ESSAYS ON STRATEGIC USE OF INTELLECTUAL PROPERTY RIGHTS

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Leonardo G. Ortega Moncada

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Thesis committee:

Dr. Peter Thompson
Scheller College of Business
Georgia Institute of Technology

Dr. Stuart Graham
Scheller College of Business
Georgia Institute of Technology

Dr. Alexander Oettl
Scheller College of Business
Georgia Institute of Technology

Dr. Annamaria Conti
IE Business School
IE University

Dr. Marco Ceccagnoli
Scheller College of Business
Georgia Institute of Technology

Date approved: April, 15, 2023

A mi mamá y a mi papá.

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SUMMARY

This dissertation examines various aspects of firms' strategic responses in the management of their intellectual property rights to external factors, with each chapter focusing on a different aspect of this complex topic. The first chapter of the dissertation investigates whether markets for technology can provide an alternative to in-house innovation as a response to escape competition. The second chapter focuses on the tradeoff incumbents face in using patents as barriers to entry or as ex-post responses to competitors' entry moves. Finally, the third chapter investigates how firms manage information asymmetry in their patent prosecution source using exposure to patent litigation.

The market for technology in the U.S. has grown exponentially in the last 30 years. This has corresponded with massive growth in imports across the industrialized world from newly industrialized economies. Chapter 1 empirically examines whether markets for technology provide a possible alternative to in-house innovation as a strategic response to "escape foreign competition." Using patent reassignments activity to measure access to external technologies, I evaluate the effect of Chinese import competition on the demand by U.S. manufacturing firms for external technologies during the period 1991-2007. The findings indicate that while external technologies are important for innovative firms, low-productivity firms experience a negative impact on the demand for external technologies when exposed to import competition. This negative impact extends to all firms when the external technologies considered are novel to them. Although exposure to import competition does not necessarily prompt firms to seek external technologies to escape competition, it could hinder the demand for external technologies related to exploring new technological spaces.

While patents have been shown to play a role as barriers to entry, they also reveal information about incumbent strategies and risks being invalidated. Chapter 2 examines the tradeoff incumbents face between using their patents ex-ante as entry deterrents or ex-post

once competitors have revealed their moves. Leveraging the unique characteristics of the pharmaceutical sector, where it is possible to observe exactly when a competitor entry threat materializes, and exploiting exogenous variation in that timing, we show that incumbents intentionally fragment and delay the full disclosure of their intellectual property rights through continuation patents. They disproportionately reveal continuation patents after a competitor entry threat becomes concrete, tailoring their response to the threat they have received and successfully delaying competitor entry through litigation. The detected incumbents' reaction is stronger when their attacked drugs are valuable and when the patents listed at the FDA approval of a drug are relatively narrow in scope.

How do firms deal with information asymmetry to reduce the transaction costs of market-based solutions? Chapter 3 provides empirical evidence on how external sources of information serve to reduce the knowledge difference between firms and suppliers engaged in market exchanges. Analyzing the sourcing of patent prosecution services in the U.S. and using patent litigation as an exogenous source of variation in exposure to external experts evaluating litigated patents (i.e., litigating patent attorneys), this paper shows that firms exposed to patent litigation are more likely to change the sourcing of patent prosecution legal services relative to unexposed firms working with the same prosecuting law firm. Moreover, this paper finds that firms behave similarly in cases where patent weaknesses detected in litigation are associated either with actions taken by the prosecuting law firm or with actions taken by the patenting firm. This result suggests that firms may overreact to information from patent litigation. These findings advance our understanding of how outsourcing firms offset the negative effects of information asymmetries and how firms' limited ability to translate external information into signals can moderate this effect.

CHAPTER 1
IMPORT COMPETITION AND THE DEMAND FOR EXTERNAL TECHNOLOGIES

Leonardo Ortega

1.1 Introduction

The accelerated trade integration over the past decades has led to intensified competition in many domestic markets. In the U.S., imports from China grew over twelvefold between 1991 and 2007 from $26 billion to $330 billion (measured in 2007 dollars), pressuring the sales and profitability of domestic firms in import-competing industries (Autor et al., 2020; Hombert and Matray, 2018). Motivated by the long-standing interest in the relationship between competition and innovation (Schumpeter, 1943; Cohen and Levin, 1989; Gilbert, 2006), a growing literature examines how firm innovation in the U.S. responds to Chinese import competition. Import competition is found to have an overall negative impact on firms' research-and-development expenditure and patent output, with considerable heterogeneity across firms.[1]

This paper considers an alternative response to import competition that has not been examined by prior literature: the acquisition of external technologies. Fueled by the exponential growth over the last thirty years, the markets for technology in the U.S. reached $27.7 billion in 2012[2], equivalent to 10% of the manufacturing R&D investment during the same year. Firms could in theory turn to the external markets for technology, in addition to (or as a substitute for) in-house R&D. The argument that firms may innovate to "escape

[1] See Shu and Steinwender (2019) for a summary of the empirical literature.

[2] Source: 2012 Economic Census from the Census Enterprise Statistics Program. This figure refers to the revenues from technological and industrial processes, which include patents, trade secrets, and proprietary technologies (excluding computer software). For more details, visit https://www.census.gov/econ/esp/2012/esp2012

competition" could apply to both in-house innovation and external technologies if the use of internal and external technologies is a widespread practice across firms. Based on a survey of 5,000 American manufacturing firms, Arora et al. (2016) find that roughly 49% of innovative firms reported they use external sources of innovation in their most important new products between 2007 and 2009. Several studies suggest that firms are more prone to demand external technologies when there exist complementaries with internal capabilities (Cohen and Levinthal, 1990; Veugelers, 1997), when they have stronger ties with universities and research institutes (Cassiman and Veugelers, 2006), when the internal efforts fail to deliver an innovative solution (Higgins and Rodriguez, 2006a; Ceccagnoli et al., 2010), or when the costs of incorporating the external technologies into the internal process are low (Ceccagnoli and Jiang, 2013). However, import competition can also affect the demand for external technologies. A more competitive domestic market pressures surviving firms to innovate to escape competition, but at the same time, it reduces returns to innovation (i.e. lower potential profits) (Aghion et al., 2005). These opposing effects induce productive firms to reconsider their overall innovative efforts.

Studying the demand for external technologies can be a challenging task due to the lack of systematic information about transactions in the markets for technology. However, the use of patent reassignments records from the USPTO Patent Assignment Dataset (PAD) can serve as a valuable proxy for changes in ownership of technologies embedded in patents. Patent (re)assignment records are legal records that firms use to transfer all or part of the rights granted by a patent to another firm. Despite its limitations, such as those pointed out by Serrano (2010) and Graham et al. (2018), patent reassignment data can provide valuable insights into the transference of technologies across firms in a setting with broad economic sector coverage that is consistent over time. By leveraging the information contained in patent records, such as technology class, patent quality (based on forward citations), and more, we can gain a more nuanced understanding of how technology is being transferred and utilized in various industries.

