilibrium prices depend on the three parameters that we are interested in, and we can now evaluate the equilibrium profits of both firms, to obtain $\pi_A^{1*}(p_A^{1*}, p_B^{1*}, p_G^{1*})$ and $\pi_B^{1*}(p_A^{1*}, p_B^{1*}, p_G^{1*})$ which will depend on the same three parameters. Recall that the 1 refers to scenario 1.

3.3.2 Two firms (A, B) producing the branded goods; firm C produces the generic.

Under this scenario, we need to introduce a third firm which produces the generic. The maximisation programs for firms A and B are given by (3.93) and (3.90) respectively.

Notice, that due to the assumptions, and since firm A does not produce the generic anymore, both firm A and B are identical, so in equilibrium they will have same prices and hence same profits. With this in mind, we obtain the FOCs for the three firms, which are shown in Appendix 2.

We solve first when $\lambda = 0$. Again, prices and/or quantities are positive only if some coefficients are negative, so we rule out this case.

When $\lambda > 0,$ the constraint will be satiated, and we obtain the following equilibrium prices

$$p_A^{2*} = 5\left(\frac{2+d_1+d_2}{5d_1+5d_2-4d_3}\right), \tag{3.111}$$

$$p_B^{2*} = 5\left(\frac{2+d_1+d_2}{5d_1+5d_2-4d_3}\right), \tag{3.112}$$

$$p_G^{2*} = 4\left(\frac{2+d_1+d_2}{5d_1+5d_2-4d_3}\right). \tag{3.113}$$

Due to our assumptions, we obtain that in equilibrium, p_A and p_B will be equal. Notice that since the constraint is satisfied with equality, the firm producing the generic will only have to set its price equal to $0.8p_A$. With these prices, we can then evaluate the equilibrium quantities to obtain the equilibrium profits $\pi_A^{2*}(p_A^{2*}, p_B^{2*}, p_G^{2*})$, $\pi_B^{2*}(p_A^{2*}, p_B^{2*}, p_G^{2*})$ and $\pi_C^{2*}(p_A^{2*}, p_B^{2*}, p_G^{2*})$ in terms of the three parameters we are interested in. Note that for both cases, the equilibrium prices we have found satisfy the second order conditions.

3.4 Comparison of Both Scenarios.

3.4.1 Profits.

In order to compare profits, we have to do some kind of simulation due to the fact that the conditions that arise when comparing profits with three parameters are very difficult to analyse analytically. Hence, the strategy followed will be to fix some parameters, and do some comparative statics with the others, and see whether the conditions that give rise to higher profits in one scenario or the other are consistent as we change the parameters.

The first exercise is to fix d_1, increase $d_2,$ and find under what conditions for $d_3,$ firm A will have incentives to produce its generic alternative. Note that we need to consider the

intervals for d_3 that ensure that prices, quantities and the Lagrange multipliers in equilibrium are all non-negative. As an illustrative example, we will present the results obtained with $d_1 = 0.5$, and d_2 increasing. Note that the exercise was repeated for different fixed values of d_1 and the results did not change qualitatively. Moreover, increasing d_1 and d_2 at the same time has the same qualitative results as keeping d_1 fixed. A summary of the results are shown in Table 2. Notice that there exist more solutions, but we only consider non-negative values for d_3.

Table 2 Range for d3 for which prices and quantities for case 1 and 2 are non-negative.

$d_1 = 0.5$	$Range\ for\ d_3\ satisfying$	$Range\ for\ d_3\ satisfying$
d_2	$p_A^{1,2*}, p_B^{1,2*}, p_G^{1,2*} \geq 0$	$q_{A1}^{1,2*}, q_{A2}^{1,2*}, q_{B1}^{1,2*}, q_{B2}^{1,2*}, q_G^{1,2*} \geq 0$
0.5	$0 \leq d_3 < 0.51$	$0 \leq d_3 < 0.36$
1	$0 \leq d_3 < 0.84$	$0 \leq d_3 < 0.68$
1.5	$0 \leq d_3 < 1.17$	$0.04 \leq d_3 < 0.99$
2	$0 \leq d_3 < 1.51$	$0.22 \leq d_3 < 0.51$
2.5	$0 \leq d_3 < 1.83$	$0.47 \leq d_3 < 1.83$

Taking into account that d_3 has to lie in the regions shown in Table 2 for the specific values of d_1 and d_2, we can compare profits for firm A under both scenarios, for this illustrative example, and see whether it will have incentives to produce the generic itself. Computing profits for firm A (note that we also include the cases for all other profit levels to be positive), we get the results which are summarised in Table 3.

