An analysis of generic competition in the UK pharmaceuticals market. Does aggressiveness of entry affect prices in the post generic entry period?*

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Abstract

Despite being regulated through the Statutory Maximum Price Scheme which, in essence stipulates the maximum reimbursement price for generic pharmaceutical products, prices of prescription drugs in the UK in the period following patent expiration can be considered and analysed as being the outcome of market interactions among manufacturers and suppliers. This paper seeks to establish the relationship between the number of generic entrants and the prices paid for pharmaceutical products in the post-patent period. In doing so, the behaviour of suppliers in terms of pricing and entry behaviour is also explored. Data on a sample of 20 top selling drugs that came off patent in the UK between 1990 and 2000 was analysed using regression models. The results of the analysis highlight the existence of two types of generic entrants, branded generics and 'pure' generics. The type of entrant determines the behaviour of the manufacturer or supplier. Furthermore, entry appears to be more aggressive in high profile markets with high volume prescribing and higher prices; however, higher levels of entry do not necessarily lead to competitive prices.

1 Introduction

Partly driven by rising costs of pharmaceuticals, healthcare expenditures in most industrialised economies have been increasing over the last few decades. According to the OECD[1], pharmaceutical spending rose by more than 70%, in real terms, between 1990 and 2001 in six OECD countries, and now accounts for more than 10% of healthcare spending in nearly all OECD countries. Much of this increase is accounted for by the introduction of new and more expensive drugs, consequently generic prescribing is increasingly being perceived as an important means of containing the increasing costs of pharmaceuticals. Public policy in most OECD countries has therefore focussed on encouraging and, in some cases, mandating generic prescribing even before an original brand name product comes off patent and consequently faces competition from

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[1] OECD Heath Data 2003

generic entrants (Barak, 2003). Such policies are at least in part driven by the general believe that competition among generic suppliers exerts a downward pressure on prices of drugs, which in most cases are significantly low compared to the prices of corresponding original brands.

The primary aim of this paper is to investigate the relationship between number of generic entrants (market structure) and price (market conduct) in the UK market for pharmaceuticals as they come off patent. A key characteristic of the pharmaceutical industry is the extended period of patent protection, which, in essence confers monopolistic power to the pioneer branded drug manufacturers in the pre-patent expiry period. Upon expiration of the patent, suppliers of pioneer branded drugs face competition from manufacturers of generic drugs that enter the market with chemically identical off-patent copies of the pioneer's drug. In entering the market for drugs that have lost patent protection, manufacturers of generic drugs may either chose to market their drugs under their own brand name[2] or simply offer the drug using the generic name. For the purpose of pricing and reimbursement the Department of Health (DoH) interestingly classifies branded generics similar to pioneer brand name drugs, although the former are also subject to patent laws; in particular, that their entry into the market is only possible upon expiration of the patent of the original brand name product. This classification thus allows for the prices of both branded generics and pioneer brands to be regulated similarly through the same price regulation scheme, while prices of pure generics are regulated through a separate scheme.

Employing regression analytical methods, this paper attempts to establish the association between number of competitors and the price levels of drugs paid by the National Health Service (NHS). In addition to analysing the whole market structure in the post-patent expiration periods, it specifically analyses the dynamics in the branded generics and the pure generics markets, each in isolation. The analysis also focuses on market shares of drug manufacturers, investigating the extent to which these are associated with prices.

This paper is organized into 6 Sections. The literature review in Section 2 focuses on similar empirical studies that have also examined changes in market structure and market conduct following entry of generic competition in pharmaceutical markets. Section 3 describes the data sources and model variables, as well as define the market as implied in the empirical analysis. Section 4 begins by highlighting the hypotheses and the model on which the empirical analysis in the later part of the Section is based. The results of the analysis are discussed and concluded in Section 5.

[2] This will often be referred to in the following Chapters as 'branded generics'. The term 'pure generics' is used in the following sections when reference is made to drugs sold under a generic name. The term 'commodity generics' is also often used. In some cases, manufacturers of generics may chose an amalgam of the generic name and the name of their company.

2 Background and literature review

2.1 Definition of market and product

For the purpose of this analysis, a market is considered to comprise the originator brand name compound and the generic version(s) of a specific drug formulation or strength that enter the market following patent expiration of the originator. One key point to note in defining the market as such is that neither the broad definition of the market (which will imply that all drugs are substitutes) nor the narrow definition (which assumes perfect substitutability between drugs) has been invoked. The market here takes the definition assumed by Tirole (1997, p. 13) which posits that a market needs to involve "either a homogenous good or a group of differentiated products that are fairly good substitutes (or complements) for at least one good in the group …". One point to note about this definition is that as far as the market for pharmacological therapies are concerned, the issue of substitutability is far from definite and, indeed, this is what necessitates a clear and an *a priori* definition of the market when analysing any drug market. For certain indications, for example, surgical treatment may sometimes be used as an alternative to pharmacological treatment and vice-versa and, therefore, the two can be considered as close substitutes thereby belonging to the same market.