To enrich the analysis of patent reassignments from the USPTO Patent Assignment Dataset (PAD), I supplement the dataset with additional information from other sources. Specifically, I utilize PatentsView to obtain bibliographical information on reassigned patents, including data on citations, technology class, grant and application date, etc. This additional information helps to paint a more complete picture of the patent transfer process and allows for a more comprehensive analysis of the technologies being transferred. Moreover, to gain a better understanding of the acquiring firms, I leverage Compustat data, which provides detailed information about publicly traded firms such as sales, number of employees, capital investment, and R&D.

The main analysis uses established identification strategies to examine the impact of Chinese import competition on firms' tendency to acquire external technology Autor et al. (2020). There are three key findings in this paper. First, external technologies matter. Empirically, we observe that firms demanding external technologies are also the most innovative ones and that the quality of reassigned patents appears to be higher. Moreover, I find evidence suggesting that firms use reassigned patents to build upon subsequent innovations and diversify into new technological spaces. Second, exposure to import competition has a negative but statistically insignificant effect on the demand for external technologies. I find no evidence of firms using external technologies as a channel to escape external competition. Nevertheless, there are significant heterogeneities across firms. In particular, low-productivity firms demand fewer external technologies as a reaction to an increase in import competition. Finally, the increase in import competition has a significant impact on the demand for external technologies related to new technological areas for the acquiring firm. Taken together, these results suggest that while exposure to import competition does not necessarily drive firms to seek external technologies as a means of escaping competition, it could impede the demand for external technologies related to the exploration of new technological spaces.

This paper contributes to the growing literature on trade and innovation literature, par-

ticularly, studies focusing on the impact of import competition on firm strategy and innovation. Autor et al. (2020) find that the negative impact of import competition concentrates on less productive firms. Hombert and Matray (2018) show that firms with more R&D stock are more likely to innovate to escape competition. Xu and Gong (2017) find that import competition has a negative impact on R&D investment for unproductive or low-margin firms, while the effect is positive for productive or high-margin firms. This paper contributes to this literature by considering an unexplored but increasingly important channel to innovate: the demand for external technologies. This study also relates to the literature on the determinants of the demand for external technologies. This literature suggests that firms are more prone to demand external technologies when there exist complementaries with internal capabilities (Cohen and Levinthal, 1990; Cassiman and Veugelers, 2006), when the internal efforts fail to deliver an innovative solution (Higgins and Rodriguez, 2006a), and when the costs of incorporating the external technologies into the internal process are low (Ceccagnoli and Jiang, 2013). I contribute to this literature by analyzing the role of downstream market structure as a determinant in the demand for external technologies.

1.2 Data

In this study, I examine the demand for external technologies through transactions in the markets for technology that involve the transfer of technologies embedded in U.S. patents from one firm to another. To measure transactions in these markets, I use the USPTO patent assignment dataset (PAD) (Graham et al., 2018), which records changes in patent ownership through three types of transactions: i) assignments on assignor's interest, ii) security interest agreements, and iii) government interest agreements. I focus solely on the first type of transaction as a proxy for transactions in the market for technology. As suggested in Graham et al. (2018), assignment records are legal instruments by which a firm transfers to another firm, partly or entirely, the rights granted by a patent.

To proxy technology transfer activity, I count the number of reassigned patents at the firm-year level. The USPTO PAD dataset enables us to track the patents that are reassigned, the original and new assignees of the patent, and the date the reassignment is recorded at the USPTO.

I complement the USPTO PAD dataset with additional information about the reassigned patents and the new assignees (e.g., buying firms). First, I use Patentsview as the main source of information about the reassigned patents. PatentsView provides data on the patents' issuance date, main technology class, and other key patent characteristics. Second, I use Compustat as the primary source of information about the new assignees for all reassigned patents. Compustat provides firm-level data, such as annual sales, number of employees, R&D investments, and other relevant financial metrics. Only firms in the manufacturing sector are considered in the sample.

To ensure the reliability and validity of the data, I carefully cleaned and preprocessed the data. To match the USPTO Assignment data with Compustat, I followed a procedure similar to the one used by Autor et al. (2020). First, I utilized standardization routines from the Patent Data Project, which involved performing extensive changes to the firm names. These changes included removing non-alphanumeric characters, punctuations, and standardizing legal denominations such as 'Incorporated' and 'INC'. Next, I matched the firms with the Compustat dataset using their names and websites, as outlined in Autor et al. (2020). Any unmatched names were then matched with two publicly available datasets containing GVKEY-firm name information: the sample from Autor et al. (2020) and the NBER PDP Patent dataset. Finally, any firms that remained unmatched and had more than 20 reassignments in 1991, 1999, and 2007 were manually checked and matched with Compustat. This rigorous matching process ensures that the resulting dataset is reliable and accurately reflects the behavior of manufacturing firms in the US patent market.

The sample used in this study consists of 2381 manufacturing firms with unique GVKEYs, spanning the years 1991, 1999, and 2007. A comparison between the entities in the sample

and the entire USPTO PAD dataset is presented in Table 1.1. The matched sample represents between 8.4%-12.8% of the total entities with reassignment records in 1991, 1999, or 2007, while in-sample entities represent between 25.9%-43.8% of the total reassignment records at the patent level during these years. However, it is worth noting that the matched sample may underestimate the true representation since many out-of-sample entities may not be in the manufacturing sector, which is beyond the scope of this study, or may not be public firms, which is beyond the scope of Compustat.

Table 1.1: Comparison between the matched sample and the USPTO Assignment data.

	In-sample	All entities	Share
Panel A: By firms			
Number of firms (1991)	563	6,718	8.4%
Number of firms (1999)	1,160	9,035	12.8%
Number of firms (2007)	1,186	11,879	10.0%
Panel B: By reassignments			
Number of reassignments (1991)	7,297	28,205	25.9%
Number of reassignments (1999)	19,211	45,962	41.8%
Number of reassignments (2007)	35,908	81,982	43.8%

Notes: This table reports the number of entities (Panel A) and reassigned patents (Panel B) in the matched and the USPTO PAD dataset. Although the number of matched entities seems relatively small, the matched sample represents an important share of the reassigned patents during the relevant period of analysis.

The measure of import exposure used in this study, originally introduced by Autor et al. (2020), serves as a valuable indicator of changing competitive pressures in the U.S. market. Specifically, it captures how changes in the volume and competitiveness of Chinese imports affect the economic outcomes of U.S. manufacturing firms as follows:

$$\Delta IP_{j,t} = \frac{\Delta Import_{j,t}^{chn,us}}{Y_{j,91} + Import_{j,91} - Export_{j,91}} \tag{1.1}$$

where $Import_{j,t}^{chn,us}$ represents the change in the import from China to the U.S. over two sub-periods $t = \{1991 - 1999, 1999 - 2007\}$, and the denominator measures the initial absorption level of the U.S. economy at the starting period (i.e. industry shipments plus

imports minus exports).