Table 3a Range for d3 for which profits for case 1 and 2 are non-negative.

$d_1 = 0.5$	$Range\ for\ d_3\ satisfying$
d_2	$\pi_A^{1,2*}(p_A^{1,2*}, p_B^{1,2*}, p_G^{1,2*}), \pi_B^{1,2*}(p_A^{1,2*}, p_B^{1,2*}, p_G^{1,2*}), \pi_C^{1,2*}(p_A^{1,2*}, p_B^{1,2*}, p_G^{1,2*}) \geq 0$
0.5	$0 \leq d_3 < 0.51$
1	$0.32 \leq d_3 < 0.84$
1.5	$0.57 \leq d_3 < 1.17$
2	$0.82 \leq d_3 < 2.24$
2.5	$1.06 \leq d_3 < 3.75$

Table 3b Range for d3 for which profits for firm A are greater in case 1.

$d_1 = 0.5$	$Range\ for\ d_3\ satisfying$
d_2	$\pi_A^{1*}(p_A^{1,2*}, p_B^{1,2*}, p_G^{1,2*}) \geq \pi_A^{2*}(p_A^{1,2*}, p_B^{1,2*}, p_G^{1,2*})$
0.5	$0 \leq d_3 < 0.66$
1	$0.07 \leq d_3 < 1.06$
1.5	$0.17 \leq d_3 < 1.46$
2	$0.35 \leq d_3 < 1.86$
2.5	$0.53 \leq d_3 < 2.26$

Therefore, combining Tables 2 and 3 together, it seems that firm A will always have incentives to produce the generic itself. Note that we are not interested in the numbers per se, but in the conditions that give rise to firm A making higher profits when it produces the generic.

Furthermore, under the range for d_3 that satisfies the required conditions, we get that the price that firm A is able to charge the consumers for its branded good can be higher for the first case i.e. when it produces the generic. Therefore, firm A is able to increase the price of its branded good under scenario 1 and make higher profits. Moreover, by producing the generic itself, firm A can charge a higher price for the generic than otherwise would charge firm C in scenario 2. Of course, this is so since the regulatory constraint is always satisfied, so that once firm A produces the generic, its price rises proportionately with the increase in the price of the branded good of firm A. Hence, the production of the generic good enables firm A to charge a different price than its competitor, something which is not profitable when there are three firms in the market.

An intuition behind this result could be that firm A is able to discriminate when it introduces the generic, since when the generic is introduced by another firm, profits for the branded

good producers are the same. Furthermore, in order for firm A to be profitable producing the generic, it requires a price insensitive market segment.

For firm B, the results obtained show that it can charge higher prices under scenario 1, and it will be better off by doing so. However, we can say that firm B will earn lower profits than firm A in case 1, for the interval of parameters satisfying the restrictions, although the same level for case 2. Firm C will only make positive profits when d_1 takes low values.

3.4.2 Consumer Surplus.

Following a similar procedure as when comparing profits, and due to the problem of obtaining analytical results which were impossible to analyse, some simulation results are presented. The idea is the same as before; we fix some parameter and we let the others change, while satisfying the restrictions imposed at the beginning. Again, we fix d_1 for convenience, and we change d_2, while calculating the range for the possible values of d_3 that satisfy the assumptions. Note that, as in the previous section, we also let d_1 change, and the qualitative results did not change.