Common to all drug products within a given market is the common generic compound on which substitutability is based. Inherent in the above definition is the fact that the market initially assumes a monopolistic structure that is later open to competition from generic entrants upon patent expiration of the original brand. This definition can be considered appropriate, particularly in the light of the key objective of this paper, which is to analyse the market structure and conduct following entry of generic competition.

In line with other studies that have focused on the same objective[3], each drug market here is represented by a specific drug formulation or drug strength and not an aggregate of the formulations and strength in which the drug is available. In all but a few cases, this was the most prescribed formulation, measured in terms of quantity of units prescribed. The merits of using single drug formulations and strengths instead of calculated aggregates is derived from the fact that for some drugs there may exist a multitude of patents each covering the different formulations or strengths of the drug. In such situations, it becomes difficult to aggregate across formulations that differ in patent expiry dates. This is the case, for example, where a drug manufacturer acquires a patent for an intravenous formulation of a compound and, as part of the product's life-

[3] For example, Aronsson et al. (2001) and Thanigavelan and Kreling (1995).

cycle management, introduces a patent-protected tablet formulation of the same active ingredient before patent expiration of the intravenous formulation. For the purpose of this analysis, it would be misleading to consider a single date as the date of patent expiration for such a compound with multiple patents, hence the need to consider only one strength or formulation.

2.2 Theory and empirical evidence on market structure – market conduct relationship

A review of literature relating to empirical analysis of competition in the pharmaceutical industry was conducted based on a literature search that focused on three main databases namely, ECONLIT, EMBASE and IPA, and using the search words 'generic' and 'competition'.

The competitive landscape of pharmaceutical markets is typically characterized by the type of competitors that a drug can face. An originator drug embodying a specific chemical entity can face competition from other drugs with similar therapeutic effects but, compared to the originator, are each based on different chemical compounds. Another possible source of competition, as highlighted in the previous sections, is from generic versions of the originator that, in essence, contain the same chemical compound in addition to having the same therapeutic effect. As indicated above, a generic competitor may either be 'branded', where the manufacturer decides to market the drug under a registered trademark name, or 'pure', in which case the drug is marketed under a generic name. How a pharmaceutical company strategically interacts within its market space will of course depend on the particular market sector (brand versus branded generics versus unbranded or pure generics) to which it belongs and to the competitors it faces; whereby in defining competition, one looks at the degree of substitutability between the marketed drugs. In analysing competition in the pharmaceutical industry, it is therefore of utmost importance to define the market *a priori*.

The focus of many studies in this area has either been on one sector considered separately, or the interaction of two sectors. In the former, the research question has centred on competition between therapeutically equivalent drugs, looking for example, at entry strategies for late entrants, assessing first-mover advantage gained by the incumbent, and evaluating various strategic responses that faced with competition the incumbent can adopt. Shankar (1997), for example, explored the alternative strategic options (accommodation, no reaction or retaliation) that, using its marketing mix variables, a pioneer drug company may adopt in reacting to entry of (therapeutically equivalent) competitors. Schmalensee (1982)[4] also looked at interactions between a pioneer and a late entrant, which is relatable to the market for drugs that can be substituted on the basis of

[4] Cited in Lu and Comanor, 1996

therapeutic equivalence. Unlike Shankar who discussed the use of marketing mix variables, Schmalensee focused on optimal pricing strategies in analysing pioneer and late entrant interactions, suggesting that the optimal strategy for the second entrant is that of penetration pricing in which the product is priced low at entry (in order to entice prospective consumers), and then later followed by price increases over time.

Unlike the market for therapeutically identical compounds, the market for chemically identical substitutes appears to command more appeal to researchers. The research questions here have, in most cases, focused on the following key issues:

- The extent of price and share erosion that typically follows entry of generic competition;
- The association between the dynamics or aggressiveness of generic entry and pricing by manufacturers of generic drugs;
- Changes in the demand structure facing the incumbent, and the incumbent's price response to entry of generic competition.

Frank and Salkever (1995) developed two pricing models in which they equate the pricing behaviour of a manufacturer of a brand name drug and a manufacturer of the generic version of the brand name drug to that of a von Stackelberg price-leader and a firm in a Nash-Cournot non-cooperative game respectively. The authors' models posit that "… a brand name drug producer is a dominant firm that makes its profit-maximising pricing decisions taking account of the reaction to its pricing choices in the generic market"; while, acting as fringe firms, each manufacturer of a generic version of the brand name drug "takes the brand name producer's price and the behaviour of rival generic producers as given in making its profit maximising pricing decision". Applying data on transactions prices paid by retail pharmacies of 32 drugs that had lost patent in the US in the mid 1980s, the authors found that average prices of prescription drugs fell when the brand-name pioneer drug came off patent. The observed reduction in average prices was however the net result of opposite trends in the prices of brand name drugs and generic drugs respectively, with prices of the former increasing and prices of the latter decreasing post generic entry. These findings suggest that the originator does not engage in a price war with generic entrants once it's drug comes off patent; rather, it is able to increase its price due to the change in the elasticity of demand it faces following entry of cheaper generic versions into the market. The demand for an originator brand name product is comprised of an elastic and an inelastic component and, upon entry of generic competition, the originator's demand curve shifts inward and become less elastic thus allowing the originator to raise its price. This breakdown of the market into two segments based on price elasticity is very evident in the US pharmaceutical market, where hospitals and HMOs are often seen to be price sensitive compared to drug stores. The data used in the study showed a 50% rise in the prices of brand name drugs five years after entry of generic competition,