The empirical setting used in this paper provides valuable insights into the dynamics of the U.S. patent market. However, it is important to note two main limitations of our analysis. First, while firms have incentives to record the transfer of patent rights at the USPTO, they are not legally required to do so. Therefore, the USPTO PAD dataset may not capture all transactions involving the transfer of patent rights. Nevertheless, recording the change of ownership can help establish a clear chain of title for the patent and can provide public notice of the new owner's rights to the patent, which can be important for investors or potential acquirers of the buying firm. As such, the USPTO PAD dataset remains a reliable source of data for capturing a substantial portion of patent transactions.

Second, our analysis is limited by the fact that Compustat only tracks publicly traded companies. As such, the behavior of private firms will be absent from our empirical analysis. However, publicly traded firms account for a significant portion of economically important transactions, and are likely to be key players in the market for external technologies. While our analysis may not capture the full range of transactions in the market, it remains a valuable and informative source of insight into the dynamics of the U.S. patent market.

1.3 Descriptive Analysis

Until the 1970s, most of the manufacturing sector in the U.S. was vertically integrated with most firms choosing to innovate internally (Arora and Gambardella, 1990; Teece, 1992). Over time, industry structures have changed and firms more often combine internal and external sources of knowledge to innovate rather than rely solely on their internal capabilities (Arora et al., 2001; Gans and Stern, 2003; Mowery, 2009). As a result, the markets for technology have grown exponentially in the last 30 years (Arora et al., 2001; Robbins, 2009) and roughly 49% of U.S. innovating manufacturing firms reported they use external sources of innovation in their most important new products between 2007 and 2009 (Arora

et al., 2016).

In Figure 2.1, the trends for U.S. manufacturing firms in the number of patent applications and patent reassignments are displayed, both showing persistent growth from 1980 to 2015. While various factors contribute to this common trend in these variables, such as the strengthening of property rights and the rise in patent application disclosure (Hegde and Luo, 2018), they ultimately demonstrate that U.S. manufacturing firms are engaging in greater internal and external innovative activities. These findings align with the results presented in Robbins (2009) and highlight the increasing significance of external technologies as a source of innovation for firms, particularly through patent reassignments.

Figure 1.1: Trends in Patent Applications and Patent Reassignments.

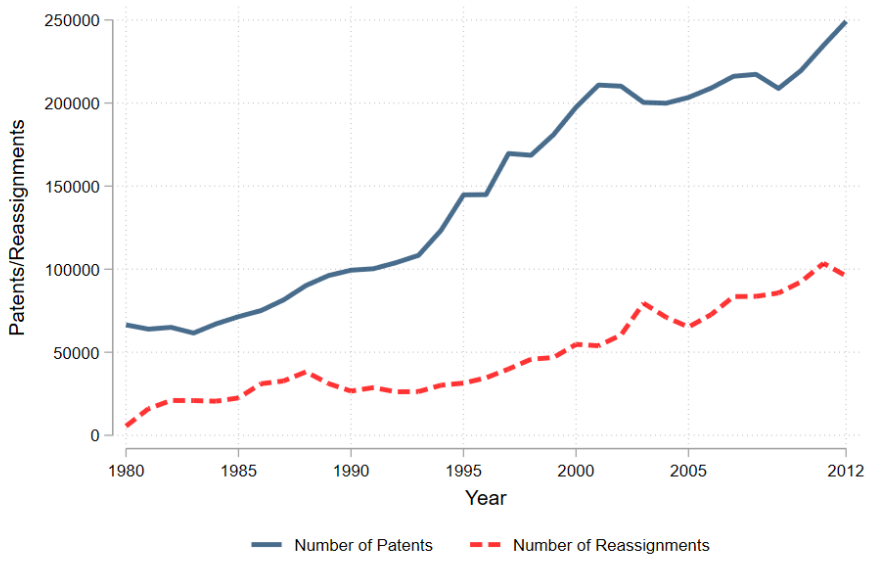


Table 1.2 offers valuable insights into the distribution of patent reassignments across various manufacturing sectors. It reveals that the computer, equipment, and chemical sectors are the most active industries in terms of demand for external technologies, indicating a greater reliance on outside sources for innovation. Together, these sectors accounted for a significant proportion of patent reassignments in 2007, representing more than 78% of the total reassigned patents.

In order to evaluate the economic significance of in-sample firms, Table 1.3 provides

Table 1.2: Distribution of the share of patent reassignment by manufacturing sector.

Sector	Patent Reassignment Year		
	1991	1999	2007
Equipment	32.2%	16.4%	16.7%
Chemical	29.2%	22.0%	18.1%
Transport	9.8%	6.5%	4.4%
Metal	10.6%	4.3%	4.8%
Computer	9.9%	38.5%	43.2%
Paper	1.2%	6.2%	5.4%
Food	2.9%	0.4%	2.3%
Stone	3.4%	1.9%	2.9%
Wood	0.4%	2.4%	0.7%
Textile	0.4%	0.1%	0.2%
Other	0.1%	1.3%	1.3%

Notes: This table reports the distribution of the share of patent reassignments by manufacturing sector during 1991, 1999, and 2007 for all firms in the sample.

a comparison between matched firms and all manufacturing firms in Compustat in 2007. The results show that in-sample firms are substantially larger in all firm characteristics examined, including sales, employment, capital investment, and R&D. On average, matched firms represent more than 72% of total sales, employment, and capital investment among all manufacturing firms in Compustat. The sample also accounts for more than 88% of total R&D investment, indicating that the vast majority of innovating firms in Compustat are included in the matched sample. This analysis confirms that the in-sample firms are a significant subset of the entire population, strengthening our findings' reliability and representativeness.

Not only are firms involved in patent reassignment transactions among the most innovative ones, but they also have a tendency to acquire patents that are technologically significant. To better understand the quality of patents acquired through reassignment transactions, it is useful to compare the average number of citations for reassigned and

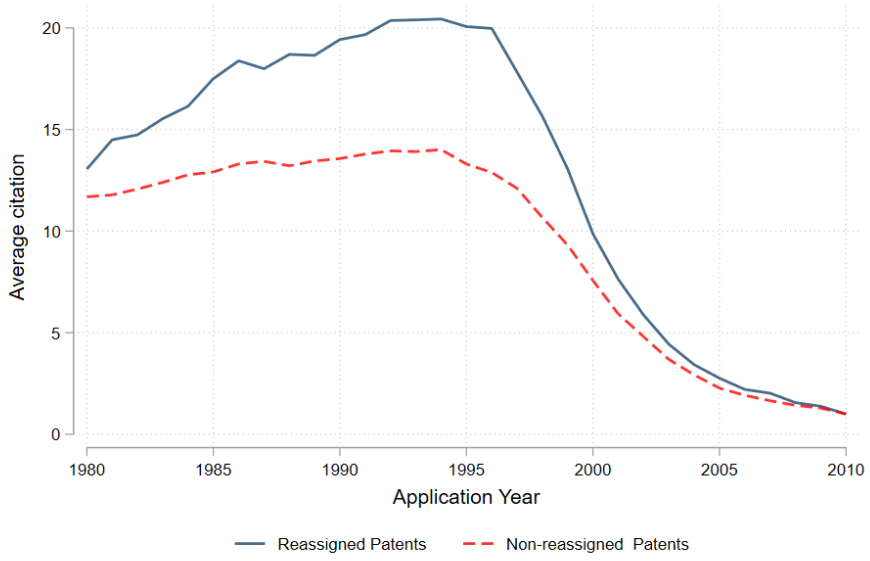
Table 1.3: Comparison between the in-sample firms and Compustat, 2007.

