Launch of a product and patents: evidence from the US cardiovascular pharmaceutical sector[1]

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Abstract

Recent literature on the role of patents in shaping competition between incumbents and new entrants shows mixed evidence, as patents can dis-courage entry into markets but may also encourage potential entrants by increasing profitability from research and development. The increasing use of patents as strategic weapons motivates this investigation of the impact of innovation on competition. In a case study of US pharmaceutical cardiovascular submarkets over the period 1988-1998, we use a panel probit model to study the impact of a firm's patents and rivals' patents in the firm's decision to launch new products. Our results show that the number of a firm's lagged patents encourages the firm's entry with new products, while rivals' initial stock of patents discourages entry, but more recent patents promote entry by opening new technological opportunities.

JEL classification: L11, L65, C11, C23, C25.

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1 Introduction

This paper focuses on the impact of innovation on entry into six US cardiovascular pharmaceutical submarkets over the period 1987-1998.

Taking advantage of the availability of the sales of every single products on the cardiovascular submarket in the sample period, the present study can sheds light on innovation's impact on competition, where competition is measured as the probability that a company will launch additional products or a first product (i.e. greenfield entry) into a specific submarket (see Schmalensee, 1978, Judd 1985). This measure of competition is not common in empirical papers since it is much difficult to collect data on product launches than to collect data on firms' sales. However seminal theoretical papers (Schmalensee, 1978, Judd 1985 already mentioned) claim that the possibility to launch additional products into a market depends on the number of existing products: "An incumbent may decide to increase the number of variety it puts on the market so as to leave fewer niches that an entrant could occupy"(Bellaflamme and Peitz 2015, page 433). This shows that the possibility to launch a new product depends on the market openness: if the market presents barriers to entry, it is impossible to enter the market with new products.

The analysis of competition among firms is one of the key topics in IO[3], and several measures of competition, including the number of companies (Netz and Taylor, 2002) and the Lerner Index (Aghion et al., 2005), have been adopted over time. Following Cockburn and MacGarvie (2011), who stimulated interest in innovation and entry, we measure competition as the probability of product launches (greenfield or not) into a specific submarket[4]. Cockburn and MacGarvie (2011) investigated the role of patents in launching new products in the software market and found a positive correlation between firms' patent holdings and their new product launches. They also re-emphasized the role of patents as barriers to entry, while other literature has pointed out the role of patents as an indicator of innovation success, technological opportunity, and innovative capabilities (e.g. Nerkar and Roberts, 2004). The launch of products into a submarket also assumes significant importance in investigations of competition because product launches can be used as a proxy for market openness (Kyle, 2007).

As in Hall, Jaffe and Trajtenberg (2005), we use patents[5] as a measure of innovation.

So, following the common practice, that consider patents (and related measures) as proxy for innovation (see among other Pakes and Griliches, 1980), we define the company's innovation as the number of patents applications done by each company, even if we are aware that not all the innovations are patented (Moser, 2013).

[3] IO is the acronym for Industrial Organization.

[4] The first author to define submarkets as technical trajectory was Dosi (1982).

[5] Regarding this point, we quote Gallini (2002).

According to Hall et al. (2005, p. 17), patents have long been recognized as a rich data source for the study of innovation and technical change, but the traditional view of patents as indicators of innovation has been changing because of their increasing strategic role (Boldrin and Levine, 2013)[6]; as Bessel and Hunt (2007) and Rentocchini (2011) pointed out, some patents have become strategic instruments with which to block rivals, extract licensing revenues or do cross-licensing, rather than instruments through which to innovate. Therefore, patents are not exclusively instruments that guarantee ownership of the outcomes of research and development (R&D). Many firms acquire large portfolios of patents "even where the primary motivation for doing this goes beyond the potential to exclude competitors" (Cockburn and MacGarvie, 2011), and the phenomenon of such patent "thickets" is assuming increasing importance in many markets (Cockburn and MacGarvie, 2009).