while at year three of generic entry, prices of generics were less than 50% of the prices of brand name products. Regarding the impact of generic entry on generic prices, the authors found that each additional entrant reduced the average price of a generic product by between 5.6% and 7.2%.

Using data on 15 compounds that came off patent in the US and for which generic versions entered the market after the Drug Price Competition and Patent Term Restoration Act was enacted[5], Jambulingam and Kreling (1995) came to a similar conclusion as Frank and Salkever regarding generic pricing and aggressiveness of entry, although they described the generic industry as an oligopolistic competitive market tending toward a pure competitive market.

Similar evidence of divergence between pioneer pricing and generic pricing, which is suggestive of multiple competitive landscapes in the pharmaceutical industry, was observed by Jones *et al.* (2001) who analysed a sample of 82 therapeutic drug categories in British Columbia, Canada. The study specifically sets out to evaluate the impact of changes in the 1987 Canadian Patent Act on the pricing of ethical drugs. It identifies the first-mover advantage usually enjoyed by pioneer brand name drugs as a key factor explaining why incumbent drug manufacturers are able to sustain the prices of their drugs at high levels even when faced with generic competition. The authors found out that changes to the Act, which basically extended the period of protection for patent holders, resulted in an increase in price differences between brand name products and generics, thus allowing them to conclude that the changes resulted in a reduction in the efficacy of generic competition in reducing overall market price.

Results from similar studies conducted in Europe highlight dissimilar patterns of pricing behaviour amongst European manufacturers of brand name originator drugs faced with generic competition. Drawing on data from five countries, Hudson (1992) modelled pricing in the pharmaceutical industry and reported that manufacturers of originator drugs in Germany and France responded to entry by reducing their price points. A more recent study (Aronsson et al., 2001) looking at the impact of generic drug competition on brand market shares in Sweden found out that brand name manufacturers lowered their prices with the introduction of a reference price system in 1993. The 1993 reference price legislation in Sweden basically related reimbursement levels to the cheapest generic substitute. As suggested by these two studies, manufacturers of brand name drugs in Europe are unlikely to respond in the same manner, i.e., increase price, as those in the US, which in turn may be suggestive of the more homogenous nature of the demand for drugs in Europe compared to the generally price elastic and less regulated US market.

[5] Commonly referred to as the Waxman-Hatch Act, this piece of regulation significantly facilitated entry of generic competition to drugs that had hitherto been patent protected.

As the above review indicates, research work focusing on the interaction between pharmaceutical drug manufacturers and the outcome of these interactions (in terms of price and market shares) has mainly taken three directions. The bulk of the literature looks at the pricing strategy of pioneers pre- and/or post entry of generic competition. A second group of authors have focused on competition within the generic industry alone, while a third has looked at competition between therapeutically equivalent molecules. The focus of this paper is on the dynamics of entry and pricing in the UK pharmaceutical market post patent expiration. It differs from most other studies in that it also analyses the market for branded generics, how these interact in terms of pricing, their entry strategies, and their market shares.

3 Datasets and data sources

3.1 Data sources

The data analysed in this paper were obtained from two main sources namely the Prescription Cost Analysis database produced by the Department of Health and the Chemist and Druggist Generics Book. The compounds included in this analysis were identified from a joint study by the Department of Health and the Association of the British Pharmaceutical Industry published in 2002 and which ranked 137 compounds that had come off patent in the UK between 1990 and 2000. Compounds in the list were each identified by a chemical name and the brand name of the original product and were ranked in terms of their net ingredient cost[6] in year 2000. The first 28 of these compounds, which together accounted for 82.4% of the net ingredient cost of prescriptions in 2000, were initially considered for this analysis. For each of the 28 compounds, yearly data on the number of items dispensed, the net ingredient cost and the quantity of each formulation of the drug dispensed were obtained from the Department of Health's Prescription Cost Analysis (PCA) database. This database provides details of the number of items and the net ingredient cost of all prescriptions dispensed in the community by community pharmacists and appliance contractors and dispensing doctors, as well as prescriptions submitted by prescribing doctors for items personally administered in England. Also included are prescriptions written in Wales, Scotland, Northern Ireland and the Isle of Man but dispensed in England. The dataset does not cover drugs dispensed in hospital or private prescriptions.