	In Sample (mean)	Compustat (mean)	Share
Sales (millions of USD)	5522.6	921.2	75.7%
Employment	12775.9	2635.0	72.0%
Capital (millions of USD)	3456.2	541.8	76.8%
R&D (millions of USD)	281.4	21.4	88.6%

Notes: This table presents average values for Sales, Employment, Capital Investment, and R&D Investment for two datasets: the in-sample and the Compustat dataset. Column 3 shows the share of each variable for firms in the in-sample dataset out of all manufacturing firms in the Compustat dataset.

non-reassigned patents over time. As illustrated in Figure 2.2, the average citation count for reassigned patents is consistently higher than that of non-reassigned patents, indicating a greater level of technological importance. This pattern highlights the strategic value of patent reassignment transactions as a means of acquiring high-quality intellectual property.

Figure 1.2: Average citation rates by granted year.



1.4 Identification Strategy

The primary goal of this paper is to assess, through empirical analysis, the degree to which firms seek external technologies in response to an increase in exposure to import competition. To achieve this objective, I employ a stacked first-difference model, which is specified as follows

$$\Delta Y_{i,j,t} = \beta \Delta ImpExp_{j,t} + \gamma X_i + \alpha_j + \delta_t + \epsilon_{i,j} \tag{1.2}$$

where $\Delta Y_{i,j}$ represents the change in the number of patent reassignments in firm i, industry j, over two sub-periods $t = \{1991-1999, 1999-2007\}$ measured as the change in pseudo-logs, $\Delta ImpExp_j$ measures the change in the level of exposure to Chinese competition in industry j in period t, and α_j and δ_t correspond to industry and time fixed effects.[3] The vector X_i contains a set of firm characteristics at the beginning of each sub-period such as sales, employment, R&D investment, and the stock of patents granted in the previous five years, as control variables in X_i. Observations are weighted by the average number of patent reassignments during 1991, 1999, and 2007, while the standard errors are clustered at the industry level (i.e. SIC code) to account for correlations across industries.

One of the main challenges in this empirical exercise is the presence of endogeneity, which is particularly pronounced when examining equilibrium outcomes such as import. For instance, the United States may experience an increase in imports from China due to an uptick in demand for Chinese goods and services by American firms (i.e., a demand-driven shock), or alternatively, Chinese firms may enter the U.S. market, leading to an increase in imports from China (i.e., a supply-driven shock). Untangling these two factors is essential for accurately estimating the causal effect of exposure to import competition on firms' demand for external technologies.

[3] Autor et al. (2020) identify those sub-periods as the time when the Chinese import competition has increased in the U.S.

In order to establish a causal link between import competition and the demand for external technologies, it is crucial to identify a source of exogenous variation in import exposure that is not influenced by U.S. firms' actions. This requires using an import competition supply-driven shock, which refers to an external force that affects the level of import competition faced by domestic firms. To address this challenge, I adopt the approach developed by Autor et al. (2020), which constructs a measure of exogenous import exposure. Specifically, Autor et al. (2020) uses Chinese imports to other developed economies as an instrument for import exposure in the U.S. market.[4] This instrument is designed to capture variations in imports that are driven by supply-side factors, such as changes in Chinese production costs, rather than demand-side factors in the U.S. market, thus providing a credible source of exogenous variation.

1.5 Main Results

1.5.1 Acquisition of Patents as Strategy

Table 1.4 provides an overview of the distribution of firms that file for patents and/or acquire reassigned patents. The pattern is consistent across both panels. Panel A demonstrates that a majority of firms that acquire patents are also actively engaged in patenting. Panel B reveals that in 2007, firms that filed for more patents were also more likely to actively acquire patents in the markets for technology. This pattern underscores the notion that external patents can serve as a complementary element to internal innovative efforts.

To assess whether firms that acquire reassigned patents actually leverage them in their subsequent innovative efforts, we could examine the number of citations to the acquired patents before and after the reassignment. Figure 2.3 illustrates that, on average, acquiring firms cite the reassigned patent more frequently after the reassignment than before. This finding suggests that firms acquiring external patents are likely building upon the embedded

[4]The included high-income countries are Australia, Denmark, Finland, Germany, Japan, New Zealand, Spain, and Switzerland.

Table 1.4: Distribution of Firms with Patents and Reassignments.

Panel A

Year	None	Only Patents	Only Reassignment	Both
1991	68.7%	22.0%	2.5%	6.8%
1999	53.3%	27.3%	4.5%	14.9%
2007	60.6%	18.6%	6.1%	14.6%

Panel B

	Reassignments			
Patents	0	$1-5$	$6-20$	>20
0	93.0%	5.8%	0.8%	0.3%
$1-5$	78.5%	17.7%	2.8%	1.0%
$6-20$	52.3%	35.9%	8.1%	3.7%
>20	16.4%	37.5%	23.6%	22.5%

Notes: Panel A shows the distribution of manufacturing firms in Compustat that neither patenting, nor reassigning patents (column 1), patenting firms without reassignments (column 2), firms with reassignments but no patenting activity (column 3), and firms filing for patents and reassignment transactions. Panel B shows the distribution of firms with patenting activity and reassignment transactions for different intensity intervals.

technologies, and utilizing them to drive their own innovation efforts forward. However, there are concerns that citation patterns like this one may not reflect genuine innovation efforts, but rather strategic behavior (Hall et al., 2001, 2005).

To mitigate this concern, I exploit a different source of information to track how acquiring firms use reassigned patents: technology classes. If reassignments are a reliable indicator of external innovation, then we should expect that reassigned patents would impact the innovation trajectory of the acquiring firm. Specifically, we would anticipate that the acquiring firm's subsequent patents would include new technology classes featured in the reassigned patents.

Figure 1.3: Average citation of reassigned patents before/after reassignment.