The analysis of patents' effect on competition at the submarket level could add new elements to the debate. Our study analyzes the impact of both the firm's and its competitors' patents on a product launch in a given submarket. This analysis helps to reveal whether patents signal fear of the competition (the "market-stealing effect") or disclose information or signal market dynamism (the "spillover effect"). The patents as measure of innovation can face a challenge: their strategic use. Patents have a double use: productive versus protective use. Some sort of degeneration of the protective use can induce to employ patents as strategic instrument, as mentioned before, while the productive use can embed both the "market stealing effect" and the "spillover effect" (Argente et alt. 2018).

With a "market-stealing effect," patents generate property rights that give their owners an advantage in the industry and they act as barriers to entry for competitors' products. With a "spillover effect," a rival's patent opens new technological opportunities for firms in the same industry, as "the disclosure of innovation by a rival through patenting may provide information on which a firm can build" (McGahan and Silverman, 2006, p. 1222). These two contrasting effects show that the evidence on patents' role in shaping the market environment for incumbents and new entrants is mixed (Cockburn and MacGarvie, 2011)[7]. Patents can be a significant barrier to new market entrants via the market-stealing effect but can also facilitate new entrants via the spillover effect[8] by increasing the profitability of R&D when rivals' patents lead to the firm's

[6] As Kyle (2007, p. 88) stated, "Competition usually results in lower prices, and given the widespread concern about the cost of pharmaceuticals, it is valuable to know what impedes further entry into a market." If a company can launch into a market or submarket a new product that is vertically or horizontally differentiated, the barriers to entry in that market are low.
[7] However, in some circumstances, patents, acting as sunk costs, may be an encouragement to entry (Cabral and Ross, 2008).

launching new products. Bloom, Schankerman and Van Reenen (2013) reconciled this two-fold effect of patents by a sort of emulation effect : in some submarkets there could be a sort of race to patenting to emulate competitors.

The remainder of this paper is organized as follows: Sections 2, 3, 4, and 5 present the paper's motivation, dataset, variables, and model, respectively, while Section 6 analyzes the empirical results, and Section 7 concludes.

2 Literature review

Aghion et al.'s (2005) seminal paper pointed out the bi-directional relationship between competition and innovation and found an inverted-U-shaped relationship between the number of patents (as a measure of innovation) and the level of competition (measured by the Lerner Index). Although it also emphasizes this bi-directionality, most of the literature has focused on the impact of competition (market structure) on innovation. However, given the presence of feedback effects (e.g. Jaffe, 2000; Hall and Harhoff, 2012), this paper seeks evidence of innovation's effect on competition, measured by the market's openness (i.e. the probability of being able to launch a new product into a submarket), and seeks to identify the impact of a firm's own patents and that of its competitors' patents on the decision to launch new products into a submarket.

On the theoretical side, the most important contribution regarding the impact of innovation on a market's structure belongs to Sutton (1998), who showed how the level of innovation can modify a market's structure and level of competition. Sutton[9] (1998) found that both horizontal and vertical differentiation take place in each submarket, so the number and quality of products launched depends on which kind of differentiation prevails: When horizontal differentiation prevails, the number of products is higher, regardless of quality; when vertical differentiation prevails, quality of new products launched is higher than the average level of quality in that submarket, so, the number of products is lower.

The company's decision to launching new products into various submarkets affects the company's share of the submarkets, while its share of the global market depends on the strength or weakness of the links among submarkets, explained by the effectiveness of R&D on the demand side and by economies of scope on the supply side.

From an empirical point of view, the investigation of patents' effects on product launches is motivated by companies' increasing strategic use of patents (Bessel and Hunt, 2007; Rentocchini, 2011) and by the debate on intellectual property rights' effect in promoting

[9] See chapter 1 of Sutton(1998).

innovation (Boldrin and Levine, 2013). Cockburn, Henderson, and Stern (2000) discussed the role of patents in the pharmaceutical sector and used patents to measure firms' accumulated knowledge capital and technological capabilities. For their part, Nerkar and Roberts (2004) modeled the success of product introductions using patents as a proxy for firms' technological resources. While papers on the pharmaceutical sector have emphasized the advantage that property rights provide, Cockburn and MacGarvie (2011) showed how patents can discourage entry by competitors. Bloom, Schankerman and Van Reenen (2013) reconciled these findings by pointing out a two-fold effect of patents: a "market-stealing effect" and a "spillover effect."