The initial list of 28 compounds was reduced to 20 after eliminating compounds for which the chemical composition of the generic entrant was significantly different from that of the original brand product. A typical example of this is Sandimmun (cyclosporin), a drug affecting the immune response and which lost its UK patent protection in April 1994. The generic entrants of oral

[6] See Section 3.2 for a definition of net ingredient cost.

cyclosporin, which include Neoral and SangCya, both branded generics, are different in bioavailability thus constraining any switch between the original and the generic products purely on the basis of price variations. Furthermore, drugs for which there was no generic entrant in the post-patent expiry period were also eliminated. The final list of 20 drugs comprised compounds for cardiovascular indications (7), musculoskeletal and joint diseases (3), infectious disease (3), central nervous system and gastro-intestinal indications (2 each), indications of the respiratory system, skin and endocrine system (1 each)[7].

From the 20 defined markets, a dataset comprising 666 cross-sectional time series or panel data points covering the period 1991 to 2002 was obtained. The dataset has an imbalanced structure, meaning that the number of [time series] observations differs across drugs. This is the case given that originator brand products were launched at varying times before and during the period covered by the PCA database. The imbalance nature of the data is also explained by variations in the number and timing of generic entry, which differs across drug markets. Only for two drugs was the year of first generic entry outside the period covered by the database.

Finally, the number of generic entrants in each drug market was counted from two sources. The number of entrants of branded drugs was counted from the PCA database, while the number of entrants in the non-branded sector was counted from previous editions of the biannually published Chemist and Druggist Generics Book.

3.2 Model variables

Three key variables, the number of items dispensed (PPXS), net ingredient cost (NICO), and the quantity of prescriptions (QNTY) were obtained from the DoH's PCA database (see Table 2 for a summarized description of variables). This database tracks the number of prescriptions of single items, therefore a prescription form listing three different items is counted as three items and not one.

The net ingredient cost of a drug is based on the drug's cost before discounts and does not include any dispensing costs or fees. It also does not include any adjustments for income obtained where a prescription charge is paid at the time the prescription is dispensed or where the patient has purchased a pre-payment certificate (DoH, PCA). QNTY is measured in terms of the standard quantity units (e.g., tablets, capsules, grams, etc.) depending on the formulation of the drug.

[7] See Table 1

Table 1: Characteristics of products included in analysis

BNF chapter name/ Brand name	Strength/formulation	BNF (generic) name	Patent expiry
Cardiovascular system			
Atenolol	Tab 50mg	Tenormin L.S.	Jan-90
Bezafibrate	Tab 200mg	Bezalip	Apr-92
Captopril	Tab 25mg	Capoten	Jan-97
Celiprolol Hydrochloride	Tab 200mg	Celectol	Apr-94
Enalapril Maleate	Tab 10mg	Innovace	Apr-99
Metoprolol Tartrate	Tab 50mg	Betaloc	Feb-92
Terazosin Hydrochloride	Tab 2mg	Hytrin	Apr-96
Musculoskeletal & joint diseases			
Fenbufen	Tab 450mg	Lederfen	Mar-91
Nabumetone	Tab 500mg	Relifex	Mar-93
Piroxicam	Gel 0.5%	Feldene	Feb-90
Infections			
Aciclovir	Tab 200mg	Zovirax	Mar-95
Cefaclor	Cap 250mg	Distaclor	Jan-94
Cephalexin	Cap 250mg	Ceporex	Feb-90
Central nervous system			
Fluoxetine Hydrochloride	Cap 20mg	Prozac	Jan-00
Zopiclone	Tab 7.5mg	Zimovane	Jan-93
Gastro-intestinal system			
Cimetidine	Tab 400mg	Tagamet	Jan-92
Ranitidine Hydrochloride	Tab 150mg	Zantac	Mar-97
Respiratory system			
Terfenadine	Tab 60mg	Triludan	Apr-92
Skin			
Ketoconazole	Shampoo 2%	Nizoral	Apr-97
Endocrine system			
Acarbose	Tab 50mg	Glucobay	Mar-99

In the analysis that follows, data points are identified by three subscripts, n (n=1, 2, ……20) identifies the drug market; i indicates whether the drug is an originator's brand name product (i=1), a pure generic product (i=2), or a branded generic product ($i>2$); and t (range: -9 to 12) represents the number of years relative to the year when generic competition first entered the market, with t=0 representing the year of first entry. Pure generics within any given drug market are represented by

a constant (i=2) because the available PCA data does not provide sales by supplier or manufacturer of pure generics, as is the case with branded generics. Using the PCA data therefore, it is not possible to precisely calculate the market share of each manufacturer of a specific pure generic drug; however, it is possible to calculate an average market share per manufacturer or supplier of a pure generic drug, since the number of suppliers of pure generics in each year in any drug market is known.