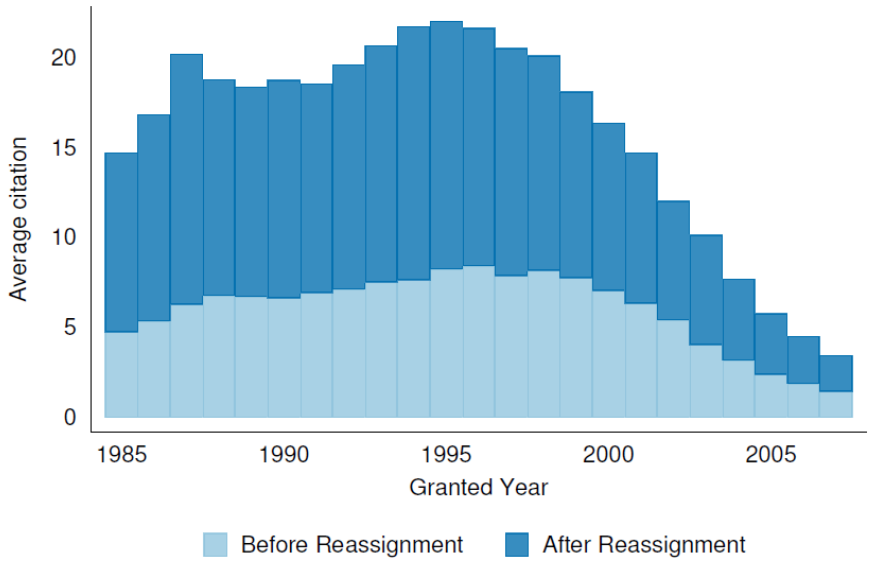
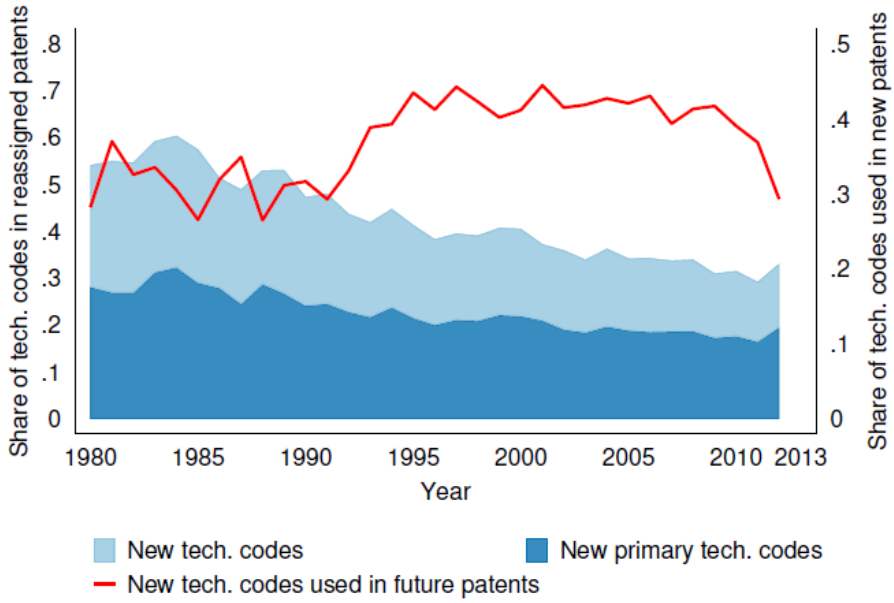


Figure 2.4 presents the average share of technology classes present in reassigned patents that are new to the acquiring firm. On average, the share of new technology classes ranges from 32% to 60% (as indicated by the light blue area). Remarkably, nearly half of these new technology classes feature as the primary technology class in the reassigned patents (as indicated by the dark blue area). Moreover, this analysis reveals that between 30% and 48% of the new technology classes in reassigned patents are used in subsequent patents of the acquiring firm (as indicated by the red line). Therefore, these findings suggest that companies not only gain access to new technology classes through reassigned patents, but also utilize them to develop new innovations.

In summary, the empirical evidence thus far suggests that firms that acquire external patents tend to be more active in patenting technologies. Furthermore, acquiring firms are found to cite the reassigned patent more frequently after reassignment, which may indicate a building upon strategy, as firms are more likely to explore new technological spaces embedded in reassigned patents.

Figure 1.4: Share of New Technology Classes in Reassigned Patents.



1.5.2 Impact of Chinese Import Competition

Do firms use external patents to escape competition? In this section, we explore this question using the trade liberalization event that occurred in China after 1999. The results from estimating Eq. (2) for the change in the number of reassigned patents as a function of exposure to Chinese competition are reported in Table 1.5. The columns represent the period of import competition exposure considered in the regression, whereas the rows indicate the estimated model. Rows (1), (3), and (5) correspond to the OLS estimation controlling for different variables, while rows (2), (4), and (6) correspond to the instrumental variables (IVs) estimation using the same controlling variables. Standard errors are clustered at the industry level. The results indicate that U.S. domestic firms react by acquiring fewer external patents when facing an increase in exposure to Chinese competition. However, the point estimate of the preferred specification (row f, column 3) is not statistically significant.

I next assess whether the effect of Chinese import competition on the demand for external technologies differs by productivity level. For this purpose, I divide the sample depending on whether their sales per worker are above or below the median value. Table 1.6 shows

that the negative effect of import competition on the demand for external technologies is particularly strong for low-productivity firms. This result is consistent across all considered specifications. Conversely, high-productivity firms experience a negative but statistically insignificant effect on their demand for external technologies.

Contrary to the initial hypothesis, these results suggest that when firms are faced with stiff competition from foreign imports, they may find it more difficult to allocate resources toward investing in external technologies. This is particularly true for less productive firms, as they may need to prioritize cost-cutting measures over investments that do not provide immediate returns. As a result, these firms may be less likely to demand external technologies as a means of escaping competition, and instead may focus on other strategies such as reducing costs or streamlining operations to remain competitive.

Table 1.5: Response in the Demand for Technologies to Trade Exposure, 1991-2007

Dependent Variable: Change in the Number of Reassigned Patents			
	Exposure Period		
	1991-1999	1999-2007	1991-2007
a. OLS (no controls)	1.328	-0.661	-1.022
	(2.647)	(0.682)	(0.624)
b. 2SLS (no controls)	3.656	0.061	0.413
	(2.634)	(1.320)	(1.251)
c. OLS (manuf. dummies)	-3.286	-0.493	-1.861***
	(2.469)	(0.748)	(0.643)
d. 2SLS (manuf. dummies)	0.306	0.619	-1.601*
	(2.077)	(0.778)	(0.913)
e. OLS (manuf. dummies + firm controls)	-0.237	0.749*	-0.519
	(2.032)	(0.418)	(0.610)
f. 2SLS (manuf. dummies + firm controls)	0.676	-0.034	-1.610
	(2.660)	(0.728)	(1.086)

Notes: This table examines the effect of changes in exposure to Chinese import competition on changes in the number of reassigned patents from 1991-2007 by estimating equation (2). The change in the number of reassigned patents is expressed as the difference in reassigned patents from t to $t+1$, divided by the average number of reassigned patents across the two periods t and $t+1$. Column (1) only considers changes in the number of reassignments between 1991-1999, while Column (2) only considers changes in the number of reassignments between 1999-2007. Column (3) includes the stack difference between 1991-1999 and 1999-2007. Models (a) and (b) have no controls. Models (c) and (d) include a full set of manufacturing sector dummies. Models (e) and (f) additionally include a set of firm-level characteristics such as sales (in logs), employment (in logs), R&D investment (as a share of sales), and the number of patent applications in the previous 5 years. All specifications in Column (3) include a period dummy variable. Robust standard errors clustered at the 4-digit SIC code are shown in parentheses. Significance noted as: $*p < 0.10$; $**p < 0.05$; $***p < 0.01$.

