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# THE INTENSITY OF COMPETITION AFTER PATENT EXPIRY IN PHARMACEUTICALS. A CROSS-COUNTRY ANALYSIS

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**Key words** : Pharmaceutical industry. Price competition. Generic entry. Market regulation. Dynamic competition.

## I. — INTRODUCTION

This paper constitutes an attempt at investigating processes of dynamic competition in pharmaceuticals, with reference to the nature and intensity of price competition in relation to patent expiry.

We focus on what happens to drug prices and to the diffusion of multi-source products both before and after patent expiry, in relation to different regulatory regimes (Jacobzone, 2000; Gambardella, Orsenigo, and Pammolli, 2000) (1).

The market for pharmaceutical products is characterized by the co-existence of most of the textbook motivations of market failures.

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(1) Voir note page suivante.

A cornerstone of the debate is clearly patent protection. While patents are usually recognized as being a fundamental incentive to innovation in pharmaceuticals, for a long time in many countries – including Germany (until 1968), Sweden (until 1978), Switzerland (until 1977) besides the usual examples of Italy and Japan – only process patents have been granted. In more recent years, the attitude towards a stronger IPR regime has been spreading. Currently, the debate on patents is re-emerging, especially as it concerns the role of patents in promoting innovation and economic development, the scope of patents granted in genetics, and on discoveries derived by publicly funded research.

Another crucial aspect concerns price regulation. There are in principle many rationales for price controls in pharmaceuticals, in relation to information asymmetries and low demand price elasticity. However, it is often argued that price regulation is unnecessary and harmful. On the one side, the industry is characterized by intense dynamic competition also within specific sub-markets. On the other side, it is maintained that price regulation distorts the price mechanisms, curbs the profits of companies and the incentives to innovation, allows the survival of less efficient firms and, in general, creates environments where competition is too lenient. Moreover, price controls per se do not reduce health expenditures, while they tend to diminish incentives for prices to act as signals of relative quality.

The debate is inherently complex, and the matter is further complicated by the fact that regulation takes very different forms, across countries and over time.

In recent years one observed a tendency towards the use of less invasive regulation and a higher reliance on market-based measures aiming at promoting price elasticity and competition on the final market.

Prominent among these measures is linked to generic competition, as an instrument for reducing prices and countervailing exclusivity power granted by patents (2).

- (1) Even within Europe, healthcare and pharmaceutical systems are hugely diversified in terms of the way they are organized and financed, ranging from national health schemes funded out of general taxes (the UK-Italy-Spain model), to mandated social insurance with pluralist providers (the Germany-France-Netherlands model). The main goal of the paper is to provide a set of comparative empirical evidences showing how major institutional differences affect patterns of industrial competitions in five major developed countries (USA, UK, Germany, France, and Italy). These countries differ significantly – among other important factors like medical traditions, size of the market, provision and financing of health care, extent of public and insurance coverage for pharmaceutical consumption, etc. – in terms of the extent and regimes of regulation, particularly as prices are concerned.
- (2) This was actually the intention of the Waxman – Hatch Act in the US in 1984.

How these mechanisms work in practice is however less than perfectly clear and despite some important previous works, we know still very little on the subject (see Mossialos, 1997; NERA, 1998; Jacobzone, 2000 ; López-Casnovas and Jönsson, 2001). We shall discuss the relevant literature in Section 2. For the time being, suffice it to mention that it is often argued that price controls discourage competition by generics and greatly reduce their competitive effect on drug prices.

We focus on how drug prices change over time, before and after patent expiry and, possibly, as a consequence of generic competition. Our results suggest that the relationships between the dynamics of drug prices, patent expiry, and generic competition are complex and differentiated across countries.

A long list of caveats is necessary at this stage. First, note that we do not look at comparisons of price levels across countries, but at price changes within countries (see Berndt, 2000; Danzon and Chow 2000).

Second, we do not analyze the determinants of generic competition (see NERA, 1998). Price levels, price changes, generic competition are likely to be endogenously co-determined. In this paper, we confine ourselves to a preliminary analysis, considering the role of some fundamental properties of the markets, like their relative size and growth, price differentials between original and generic products, but falling short of providing a fully-fledged (let alone a simultaneous model) of generic competition and prices.

Third, we do not examine how price dynamics and generic competition affect innovation, nor how price levels and their changes affect welfare (see Comanor, 1986; Grabowski, Vernon, 1992; Scherer, 1993).

Finally, we do not directly relate the observed dynamics to specific features of the regimes of regulation across countries.

The paper is organized as follows. First, we briefly discuss the recent relevant literature on these subjects. In Section 3, we describe the data base. Section 4 provides some descriptive evidence on the dynamics of the prices of different types of drugs (original, licensed, other branded and unbranded products), on the diffusion of generics and on market concentration. In Section 5, we perform some preliminary multivariate analysis to dig further into these issues. We look at the determinants of price dynamics focusing on the impact of patent expiry and competition by multi-source drugs. Next, we examine some of the relationships between the pattern of diffusion of generics, price differentials between original and generic products, size and rate of growth of markets. Section 6 concludes the paper.

## II. — AN OVERVIEW OF RELEVANT ISSUES

Previous literature has examined the factors influencing the diffusion of generics and their impact on drug prices. Most of these studies have focused on the US market and have not considered directly the role of patent expiry (3).

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 (see Danzon and Chow, 2000).

In particular, Hudson (2000) examines directly the relationship between patent expiry and the diffusion of generics. He shows that both generic entry and the lag between patent expiry and generic entry are linked to the size of the market at the time of patent expiry. 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. In the US the impact of generic entry on original brand sales is found to be much bigger as compared to the United Kingdom, Japan and Germany. This result might reflect the larger size of the US market, but also different regulatory environments that putting little pressure on patients, doctors and pharmacists not to request expensive branded products and keeping relatively low prices of branded drugs actually make generic entry less attractive and reduce its overall impact on prices. Hudson makes the additional point that more successful drugs attract – others things being equal – generic competition and thus tend to lose sales after patent expiry. Conversely, less successful drugs will suffer less from generic competition. Thus, the value of patents for a company has to be computed taking into account not only the period of patent protection, but also to the period after patent expiry. 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 expiry and generic entry, the firm's revenues will not disappear immediately but will be eroded over a period of time. In other words, the value of patents extends after patent expiry.

These results suggest that generic competition has lower effects on prices in tightly regulated countries for different reasons. First, regulation – almost by

- (3) Hurwitz and Caves (1988) found that original brand market share is directly proportional to the age of the original brand and to own brand promotional spending, while it is negatively correlated to entrants' potential spending and to the number of entrants. This latter variable was found to be proportional to the total size of the market and to the age of the original brand. Grabowski and Vernon (1992) and Suh (1993) showed that in the US generics entered the market at a significant price discount, which then declines over time. The price of the original brand actually increased – in nominal terms – after the entry of generics. In a more recent study, Grabowski and Vernon (1996) found that generic competition has been intensifying in the US, with major brand names typically losing half of their market share within a year of patent expiry. Similarly, Caves, Whinston and Hurwitz (1991) found that the price of the original brand declines over time as more generic entrants appear.

definition – keeps the prices of branded patented drugs lower. This reduces the attraction of generic entry. Second, generic competition is further reduced because patients, doctors and physicians have less incentives to substitute low priced drugs (generics) to original branded products. Thus, demand elasticity tends to be lower. Third, producers try to exploit the regulatory regimes by co-marketing generics with generic suppliers or producing minor new products and negotiating comparatively higher prices.