The current literature has not generally taken into account the role of a firm's own patents and those of its competitors in new product launches; although one McGahan and Silverman (2006) is one of the few exceptions, they studied the effect of rivals' patents on the focal firm's value, not on the level of competition. This paper's submarket-level analysis of the impact of a firm's own patents and those of its rivals on the entry decision is a step forward. With the assignment of each company's patents to a specific pharmaceutical submarket, this analysis measures patents' role as either a barrier to entry or a way to disclose information to competitors in the submarkets.

3 Data and Descriptive Statistics

The primary source of data is the IMS Health dataset, from which we obtained annual sales for all the companies active in the pharmaceutical market in the United States from 1988 to 1998[10]. The dataset refers to the sales of any product offered for purchase, classified according to the Anatomical Therapeutical Classification (ATC), with a breakdown up to the 3-digit level[11], allowing us to identify the effects of competition, capture companies' heterogeneity, and reproduce the analysis at the same level as that adopted by the antitrust authorities. The sales in real value were obtained using the US gross domestic product (GDP) deflator. We also used patent applications in the US cardiovascular pharmaceutical submarket from 1988 to 1998, obtained from the KITeS-Cespri Patent Database[12], which contains information on all patent applications at the European Patent Office (EPO) and at the US Patent and Trademarks Office (USPTO). The database includes the applicant's name, the inventor's name, the patent class and all citations.

[10] Data collected by IMS Health was obtained by one of the authors during research conducted at the University of Siena, while working on the EPRIS Project.
[11] At the following link is possible to find the standard classification ATC adopted for the pharmaceutical sector: www.whocc.no/atc (ddd index).
[12] For a detailed description, see http://db.kites.unibocconi.it/

The available patent data refer to only six of the nine 3-digit subsectors that belong to section “C *Cardiovascular system” of the* ATC classification. The subsections considered are listed in Table 1.

Table 1 about here

In terms of average sales during our observation period, the submarkets listed in Table 1 represent about 20 percent[13] of the pharmaceutical sector, so they are a valid sample for study. Patterns have emerged in the recent past that could motivate the use of a more updated dataset. However the cost of finding and developing new drugs remains high as the entry costs. For these reasons, although further investigation with an updated dataset will be useful, our analysis is sufficiently general and it can establish a case study that, doesn't depend on whether the period of investigation is recent, for other pharmaceutical submarkets and manufacturing sectors with similar characteristics (i.e. high entry costs).
The role of a firm's own patents and those of its competitors in the success of new product launches will continue to be in need of further study.

Investing in new pharmaceutical products is appealing even though the success of newly developed products is highly uncertain given the high R&D investment required for all drugs. Acemouglu and Linn (2004), who analyzed the effect of market size on new drugs' market entry, pointed out that a 1 percent increase in the market size for a drug category leads to a 4 to 6 percent increase in the number of new drugs introduced to the market.

We use patent data to gain information about the firms in a specific submarket. However, while patents can be easily assigned to firms, the IPC patent classification and the ATC classification for the product sold do not necessarily correspond, so we cannot necessarily associate each firm's patents to a specific 3-digit ATC class. Therefore, we used information from the Pharmaceutical Substance (Georg Thieme Verlag), IMS Life Cycle Patent Focus (IMS Health), and Adis R&D Insight (Wolter Kluwer Pharma Solutions) databases, which provide information on pharmaceutical products, their ATC classifications and related patents. For each 3-digit ATC submarket in our sample, we obtained all the patents with priority dates (i.e. date of first filing)

[13] This percentage has been obtained by our elaborations on the available dataset that refers to all the pharmaceutical sector. We consider only a reduced number of sectors because we have the correspondence between patents and submarkets only for the six of the nine 3-digit subsectors that belong to section “C *Cardiovascular system” of the* ATC classification mentioned in the text.

between 1987 and 1998 that are associated with the products classified in that submarket[14]. Then we used the patent numbers to associate each patent with its applicant.