Table 1.6: Response in the Demand for Technologies to Trade Exposure by firm sales per worker, 1991-2007

Dependent Variable: Change in the Number of Reassigned Patents		
	Exposure Period	
	1991-2007	
	Sales p.w. $\leq$ med	Sales p.w. $>$ med
a. OLS (no controls)	-2.067***	-0.649
	(0.533)	(1.180)
b. 2SLS (no controls)	-1.598**	-1.772
	(0.746)	(2.123)
c. OLS (manuf. dummies)	-2.983***	0.349
	(0.442)	(0.878)
d. 2SLS (manuf. dummies)	-2.712***	-0.804
	(0.668)	(1.742)
e. OLS (manuf. dummies + firm controls)	-2.988***	0.848
	(0.542)	(0.798)
f. 2SLS (manuf. dummies + firm controls)	-2.371***	-1.603
	(0.691)	(1.683)

Notes: This table examines the effect of changes in exposure to Chinese import competition on changes in the number of reassigned patents from 1991-2007 by estimating equation (2). Firms are divided into two groups depending if their sales per worker are below the median (column 1) and above the median (column 2). The change in the number of reassigned patents is expressed as the difference in reassigned patents from t to $t+1$, divided by the average number of reassigned patents across the two periods t and $t+1$. Models (a) and (b) have no controls. Models (c) and (d) include a full set of manufacturing sector dummies. Models (e) and (f) additionally include a set of firm-level characteristics such as sales (in logs), employment (in logs), R&D investment (as a share of sales), and the number of patent applications in the previous 5 years. All specifications in Column (3) include a period dummy variable. Robust standard errors clustered at the 4-digit SIC code are shown in parentheses. Significance noted as: *$p < 0.10$; **$p < 0.05$; ***$p < 0.01$.

Since the demand for external technologies seems to be an important element to explore new technological areas, I explore whether the exposure to Chinese competition also affects the incentives to expand the technological space of domestic firms. That is, the following analysis evaluates whether firms facing pressure from foreign firms escape competition by innovating in a novel technological space. The main dependent variable is the number of reassigned patents in technology classes that are novel to the acquiring firm.

In contrast with this hypothesis, Table 1.7 shows that, on average, firms exposed to import competition are less likely to acquire external patents in novel technological spaces for

the acquiring company. Similarly, Table 1.8 explores the heterogeneity of this effect across firm productivity. The results are in line with the aggregate results in Table 1.5 and Table 1.6. They indicate that both low- and high-productivity firms react by demanding fewer external novel technologies as a result of an increase in import competition. These results suggest that import competition not only could have a negative impact on the demand for external technologies in underperforming firms, but it also could reduce the incentives to explore new technological spaces for all exposed firms.

Table 1.7: Response in the Demand for New Technologies to Trade Exposure, 1991-2007

Dependent Variable: Change in the Number of Reassigned Patents with new technology class			
	Exposure Period		
	1991-1999	1999-2007	1991-2007
a. OLS (no controls)	4.199*	-2.603***	-2.108***
	(2.322)	(0.829)	(0.631)
b. 2SLS (no controls)	6.364*	-2.380	-1.855
	(3.781)	(1.738)	(1.596)
c. OLS (manuf. dummies)	2.301	-2.099***	-1.923***
	(3.317)	(0.571)	(0.542)
d. 2SLS (manuf. dummies)	4.555	-1.364	-1.722
	(4.720)	(1.131)	(1.978)
e. OLS (manuf. dummies + firm controls)	-0.327	-0.334	-1.302*
	(3.371)	(0.450)	(0.747)
f. 2SLS (manuf. dummies + firm controls)	0.030	-1.685	-4.155**
	(4.175)	(1.197)	(1.948)

Notes: This table examines the effect of changes in exposure to Chinese import competition on changes in the number of reassigned patents with new technologies classes for acquiring firms from 1991-2007 by estimating equation (2). The change in the number of reassigned patents is expressed as the difference in reassigned patents from t to $t+1$, divided by the average number of reassigned patents across the two periods t and $t+1$. Column (1) only considers changes in the number of reassignments between 1991-1999, while Column (2) only considers changes in the number of reassignments between 1999-2007. Column (3) includes the stack difference between 1991-1999 and 1999-2007. Models (a) and (b) have no controls. Models (c) and (d) include a full set of manufacturing sector dummies. Models (e) and (f) additionally include a set of firm-level characteristics such as sales (in logs), employment (in logs), R&D investment (as a share of sales), and the number of patent applications in the previous 5 years. All specifications in Column (3) include a period dummy variable. Robust standard errors clustered at the 4-digit SIC code are shown in parentheses. Significance noted as: $*p < 0.10$; $**p < 0.05$; $***p < 0.01$.

Table 1.8: Response in the Demand for New Technologies to Trade Exposure by firm sales per worker, 1991-2007

Dependent Variable: Change in the Number of Reassigned Patents with new technology class		
	Exposure Period	
	1991-2007	
	Sales p.w. ¡ med	Sales p.w. ¿ med
a. OLS (no controls)	-1.298	-3.128**
	(0.839)	(1.423)
b. 2SLS (no controls)	-0.743	-8.945*
	(0.957)	(5.020)
c. OLS (manuf. dummies)	-2.697***	-0.138
	(0.784)	(1.432)
d. 2SLS (manuf. dummies)	-2.552***	-6.653*
	(0.895)	(3.455)
e. OLS (manuf. dummies + firm controls)	-2.546***	-0.037
	(0.814)	(1.511)
f. 2SLS (manuf. dummies + firm controls)	-2.170**	-7.325**
	(0.891)	(3.672)

Notes: This table examines the effect of changes in exposure to Chinese import competition on changes in the number of reassigned patents with new technologies classes for acquiring firms from 1991-2007 by estimating equation (2). Firms are divided into two groups depending if their sales per worker are below the median (column 1) and above the median (column 2). The change in the number of reassigned patents is expressed as the difference in reassigned patents from t to $t+1$, divided by the average number of reassigned patents across the two periods t and $t+1$. Models (a) and (b) have no controls. Models (c) and (d) include a full set of manufacturing sector dummies. Models (e) and (f) additionally include a set of firm-level characteristics such as sales (in logs), employment (in logs), R&D investment (as a share of sales), and the number of patent applications in the previous 5 years. All specifications in Column (3) include a period dummy variable. Robust standard errors clustered at the 4-digit SIC code are shown in parentheses. Significance noted as: $*p < 0.10$; $**p < 0.05$; $***p < 0.01$.

1.6 Discussion

The increased trade integration in recent decades has resulted in intense competition in many domestic markets, particularly in industrialized economies. While prior literature has examined the negative impact of Chinese import competition on firms' research-and-development expenditure and patent output, this paper considers an alternative response to import competition: the acquisition of external technologies.

Using U.S. patent reassignments data and established identification strategies to examine the impact of Chinese import competition on firms' tendency to acquire external technology. I find that external technologies are an important element in the innovation strategy

of the firm. Firms acquiring external technologies tend to build upon them in subsequent innovations and diversify into new technological spaces. Contrary to the hypothesis of using external technologies to escape foreign competition, exposure to import competition has a negative effect on the demand for external technologies for low-productivity firms and for firms' efforts to explore new technological spaces. These results suggest that firms exposed to foreign competition prioritize cost-cutting measures over investments that do not provide immediate returns.