Conversely, in less regulated regimes, innovators of high quality drugs enjoy higher prices. This attracts the entry of generics. The original brand producer may try to differentiate its product vis-à-vis generics, e.g. through advertising, and operate market segmentation. In this case, pre-entry prices of pioneer brands can be maintained or, in some cases, extended, upon patent expiry because of strong brand loyalty toward original brands (Caves, Whinston, Hurwitz, 1991; Grabowski and Vernon, 1992). Alternatively, pioneer off-patent products become OTCs (e.g., Pepcid, Zantac, Tagamet) and are paid for out-of pocket. Competition by generics becomes substantial very soon, prices fall and market shares of the branded drug are eroded. In practice, in these countries, markets generate a sharp distinction between innovators and imitators (producers of generics).

### III. — DATA

Data for this paper are drawn by the MIDAS – IMS International database that provides quarterly data on the sales of pharmaceutical products for the time period July 1987 – December 1998 for five countries : the US, the United Kingdom, Germany, France and Italy.

For each product, we aggregate the information across different forms and dosages.

Sales are expressed as quantities (SU: number of Standard Units (4)) and in US dollars. The values in US dollars have been calculated using the US Exchange rate for the latest available time period. This measure is indicated as LCD, Local Currency Dollar. Sales have been deflated using the Consumer Price Index (OECD data), 1998.

Products in our sample cover 103 molecules with known date of patent expiry for 1986-1996 (see Table 1).

We use quarterly data on the average number of Defined Daily Doses (DDD) in SU.

(4) 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, a spoonful (5 ml).

*Table 1 - Number of molecules in the sample*

Country	Number
USA	54
UK	70
Germany	68
France	77
Italy	15

The database doesn't provide information on DDDs for three active ingredients in Germany, one in the US and in the UK. We work therefore on a sample of 284 active ingredients. Only for 137 of them, entry of multi-source drugs has taken place.

For each package, we do know :

- Date of patent expiry (month and year) ;
- Manufacturer ;
- Corporation owning the patent ;
- Role in the market: Originator, Licensed, Other Brand or Unbranded.

The descriptive analysis has been performed aggregating the data on a yearly basis from 1988 to 1998.

As for quantities, we consider the number of DDDs, obtained by computing, for each package, the ratio of sales (in SU) to the average daily dose (5) (in SU) (6). The price per DDD has been obtained as the ratio of the value of sales (LCD) to the value in terms of DDD (nDDD).

#### **IV. — THE DYNAMICS OF PRICE INDEXES**

##### **IV.1. The Dynamics of the Prices of Original and Licensed Products and Average Prices**

First, we look at the dynamics of price indexes, before and after patent expiry. For Original and Licensed products, the index is computed from the average (weighted with quantities sold) of the price indexes of all the products included in the sample. The prices indexes are computed as the ratio of the market price at time  $t$  and the price at the time of patent expiry.

- (5) Averages of daily doses over a five year period.
- (6) Data are independent of both dosage and the pharmaceutical form. Thus, it is then possible to aggregate, for each product, the values referring to different forms and dosages.

*Table 2 - Price Indexes for Original Products (LCD Weighted Average),  
Pre and Post Entry Periods*

Country	-4	-3	-2	-1	0	1	2	3	4
USA	0.86	0.90	0.95	0.97	1.00	1.02	1.05	1.07	1.05
UK	1.24	1.23	1.12	1.07	1.00	0.95	0.92	0.90	0.85
Germany	1.27	1.19	1.09	1.06	1.00	0.95	0.92	0.89	0.85
France	1.51	1.27	1.05	1.01	1.00	1.00	0.99	1.00	1.01
Italy	1.37	1.26	1.16	1.04	1.00	0.98	1.00	0.96	0.92

*Table 3 - Price Indexes for Licensed Products (LCD Weighted Average),  
Pre and Post Entry Periods*

Country	-4	-3	-2	-1	0	1	2	3	4
USA	0.92	0.91	0.93	0.96	1.00	1.04	1.05	1.03	1.02
UK	1.27	1.22	1.26	1.20	1.00	0.88	0.83	0.79	0.78
Germany	1.29	1.23	1.13	1.11	1.00	0.95	0.92	0.93	0.94
France	4.16	2.62	1.89	1.03	1.00	1.01	1.00	1.02	1.02
Italy	1.42	1.23	1.14	1.01	1.00	0.96	0.96	0.95	0.97

Tables 2 and 3 show a very similar pattern for Original and Licensed products. In both cases in the US the prices grow (substantially in the case of Original products) in a period spanning four years before and after (two years for Licensed products) patent expiry (from 0.86 to 1.05). The European countries are characterized instead by a rather different dynamics. Prices decline continuously over time approaching patent expiry. Afterwards, prices continue to fall in Germany and in the UK. They remain stable in France and in Italy (until the third year after patent expiry). Over the whole period considered, the reduction of the prices of Original products is particularly strong in France and is quite similar in the other countries.

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 at time of the launch of the drug and then they are seldom allowed to be increased. As a consequence, their real price tends to fall over time. Conversely, US producers seem to practice some form of penetration pricing. After patent expiry, moreover, they are able to segment the market and charge premium prices on branded drugs.

Let us examine now the dynamics of average prices (Table 4). In the US, the average price increases before patent expiry and, after that date, it remains stable. Considering that – as just noted – the price of Original and Licensed products continuously increases, this result presumably reflects the entry of multi-source drugs that are sold, on average, at a lower price. On the whole, however, average prices do not decline after patent expiry and, if anything, they increase as compared to the initial period. Interestingly enough, this dynamics suggests that price increases before patent expiry can be used as an entry-defending strategy by the pioneer firm, softening price competition with gene-

ric drugs and, possibly, enhancing the demand of branded products. As for European countries, not only average prices decrease steadily over time, but their dynamics is practically identical to the dynamics of Original and Licensed products. In particular, in France, average prices fall sharply before the patent expires and then remain constant : that is to say, either the competition of generics does not affect the dynamic of prices or the price of generics move precisely like the price of original and licensed drugs.

Table 4 - Price Indexes for All Products (LCD Weighted Average),  
Pre and Post Entry Periods

Country	-4	-3	-2	-1	0	1	2	3	4
USA	0.87	0.90	0.95	0.99	1.00	1.00	1.00	1.01	1.01
UK	1.24	1.23	1.15	1.09	1.00	0.93	0.89	0.85	0.80
Germany	1.27	1.19	1.09	1.07	1.00	0.94	0.91	0.89	0.86
France	2.04	1.64	1.27	1.02	1.00	1.00	0.99	1.00	1.01
Italy	1.37	1.23	1.15	1.03	1.00	0.97	0.98	0.95	0.95

## IV.2. The Dynamics of the Prices of Multi-Source Products

In this section we compare the price indexes of the different types of products to the price of the Original drugs. Here, we distinguish – within multi-source drugs – between branded (*Other Brand*) and unbranded generics (*Unbranded*). We computed take as a basis the average price of the Original products corresponding to the multi-source drugs considered first at the time of patent expiry (Figure 1). Thus, figure 1 illustrates how the prices of the other types of products change over time relative to the average price of original products at the moment at which the patent expires ( $t = 0$ ).

