

Dynamic Competition in Pharmaceuticals: Patent Expiry, Generic Penetration, and Industry Structure*

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This paper investigates patterns of industrial dynamics and competition in the pharmaceutical industry, with particular reference to the consequences of patent expiry in different countries. We focus on the competition at the level of single chemical entities, distinguishing between original brands and generic products. Quarterly data, spanning from July 1987 to December 1998, on sales of pharmaceutical products in four countries (USA, UK, Germany, and France) constitute the basis of our analysis. All the products containing major molecules whose patent expiration date lies between 1986 and 1996 are included in our sample. We show how diffusion of generics is linked to the characteristics of the market and investigate how price dynamics of original products are affected by generic competition. Our empirical investigation shows that the dynamics of drug prices and the competition by generic drugs vary significantly across countries. This heterogeneity notwithstanding, a clear distinction seems to emerge. On the one side, systems that rely on market based competition in pharmaceuticals promote a clear distinction between firms that act as innovators and firms that act as imitators after patent expiry. Here, original products enjoy premium prices and exclusivity profits under patent protection, and face fierce price competition after patent expiry. On the contrary, in systems that rely on administered prices, penetration by generic drugs tend to be rather limited. Its descriptive and preliminary nature notwithstanding, our analysis seems to have relevant implications at different levels of generality, especially for Europe.

Key words: *pharmaceuticals, patent expiration*

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I. Introduction

The paper attempts to set up a model of generic competition and prices, considering the role that some fundamental properties of the markets (like their relative size and growth) have in shaping the dynamics of market structure following patent expiration in four major developed countries (USA, UK, Germany, and France).

The history of their national regulatory systems is characterized by a set of highly differentiated trajectories and patterns ([10], [17]), that has led to hugely diversified healthcare and pharmaceutical systems, in particular in terms of the extent and regimes of regulation. The evaluation of the efficiency of different forms of government intervention is both theoretically and empirically complex and difficult and is further complicated by the fact that regulation takes very different forms across countries and over time. This situation has constantly led to controversies and sometimes bitter confrontation. The focal issues in the debate are clearly patent protection and price regulation, two issues that are deeply intertwined.

On the one side, it is widely recognized that patents have an important role as an incentive to innovation in pharmaceuticals. On the other side, the monopoly power conferred to patent holders should be countervailed by limiting the opportunity to raise prices in a market characterized by informational asymmetries and low demand price elasticity. However, price regulation is vigorously opposed by the industry and by many economists. First, it is argued that the industry is actually extremely competitive, even in specific sub-markets. Second, it is maintained that price regulation distorts the price mechanisms, curbs the profits of companies and hence the incentives to innovation, and in general creates environments where competition is too lenient. Recently policies have moved towards the use of less invasive regulation and a higher reliance of more market-friendly measures. Prominent among these is the support for the introduction and diffusion of generics after patent expiration. An analysis of the factors fostering and limiting the diffusion of generics, and a description of the main differences across countries will be the central focus of the paper.

The paper is organized as follows. Section 2 reports a brief history of the regulatory measures aimed at the diffusion of generics in our sample of countries. In section 3 the relevant literature

dealing with price dynamics and market structure is briefly discussed. In Section 4, we describe the database. Section 5 provides some descriptive evidence on price dynamics of original drugs and on the diffusion of generics. In Section 6, some preliminary multivariate analysis looking at the determinants of these phenomena is performed. Section 7 concludes the paper.

II. Generic Policies

The diffusion of generics is highly affected by institutional factors and by incentives which are in place to foster the prescription, the dispensing and hence the consumption of generic drugs.

As it is shown in Table 1, the countries in our study differ substantially in the policies adopted and in the incentives placed on doctor, pharmacists and patients (see [5], [11], [21]).

// Table 1 around here //

In the USA, the main spur to the diffusion of generics came from the Hatch-Waxman Act (1984). The Act restored part of the patent life lost during the pre-market regulatory process for newly introduced products and allowed generic entrants to submit an Abbreviated New Drug Application (ANDA) to facilitate their entry after patent expiry. Moreover, the Hatch-Waxman Amendment to the Act allows generic manufacturers to use a product which is still protected by a patent to prepare their marketing authorization application.

In the same year the last anti-substitution law was repealed, even if most of anti-substitution laws were repealed during mid- to late-1970s ([5]). In the US, consumers can refuse generic substitute, while generic substitution is generally not allowed in Europe except in cases of emergency or in hospitals. Germany is an exception in this respect and also in France generic substitution is allowed from 1999.