The empirical results also have important policy implications. The negative impact of import competition on the demand for external technologies suggests that policies aimed at reducing trade barriers and increasing import competition may have unintended consequences on firms' innovation efforts. On the other hand, policies that promote the adoption of external technologies, such as funding for technology transfer offices and public-private partnerships, may be more effective in stimulating innovation in import-competing industries. Overall, the paper contributes to a better understanding of the response of firms to import competition, highlighting the importance of external technologies as an alternative to in-house R&D.

CHAPTER 2

SHARPEN YOUR SWORD FOR LITIGATION: INCUMBENT STRATEGIC REACTION TO THE THREAT OF ENTRY

Annamaria Conti[1], Leonardo Ortega, and Elie Sung[2]

2.1 Introduction

Strategy scholars have spilled much ink on how firms should deal with the threat of competition from new entrants (Prince and Simon, 2015; Conti and Valentini, 2018) by making significant investments upfront in building barriers to entry (Cookson, 2018; Seamans, 2012). Yet, for these barriers to work as effective deterrents, they must impose substantial fixed costs on potential entrants and be employed credibly by the incumbents if potential entrants carry their threats into execution (Dixit, 1980; Fudenberg and Tirole, 1984; Bulow et al., 1985). These conditions are not obvious to fulfill. Moreover, by acting first, incumbents can reveal fundamental information about their products, giving weapons to their competitors (Lieberman and Montgomery, 1998). Patents are no exception. In principle, the strongest patents could be used as entry deterrents imposing costs on potential entrants if they infringe on them (Gilbert and Newbery, 1982; Ellison and Ellison, 2011). However, assessing the strength of a patent ex-ante is difficult, as patents are probabilistic assets whose value is ultimately determined in litigation (Lemley and Shapiro, 2005a). Moreover, patents could reveal important information that might help competitors find ways to invent around or invalidate them.

This paper examines the tradeoff incumbents face between using their patents ex-ante as entry deterrents or ex-post once competitors have revealed their moves. While scholars

[1]IE Business School, IE University.
[2]Strategy and Business Policy, HEC Paris.

have discussed the strategic use of patents to defend or enhance an incumbent's bargaining position vis-à-vis potential entrants (Hall and Ziedonis, 2001; Ziedonis, 2004; Shapiro, 2000), there is little statistical evidence on the strategic timing of disclosure of patent information (Righi and Simcoe, 2020). Yet, under US patent law, there is room for such an opportunistic behavior as firms can employ continuation patents to seek protection for new claims relative to a parent patent whose filing date is retained (Hegde et al., 2009). This practice allows patent holders to fragment the intellectual property protecting an invention and delay its full disclosure. Leveraging the characteristics of the pharmaceutical sector, we show that incumbents manage their patent portfolios, making use of continuation patents to delay the full disclosure of branded drugs' intellectual property until the threat of competitor entry has materialized and to prepare for litigation. Our results point to second-mover advantages such that incumbents force potential entrants to act on incomplete information, capitalize on the information they infer from the competitors' threats, and subsequently tailor their patent response to more effectively delay entry.

To carry out our empirical analysis, we must observe the exact moment a competitor threat materializes, the product that is being threatened, the link between a product and its protecting patents, and the consequences of disclosing this link. Unlike other industries, the pharmaceutical sector allows us to observe all of these aspects. In this context, we exploit plausibly exogenous variations in the timing of entry threats by generic manufacturers -that is, the potential entrants- investigating the reaction of brand-name drug producers -that is, the incumbents- after they experience a Paragraph IV challenge by a generic competitor. These Paragraph IV challenges, also called certifications, are mechanisms introduced by the US 1984 Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Act (Grabowski and Vernon, 1996; Grabowski, 2007). By submitting certifications, generic manufacturers claim that the patents protecting a given branded drug either are invalid or will not be infringed, thus disclosing their intention to enter the market. Upon approval by the Food and Drug Administration (FDA), generic producers can

then enter the market before the patents of a branded manufacturer have expired and without the hurdle of going through clinical trials.

We assembled a fine-grained dataset of 286 brand-name drug manufacturers and their 1,454 small-molecule new drug applications (NDAs).[3] Critically, we can observe the set of patents protecting a specific drug through the Approved Drug Products with Therapeutic Equivalence Evaluations, that is, the Orange Book. This repository not only contains information on *which* patents protect a given drug but also on *when* the patent information is listed and, thus, disclosed. We complement this information with data on Paragraph IV challenges from the FDA Office of Generic Drugs and with data on litigation cases from the Paragraph Four Reports.

Our identification strategy rests on the assumption that it is difficult for a branded manufacturer to predict the exact timing of generic entry threats. Discussions with practitioners -confirmed by our data- support this assumption. To bolster our empirical approach, we saturate our models with a wide array of fixed effects, including drug, drug's applicant, drug's age, and year-by-therapeutic-class fixed effects. We find that branded manufacturers react to a Paragraph IV challenge by listing 0.34 more patents for each existing drug application challenged. This corresponds to a 12% increase in the average number of patents listed in the Orange Book. These patents are disproportionately continuation patents, whose share increases by 11% relative to the mean. These results provide a strong indication that branded manufacturers intentionally delay the full disclosure of the intellectual property protecting their drugs through continuation applications and until the threat of generic entry materializes.

While the interpretation of our findings is plausible, the added patents might protect innovations related to an approved drug application and/or innovations listed in future applications; that is, the threat of generic entry might induce branded manufacturers to increase their innovation effort to differentiate themselves from generic producers. In contrast with

[3]We focus our analysis on small-molecule drugs because the Paragraph IV mechanism does not apply to large-molecule drugs, that is, biologics.

this alternative explanation, we show that branded manufacturers do not react to a Paragraph IV challenge by adding modifications of an existing product to an approved drug application. Additionally, and in line with the findings of Branstetter et al. (2022), once a given therapeutic class has been affected by a Paragraph IV challenge, these manufacturers significantly curtail the number of NDAs in that class.

According to the rules, while a generic producer is under no obligation to provide Paragraph IV certifications for patents added after a Paragraph IV submission, the brand-name drug manufacturer can still use these patents to sue the generic company (Dogan and Lemley, 2008; Voet, 2020). Hence, the questions become whether these patents are used in litigation and, if so, whether they are effective in delaying generic entry. In a similar vein with Tu and Lemley (2021), we show that the added patents are disproportionately used in litigation. Moreover, we find that among patents added after a Paragraph IV challenge, continuation patents are predominantly used in the later stages of litigation. Importantly, we show that continuation patents added ex-post are disproportionately similar to the complaints that branded manufacturers file to initiate litigation against generic producers. This suggests that there are advantages in waiting, as brand-name manufacturers can tailor their response to competitor threats using incremental information they infer from the threats. Additionally, we find that adding a continuation patent to an approved drug application after a Paragraph IV challenge is associated with a four-percentage-point decline in the likelihood that a generic has entered the market in a given year. We obtain a similar effect when we examine the addition of a continuation patent after litigation in those instances when a Paragraph IV challenge ends in litigation. Overall, these are considerable effects: as we show that branded manufacturers' sales of a given drug drop by approximately 49% after a generic drug becomes available, even relatively small delays in competitor entry can profoundly affect firm revenues.