The *box plots* used in Figure 1 represent the distribution of price indexes (on a quarterly base) from the date of patent expiry to 24 quarters (6 years) after that date. Each vertical rectangle gives information on the distribution of the price indexes for each specific category of products (*Original, Licensed, Other Brand e Unbranded*) in each period. Through the *box plots*, we obtain a visual representation of the dynamics and of the variability of the price indexes in each period (7).

- (7) Consider a single box. The bold line running through the rectangle is the median of the distribution. Thus, 50% of the observations are above the bold line and the other 50% are below it. The colored rectangle represents the interquartile deviation, that is to say the difference between the third and the first quartile. Therefore, it contains 50% of the observations. The lines above and below the rectangle are extended until the maximum and minimum values of the distribution (without considering outliers). The circles outside the distribution are in fact those cases with values between 1.5 and 3 times the box length from the upper or the lower edge of the box that are distant from the extreme of the rectangle more than three times its length. In order to make the box plots easier to read, we don't show the outliers, i.e. those cases with values larger than three times the box length from the upper or the lower edge of the box.

Figure 1: Price Indexes for Pre and Post Entry Periods, Different Types of Products (I)

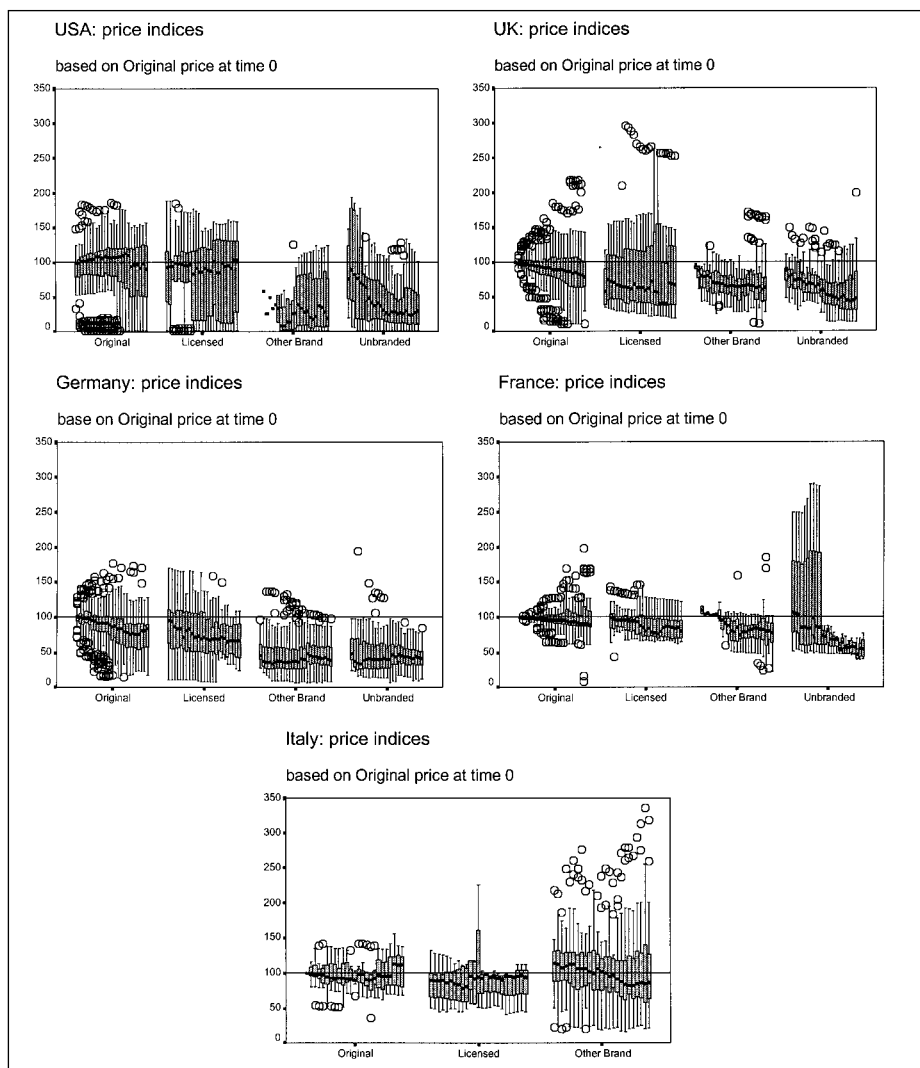


Figure 1 shows that in all countries except Germany (and the case of *Other Brands* in the US) the median of these indexes falls over time. Moreover, the box plots show that unbranded products seem to introduce some price competition in the US and the UK, while they do not have a significant impact on price levels in France and in Italy.

### IV.3. Patterns of Entry of Multi-source Drugs

Table 5 shows the aggregate market shares of the weighted averages of sales and quantities sold before and after patent expiry of Original and Licensed products.

Figure 2: Market Shares for Pre and Post Entry Periods, Different Types of Products (I)

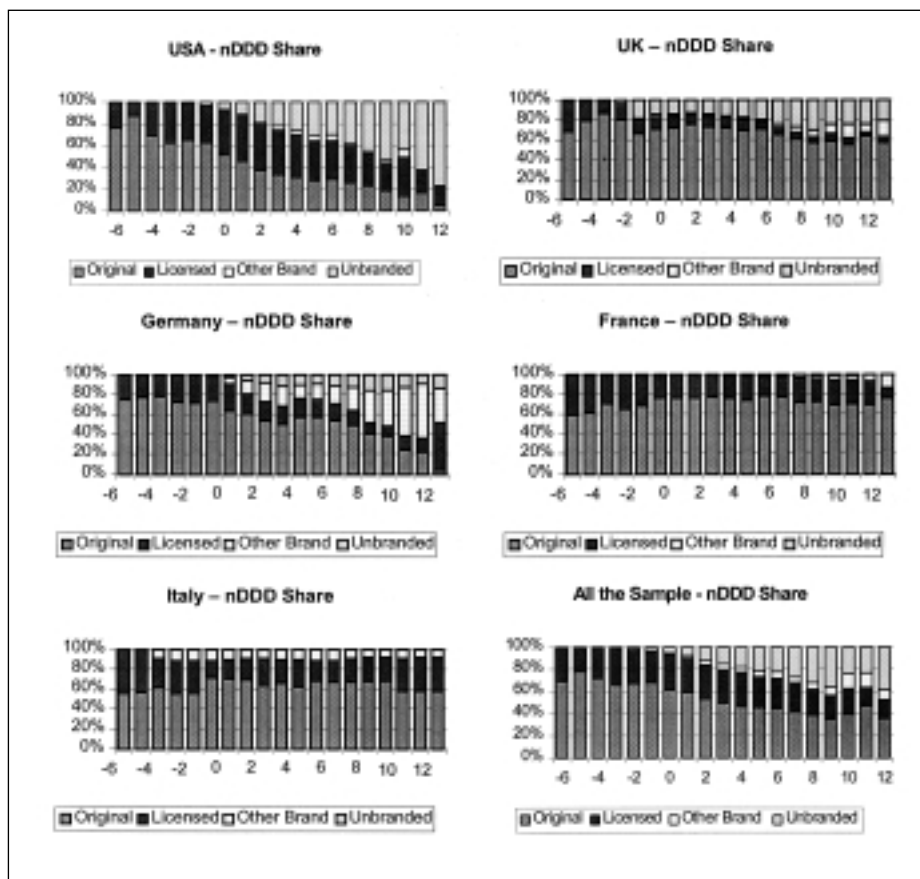


Table 5 - Market shares for Original and Licensed products (LCD weighted average)