However, in most European countries, measures have been taken during the 1990s to make patients and health providers (doctors and pharmacists) more price-conscious and price-sensitive ([17], [20], [21]).

A recent form of cost sharing is the reference price system, introduced in Germany¹ in 1989 with the Health Care Reform Act. Under this system the reimbursement is limited to a certain level, e.g. the average or the lowest price of “bio-equivalent” drugs, including generics ([18]).

In Germany, the policies to foster the diffusion of generics have recognized the importance of involving manufacturers, physicians and patients and have therefore been effective. Indeed, Germany, together with UK, is the country in which the diffusion of generics is more striking. The main difference between the two countries is that in UK generics are mainly unbranded, while in Germany we observe mainly branded generics. For the UK, this is explained in terms of the high difference in prices between the procedure to get approval of branded drugs versus unbranded ones.

In both countries there exists a “black-list” where drugs that are excluded from reimbursement due to their low therapeutic value are recorded. In the UK, moreover there exists a “white list” of chemical entities that the NHS suggests² to prescribe in their generic version. Need it here to mention that open generic prescribing has been common in the UK since 1970s.

Important steps in the diffusion of generics have also been the introduction of the Prescribing Analysis and Cost Scheme (1988), an information system aimed at controlling and, indirectly, monitoring generic prescribers’ behavior and of the fund-holding scheme (1990) by which a budget is given to physicians to provide health care to their patients. However, there are no financial sanctions if medicine budgets are overspent.

In Germany a ceiling on total pharmaceutical expenditure (initially only in West Germany) was introduced in 1989 with the Health Care Reform. It also considered sanctions to medical associations and eventually to pharmaceutical manufacturer if the budget was overspent. Since 1994, the ceiling is still fixed at national level, but the responsibility for its overspending is placed on each Lander.

The situation in France is quite different and generic products have a very low diffusion. An obstacle was in the fact that this country has provided a national patent extension which grants

¹ In Germany the co-payment of patients to the pharmaceutical expenditure was established in 1977 as a mean to control the expenditure.

longer coverage than the one set in the EU regulation. However, France is undergoing major changes with the aim to foster the diffusion of generics. As a first step, a definition of generic has been established in law³. Following this definition, in 1997, the Agence des Médicaments set out a list of generic medicines equivalent to original products.

How all the mechanisms described in this section work in practice is unfortunately less than perfectly clear and despite some important previous work⁴, we still know very little on their effects on the diffusion of generic products.

III. Literature Review

A vast literature has analyzed the dynamics of original brand market shares and prices responding to generic entry after patent expiration. With few exceptions, studies have focused on the US market.

Original brand market share has been found to be directly proportional to the age of the original brand, while it is negatively correlated to the number of entrants. This latter variable was found to be proportional to the total size of the market and negatively related to the age of the original brand ([16]).

Even if their market share decreases after patent expiration, prices of original brand increase after the entry of generics. These enter the market at a significant price discount that then declines over time ([12], [23]). In a more recent study ([13]), generic competition was found to be intensifying in the USA, with major brand names typically losing half of their market share within a year of patent expiry.

Ching ([6]) developed an empirical dynamic oligopoly model to study competition between brand-name original and generic drugs. The model highlights the role of consumer learning and consumer heterogeneity in explaining respectively the initial slow increase in market share for generic drugs and the pricing increase of original brand after generic entry.

² In some cases physicians are obliged to prescribe the generic version of the drug.

³ This is still missing in UK and Germany.

⁴ The passage of the Hatch-Waxman Act was found to be followed by a dramatic increase in the number of generic drugs in the US market ([12], [13]).

With regards to the diffusion of generic, Scott Morton ([22]) takes a different perspective and analyzes the entry decision of generic manufacturers in the market opened by patent expiration. Size and the percentage of hospital sales are market characteristics that turn out to facilitate entry (also products that threat chronic conditions are found to attract entry).

More recent studies have addressed the issue looking also at other countries and have suggested that both generic penetration and the impact on prices is linked to the extent of price regulation.

According to Danzon and Chao ([8]), strict price regulation lowers prices for older and globally diffused molecules as compared to less-regulated regimes. Conversely, generic competition operates as a more effective control on prices in less regulated regimes, where more competitors enter the market and price competition among the original brand producers and among producers of generics is stronger.