Table 2: Brief definition of key variables

Variable number	Variable	Definition of variable
1	PPXS	Number of prescriptions
2	NICO	Net ingredient cost = the cost of drugs dispensed, with adjustments for discounts and dispensing costs or fees
3	QNTY	Quantity of drug dispensed, measured in units depending on the formulation
4	PRICE	Price per unit of drug dispensed. Obtained by dividing NICO by QNTY
5	PRIND	Price index, whereby the price (as defined above) is calculated by dividing the price of drug by the price of its pioneer brand at one year prior to patent expiry
6	TSALE	Market size, computed by summing quantity dispensed across all products within a given drug market
7	SHARE	Quantity of drug dispensed, as a proportion of total quantity of compound dispensed
8	NUNGE	Number of manufacturers of pure generics
9	NBRGE	Number of manufacturers of branded generics
10	TOGEN	Total number of generic manufacturers
11	DBRGE	Dummy variable, taking the value 1 if drug is a branded generic, otherwise 0
12	DUNBG	Dummy variable, taking the value 1 if drug is a pure generic, otherwise 0
13	DISX	Dummy variable, taking the value 1 if drug is for treating a chronic condition, otherwise 0
14	YRFGE	Number of years relative to year of first generic entry

Notes: Data on variables 1 to 3 obtained from PCA database; variables 4 to 7 derived from variables 1 to 3; entries for variable 8 counted from previous editions of the Chemist and Druggist; entries for variable 9 counted from the PCA database.

4 Results of Analysis

4.1 Summary statistics

This section reports summary statistics of the data with regards to the number of entrants, average price and market shares.

The aggressiveness of generic entry showed significant differences across drugs. In, seven, five and three of the 20 markets, there was no branded generic manufacturer at year one, two and three respectively after first entry of generic competition, suggesting that branded generic manufacturers were more likely to delay entry and their strategy to enter may not be driven by the desire to obtain first-to-market advantage within the branded generics market. On the other hand, as much as 10 pure generic manufacturers had entered the market in seven markets within one year after the first generic entrant.

Table 3: Trends in average pricing

	Year -1	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Pioneer							
Ave.	1.00	0.99	0.92	0.92	0.89	0.87	0.87
St. dev.	*0.00*	*0.05*	*0.20*	*0.22*	*0.24*	*0.27*	*0.27*
Observations	*15*	*18*	*20*	*18*	*14*	*13*	*13*
Pure generic							
Ave.		0.90	0.77	0.66	0.63	0.55	0.53
St. dev.		*0.15*	*0.26*	*0.26*	*0.31*	*0.31*	*0.31*
Observations		*18*	*19*	*17*	*13*	*13*	*13*
Branded generics							
Ave.		0.90	0.86	0.86	0.88	0.85	0.82
St. dev.		*0.11*	*0.19*	*0.22*	*0.23*	*0.27*	*0.33*
Observations		*20*	*32*	*33*	*31*	*34*	*32*

Notes: The coefficients for individual drugs were obtained by including dummy variables for each drug. The period covered by the regression is 5 years after entry of first generic competitor, although the period will be less than 4 years if first entry occurred after 1998.

Table 3 shows the average of the price index at one and five years before and after entry of first generic competitor. At five years post first entry, generics would be selling at approximately 50% of the originator's price at one year prior to entry of first generic competitor

Aside the averages reported in the above, trend regressions were also run to test the effect of the nature of the disease (chronic versus acute) on prices (results not shown). This was done by including the dummy variable (DISX) in the multiplicative form (i.e., multiplied to the trend variable, YRFGE) in a regression of PRIND on YRFGE, with data points referring only to originator brands and covering the post patent expiry period. The estimated coefficient of the multiplicative variable was not statistically significant at the 5% level of significance, suggesting that the downward trend of originator prices in the post-patent expiry period did not differ by nature of the disease for which drugs are indicated and marketed.

Table 4 shows trends in the average shares within each market sector from the year of first generic entry to 5 years after the initial entry. Up to five years after entry of generic competition, branded generics, on average, account for approximately 1% of the market, with the remaining 99% shared between pure generics and pioneer brands. On average shares of the pioneer brand products decrease over time, and this decline is accompanied by an increasing share of pure generics and an apparent decline in the share of branded generics. By the fifth year after the first entry, pure generics together account for an average of 83% of their respective markets.

Table 4: Average market shares, by market sectors

	No. of years relative to year of entry of first generic competitor						
	Year -1	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Pioneer							
Ave. share	100.0%	50.5%	34.1%	25.2%	25.6%	19.6%	16.5%
Stan. Dev.	*0.0%*	*30.6%*	*26.6%*	*24.2%*	*19.8%*	*17.9%*	*17.6%*
Observations[2]	*15*	*18*	*19*	*17*	*13*	*13*	*13*
Pure generics[1]							
Ave. total share		48.9%	64.8%	73.9%	73.4%	79.6%	82.8%
Stan. Dev.		*30.2%*	*27.4%*	*25.2%*	*19.3%*	*17.1%*	*17.2%*
Observations[2]		*17*	*18*	*16*	*13*	*13*	*13*
Branded generics							
Ave. share		0.6%	1.1%	1.0%	1.0%	0.8%	0.6%
Stan. Dev.		*2.5%*	*3.6%*	*2.7%*	*2.2%*	*1.6%*	*1.3%*
Observations[3]		*20*	*32*	*33*	*31*	*34*	*32*

Notes:
1) Ave. share refers to the average of total shares of pure generic manufacturers across all markets.
2) Refers to number of drug markets
3) Refers to number of branded generics

As indicated by the relatively large size of the standard deviations, large variations exists between shares across the various drug markets, particularly in the pioneer and brand generics sectors. An

analysis of correlation coefficients (results not shown) shows that shares of pioneer brand drugs in the post-patent period increased with decreasing market size (TSALE), the largest share values found in markets with the least sales value, which also corresponded to the markets where entry of generic competition was least aggressive.