Country		-4	-3	-2	-1	0	1	2	3	4
USA	LCD	99.99	100	100	98.39	97.39	95.00	92.29	91.84	91.41
	nDDD	100	100	100	97.71	95.32	92.50	88.23	86.69	86.07
UK	LCD	100	97.42	89.71	91.27	92.18	92.14	91.96	92.25	91.65
	nDDD	100	97.31	89.34	90.62	91.09	90.48	89.75	89.03	87.50
Germany	LCD	99.81	99.72	99.89	99.32	96.00	91.17	89.95	88.62	89.33
	nDDD	99.81	99.65	99.86	99.22	91.14	86.10	85.55	84.31	87.53
France	LCD	99.98	100	100	99.72	99.84	99.83	99.43	98.98	98.76
	nDDD	99.97	100	99.99	99.72	99.86	99.85	99.35	98.71	98.47
Italy	LCD	89.84	86.65	86.63	86.65	88.52	90.23	88.97	91.04	92.65
	nDDD	87.75	86.02	86.41	89.15	91.49	92.78	92.47	92.95	93.75

In all countries the Original and Licensed products control on average more than 95% of the market at the date of patent expiry, both in terms of sales and in terms of quantities sold (number of sold DDDs), except Italy and the UK where this share is somewhat lower.

After four years, the market share of generics is quite similar across countries, with the notable exception of France, where there is practically no entry of *multi-source* products. In the US, Germany and UK, the erosion of the market share of Original and Licensed products is larger in terms of quantities than in terms of sales because the prices of *multi-source* drugs are lower in these countries than the average prices charged by the patent holders.

In the longer run, a clear distinction can be detected between *Other Brand e Unbranded* multi-source drugs (Figures 3 and 4). After around a decade after

Figure 3: Market Shares for Pre and Post Entry Periods, Different Types of Products (II)

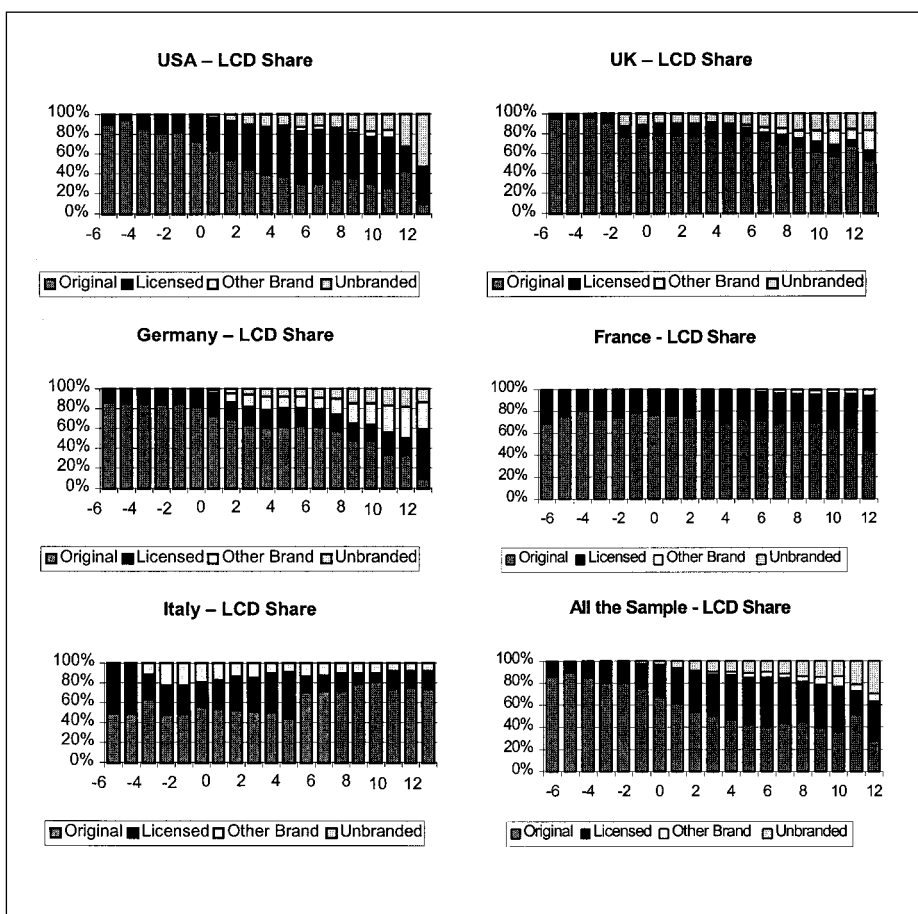
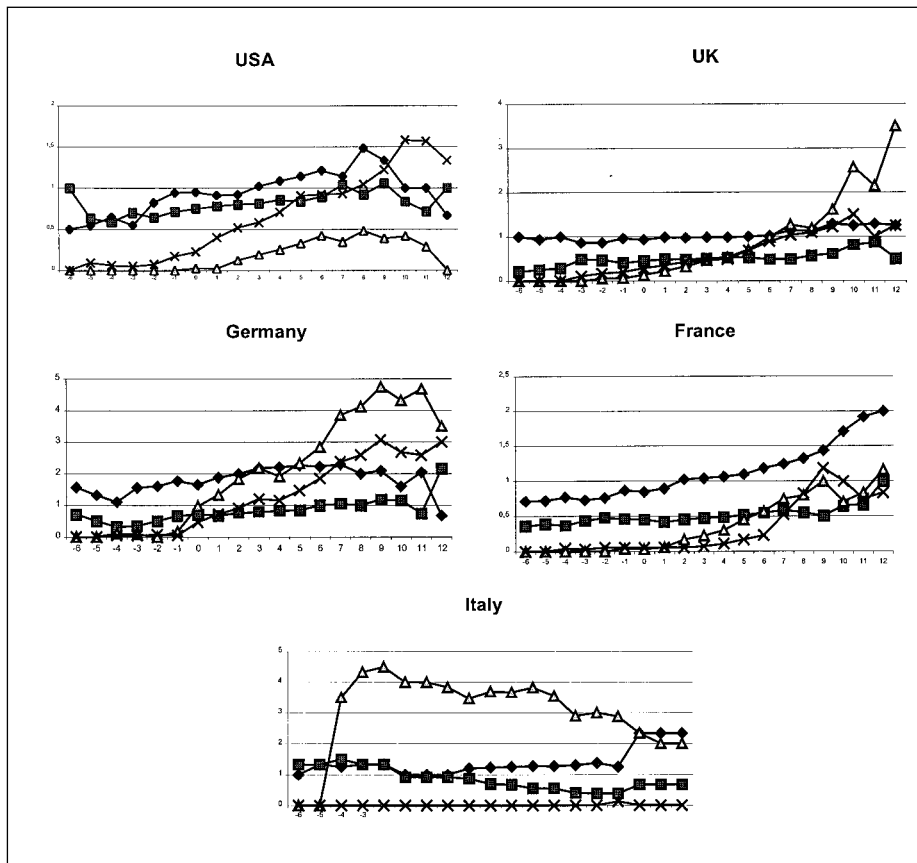


Figure 4: Average Number of Products per Molecule for Pre and Post Entry Periods, Different Types of Products (II)



patent expiry, the penetration of generics is quite strong in the US and in Germany, less so in the UK and especially in France and in Italy where, as noted earlier, there is practically no entry. In terms of sales, the entry of the *Unbranded* is larger in the US and in the UK, whereas in Germany one observes a significant entry of the *Other Brand* products. In Italy, *Other Brand* products enter the market before patent expiry and their share remains basically constant over time.