In a study ([15]) that examines directly the relationship between patent expiry and the diffusion of generics in four countries (USA, United Kingdom, Germany and Japan), it is shown that both generic entry and the time lag between patent expiry and generic entry are linked to the size of the market at the date of patent expiry⁵. Second, the speed at which the original brand loses revenue is proportional to both the size of the market and the price of the original brand prior to generic entry.

Bae ([3]) focuses again on the US market and analyzes the factors that influence the speed and the likelihood of generic entry. In his study a new variable, i.e. the degree of competition and perceived profitability (measured by the number of products in a therapeutic market) is introduced in the empirical model. This variable is found to be related to the generic entry rate.

Hollis ([14]) analyzes the impact of the practice by patent holders in Canada to license their product to “pseudo-generic” manufacturers upon the expiry of their patent. This strategy is shown to discourage entry by generic firms into drug markets. The issue of strategic licensing

⁵ This has implications regarding the value of the patent. Since patent expiry does not always induce the entry of generics and, in any case, there is a lag of sometimes several years between patent expiration and generic entry, the firm revenues will not disappear immediately but will be eroded over a period of time. Therefore, the value of patents for a company has to be computed taking into account not only the period of patent protection, but also the period after patent expiry. In other words, the value of patents extends after patent duration ([15]).

by a patent holder to deter entry by competitors is also recognized by a strand of theoretical literature in which an incumbent, whose patent is approaching its expiration date, is able to deter entry by licensing its technology ([2], [9], [24]).

In what follows, we take on some of these issues and examine jointly the dynamics of prices and market shares, both in term of values and quantities, of drugs sold under different licensing status.

IV. Data

Our database has been constructed using the MIDAS – IMS International database. This provides quarterly data from July 1987 to December 1998 on the sales of all pharmaceutical products containing major molecules whose patent expiry is known to lie between 1986 and 1996. The countries covered by the database are the USA, the United Kingdom (UK), Germany, and France⁶.

Data report sales for each different forms and dosages of the products, expressed both as quantities (number of Standard Units⁷, henceforth SU) and as values in US dollars, converted using the US Exchange rate for the latest available time period. This measure is indicated as LCD, Local Currency Dollar. The values of sales have been deflated using the Consumer Price Index (OECD data), 1998.

For each package the database provides information on the average number (on all diagnoses) of daily doses⁸ expressed in SU. We used this variable to aggregate sales at the product level. First, we computed, for each package, the number of daily doses (nDDD) as the ratio of the sales (in SU) to the average daily dose (in SU). Using this measure, which is independent of both dosage

⁶ The database also contains data on 15 molecules in Italy. They haven't been considered in the analysis due to the extremely low diffusion of generic products in this country.

⁷ Standard Units (SU) make possible to compare solid and liquid products. In the case of solid products, the SU is a capsule or a tablet. For liquid products, it is a spoonful (5 ml.).

⁸ This variable is however available only for the time interval January 1996 – December 1998 for Germany and January 1993 – December 1998 for the other countries, therefore we considered the average over the observation period, separately for each country. The database didn't provide information on average daily doses for three active ingredients in Germany, one in the USA and one in the UK that have been disregarded.

and pharmaceutical form, it is possible to aggregate, for each product, the values referring to different forms and strengths⁹.

The price per average daily dose has been obtained as the ratio of the value of sales (LCD) to the quantity in terms of nDDD.

Considering as different the active ingredients in different countries, we come up with a sample of 269 active ingredients¹⁰.

For each of them, the database provides information on the month and year of patent expiry of the molecule, on the launch date (month and year) of each product and the typology of entry in the market: Originator, Licensed, Other Brand and Unbranded.

The analysis of the dataset has been performed aggregating the data on a yearly basis for the period 1988 – 1998 and the time origin has been set at the time of patent expiration.

V. Descriptive Analysis¹¹

First we look at the dynamics of price indexes, both before and after patent expiration for the Original products. Here we consider as Original the products launched at least three years before the patent expiration¹².

The index reported in Figure 1 is computed from the average (weighted with sales value) of the price indexes, computed as the ratio of the market price at time t and the price at the time of patent expiration, of all the products considered.

// Figure 1 about here //

In the USA the prices of Original products grow substantially in the period before and after patent expiration, whereas the European countries are characterized by a substantial decrease over time (the exception being France). This result is consistent with the observation that prices tend to fall with age in Europe and especially in regulated countries, where prices are set when

⁹ Such an aggregation would be problematic in case SU are considered, because it is not meaningful to sum values that refer to different dosages.