In order to calculate consumer surplus, the approach taken is as follows: since we are interested in calculating it in equilibrium, we find the area under each demand curve (q_{A1} to q_G) from its own equilibrium price up to the intercept, taking the other prices as fixed and equal to their equilibrium values. Then, we add them up for both scenarios.

As we did before with profits, we can take $d_1 = 0.5$ as an illustrative example. Table 4 summarises the results. As one would expect, due to the increase in prices, we get that for

the consistent range of d_3, consumer surplus is greater when there are three firms in the market i.e. $CS^2 \geq CS^1$.

Table 4 Range for d_3 for which consumer surplus for case 2 is greater

$d_1 = 0.5$	$Range\ for\ d_3\ satisfying$
d_2	$CS^2 \geq CS^1$
0.5	$0 \leq d_3 < 0.75$
1	$0 \leq d_3 < 1.03$
1.5	$0 \leq d_3 < 1.41$
2	$0 \leq d_3 < 1.79$
2.5	$0 \leq d_3 < 2.176$

3.5 Conclusions and Future Research.

Using a market segmentation model we have illustrated that, under our assumptions, firm A will have an incentive to produce its generic alternative, rather than having a third firm producing it, once the patent for its active ingredient has expired. The model assumes that there exist two firms, producing two drugs with a different active ingredient, although we treat them as perfect substitutes. However, we do allow for a degree of differentiation between the branded and the generic good. This is done to take into account empirical results that suggest that consumers do not switch immediately to generic drugs once they are introduced. We assume that the marginal cost of the generic is less than the marginal cost for the branded good. This could be regarded as a realistic assumption if we take into account the characteristics of both goods, since the latter usually comes in a box with more labelling, while the former comes in a white box.

We assume symmetry in the demand functions for the branded goods that firm A and firm B face, both for the demand-sensitive and insensitive segment. We segment the market in

the basis of different responses of consumer's demand of branded goods: some consumers' demands are not dependent on the price of the generic (intuitively, and loosely-speaking, they could be treated as "loyal" customers), while some are affected by it.

In order to make the analysis tractable, we do some simulation exercise to see whether the firm whose patent for its active ingredient has expired has incentives to produce the generic alternative. For illustrative purposes, we give a full set of results for particular values of the parameters. The qualitative conclusions reached are similar with many other set of values. We find, that given our assumptions, this firm will always have the incentive to produce it. The firm uses the generic as a means to increase the price of its branded good in order to obtain higher profits. Furthermore, this firm can charge a higher price for the generic good compared to the price that would otherwise be set by a third firm producing the generic alternative. This is due to the fact that the regulatory constraint, that the price of the generic has to be less than or equal than the price of the pioneer good, is satisfied with equality. This implies that whoever produces the generic has incentives to introduce it with the highest price possible. Hence, since firm A uses the production of the generic as a means to increase the price of its branded good, the price of the generic rises accordingly.

Notice that due to the assumptions of firm A and firm B being identical with respect to both the demand functions they face and the costs of producing the branded good, they obtain the same profits when a third firm produces the generic. Hence, when firm A produces the generic, not only is it better off with respect to the case when there are three single product firms, but it also earns higher profits than firm B in case 1.

Consumer surplus is lower under the first scenario, where there are only two firms in the market. This is because of the strategy by firm A of producing the generic, in order to increase the price of both goods.

The policy implications of these results are that, since the promotion of generic drugs is coming from many different sides of the economy, from a social point of view, their entry should be encouraged through firms not producing their own branded good, but rather through firms who specialise in the production of generics. Hence, entry barriers to these firms should be made as low as possible. However, if we see in reality that existing firms producing branded goods decide to produce generics themselves, it could be a signal that they are using these as a means of increasing the price of the branded goods in order to increase their profits. This is the pattern that we are observing now, since nowadays we are confronted with many "branded generics" and higher prices for the branded goods. These firms not only use their natural advantage of producing their generic alternative in order to gain the first mover advantages in the market for generic goods, but also use them strategically to increase the price of the branded good to exploit their loyal customers. Hence, this paper is in line with those that estimate an increase in the price of the branded good once the generic drug is in the market. However, this increase in price results from the strategic use of their generic alternatives by already established firms.