To make a long story short, we consider the existence of detectable correspondences between specific patterns of competition in the final market and specific regulatory measures/frameworks. As an example, in the UK, it is clearly detectable the role of generic prescribing practices that facilitates transition from original to generic products as patents expire.

Another relevant factor in explaining the existence of differences in patterns

of industrial competition among countries is transition to OTC. In the US, and largely in the UK, OTC products are not reimbursed. On the contrary, in France and Spain they might be available OTC, but are still reimbursed if prescribed.

A further indicator of the extent of penetration of multi-source drugs is the ratio between the number of products (in each category) and the number of molecules that are present in the market. Figure 5 shows the dynamics of these ratios before and after patent expires.

The story that emerges from the observation of these indicators confirms once again the previous findings. In the US, the ratio relative to Licensed products grows slightly, while the Original products fluctuate over time. *Other Brand* and *Unbranded* products are practically non-existent before patent expiry. Afterwards they grow rapidly in the following decade and then the ratio starts to decline.

In France, the ratio for the *Original* products grows continuously. *Other Brand* and *Unbranded* products increase very slowly until six years after patent expiry and then grow rapidly for around three years, although the value of the ratios remains quite small and starts to decline again.

## V. — TOWARDS AN INTERPRETATION : MULTIVARIATE ANALYSIS

In this section, we perform some simple multivariate analysis in order to investigate some of the factors that might influence the dynamics of prices, market shares and the number of producers of multi-source products.

The literature discussed in Section 2 suggested first that the dynamics of drug prices actually follows quite different patterns across countries, partly as a consequence of the regulation mechanisms. In particular, in strictly regulated markets, nominal prices of original and licensed products remain fixed and are not allowed to vary as time goes by. Real prices would then tend to fall over time, purely as a consequence of a time trend (or of the age of the molecule).

Second, lower prices, coupled with little incentives for doctors, pharmacists and patients to prescribe and use cheaper generics, do not attract the entry of multi-source drugs and reduce competition among them. On the contrary, in these countries multi-source suppliers are usually licensed co-marketers rather than competing generic manufacturers or minor new products that enter to obtain a higher regulated price. Conversely, in less regulated regimes, since innovators of high quality drugs enjoy higher prices, entry by generics is stimulated. The original brand producers, however, differentiate their products and are able to increase the prices of branded drugs even after patent expiry. However, as times goes by and the competition by generics becomes substantial and the market shares of the branded drug is eroded, prices will start to decline.

Third, generic entry is linked to the size of the market at the time of patent expiry and – relatedly – 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.

The descriptive evidence so far does confirm some of these results, but it raises questions on other aspects. The diverging dynamics of the prices of original and licensed products across countries is largely confirmed by our data. Similarly, the stronger penetration of multi-source drugs in the US and the low diffusion of generics in tightly regulated countries like France and Italy is also confirmed.

However, our descriptive analysis tells little about the determinants of price dynamics, especially as patent expiry and generic competition are concerned. Similarly, it is worth asking what drives generic entry and diffusion in different countries.

The following, simple, multivariate analysis is just meant to start to shed some light on some of these problems.

Our panel refers to quarterly data over the period July 1987 - December 1998. It considers both molecules and products, the number of which (after eliminating a few outliers from our original sample) is reported in Table 6.

*Table 6 - Number of molecules and products by country*

<b>Country</b>	<b>Number of Molecules</b>	<b>Number of products</b>
USA	52	182
UK	66	256
Germany	62	686
France	75	243
Italy	15	93
<i>Total</i>	<i>270</i>	<i>1460</i>

The data have been organized around the date of patent expiry. In other words, for each product time zero is the date of patent expiry. The period immediately preceding this date is indexed as t-1, the period just after this date is indexed as t+1, etc. Clearly, in the panel different products are present for periods of different length. Given, our procedure for organizing the data, however, we simply treat our data as an unbalanced panel.

We estimate both the fixed effects and the random effects specifications, and then discriminate between the two using the Hausman Test.

## V.1. Determinants of the Dynamics of the Prices of Original and Multi-Source Drugs

We begin by looking at the dynamics of the prices of Original products before and after patent expiry and in particular if it is influenced by patent expiry and/or by the entry of *multi-source* drugs.

The dependent variable is the average price of Original products, with the following independent variables (see also Suh, 1993) :

- TIME: time (quarters) before and after patent expiry. Thus the variable takes values equal to -1, -2, etc. before patent expiry and 1, 2, etc. after that date.
- PE: dummy variable indicating patent expiry. This variable takes a value equal to zero before patent expiry and a value equal to one afterwards.
- GEN: dummy variable indicating the presence of multi-source drugs, i.e. the variable takes a value equal to one when there are positive sales of multi-source drugs.
- HHI, the Herfindahl index of market concentration, calculated at the level of each molecule, obtained as the sum of the squared market shares of each manufacturer operating on the market defined by the molecule under study.

Table 7 reports the results of our analysis.

The variable TIME has always significant coefficients. It is positive in the case of the US and negative in the other countries. This result confirms the descriptive evidence discussed earlier as well as the previous analyses : the average price of Original products increases over time in the US and decreases in the other countries.

The dummy variable for patent expiry is significant only in Germany, with a negative sign, and in Italy, with a positive sign. Thus, only in Germany patent expiry is directly correlated with a reduction of the price of original drugs. Conversely, in Italy, the prices of original products actually increase after patent expiry. However, patent expiry induces significant modifications in price dynamics over time in the US, France and Italy, as shown by the interaction between the variable TIME and the variable PE. In the US, this variable has a negative sign: after the date of expiry prices increase more slowly. In France and Italy, the sign is positive: after patent expiry, the tendency towards price reduction in each following quarter becomes weaker. The interaction variable is non significant in Germany (where however the dummy for patent expiry, PE, is significant) and in the UK: here patent expiry does not have any independent or additional impact on the tendency towards price decline over time. Thus, rather than being a discrete shock on (competition and) prices, the expiration of patents tends to induce changes in price dynamics. This result