Table 2 about here

During the period covered by our data, thirty-six companies operated in the submarkets under consideration (Table 1), although the companies often operated in more than one subsector, as shown in Table 2. The original IMS Health dataset contains annual sales for all pharmaceutical products in each submarket, considered separately by presentation (e.g. tablets, ampules), quantity of the active ingredient (e.g. 250 mg, 500 mg), and so on. We based the identification of the various products on a drug code supplied by IMS Health. For example, in the 3-digit sub-sector in Table 1, the IMS Health dataset contains 190 drug codes. Then we obtained the sales of a specific product by summing at the company level for each specific submarket and for each year the sales of all the pharmaceutical items in the dataset that were identified by the same code.

Since we study the effect of patents on international companies' decisions to launch new products into particular submarkets, we defined the *Entry* event, defined as occurring when the sales for at least one drug code for a given company becomes greater than zero. *Entry* can refer to a greenfield entry (i.e. when a company did not previously have other products in that submarket) or an expansion of the range of products a company offers. Thus, we do not consider the *number* of single new products a company launches but the *entry decision* to introduce one or more products into a submarket by a company *i* at time *t*. As a result, our unit of analysis is "companies per submarket"; in other words, our observations are the sales of company *i* in submarket *j* at time *t*. Since not all of the companies are in all of the submarkets, our dataset contains 91 units of analysis and 1,092 observations. The number of entry decisions by submarket in the period considered and the number of observations are reported in Table 2. Submarkets C10A, C2A, and C3A have the most entries, but submarket C3A has the highest number of product launches (low-ceiling diuretics, thiazides), and submarket C10A has the highest number of observations.

Table 3 about here

[14] This work was performed by N&G Consulting (Milan, Italy) with the help of a consultancy with patent expertise.

Table 3 reports the patent applications by 3-digit class and year and compares them to the average number of products offered for purchase in the period. The C10A-class has the highest number of patents, even though its average number of products is among the smallest.

Table 4 about here

Table 4 shows the number of entries by company; only two companies in our sample launched more than ten products.

4 Variables and Model

The panel-probit model is a natural tool with which to analyse the Entry event, as defined in section 3. Following Bresnahan and Reiss (1991), Hendricks, Piccione and Tan (1997) and Netz and Taylor (2002), we adopted a standard entry-exit reduced-form model and analyzed the probability of an entry decision as a function of firm-specific and submarket-specific regressors.

Our variables include company characteristics like exit choices (*Exit*)—that is, the decision to reduce the number of products the company offers in a submarket; several indicators calculated on the basis of the company's size that measure the its positioning in the global pharmaceutical market and in each submarket; and the company's own patents and those of its competitors, both of which lie at the core of our analysis. The measure of the stock of patents held by a firm in a submarket is calculated as past patented ideas using the perpetual inventory method for each company in each 3-digit ATC submarket. The stock of patents is built as follows:

$$S(t) = (1-\delta) * S(t-1) + P(t-1) \ and \ S(t=1) = P(t=1)/(g+\delta) \quad (1)$$

where P (t-1) is the number of patents at time t-1, *g* is the average growth rate in patenting (firm- and submarket-specific), and δ is the depreciation, which is assumed to be 0.15, as is common in the relevant literature (e.g. Bottazzi and Peri, 2007). Patents can be weighted by citations or by families**.** Following Hall et al.'s (2005) approach, which takes into account all economic information, we weight the patents by citations to measure the patents' usefulness and originality by designing a map of interconnections with later patents. As Hall et al. (2005) pointed out, since investing in further development of a patent suggests that the cited innovation is valuable, citations indicate the relevance of the individual patents to the submarket, especially if citations are still seen years after the patent is granted or if they generate more spillovers.

The submarket-specific variables considered refer to the demand for pharmaceutical products, an indicator of the degree of competition (measured by the number of incumbents and the number of products offered by competing incumbents in each submarket) and of a submarket's desirability and attractiveness (measured by the size of each ATC3 submarket on the global pharmaceutical market). The incumbent companies' patents in each submarket are also considered. The behavior of general demand for pharmaceutical goods is given by the growth rate of the real total prescription drug expenditures per capita in the US in the period considered.