4.2 Regression analysis

4.2.1 A note on the regression model

The results of the regression analysis reported in the following sections are based on fixed effects regression models, which is one way of modelling a panel or cross-sectional time series data such as the one used in this analysis[8]. A fixed effects model permits us to utilize the information that certain sets of observations would be coming from certain units. In the following regression analysis, the units or cross-sectional dimension of the data correspond to a drug market (i=1, 2, ……20), which is further split into sectors and into individual drugs within sectors; while the time series dimension corresponds to the number of years, t, before or after entry of first generic competition in the market. The data is imbalanced, meaning that the range values for t varies across units, the minimum value being –10 (for an incumbent brand that was on the market in 1991 onward, but only went off patent in 2001), and the maximum value being 11 (for any drug within a market in which the patent of the pioneer expired in 1991). Regression analysis was conducted using Stata software, version 6.

The regression models in the following sections tests two hypotheses which are be loosely formulated as follows:

H_1: There is no systematic difference between the price – market share relationship of branded and unbranded drugs.

H2: There is no effect of generic entry on prices of branded and unbranded drugs.

4.2.2 Market share and price (H_1)

Two regression models, regression-1 and regression-2, were specified to test the first hypothesis relating price to demand (or market share). Regression-1 tests the hypothesis in the context of the overall market dynamics, thus, it is based on data pooled across all three market segments (pioneer brands, branded generics and pure generics); while the focus of regression-2 is on the market for branded generics only. It was not possible to run a type-2 regression for the pure

[8] An elaborate discussion on the use of fixed-effects model in estimating from panel data is provided in Johnston and DiNardo (1997).

generics market sector due to lack of data on individual market shares of manufacturers in this sector.

$$SHARE_i = \alpha_1 + \beta_1 PRIND_i + \delta_1 (DumB1_i * PRIND_i) + \delta_2 (DumB2_i * PRIND_i) + \delta_3 (DumB3_i * PRIND_i) + \mu_i \quad (1)$$

$$SHARE_{3i,t} = \alpha_1 + \beta_1 PRIND_{3i,t} + \delta_2 (PRIND * DumCard_{3i,t}) + \mu_{3i,t} \quad (2)$$

Table 5 shows the results of regressions to test the first hypothesis (H_1) on market share. The regression models market share as a function of price index. The specified model was extended to include three dummy variables, *Dum*B1, *Dum*B2 and *Dum*B3 in a multiplicative form i.e., multiplied to the price index variable. Each of the dummy variables takes the value 1 if the drug is an original brand product, a pure generics and a branded generics, respectively. Introducing the dummy variables in the multiplicative form allows for the estimation of differential slope coefficients for each product type.

The total number of observations across all 20 drug markets was 511, and the adjusted R-squared was 0.63. PRIND was dropped in the output of the regression analysis because of perfect multicollinearity between independent variables that was caused by including all three categories of the dummy variable in the regression. The introduction of the dummy variables in the multiplicative form enables us to differentiate between the slope coefficients of the three product types. The negative coefficients of the multiplicative dummy variables for original brand and branded generic products suggests that an increase in the price of branded products was associated with a fall in their market shares relative to other product types within their specific markets. A coefficient of –0.21 and –0.39 therefore implies that an increase in the price of original brand products and branded generics relative to the price of the original brand product one year pre-entry of generic competition by 10% was associated with a decrease in market share of 2% and 4% for the original brand and branded generics respectively. In contrast, the overall share of pure generic manufacturers relative to the shares of branded generics and the original brand product within a given drug market tended to increase with the average price of pure generics within that market. A coefficient of 0.47 implies that a 10% increase in price of pure generics was associated with a 4.7% increase in the overall share of pure generics within a given drug market.

Regression-2 models market share and pricing taking the branded generics market in isolation. The regression is therefore based on data points relating to branded generics only, and analyses the association between the price paid for branded generic drugs and the average market share they each command. A differential slope coefficient for cardiovascular drugs was estimated by including a dummy variable *Dum*Card (cardiovascular drug = 1 and non-cardiovascular drug = 0),

in a multiplicative form (PRIND**Dum*Card). A differential slope was tested for cardiovascular drugs only as this was the only therapy area for which sufficient data was available.