Table 7 - Dependent Variable : Average price of Original products

	USA	UK	GERMANY	FRANCE	ITALY
<b>HHI</b>	-0.1292 (0.0812)	0.3831** (0.0690)	0.3865** (0.0689)	-0.0252 (0.0316)	-0.2605* (0.1130)
<b>TIME</b>	0.0226** (0.0022)	-0.0119** (0.0012)	-0.0057** (0.0021)	-0.0053** (0.0004)	-0.0110** (0.0016)
<b>PE</b>	-0.0085 (0.0359)	-0.0247 (0.0212)	-0.1593** (0.0323)	-0.0063 (0.0062)	0.0761* (0.0351)
<b>GEN</b>	-0.3501** (0.0686)	-0.0622 (0.0323)	-0.1000 (0.0678)	0.1737** (0.0162)	0.1863** (0.0417)
<b>TIME x GEN</b>	-0.0071** (0.0018)	0.0082** (0.0012)	-0.0005 (0.0016)	-0.0011** (0.0004)	-0.0039** (0.0013)
<b>TIME x PE</b>	-0.0117** (0.0027)	-0.000023 (0.0014)	-0.0010 (0.0023)	0.0046** (0.0004)	0.0131** (0.0019)
<b>PE x GEN</b>	0.3794** (0.0745)	-0.0156 (0.0360)	0.1102 (0.0757)	-0.1477** (0.0189)	-0.2166** (0.0421)
<b>Constant</b>		0.7197** (0.1464)	0.9918** (0.1450)	0.6755** (0.0944)	0.6850** (0.1506)
<b>Hausmann Test</b>	15.6244*	0.0001	9.4439	0.0001	12.9381
<b>R<sup>2</sup> or s<sub>ε</sub><sup>2</sup></b>	0.9373	0.2039 <sup>2</sup>	0.3109 <sup>2</sup>	0.0756 <sup>2</sup>	0.1347 <sup>2</sup>
<b>s<sup>2</sup> or s<sub>α</sub><sup>2</sup></b>	0.2589 <sup>2</sup>	0.9629 <sup>2</sup>	0.9818 <sup>2</sup>	0.7322 <sup>2</sup>	0.8845 <sup>2</sup>
<b>n. observations</b>	1255	1925	1999	2489	542
<b>n. molecules</b>	33	49	47	57	13

Standard errors in parentheses

\* significant at 5% level

\*\* significant at 1% level

supports the conclusion by Hudson that effective patent life extends beyond the date of expiration.

The presence of multi-source drugs is significant in the US, with a negative sign, as well as in France and Italy, with a positive sign: multi-source products tend to reduce the price of original drugs in the US, while they have the opposite effect in France and Italy, consistently with the descriptive analysis. Moreover, multi-source drugs have an effect on the time profile of prices. Their presence tends to reduce price changes over time in the US (the price increase of originals over time is slowed down by the competition of generics), France and Italy (the decline of the prices of originals over time is magnified by generics). In the UK, prices decline over time at a slower rate if there is generic competition, possibly reflecting the existence of significant differences at the level of relevant sub markets (see also Jönsson and Ekelund, 2001). The interaction between patent expiry and the presence of generics is significant in the US (with a positive sign), in France and Italy (with a negative sign). Finally, market concentration has a significant coefficient in the UK and Germany, with a positive sign, and in Italy, but with a negative sign.

Let us look now at the dynamics of the average prices of multi-source drugs (Table 8). In all countries except Italy prices tend to decline over time. The coefficient of the variable measuring market concentration is significant and positive in the US and France. That is to say, prices of generics are higher in more concentrated markets. The coefficient of the variable HHI is insignificant in the UK and Germany and once again negative in Italy : here the prices of generics are lower in highly concentrated markets.

Table 8 - Dependent Variable: Average price of multi-source drugs

	USA	UK	GERMANY	FRANCE	ITALY
<b>HHI</b>	0.3716** (0.1007)	0.0682 (0.0536)	-0.1924 (0.1603)	0.3530** (0.0696)	-1.3109** (0.1281)
<b>TIMEA</b>	-0.0171** (0.0011)	-0.0066** (0.0006)	-0.0131** (0.0024)	-0.0039** (0.0006)	0.0002 (0.0008)
<b>Constant</b>		0.8031** (0.1718)	1.1375** (0.1925)		1.3267** (0.1986)
<b>Hausmann Test</b>	15.843*	0.0001	2.876	9.5081*	0.544
<b>R<sup>2</sup> or s<sub>ε</sub><sup>2</sup></b>	0.6877	0.1145 <sup>2</sup>	0.4793 <sup>2</sup>	0.9324	0.1401 <sup>2</sup>
<b>s<sup>2</sup> or s<sub>α</sub><sup>2</sup></b>	0.2608 <sup>2</sup>	0.9153 <sup>2</sup>	0.8411 <sup>2</sup>	0.1145 <sup>2</sup>	0.5855 <sup>2</sup>
<b>n. observations</b>	821	748	833	567	305
<b>n. molecules</b>	34	29	34	23	9

Standard errors in parentheses

\* significant at 5% level

\*\* significant at 1% level

## V.2. Entry and Market Shares of Generics

Now, we turn to the role of patterns of entry and of generic penetration.

First, we regress the number of producers of multi-source drugs on the following independent variables (we consider only the molecules where there are multi-source products) :

- MKGR: market growth ;
- RATIO: ratio of the average price of multi-source drugs to the average price of original products ;
- MKTSZ: relative market size, calculated as the ratio between the total sales of a molecule and the total sales of all products in the sample ;
- TIMEA: number of quarters following the date of patent expiry.

Table 9 - Dependent Variable: Number of producers of multi-source drugs

	USA	UK	GERMANY	FRANCE	ITALY
<b>MKTGR</b>	-0.0004 (0.0011)	-0.0020 (0.0047)	0.0035 (0.0079)	0.0013 (0.0028)	-0.0067* (0.0031)
<b>RATIO</b>	0.2411** (0.0294)	0.4859 (0.2725)	-0.9602* (0.4370)	0.0894 (0.0525)	0.5456* (0.2312)
<b>MKTSZ</b>	0.0063 (0.0063)	0.3795** (0.0340)	-0.9279 (0.4842)	-0.0522 (0.0898)	1.6323* (0.6743)
<b>TIMEA</b>	0.0302** (0.0024)	0.0943** (0.0053)	0.3807** (0.0139)	0.1019** (0.0076)	-0.0331** (0.0076)
<b>Constant</b>					4.6249* (1.929)
<b>Hausmann Test</b>	12.8316*	25.4752**	86.0922**	21.5972**	0.1554
<b>R<sup>2</sup> or s<sub>ε</sub><sup>2</sup></b>	0.7433	0.7712	0.8948	0.5886	1.1713 <sup>2</sup>
<b>s<sup>2</sup> or s<sub>α</sub><sup>2</sup></b>	0.5431 <sup>2</sup>	1.3576 <sup>2</sup>	2.9036 <sup>2</sup>	1.3533 <sup>2</sup>	5.8338 <sup>2</sup>
<b>n. observations</b>	588	655	652	461	259
<b>n. molecules</b>	23	25	26	21	9

Standard errors in parentheses

\* significant at 5% level

\*\* significant at 1% level

Table 9 shows that the coefficient of the variable TIMEA is significant in all countries and positive everywhere except Italy : the number of producers of multi-source drugs grows over time in all countries, but it actually declines in Italy. The rate of growth of the market does not seem to be related to the entry of multi-source producers – with the exception of Italy, but with a negative sign – and market size induces entry only in the UK and in Italy. Interestingly, entry appears to be affected by price differentials (the variable RATIO) only in the US and Italy, with a positive sign, and in Germany with a negative sign. This result is quite interesting. It tells that in the US and Italy entry is higher in those products where multi-source products can charge relatively higher prices as compared to those of originals, but the opposite happens in Germany. In the other countries price differentials do not seem to matter much.