¹⁰ We have 54 molecules in the USA, 70 in the UK, 68 in Germany and 77 in France.

¹¹ This section builds on the work performed in [19].

the drug is launched and then they are seldom allowed to be increased (therefore they decrease in real terms).

In a previous work ([19]), we compared directly the price indexes of the different types of products (distinguishing licensed, other brand and unbranded products) to the price of the Original drugs after patent expiration. The main findings regarded the dynamics of prices of other brand and unbranded products, both over time and compared to the average price of Original products. The picture that emerged from the analysis was one in which quite different patterns of competition characterize the different countries. In the USA there exists a sharp separation between the price dynamics of Original products on the one hand and of multi-source drugs on the other. Generics enter the market after patent expiration with a significant price discount. Afterwards, while the prices of Other Brands rise relative the original products, unbranded drugs continuously reduce their price.

In UK and Germany, multi-source product prices are lower than the Original product at the time of patent expiration and stay lower as the price of the original product changes over time. However, the prices tend to converge over time in Germany, as the price of original products declines while the price of multi-source drugs remains constant. This is likely the result of the introduction of a reference price system.

France, finally, exhibits yet another pattern of competition. In this country, multi-source drugs enter the market, at prices that are, on average, higher than the prices of Original products. Afterwards, prices of multi-source drugs decline, while the decrease in the prices of Original products stops.

So far, we have discussed price dynamics. In what follows, we focus on another key issue: the entry and penetration of multi-source products.

Figure 2 reports the market shares of other brand and unbranded products for the whole sample distinguishing each country.

¹² In this way we highlight the dynamics of product prices that are not launched in proximity of patent expiration or after this date. These products can be considered as strategic responses by the patent holder to patent expiration and should be analyzed separately.

Around a decade after patent expiration, the penetration of generics is quite strong in the USA and in Germany, less so in the UK and especially in France, where there is practically no entry.

// Figures 2 about here//

These results are in line with the findings of the literature analyzed in Section 3. In tightly regulated countries, nominal prices of original products remain fixed and are not allowed to vary as time goes by. Lower prices presumably do not attract the entry of generic drugs, which is in fact lower in more regulated markets. Conversely, in less regulated regimes (like the USA), innovators of high quality drugs enjoy higher prices. This attracts the entry of generics.

VI. Generic Entry and the Pricing of Original Products

The descriptive evidence discussed so far does confirm some results of the literature discussed in Section 3, but it raises additional questions. The stronger penetration of multi-source drugs in the USA and the low diffusion of generics in tightly regulated countries like France are largely confirmed by our data. However, our descriptive analysis tells little about the determinants of generic competition and price dynamics.

The following multivariate analysis is meant to shed some light on these problems.

First, we analyze the determinants of generic entry after patent expiration. For this purpose, we selected the molecules whose patent expired between July 1988 and December 1995.

The market share captured by the unbranded products is related to the state of the market in previous times. In order to take into consideration the mean approval time lag between the entry decision and the actual launch of the generic drug on the market, all explanatory variables in our model are three years lagged.

The market share of licensed products (MS_LIC) has been included among the explanatory variables to check whether licenses can be used to inhibit the diffusion of generics. Moreover, we consider basic characteristics of the market such as market size, measured in millions of nDDDs (MKTSZ) and its square (MKTSZ2), the percentage of sales to the hospital segment, calculated using nDDD (HOSP), the average market growth (MKTGR), which have been found

to be important determinants of generic entry in previous research, and the number of different brand names on the market (NPRDOR).

We check the effect of price margins on generic entry, as measured by the average price of original products (weighted using nDDD sales) to the minimum price on the market¹³ (RATIO).

Country dummy variables have been included, taking the USA as the omitted group.

We apply a censored tobit model for panel data with random effects. Indeed in the 48% of the markets there was no generic entry. The tobit model with random effects allows us to control for unobservable market-specific determinants of generic entry at the sub-market (molecule) level.

Estimates are obtained using STATA which calculates the integral that appears in the likelihood function by Gauss-Hermite quadrature. Results are reported in Table 2.

// Table 2 around here //

Our results confirm that high margins attract the entry of generic drugs. On the contrary, the existence of licensed products is an obstacle to the diffusion of generics: the higher the market shares of licensed products the lower the diffusion of generics three years apart.

In line with previous analytical results, total market size turns out to be an important determinant of the diffusion of generic products: in larger markets unbranded products gain larger market shares.