Of course, possible extensions to the model are plausible. For example, when we consider firm A introducing the generic, we assumed that costs are independent. However, economies of scope could arise if firm A decides to produce both goods. In this respect, firm A could enjoy economies of scope if it could use the same capital to produce the

branded and the generic drug. One would expect that this possibility would reinforce the results presented here.

Another extension could be to introduce a certain degree of differentiation between the branded goods. This of course has the implication that more parameters would appear, making the analysis more difficult.

We have assumed that only one generic can be produced, although this may not be the case. If we relax this assumption, many scenarios are possible. For example, we could have both firm A and firm C, or alternatively, a competitive fringe producing the generic. Moreover, we could make firm B lose its patent too, so competition in generics could also exist. Of course, we could make the model dynamic in order to take into account the existence of first mover advantages in the generic market. Hence, the model could be extended to cover more cases.

3.A APPENDIX 1

The Khun Tucker conditions for firm A and the first order conditions for firm B are, respectively, as follows for case 1:

$$\frac{\partial \pounds_A (p_A, p_G, \lambda)}{\partial p_A} = 2 - 2(d_1 + d_2) p_A + (d_1 + d_2) p_B - 0.8 d_3 + 0.8\lambda \leq 0 \qquad (114)$$

$$p_A \left(\frac{\partial \pounds_A (p_A, p_G, \lambda)}{\partial p_A} \right) = 0 \qquad (115)$$

$$\frac{\partial \pounds_A (p_A, p_G, \lambda)}{\partial p_G} = 2 + 2d_3 p_A - 2d_2 p_G + d_3 p_B - d_3 + 0.8 d_2 - \lambda \leq 0 \tag{116}$$

$$p_G \left(\frac{\partial \pounds_A (p_A, p_G, \lambda)}{\partial p_G} \right) = 0 \tag{117}$$

$$\frac{\partial \pounds_A (p_A, p_G, \lambda)}{\partial \lambda} = 0.8 p_A - p_G \geq 0 \tag{118}$$

$$\lambda \left(\frac{\partial \pounds_A (p_A, p_G, \lambda)}{\partial \lambda} \right) = 0 \tag{119}$$

$$p_A \geq 0, p_G \geq 0, \lambda \geq 0, \tag{120}$$

$$\frac{\partial \pi_B (p_A, p_B, p_G)}{\partial p_B} = 2 - 2 (d_1 + d_2) p_B + (d_1 + d_2) p_A + d_3 p_G + d_1 + d_2 = 0 \tag{121}$$

3.B APPENDIX 2

The first order conditions for firm A and firm B under case 2 are:

$$\frac{\partial \pi_A (p_A, p_B, p_G)}{\partial p_A} = 2 - 2 (d_1 + d_2) p_A + (d_1 + d_2) p_B + d_3 p_G + d_1 + d_2 = 0 \tag{122}$$

$$\frac{\partial \pi_B (p_A, p_B, p_G)}{\partial p_B} = 2 - 2 (d_1 + d_2) p_B + (d_1 + d_2) p_A + d_3 p_G + d_1 + d_2 = 0 \tag{123}$$

The Khun Tucker conditions for firm C are given by (3.97) to (3.101) and once we have substituted for the particular functional forms, we get

$$\frac{\partial \pounds\left(p_G, \mu\right)}{\partial p_G} = 2 - 2d_2 p_G + d_3\left(p_A + p_B\right) + 0.8d_2 - \mu \leq 0 \tag{124}$$

$$p_G\left(\frac{\partial \pounds\left(p_G, \mu\right)}{\partial p_G}\right) = 0 \tag{125}$$

$$\frac{\partial \pounds\left(p_G, \mu\right)}{\partial \mu} = 0.8p_A - p_G \geq 0 \tag{126}$$

$$\mu\left(\frac{\partial \pounds\left(p_G, \mu\right)}{\partial \mu}\right) = 0 \tag{127}$$

$$p_G \geq 0\ ,\ \mu \geq 0 \tag{128}$$

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