Let us look now at the market share of generics. Table 10 reports the results for the regression of the market shares of each multi-source product (i.e. here the regressions are taken at the level of each single product, not of each single molecule) on the same independent variables of the previous equation, i.e :

- MKTSZ : relative market size, calculated as the ratio between the total sales of a molecule and the total sales of all products in the sample ;
- MKGR : market growth in terms of sales ;

Table 10 - Dependent Variable : Market share of multi-source products

	USA	UK	GERMANY	FRANCE	ITALY
<b>MKTSZ</b>	-0.0500 (0.1402)	-0.3694 (0.2230)	-2.6716** (0.5378)	0.3520 (0.6252)	-2.9636 (3.174)
<b>MKGR</b>	-0.0792** (0.0125)	0.0001 (0.0070)	0.0037* (0.0018)	0.0106** (0.0035)	0.0108** (0.0032)
<b>RATIO</b>	0.2421 (0.2141)	1.0173** (0.3224)	0.3462** (0.1104)	0.0300 (0.0750)	0.5732** (0.2212)
<b>TIMEA</b>	0.4788** (0.0249)	0.2243** (0.0103)	0.0746** (0.0037)	0.1254** (0.0122)	0.0123 (0.0092)
<b>Constant</b>					
<b>Hausmann Test</b>	19.707**	27.350**	37.785**	269.14**	45.451**
<b>R<sup>2</sup> or s<sub>ε</sub><sup>2</sup></b>	0.9057	0.9226	0.8962	0.8673	0.6863
<b>s<sup>2</sup> or s<sub>α</sub><sup>2</sup></b>	6.6109 <sup>2</sup>	3.7211 <sup>2</sup>	2.2178 <sup>2</sup>	2.6275 <sup>2</sup>	2.9736 <sup>2</sup>
<b>n. observations</b>	1072	2177	6721	1141	1288
<b>n. products</b>	53	129	353	104	58
<b>n. molecules</b>	22	25	25	21	9

Standard errors in parentheses

\* significant at 5% level

\*\* significant at 1% level

- **RATIO** : ratio of the price of multi-source drugs to the average price of original products;

- **TIMEA** : quarters since patent expiry.

The size of the market (MKTSZ) is significant only in Germany, but with a negative sign. That is to say, market size *per se* does not induce larger market shares for multi-source products. If anything, generics have larger market shares in niche markets in Germany. Fast growing markets are associated with larger market shares of generics in Germany, France and Italy and negatively so in the US.

The variable RATIO, i.e. the ratio of the price of multi-source drugs to the average price of original products is insignificant in the US and France but it is significantly and positively related to market shares of generics in the UK, Germany and Italy.

Finally, the coefficient of the variable TIMEA is positive and significant in all countries, i.e. the market share of multi-source drugs tend to grow over time everywhere, once again except Italy, where this share does not significantly change. This result confirms that generic entry builds up over time rather than following immediately patent expiry. Again, this observation is consistent with

the point made by Hudson that effective patent protection extends beyond patent life and that different institutional regimes induce different effect on firms behavior before and after patent expiry.

In conclusion, let us examine the difference between the average price of Original products and the average price of multi-source drugs (DIFF). The independent variables included in the regression are :

- HHI: the Herfindahl Index;
- MKGRD: market growth in terms of quantities (number of DDDs);
- MKTSZD: market size in terms of quantities (number of DDDs);
- TIMEA: time elapsed since patent expiry.

The difference between the prices increases over time in the US, UK and France, while it decreases in Germany, consistently with the descriptive evidence (Table 11). The coefficient of the variable TIMEA is not significant in Italy. Market growth (MKGRD) and market size (MKSZD) are not significant in all countries, whereas market concentration (HHI) has a positive effect on price differentials in the UK and a negative effect in the US.

*Table 11 - Dependent Variable : Difference between the average price of Original products and the average price of multi-source drugs*

	USA	UK	GERMANY	FRANCE	ITALY
<b>HHI</b>	-0.6299** (0.1763)	0.3265** (0.0678)	-0.0989 (0.1237)	-0.1803 (0.1004)	-0.0171 (0.0999)
<b>MKTGRD</b>	0.0004 (0.0010)	-0.0002 (0.0004)	0.0002 (0.0010)	-0.0001 (0.0002)	-0.0002 (0.0002)
<b>MKTSZD</b>	-0.0020 (0.0044)	-0.0002 (0.0034)	0.0106 (0.0181)	0.0038 (0.0036)	-0.0129 (0.0160)
<b>TIME</b>	0.0217** (0.0019)	0.0023** (0.0007)	-0.0046* (0.0020)	0.0024** (0.0008)	-0.00002 (0.0005)
<b>Constant</b>	0.8331** (0.2473)	-0.1265 (0.0779)	0.3363** (0.1229)		-0.0439 (0.0766)
<b>Hausmann Test</b>	4.0707	0.0001	4.0426	9.7698**	0.0001
<b>R<sup>2</sup> or s<sub>ε</sub><sup>2</sup></b>	0.3946 <sup>2</sup>	0.1332 <sup>2</sup>	0.3702 <sup>2</sup>	0.5079	0.0807 <sup>2</sup>
<b>s<sup>2</sup> or s<sub>α</sub><sup>2</sup></b>	1.1626 <sup>2</sup>	0.3161 <sup>2</sup>	0.4005 <sup>2</sup>	0.1198 <sup>2</sup>	0.1700 <sup>2</sup>
<b>n. observations</b>	588	655	652	461	259
<b>n. molecules</b>	23	25	26	21	9

Standard errors in parentheses

\* significant at 5% level

\*\* significant at 1% level

### V.3. Patterns of Competition

Summing up, we observe quite distinct patterns of competition across countries. In this section we do focus on two extreme cases: France and the US.

In the US, we observe a positive time trend for the price of originals and a negative one for the prices of generics. Patent expiry slows down the trend towards higher prices of original products over time. Similarly, multi-source drugs tend to limit their price growth at the time of patent expiry and in each following quarter. Conversely, the prices of generics tend to fall continuously over time. Market concentration does not affect the prices of original products: presumably, patent protection confers strong exclusivity power. Concentration, however, increases the prices of generics. Thus, price differential between the average price of respectively original products and generics grows over time and it is lower in highly concentrated markets. The number of producers and the market share of generics grow over time and they are not affected by market size or market growth. If anything, the share of generics appears to be lower in fast growing markets. Entry, but not markets shares, is higher when multi-source drugs can earn higher prices relatively to originals.

In France (and in Italy) both the prices of originals and generics fall over time. In both countries, this tendency weakens after patent expiry (in Italy the price of original products actually increases after patent expiry) and in relation to generic penetration. Concentration reduces prices in Italy, while it increases the price of generics in France. The number of generic producers increases over time in France, while it decreases in Italy: here, entry is stronger in large, slow-growing markets, where generics keep high relative prices as compared to originals. As mentioned previously, in these countries imitative products have tended to enter the market before patent expiry largely through co-marketing agreements, in the attempt to obtain higher prices from the regulators.