The proliferation of different brand names on the market has a positive effect on generic diffusion as patent holders are not able to create strong and spread brand loyalty before patent expiry.

Finally it is worthwhile to notice that the size of the hospital segment has a negative impact on generic market shares¹⁴.

¹³ The minimum price of all the products in the market is taken as a proxy of marginal cost. This approach is slightly different from the customary approach in the literature, which is to consider the price of the unbranded products as a proxy for marginal cost. The choice has been driven by the high percentage of molecules that do not incur in generic entry within our sample. By considering the minimum price of all the product on the market the RATIO variable can be computed for each molecule.

¹⁴ This is apparently at odds with previous findings. Studies focusing on the US pharmaceutical industry found a positive relationship between the share of sales to the hospital segment and the entry of generic products, consistent with the fact that there exist institutional factors facilitating generic entry in the hospital segment ([22]).

Let us now turn to the factors driving the dynamics of original prices after patent expiration. Specifically we test a model for the ratio of the median price of original products over the minimum price of all the products on the market. In the analyses that follows we take into consideration all original products present on the market three years before patent expiration. We added the number of generic products on the market (NPRDUNB) to the previous set of regressors. All independent variables are one year lagged.

We apply a model for panel data considering all data from patent expiration to 5 years afterwards. We chose the random effect specification of the model based on the result of the Hausman test (see Table 3).

// Table 3 around here //

The results of the regression highlight the fact that MS_LIC has a positive and slightly significant effect on the dependent variable. The presence of licensed products also increases the difference between original price and the minimum price on the market even if this effect is weaker than in the previous regression on generics market share.

The number of products on the market, both Original and Unbranded products, doesn't have an effect on the ratio of prices. On the contrary, the size of the market has a positive effect on the price of original drugs.

VII. Concluding Discussion

This paper has shown that the dynamics of prices and the diffusion of generic products after patent expiry vary significantly across countries.

This heterogeneity notwithstanding, a clear distinction seems to emerge from our empirical investigation. On the one side, systems that rely on market based competition in pharmaceuticals promote a clear distinction between firms that act as innovators and firms that act as imitators after patent expiry. Here, original products can enjoy premium prices and exclusivity profits under patent protection, and face fierce price competition after patent expiry. Policies supporting price competition through the diffusion of generics after patent expiration seems to be effective. The quintessential example of such dynamics is given by the US where

the real prices of Original products rise over time, also after patent expiration, and the generic producers continuously gain market share after patent expiration selling their products with a significant price discount. On the contrary, in systems that rely on administered prices the diffusion of generic after patent expiry is rather limited, even in the long run (see the case of France). In this setting, the monopoly power conferred to patent holder is counterbalanced ex ante, through price regulation, which somehow limits the effectiveness of generics diffusion as a way to induce price competition in the market after patent expiration.

This heterogeneity in price dynamics and generic diffusion across countries can certainly be, at least partially, explained in terms of the different regulatory environments. Different countries have different medical traditions, different institutional settings for financing and provision of health care, and different sets of incentives placed on physicians, pharmacists and customers to use cheaper generics. However, the simple model developed in the paper helps us in understanding how market characteristics are linked to the market share of generic products and to Originals price dynamics and in shaping the ground on which policies fostering the diffusion of generics can be effective.

Coherently with previous studies, larger markets seem to attract larger generic entry. Absolute size at the sub-market level exerts a significant effect in determining the extent and impact of generic competition (see also [15] and [21]). Also higher margins foster generic penetration, suggesting that price regulation, even if counterbalancing the power of monopolistic producers before patent expiration, can be an obstacle to the setting up of a competitive environment in the off-patent segment of the pharmaceutical market.

Another factor slowing down generic entry is given by a high presence of licensed products on the market: their share has turned out to be an obstacle to the diffusion of unbranded products.

With regards to price dynamics, our results are weaker than results on the market share regression. However, in the latter regression, the presence of licensed products affects positively the difference between original price and the minimum price on the market, and the number of both Original and Unbranded products on the market doesn't affect the ratio of prices.