Table 5: Market share and price (regression analysis)

	Regression-1[1]	Regression-2[2]
Dependent variable[3]	$SHARE_{1,2,3}$	$SHARE_3$
Constant	0.393	-0.01
	<0.001	*0.01*
PRIND	dropped	0.013
		0.024
PRIND**Dum*B1*	-0.214	
	<0.001	
PRIND**Dum*B2	0.471	
	<0.001	
PRIND**Dum*B3	-0.399	
	<0.001	
PRIND**Dum*Card		0.024
		0.01
n	509	271
N	20	13
Adj. R-Sq	0.63	0.22

Notes:

1) Regression-1 is based on entire pooled data. Shares of pure generics represent sum of shares across all manufacturers of pure generics within each specific drug market
2) Regression-2 is based on branded generics only
3) Subscripts of the dependent variable indicate the reference sub-market (original brand products(1), pure generics (2), branded generics (3)) on which the regression analysis is based

Numbers in italics refer to p-values of estimated parameters

The specification also includes dummies for each drug market, but the estimated coefficients for the dummies, which will give the differential coefficient of the constant term, are not reported here.

Pooling the data for SHARE and PRIND for branded generics produced 217 data points for Regression-2. The coefficient of the price index variable (PRIND) was positive, implying that an increase in prices of branded generics was associated with an increase in the market share of the manufacturer of the branded generic drug whose price had been increased. A coefficient of 0.013 for PRIND in regression-2 implies that a 10% increase in the price of a given branded generic drug relative to the pre-entry price of the original brand drug within the same drug market was associated with a 0.1% increase in the market share of the drug relative to the share of the other branded generics product within that drug market. This association was even stronger in the case of cardiovascular drugs, with a 10% increase in price being associated with an additional 0.2% in market share.

In conclusion, the market share of a drug appears to be related to its price. The impact of a change in prices on a drug's market share would depend on whether the drug is a pioneer brand, a branded generic or a pure generic drug. Also, the impact of a change in price of a branded generic drug on its competitiveness appears to be different depending on the market space that is being taken into consideration. An increase in price is associated with a decrease (increase) in market share if the market space comprises all three market sectors (only the branded generics sector).

4.2.3 Price and number of market entrants (H_2)

Four regression models were specified to test the second hypothesis (H_2) associating market conduct (price) and market structure (number of manufacturers). A third variable reflecting the popularity of the market and proxied by the frequency of prescriptions (PRESC) was added to the regression models.

Table 6: Price and market structure (regression analysis)

	Reg. 3[1]	Reg. 4	Reg. 5	Reg. 6
Dep. variable	$PRIND_{1,2,3}$	$PRIND_1$	$PRIND_2$	$PRIND_3$
Constant	0.737	0.945	0.602	0.804
	<0.001	*<0.001*	*<0.001*	*<0.001*
TOGEN	0.008			
	0.18			
NUNGE		0.006	0.017	
		0.298	*0.023*	
NBRGE		-0.032		0.001
		0.031		*0.95*
PRESC	< -0.001	<-0.001	0.017	< -0.001
	0.114	*0.493*	*0.002*	*0.054*
n	509	120	118	271
N	19	19	19	13
Adj. R-Sq	0.35	0.84	0.8	0.4

Notes:

1) Regression-3 is based on data pooled across all three market sectors. Regressions 4-6 are based on sector specific data, as indicated by the subscripts of the dependent variables. 1= pioneer brand, 2= pure generic and 3=branded generics.
2) Numbers in italics refer to p-values of estimated parameters

$$PRIND_{mi,\,t} = \alpha + \beta_1 TOGEN_{mi,\,t} + \beta_2 PRESC_{mi,\,t} + \mu_{mi,\,t} \quad (3)$$

$$PRIND_{1i,t} = \alpha + \beta_1 NUNGE_{1i,t} + \beta_2 NBRGE_{1i,t} + \beta_3 PRESC_{1i,t} + \mu_{1i,t} \quad (4)$$

$$PRIND_{2i,t} = \alpha + \beta_1 NUNGE_{2i,t} + \beta_2 PRESC_{2i,t} + \mu_{2i,t} \quad (5)$$

$$PRIND_{3i,t} = \alpha + \beta_1 NUNGE_{3i,t} + \beta_2 PRESC_{3i,t} + \mu_{3i,t} \quad (6)$$

Regression-3 models the association between the total number of generic manufacturers (TOGEN), including branded generics and pure generics, and drug price (PRIND). As indicated in Table 6, the magnitude of the coefficients for TOGEN and PRESC were both very low. Moreover, the coefficients of both variables were statistically insignificant at the 5% level of significance, suggesting that overall there is no relationship between pricing and the number of generic entrants.

Regression-4 models pricing of pioneer drugs as a function of the number of pure generic (NUNGE) and branded generic (NBRGE) entrants post-entry of generic competition. Only the coefficient of NBRGE was statistically significant at the 5% level of significance, thus suggesting that the pricing behaviour of originators when their products come off patent may be related to the level of competition from branded, not pure, generics. A coefficient of –0.032 implies that an increase in the number of manufacturers of branded generic drugs by one is associated with a fall in the originator's price by 3.2% compared to the pre-entry price. The coefficient of PRESC was not statistically significant.