Data on total prescription drug expenditures comes from National Health Expenditure Accounts (NHEA)[15], expressed in nominal terms and not adjusted to remove the impact of changes in healthcare prices. Although a price index for personal healthcare goods and services is available, there is no corresponding price index for the aggregate national health expenditure (NHE), so the data are transformed in real terms using the US consumer price index (CPI). The differences in the NHE's annual growth rates reflect trends in the factors that affect healthcare spending, including technological developments and changes in the population's composition by age and sex (demographic effect), the use of healthcare goods and services, and prices for healthcare goods and services. Finally, the launch of new pharmaceutical products is a long process that requires the company to make many decisions internal to the company and to run through many phases of authorization. The decision to launch a product is the last step of a long, dynamic process that begins with an R&D expenditure, so all of the explanatory variables in the model present a one-period lag to minimize loss of information while also showing the dynamic of the R&D process. Therefore, we employ the regressors described in Table 5.

Table 5 about here

Table 6 reports the main descriptive statistics for the variables used.

Table 6 about here

[15] Data are available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html

4.1 Model specification

Given the definition of the entry decision described in Section 4, our dependent variable *Entry* is represented by a dummy variable $y_{ij,t}$, which takes the value of 1 if firm *i* decides to launch a new product into submarket *j* at time *t*, and zero otherwise. We used a probit model to analyze the role of patents on the firm's entry decision:

$$Pr(y_{ij,t} = 1) = \Phi(\beta_0 + \beta_1 x_{1ij,t-1} + \ldots \beta_k x_{kij,t-1} + c_i) \qquad (2)$$

where $\Phi(z)$ is the cdf of the N(0,1) distribution, and c_i is the unobserved heterogeneity.

One well known method with which to incorporate unobserved heterogeneity is to include a set of subject-specific parameters c_i (e.g. Halaby, 2004; Wooldridge, 2005, 2010, 2011) that can be treated as fixed or random. The use of fixed effects could lead to the incidental parameters problem so, given our sample size, it may be preferable to a spare degree of freedom. As Wooldridge (2010, p. 286) pointed out, if the key explanatory variables do not vary much over time, a fixed effect estimator can lead to an imprecise estimate, that is, it can have greater variance. Moreover, the assumption of normal distribution for c_i allows us to evaluate the population average effect (APE) (Wooldridge, 2010).

These considerations and the nature of the available data suggest a random effect probit model. We used STATA14 to obtain maximum likelihood estimates through the adaptive Gauss-Hermite quadrature.

Exploiting Wooldridge's (2005) contribution related to unobserved heterogeneity and following Amisano and Giorgetti (2013), we entered the potential endogenous variables into the model with their initial conditions—that is, their values at the initial period of observation. We divided the covariates into three groups: $x_{(1i)}$, which consists of the strictly exogenous regressors; $x_{(2i)}$, which consists of the regressors that are not strictly exogenous; and $x_{(3)}$, which consists of the regressors that do not vary across units. The distribution of the random effects c_i is conditioned on all of the average sample[16] values of the regressors in $x_{(1i)}$ and on the initial values of $x_{(2i)}$. The resulting specification is:

[16] To reduce the number of regressors, the values of exogenous regressors enter with their mean values (Mundlak, 1978; Heckman, 1981).

$$
\begin{aligned}
c_i &= \gamma_1^{'} \bar{\mathbf{x}}_{(1i)} + \gamma_2^{'} x_{(2i)} + \alpha_i & (3)\\
\bar{\mathbf{x}}_{1i} &= \frac{1}{T}\sum_{t=1}^{T} \mathbf{x}_{(1it)} & (4)
\end{aligned}
$$

In particular, as in Wooldridge (2005), we assume that

$$
(c_i | \mathbf{X}_{(1i)}, \mathbf{x}_{(2i0)}, \boldsymbol{\theta}) \backsim N\left(f(\mathbf{X}_{(1i)}, \mathbf{x}_{(1i0)}, \boldsymbol{\theta}), \sigma_c\right) \qquad (5)
$$

and we use a linear specification for the conditional expectation. In our case, the endogenous variables that enter with their initial conditions are:

$$
x_{(2i)} = [DS_{ij,0}, DG_{i,0}, y_{ij,0}, Cit_{ij,0}, OCit_{j,0}, Comprod_{ij,0}]
$$

Finally, since the growth rate of the real total prescription drug expenditures per capita is constant across units, that variable plays the role of a time dummy.