Irrespectively of any comparison with the US market, these findings seem to be relevant in terms of policy implications for the European Countries and open revenues for further research. Need it here to mention that we do not directly address the issue of efficiency of specific policies in fostering or limiting the diffusion of generics within a country. This is certainly an important issue to be addressed, however a first step towards this direction comes from the inclusion of country dummies in the regression. Their high significance (in the regression on market shares) suggests that the regulatory environment and the institutions characterizing the country matter. This issue deserves further investigation together with the understanding of the contribution to the generation of inconsistencies, likely inefficiencies in the use of resources, uneven standards of medical care, and distortions in the functioning of markets linked to the high diversity (both in the way they are organized and financed) of European national health care. Even if these diversified systems reflect different social values, ethics, and level of wealth across Europe, they constitute an impediment to the creation of a unified European market, with all its implied consequences in terms of size of the market, economies of scale, and higher competition.

On a complementary side, as for industrial policy and competitiveness issues, empirical literature shows that an increased market competition can contribute to foster¹⁵ efficiency and to design adequate incentives to innovate ([1]; [4]). This is particularly relevant in the off-patent segment of the pharmaceutical market and within the European environment, where the promotion of patterns of industrial reorganization and selection allowing higher prices and returns on investment for innovative products that are still on patent can help in fostering generic competition and the innovativeness of firms operating in this sector.

These implications notwithstanding, much more work remains to be done on these issues.

¹⁵ Even if the empirical research on the relationship between competition and innovation was pointed to be inconclusive ([1], [7]), a recent study, that analyzes British firms between 1972 and 1982 and takes into account the dynamic feedback between innovation and market power and the heterogeneity of the firms, finds that firms with larger market share tends to innovate more. However this effect is counterbalanced by the fact that concentration has a negative impact on the probability to innovate, suggesting that competition has a positive impact on the number of industry innovations ([4]). Empirical evidence on the relationship between competition and productivity support the existence of a positive relationship between these two variables (for a survey see [1]).

References

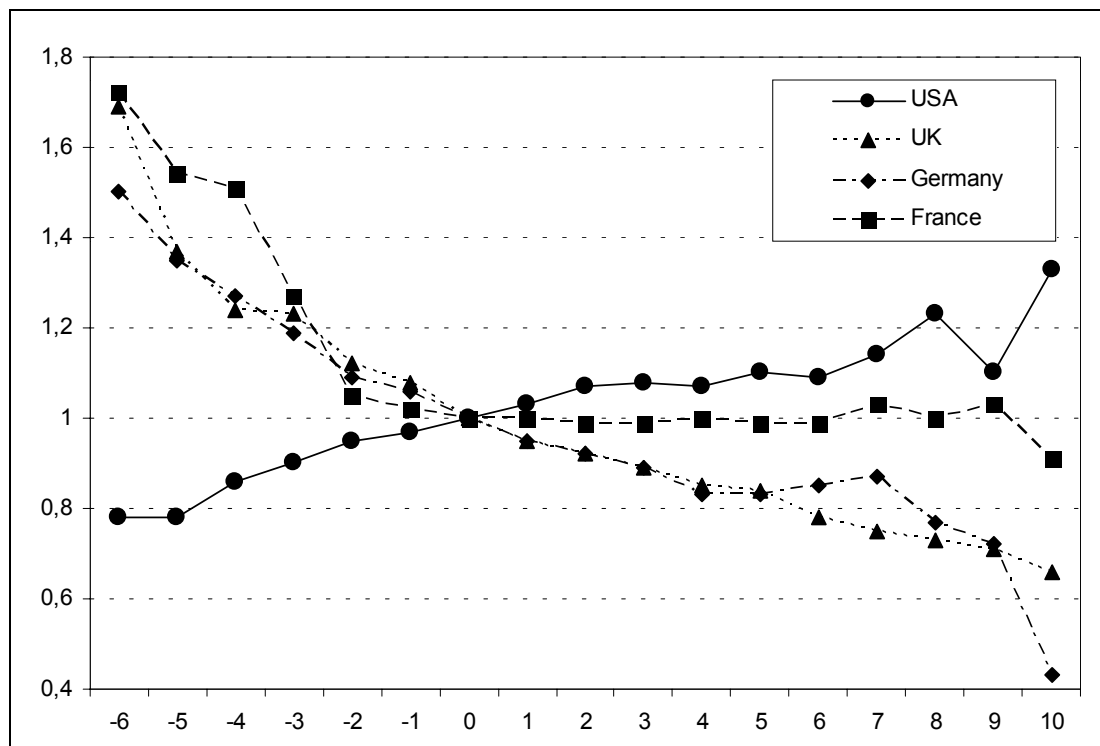
- [1] Ahn S (2002), Competition, Innovation, and Productivity Growth: a Review of Theory and Evidence. OECD Economics Department Working Paper, 317
- [2] Ashiya M (2000), Weak Entrants are Welcome. *International Journal of Industrial Organization*, 18, 975-984
- [3] Bae JP (1997), Drug Patent Expirations and the Speed of Generic Entry. *HSR: Health Services Research*, 32:1, 87-101
- [4] Blundell R, Griffith R, Van Reenen J (1995), Dynamic Count Data Models of Technological Innovation. *The Economic Journal*, 105, 429, 333-344
- [5] Caves RE, Whinston MD, Hurwitz MA (1991), Patent expiration, entry and competition in the US pharmaceutical industry. *Brookings Papers on Economic Activity. Microeconomics*, 1- 48
- [6] Ching ATT (2000), Dynamic Equilibrium in the Prescription Drug Market after Patent Expiration. *PhD Dissertation*, University of Minnesota.
- [7] Cohen W, Levin R (1989), Empirical Studies of Innovation and Market Structure. In R Schmalensee and J Willing (eds), *The Handbook of Industrial Organization*, I, Amsterdam: North Holland
- [8] Danzon PM, Chao LW (2000), Cross-national Price Differences for Pharmaceuticals: How Large and Why? *Journal of Health Economics*, 19, 159-195
- [9] Eswaran M (1994), Licensees as Entry Barriers. *The Canadian Journal of Economics*, 27, 3, 673-688
- [10] Gambardella A, Orsenigo L, Pammolli F (2001), *Global competitiveness in pharmaceuticals. A European perspective*. Directorate General Enterprise, European Commission, Brussels
- [11] Garattini L, Tediosi F (2000), A Comparative Analysis of Generics Markets in Five European Countries. *Health Policy*, 51, 149-162
- [12] Grabowski HG, Vernon JM (1992), Brand Loyalty, Entry and Price Competition in the Pharmaceuticals after the 1984 Drug Act. *Journal of Law and Economics*, 35, 331-350
- [13] Grabowski HG, Vernon JM (1996), Longer patents for increased generic competition in the US. *PharmacoEconomics*, 10, 110-123