## VI. — CONCLUDING DISCUSSION

The results of this paper can be summarized under three main headings: a) descriptive analysis of the dynamics of drug prices and penetration of generics; b) effects of patent expiry and generic competition over drug prices at the level of specific chemical entities; c) determinants of the diffusion of multi-source products.

First, in general, this paper has shown that the relationships between the dynamics of drug prices, patent expiry and competition by multi-source drugs are quite complex and that they vary significantly across countries.

A clear distinction seems to emerge from our empirical investigation. On the one side, systems that rely on market based competition in pharmaceuticals (particularly the US) promote a clear distinction between firms that act as innovators and firms that act as imitators after patent expiry. To put it in a nut-

shell, Original products can enjoy premium prices and exclusivity profits under patent protection, then facing fierce price competition after patent expiry. On the contrary, systems that rely on administered prices (France and Italy) nurture strategies of pre-emptive brand proliferation and horizontal differentiation by imitative brand name products well before patent expiry (Italy being an extreme case).

The US display many of the textbook features of a market characterized first by strong patent protection and then by competition by generics (8). Multi-source drugs start to enter the market at the time of patent expiry at substantially lower prices than original drugs and they gradually and consistently gain market shares over time. All in all, in the US the patterns of competition generate a sharp distinction between « innovators » and « imitators ». Yet, innovators defend themselves from competition not so much by reducing prices, but also (and perhaps mainly) by succeeding in segmenting the market and making demand inelastic. Price increases generate higher profits because the revenue gains from them offset the revenue loss associated with lower levels of demand. Thus, even if some breakthrough products and companies do not support their original products in competition with the «specialized» generic houses, on the whole average drug prices for branded products tend to remain stable or even increase over time.

At the opposite extreme of the US, in France and Italy the prices of both originals and generics tend to fall over time, well before patent expiry. Moreover, multi-source drugs (mainly Other Brands) enter the market before patent expiry, at prices higher than the (falling) prices of Original products largely through co-marketing agreements in the attempt to obtain higher prices from the regulators. The diffusion of generics is quite small, however, even in the long run and especially in Italy. Over time, the prices of multi-source drugs decline in France and remain stable in Italy, while the decrease in the prices of Original products stops. As a consequence, the average price remains stable after (is not affected by) patent expiry.

At another extreme (with the UK and Germany falling between the two), in France (and Italy), patents do not appear to work very effectively, neither in conferring strong advantages and incentives to innovators, nor in curbing prices

- (8) These dynamics are reflective of the substantial increase in the competitive forces at work in the US pharmaceutical and health care industries, in relation to the diffusion of organizations such as Health Maintenance Organizations (HMOs), Pharmacy Benefit Managers (PBMs), and mechanisms such as maximum allowable costs (MAC), documentation of therapeutic equivalence, cost sharing mechanisms, mandatory generic substitution for brand name written prescriptions or, in some cases, even therapeutic substitution. These organizations and mechanisms and, to a different extent, the fixation of upper payment limits for multi-source drug products by Federal Medicaid, have promoted price competition after patent expiry and the use of generic products in the US. Pressures towards price competition notwithstanding, producers of original drugs are sometimes able to maintain, and even increase, their prices after patent expiry.

after expiry. Rather, firms are induced to introduce small variations on the original products, enjoying relatively higher prices, while strategic alliances, especially in the form of comarketing and licensing agreements, are effective in keeping branded products from competition with generic medicines.

The second set of results refer to the impact of patent expiry, generic competition, and market concentration on drug prices. The paper shows that as such patent expiry does not impact directly on price dynamics. At the most, it slows down price changes, with the only exception of Germany. Generic competition effectively tends to reduce the price of original products only in the US, but has the opposite effect in Italy and France. Finally, market concentration has a different impact on the price of respectively original and multi-source drugs. Concentration, measured at the level of single molecules is actually associated with higher prices of original products in the UK, Germany and France, but with lower prices in Italy and is irrelevant in the US. Conversely, it induces higher prices of multi-source drugs in the US and France and again lower prices in Italy, while it is non significant in Germany and the UK. These results broadly corroborate views according to which the effective patent life of a product goes beyond patent expiry (see Hudson, 2000).

Third, our results show that while generic competition has tended to grow over time in all countries (with the remarkable exception of Italy), this pattern is sustained by different factors/variables in different countries. This suggests that the diffusion of generics is strongly affected by the specific features of national systems of regulation. In particular, other components bear a strong relevance, such as the overall level of pharmaceutical prices in a country, doctors having direct access to PC based comparative price data for medicines, generic substitution permitted in the country, and the existence of effective patient co-payments (for example, in France copayment is co-insured). Prominent among them are certainly the extent and the forms of regulation.

The diffusion of generics and their impact on drug prices is certainly lower in France and Italy, where prices are regulated than in the US and Germany, where prices are high and are much less regulated. Price regulation may reduce both the incentives and the possibilities to generic competition, both by keeping the prices of original products low and by not imposing strong incentives to patients and physicians to not use more expensive branded drugs. However, even in Germany, as well as in the other European countries considered in this paper, generics are mainly Other Branded products, which are launched at relatively high prices, and whose diffusion is sustained by marketing strategies different from price competition. Finally, even in the US, where the penetration of generics is quite strong, their competitive pressure on prices is compensated by increases in the prices of branded drugs. At the level of each single molecule, this strategy lessens generic competition, accommodating entry. At the firm level, this might reflect multiproduct market power enhancing strategies, in which the pioneer firm uses price increases of the original drug to boost the demand of a new substitute, expanding its market size.

Thus, factors other than the market institutional framework are certainly important. Different countries have different medical traditions, different institutional settings for financing and provision of health care, and different absolute size. This latter variable, in particular, is likely to exert a significant effect in determining the extent and impact of generic competition, particularly at the sub market level (see also Hudson, 2000 and NERA, 1998).

As for the effect of the analyzed phenomena on innovativeness and welfare, our work confirms that systems that rely on administered prices tend to stifle price competition, to protect less efficient companies, and to encourage strategies aiming at introducing incremental variations of existing products (see Thomas, 1996; Gambardella, Orsenigo, and Pammolli, 2000).

Irrespectively of any comparison with the US market, these findings seem to be relevant in terms of policy implications for European Countries.

First, European national healthcare systems are still highly diversified in terms of the way they are organized and financed, ranging from national health schemes funded out of general taxes (the UK-Italy-Spain model), to mandated personal insurance with pluralist providers (the Germany-France-Netherlands model). While these variations reflect different social values, ethics, and levels of wealth across Europe, they might contribute to generate inconsistencies, inefficient uses of resources, uneven standards of medical care, and distortions in the functioning of markets. Moreover, 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.

Second, as for industrial policy and competitiveness issues, an increased market competition in the off-patent segment of the market can contribute to foster efficiency and to design adequate incentives to innovate within the European environment, promoting patterns of industrial reorganization and selection and, moreover, allowing higher prices and returns on investment for innovative products that are still on patent.

*(Voir références page suivante)*

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