5 Results

We used our results, collected in Table 7, to determine the effects of a firm's own patents and those of its rivals on the probability that the firm will launch new products and found that the firm's own patents promote the chances of entry, while rivals' patents have a two-fold effect: their initial stock of patents ($OCit_{j;0}$) has a negative effect on entry, and their most recent patents ($Ocit_{j;t-1}$) have a positive effect. The negative effect of the initial level of patents cannot be considered a standard barrier to entry because the pharmaceutical sector does not usually feature competition among branded products so much as competition between branded and generic products[17]. This result can be interpreted more as "fear of competition" than as a standard barrier to entry.

The positive effect of rivals' most recent patents ($Ocit_{j;t-1}$) on the probability that a firm will launch new products can be explained by the flow of knowledge to potential competitors and the opening of new technological opportunities: in this case, the patents' "spillover effect" prevails. In other words, our results suggest that the rivals' patents in the initial period are a potential threat to launches of new products, but over time the dissemination and the disclosure effects of rivals' newer patents prevails. Our research uses a one-period lag for all patents held by competitors and the firm, thereby capturing the dissemination effect of knowledge better than the disclosure effect does.

[17] We thank Margaret Kyle for this suggestion.

Although it should be better to have a lag of ten years when measuring the disclosure effect of patents (DeNicolò, 2007), taking this advice into account is impossible with the time span covered by our available sample period without losing a great deal of information. Our view is that the estimated effect of a firm's patents can be seen as a dissemination effect more than as the opening of new technological opportunities. The number of competing firms ($IMp_{j;t-1}$) is not significant, while the number of competing products ($Comprod_{j;t-1}$) has a double effect. The lagged number of products that competitors have in a submarket is negative and significant, and it takes the role of a barrier to entry, while the initial number of competing products is positively significant. This result suggests that, although the initial number of competitors' products could be considered a proxy for a submarket's attractiveness, as time goes by, the number of competing products becomes a disincentive to launching additional products.

The measure of each submarket's attractiveness ($Ap_{j;t-1}$), given by the relative weight of each submarket over the entire pharmaceutical sector, is not significant.

Since the decision to patent in many markets is determined by the behavior of all competitors, the need arises to control for each submarket's attractiveness. The presence of many patents in some submarkets seems to be a sort of emulation process among companies (e.g. Bloom, Schankerman and Van Reenen, 2013).

The growth rate of the prescription drug expenditures per capita ($PcEx_{t-1}$), which expresses the dynamics of pharmaceutical demand in the US, is not significant. This result is in contrast to Acemoglu and Linn (2004), who found a significantly positive market size.

Our estimates show that the regressors DG and DS, which measure the relative size of each company in the pharmaceutical market and in each submarket, respectively, and are used to capture the predation effect by incumbents, have no effect.

Table 7 about here

Table 8 about here

Table 8 shows the Average Marginal Effects (AME) and the elasticities. Competitive products' elasticity indicates that they are a deterrent to launching additional products, while incumbents' patents have positive elasticity.

6 Conclusions

This paper presents an analysis of patents' impact on competition, where we decide to measure competition as the probability that a firm will launch an additional product.

The analysis is performed for the pharmaceutical sector in United States in the period 1988-1998. Patterns have emerged in the recent past that could motivate the use of a more updated dataset (Chandra, Garthwaite and Stern, 2017; Chandra and Garthwaite, 2018) since changes have occurred recently in the pharmaceutical sector that have: a) reduced the efficiency of R&D (although the costs for new molecular entities are decreasing), b) shifted the sector from traditional to personalized drugs, c) increased research on orphan drugs, and d) increased interest in oncological products and those for autoimmune diseases. However**,** the paper's case study is sufficiently general that it doesn't depend on whether the period of investigation is recent or more distant.