- [14] Hollis A (2000), The Effect of Brand-Controlled “Pseudo-Generics” on the Canadian Pharmaceutical Market. Department of Economics, University of Calgary
- [15] Hudson J (2000), Generic Take-Up in the Pharmaceutical Market Following Patent Expiry. A Multi-Country Study. *International Review of Law and Economics*, 20, 205-221
- [16] Hurwitz MA, Caves RE (1988), Persuasion or Information?: Promotion and the Shares of Brand Name and Generic Pharmaceuticals. *Journal of Law and Economics*, 31, 299-320
- [17] Jacobzone S (2000), *Pharmaceutical Policies in OECD countries: reconciling social and industrial goals*. OECD Labor Market and Social Policy Occasional Papers, 40
- [18] López-Casanovas G, Jönsson B, eds., (2001), *Reference Pricing and Pharmaceutical Policy: Perspectives on Economics and Innovation*. Kluwer, Dordrecht
- [19] Magazzini L, Orsenigo L, Pammolli F (2002), The intensity of competition after patent expiry in pharmaceuticals: a cross-country analysis. *Revue d’Economie Industrielle*, 99.
- [20] Mossialos E (1997), Citizens’ View on Health Systems in the 15 Member States of the European Union. *Health Economics*, 6, 109-116
- [21] NERA (1998), *Policy relating to generic medicines in the OECD*. Report for the European Commission, Brussels
- [22] Scott Morton FM (1997), Entry Decision in the Generic Pharmaceutical Industry. *NBER Working Paper*: 6190
- [23] Suh DC (1993), Effect of Multiple Source Entry on Price Competition After Patent Expiration in the Pharmaceutical Industry. *PhD Dissertation*, University of Minnesota
- [24] Yi S (1999), Entry, Licensing and Research Joint Ventures. *International Journal of Industrial Organization*, 17, 1-24

France	1990	Marge dégressive lissée (regressive margin for pharmacies) Law allowing lengthening of patent protection (7 years)
	1996	Decree defining generic medicines
	1997	List of equivalent generic medicines for off-patent original products by the Agence des Médicaments Convention Medicale
Germany	1977	Krankenversicherungs-Kostendämpfungsgesetz (Law on Cost Containment)
	1980	Regressive margins for pharmacies and wholesalers
	1989	Gesundheitsreformgesetz (Health Care Reform Act)
	1993	Price cut for all the drugs out of the reference price system.
UK	1985	Introduction of the 'Black list' and of the 'White list'
	1988	Prescribing Analysis and Cost Scheme
	1990	Fund-holding scheme
	1993	Extension of the 'black-list'
USA	1984	Waxman-Hatch Act The last anti-substitution law was repealed