Regression-5 and regression-6 model the pricing dynamics within the market for pure generics and the market for branded generics, with the number of competitors within each market segment considered as the independent variable, respectively. Only the coefficient of NUNGE in regression-5 was statistically significant at the 5% level of significance. The coefficient of NUNGE in regression-5 was positive, thus suggesting that manufacturers of pure generics are attracted to drug markets with a relatively higher price point. The coefficient of the popularity variable (PRESC) in regression-5 is also statistically significant at the 5% level of significance, thus suggesting that both popularity, as measured by the number of prescriptions, and the number of entrants are associated with the average price charged in the pure generics market sector.

The coefficient of NBRGE in regression-6 was very small in addition to being statistically insignificant; therefore, in contrast to the market for pure generics, the number of competitors within the market for branded generics did not appear to be related to pricing within this market sector.

5 Discussion and conclusion

In the foregoing analysis, an attempt was made to characterize the UK pharmaceutical market and, in particular, to analyse the behaviour of drug manufacturers following patent expiration of a pioneer brand. In the market for pharmacological therapies, the incumbent drug manufacturer that is still under patent protection only faces competition from manufacturers of other molecules with a similar therapeutic effect; otherwise it enjoys monopoly power until the brand comes off patent. Once the pioneer's patent expires, two types of generic versions of the pioneer brand, namely branded generics and pure generics may enter the market.

It was found that the behaviour adopted by each type of generic entrant does differ from one another in several ways. In addition, it was found that although manufacturers of pioneer brands gradually reduce the price of their brands over time, in line with findings from previous work (Frank and Salkever, 1995, Suh et al., 2000), they continue to maintain price points that lie significantly higher compared to those of generic competitors that enter their respective markets in the post patent expiration period. Responding to entry in this manner, the incumbent drug manufacturer can, in line with theory, be labelled as the price leader in the von Stackelberg price-leader model that was implied in a similar study conducted in the US (Frank and Salkever, 1995). Similarly, manufacturers of pure generics can be thought of as acting in a market space with characteristics similar to those of a perfect competition, where they compete on price (via discounts offered to pharmacists and prescribing doctors) for market share. Upon entering the market, manufacturers of branded generics charge lower prices compared to the incumbent, and then compete with one another on non-price factors (branding), which equates their behaviour to that of firms acting in a monopolistic competitive market, as they each face a downward-sloping demand curve for similar but differentiated products.[9]

US-based studies (Frank and Salkever, 1995, Suh et al., 2000) have associated the existence of such a two-tier market comprising the pioneers who maintain high prices and generic manufacturers who sell generic substitutes at significantly lower prices to the co-existence of a price elastic and a price inelastic demand. Upon expiration of the patent of the pioneer, demand from the relatively price sensitive institutional traders (such as hospitals and manage care organisations), who often mandate generic substitution by creating and enforcing formularies, shifts to the cheaper generics. The residual relatively price insensitive demand, which is then covered by the incumbent, is comprised of retail traders such as pharmacies and consumers. Suh et al. (2000) attribute the existence of this price-inelastic component of demand in the US to patient preference for "higher-quality" drugs that are covered by third party payers. Other named source of price insensitivity in the US is the fact that physicians do not have substantial economic incentive

[9] For an elaborate discussion on monopolistic competition, see Tirole (1997)

to chose lower priced drugs and that they are often ignorant of specific drug prices (Hurvitz and caves, 1988).

In contrast to the US health market where there exists a multitude of providers, the UK pharmaceutical market has, in essence, only one dominant payer, the National Health Service (NHS). Having only one buyer, one would therefore expect the demand for drugs in the UK to be very price elastic or, at least, that the price insensitive component of demand will be inexistent. If this is the case, then the immediate question to be asked is: how are manufacturers of branded generics still able to market their drugs and maintain a market share, albeit small?

It is obvious that certain factors (such as patient preferences and physician familiarity with brand names that are usually easier to remember) that drive the inelastic demand for drugs and that are characteristic of the US drug market are also present in the UK market. However, one additional aspects of the regulatory framework - the fact that generic prescribing and generic substitution (by community pharmacists) is not mandated may at least in part provide an explanation for the reduced price elasticity observed in the UK pharmaceutical market. Although physicians are trained and encouraged to prescribe generically, a major source of their incentives in making prescribing choices is derived from the discounts they receive from drug manufacturers, including manufacturers of branded generics. Where there is brand loyalty and patient preference for a specific brand, it is more likely that the brand in question will be the originator's brand. A plausible explanation for the demand for branded generics in the UK is the incentives that prescribing physicians derive through discounts offered by the manufacturers of branded generics.

In conclusion, the results of the foregoing analyses show that behaviour of drug manufacturers in terms of pricing and entry strategy and likewise market shares differ and is sector-specific, meaning that the strategy adopted by a drug manufacturer will depend on the type of manufacturer, with incumbents, manufacturers of branded generics and manufacturers of pure generics adopting different entry and pricing strategies.

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