Our results show that firm's own recent patents promote the chances of launching another product, while the firm's own initial patents are not significant. This result is in line with other results in the literature where own patents increase the probability to launch new products, as regards this point we could quote, another time, for the software industry, Cockburn and MacGarvie (2011).

Our results show that competitors' patents can have either positive or negative effects on entry. Competitors' initial successes in exploiting existing technological opportunities can frustrate entrant's efforts and, thus, discourage entry, as suggested by the patent literature (Aoki, 1991) and Kyle (2007), who found that rivals' patents induce "a sort of fear of competition". On the other hand, incumbents' most recent patent holdings appear to promote entry, suggesting that new information flows to competitors through patents and opens new technological opportunities for them. In this case, the "spillover effect" prevails on the "barrier to entry effect"of patents, showing a dissemination effect.

So our research finds a double effect of competitor's patents: a spillover effect and a barrier-to-entry effect, that, as regards the pharmaceutical sector should be more properly named, "a sort of fear of competition". These effects, neglected by the literature regarding their impact on the launch of products and on the level of competition (with the exception of Gahan and Silverman, 2006 that took into account the role rivals' patents but not on the launches of new product) deserve further analysis in other manufacturing sectors as well. The prevalence of one of these effects over the other will depend on the sector's technology level since R&D-intensive sectors behave differently from other sectors. At the same time, the evaluation of these effects must take into account the role that emulation plays (Bloom, Schankerman and VanReenen, 2013), such that, in some sectors all competitors will decide to issue patents because of a general tendency to do so. A way to take this role into consideration is by introducing the attractiveness of each submarket, as done in the present paper, but a richer dataset can offer other possibilities and underscore the recent increase in the use of patents as strategic tools (Bessel and Hunt, 2007; Rentocchini, 2011): so our study could be a useful starting point for comparative analysis. Performing the same analysis in other sectors could help policymakers to disentangle the spillover effect and the barrier to entry effect of rivals' patents.

The results obtained from our case study also have some policy implications in the framework of the recent debate on the role of patents in promoting innovation (see, e.g., Boldrin and Levine, 2013). An increased level of intellectual property rights has not always been associated with an increased level of innovation'; in fact, the opposite has sometimes happened. A prime example is the computer software sector (Boldrin and Levine, 2013), where "the contemporary FLOSS (Free Libre and Open Source Software) community is an example of how collaboration and exchange of ideas can thrive without the monopoly power granted by patents" (Boldrin and Levine, 2013) [18].

Patents' contribution to fostering innovation and the revision of intellectual property rights regimes could be re-evaluated by giving the right attention to the role of rivals' patents, taking into account the increasing use of defensive patenting and patent trolls (Boldrin and Levine, 2013). The challenge will be to use new data to take into account the dual role of rivals' patents by trying to control, with updated data, if the results whether new products are protected by patents.

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Code	Description
C1C	Cardiac stimulants excl. cardiac glycosides
C2A	Antiadrenergic agents, centrally acting
C3A	Low-ceiling diuretics, thiazides

C4A	Peripheral vasodilators
C5A	Agents for treatment of hemorrhoids and anal fissures for topical use
C10A	Lipid modifying agents, plain

Table 1: 3-digit Cardiovascular Submarkets considered

Submarket	n. companies operating in Each Submarket	N. obser.	Entry
C1C	9	108	15
C2A	20	240	33
C3A	26	312	40
C4A	12	144	19
C5A	8	96	13
C10A	16	192	33
Total		1092	153

Table 2: Companies, Number of observations and Entries by Submarket

Submarket	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	Total num. Of patents	Average number of products
C1C	2	0	1	0	1	1	0	2	6	1	4	0	18	16
C2A	1	1	0	2	2	0	2	4	6	5	4	0	27	29
C3A	0	0	1	0	0	0	0	2	1	1	1	1	7	62
C4A	2	6	5	4	7	1	2	5	7	6	5	0	50	14
C5A	0	0	0	0	0	1	3	2	1	0	1	2	10	14
C10A	8	12	6	8	6	15	19	12	19	23	4	2	134	14

Table 3: Number of Patent Applications by Submarket and Year

Formattato: Inglese (Stati Uniti)