Sources: Caves, Whinston and Hurwitz ([5]); Garattini and Tedioli ([11]); NERA ([21]);

Table 1: Policies fostering the diffusion of generics



**Figure 1: Price Indexes for Original Products:
Ratio of price at time t and price at the time of patent expiration ($t = 0$)**

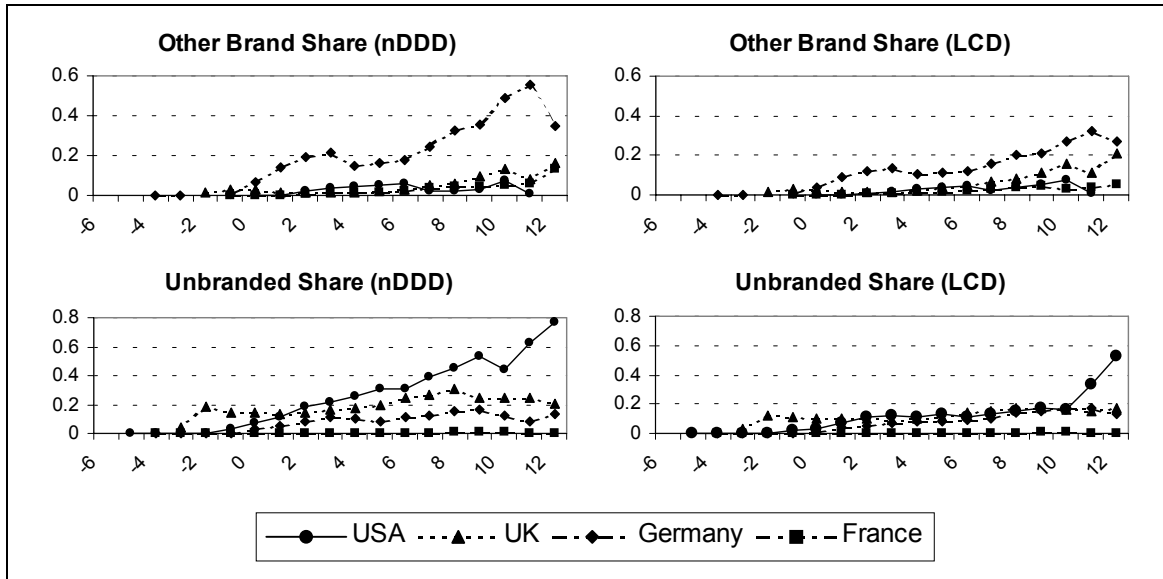


Figure 2: Market Shares of Other Brand and Unbranded Products Before and After Patent Expiry

Variable	Coefficient	Std. Error	p-value
MS_LIC	-0.275	0.0277	0.000
RATIO	0.320	0.065	0.000
HOSP	-0.115	0.044	0.009
MKTSZ	0.023	0.004	0.000
MKTSZ2	$-.16 \times 10^{-4}$	$.48 \times 10^{-5}$	0.001
MKTGR	-0.046	0.034	0.174
NPRDOR	1.594	0.100	0.000
France	-12.117	1.142	0.000
UK	-9.272	1.138	0.000
Germany	-4.912	1.208	0.000
Constant	-0.393	1.170	0.737
σ_α	12.533	σ_u	4.287
ρ	0.895	Log Likelihood	-974.338

Table 2: Regression Results for the Market share of Unbranded drugs after patent expiration

Variable	Coefficient	Std. Error	p-value
MS_LIC	0.039	0.020	0.054
NPRDOR	0.475	0.470	0.312
NPRDUNB	0.114	0.289	0.694
MKTSZ	0.035	0.005	0.000
MKTSZ2	$-.22 \times 10^{-4}$	$.29 \times 10^{-5}$	0.000
MKTGR	$.41 \times 10^{-3}$	0.003	0.875
France	-2.695	1.512	0.075
UK	-1.923	1.571	0.221
Germany	-1.369	1.675	0.414
Constant	1.661	1.488	0.270
R-square (within)	0.36	Hausman Test	10.92
			(p-value 0.09)

Table 3: Regression Results for the Original prices after Patent Expiration