Num of Entries	N. of firms
1-2	14

3-5	11
6-8	6
9-10	3
11	2
Total	153

Table 4: Companies by Entry

Variable	Description
$Exit_{ij;t-1}$	Built in a way similar to the Entry event, the lagged variable Exit measures company ''s decision to withdraw at time t1 one or more products from the submarket j.
$Cit_{ij;t-1}$	The lagged number of a firm's own patents, weighted by citations, into a particular submarket, evaluated according to equation (1).
$Ocit_{j;t-1}$	The lagged number of patents, weighted by citations, competitors own in a particular submarket, evaluated according to equation (1).
$Comprod_{j;t-1}$	The lagged number of products offered by competing incumbents in each submarket.
$IMp_{j;t-1}$	The lagged number of competing incumbent companies in each submarket, as a measure of competition.
$PcEx_{t-1}$	The growth rate of the per-capita real total prescription drug expenditures in US in the period considered. Since this variable is constant across units, it plays the roles of time dummies.
$Ap_{j;t-1}$	The attractiveness of each submarket given by the ratio of the total sales in submarket j to the total sales in the whole market.
$DG_{i;t-1}$	The relative distance between company i's sales and those of the company with the largest sales in the whole market, lagged at time t. $DG_{i;t}= \frac{max_i\ (sales_{i,t-1}) - sales_{i,t-1}}{max_i\ (sales_{i,t-1})}$.
$DS_{ij;t-1}$	1, the relative distance between company i's sales and those of the company with the largest sales in the submarket j, lagged at time t-1: $DS_{ij;t}= \frac{max_i\ (sales_{ij,t-1}) - sales_{ij,t-1}}{max_i\ (sales_{ij,t-1})}$

Table 5: Variable Definitions

Variable	Mean	Std. Dev.	Min.	Max.
Cit	16.20	40.40	0.0	307.2
Ocit	262.60	277.90	3.8	997.6

Comprod	29.50	19.90	6.0	64.0
IMp	14.50	7.20	6.0	25.0
PcEx	7.80	3.20	2.5	12.3
Ap	0.01	0.012	.001	.056
DG	0.67	0.32	0	.99
DS	0.84	0.28	0	1.0

Table 6: Descriptive statistics

Variable	coe	std. err.	z	p-value
$Exit_{ij;t-1}$	-0.176	0.150	-1.17	0.242
$Cit_{ij;t-1}$	0.007	0.003	2.15	0.032
$Ocit_{ij;t-1}$	0.002	0.001	2.16	0.031
$Comprod_{ij;t-1}$	-0.122	0.043	-2.84	0.004
$IMp_{ij;t-1}$	0.028	0.041	0.67	0.503
$PcEx_{t-1}$	-0.012	0.022	-0.54	0.588
$Ap_{ij;t-1}$	6.920	8.983	0.77	0.441
$DG_{i;t-1}$	-1.094	0.839	-1.30	0.192
$DS_{ij;t-1}$	-0.397	0.435	-0.91	0.361
$Exit_{ij;0}$	0.071	0.320	0.22	0.824
$Comprod_{ij;0}$	0.110	0.037	2.96	0.003
$DG_{i;0}$	1.302	0.816	1.60	0.110
$DS_{ij;0}$	0.323	0.480	0.67	0.501
$Cit_{ij;0}$	-0.005	0.004	-1.51	0.130
$Ocit_{ij;0}$	-0.002	0.001	-2.18	0.030
Const	-1.542	0.343	-4.49	0.000

Table 7: Probit estimates

Variable	AME	Elast.
$Exit_{ij;t-1}$	-0.020	-0.127
$Cit_{ij;t-1}$	7.e-4	0.204
$Ocit_{ij;t-1}$	2.e-4	1.019
$Comprod_{ij;t-1}$	-0.014	-7.526
$IMp_{ij;t-1}$	0.003	0.830
$PcEx_{t-1}$	-0.001	-0.183
$Ap_{ij;t-1}$	0.799	0.184
$DG_{i;t-1}$	-0.126	-1.482
$DS_{ij;t-1}$	-0.046	-0.694

Table 8: Probit estimates: marginal effects and elasticities