Our heterogeneity analysis further elucidates the mechanism we study, showing that incumbent firms use the detected patent strategy more intensively when the opportunity costs

of delaying competitor entry are relatively low. For instance, we find that the reaction of brand-name drug manufacturers is stronger when a protected drug is valuable. We also find that branded manufacturers react more strongly to generic entry threats when the patents listed at the FDA approval of a drug are narrower in scope.

By examining a setting in which we can precisely observe the patent strategies of incumbents and the reaction of potential entrants, our paper extends the literature on the use of patents for strategic goals (Teece, 1986; Cohen et al., 2000; Ziedonis, 2004; Ceccagnoli, 2009; Hegde et al., 2009; Cockburn and MacGarvie, 2011; Torrisi et al., 2016; Righi, 2022; Palermo et al., 2019). The strategy we uncover is akin to the mechanism of "submarine" patents (Graham and Mowery, 2004), whereby patent holders would file continuation applications to intentionally delay the issuance and publication of patents, "re-surfacing" those patents at specific points in time (Lemley and Shapiro, 2005a). According to the literature, this mechanism was used less after the 1999 changes in the US patent law mandated the publication of a large share of patent applications after 18 months. But, our study demonstrates that incumbents continue to act opportunistically, relying on the fact that it is not obvious for competitors to associate a product with its protecting patents. This is because incumbents' patent portfolios are large, continuation patents are applied for at different points in time, single patents can protect multiple products, and a single product can be protected by multiple patents. Our investigation extends the findings of Righi and Simcoe (2020), who show that in the software sector, firms wait until a given technology has proven viable to modify the claims of parent patents and then claim priority over that technology. We examine a different game, in which incumbents already have a product and utilize continuation patents to generate uncertainty over the intellectual property protecting it. That way, incumbents induce potential entrants to carry out their threats in the fog and capitalize on the information inferred from these threats to exploit the most convenient patents in litigation. In unveiling the characteristics of this game, we also add to an emerging literature on virtual patent markings —the online provision of notice to the public that a product is

patented (De Rassenfosse, 2018). While US legislation requires marking for a patentee to recover damages in any action of infringement, only a few patent holders provide it. Our analysis highlights the costs of disclosing this information.

Finally, our study contributes to the literature on the consequences of Paragraph IV challenges. Grabowski and Kyle (2007) highlighted a steady rise in the number of Paragraph IV challenges between 1995 and 2005. Grabowski and Vernon (1996) and Berndt and Aitken (2011) found that, upon the entry of generic manufacturers, the market share of branded manufacturers declines dramatically. Moreover, Higgins and Graham (2009) and Branstetter et al. (2022) found a negative relationship between generic entry and innovation within therapeutic markets, while Panattoni (2011) and Filson and Oweis (2010) found that generic entry reduced firm value. In contrast with these studies, we show that waiting to list their patents in the Orange Book once the threat of generic entry has materialized gives incumbents a second-mover advantage and ultimately delays generic entry.

2.2 Regulatory framework in the pharmaceutical sector

The development of a drug is a lengthy and costly process (DiMasi et al., 1991). It begins with the identification of a drug target, that is, a molecule in the body that is associated with a particular disease process, and the screening of several compounds that could bind with the target and produce a desired therapeutic effect. In the meantime, a firm applies for patents starting from the discovery of the drug target and continuing during the subsequent drug development phases, in which the firm winnows down the number of candidate compounds in pre-clinical, non-human trials and tests the selected lead compounds in human trials. Pre-clinical and clinical trials last ten years on average and can cost between $500 million and $2 billion per drug (Adams and Brantner, 2006). After the conclusion of these trials, a drug manufacturer submits an NDA to the FDA for approval.

While the US Patent & Trademark Office (USPTO) grants patent protection for 20 years from the initial filing, the effective patent term is considerably smaller because of the lag

between the date a patent is obtained and the date the protected drug is launched. This lag is rather long. In fact, by the time a product is launched, the remaining patent term is reduced to approximately half.[4] To avoid discouraging pharmaceutical firms from investing in innovation, the 1984 Drug Price and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Act," introduced the possibility of extending the life of the patents protecting a given drug.

A brand-name drug manufacturer must now submit an NDA to the FDA, listing all the patents protecting a given drug in the FDA's Orange Book. If some patents protecting that drug are granted after the NDA is approved, the manufacturer has 30 days from the grant date of the new patents to list them in the Orange Book (Holovac, 2004). Beyond this thirty-day interval, patents can still be added to the Orange Book, but do not guarantee protection against the entry of generic manufacturers. This rule represents a strong incentive for branded manufacturers to list patents in the Orange Book within the thirty-day limit.

After a drug application is approved, the FDA can restore up to five years of the patent term to compensate the brand-name drug manufacturer for the time used by the FDA in the drug approval process (Grabowski and Kyle, 2007).[5] Additionally, the FDA can grant a branded firm a "data exclusivity" period, which runs independently of and in parallel with the patent term. During this data exclusivity period, generic manufacturers are not allowed to enter the market. New chemical entities (NCEs) are guaranteed a five-year data exclusivity period, while drug reformulations, which are not as novel as NCEs, obtain three years of data exclusivity.[6] Once the data exclusivity period ends, branded drugs are only protected by their patents until the patents' expiration date. The sum of the data exclusivity period and the remaining patent protection term after the data exclusivity ends is called market exclusivity (Gaessler and Wagner, 2022).

[4] $https://www.ajmc.com/view/a636-article.$

[5] This is provided that the remaining life of a patent does not exceed 14 years.

[6] NCEs are drugs that contain no active moiety that has been approved by the FDA in any other application. The reason why they receive extra protection is that they are particularly valuable for the branded manufacturer because they can be redeployed to produce follow-on drugs (Hemphill and Sampat, 2011). "Orphan drugs," that is, drugs targeting small patient populations, receive seven years of data exclusivity.

The goal of the Hatch-Waxman Act is broader than just protecting pharmaceutical firms' R&D efforts; it is to strike a balance between stimulating R&D research by providing *ad hoc* incentives for branded firms and improving consumer welfare by facilitating market entry of generic manufacturers (Grabowski, 2007). Before the passage of the Hatch-Waxman Act, generic manufacturers seeking to sell their products in the US had to prove the safety and efficacy of their products through *ad hoc* clinical trials. Although the outcome of these trials was not as uncertain as that of brand-name drug manufacturers, the trials entailed considerable costs for the generic companies. To reduce these costs, the Hatch-Waxman Act eliminated separate clinical trial requirements for generic manufacturers (Higgins and Graham, 2009).

Since the passing of the Act, generic manufacturers must file an Abbreviated New Drug Application (ANDA) with the FDA. To obtain FDA approval, an ANDA must demonstrate therapeutic equivalence with branded products without additional clinical trials[7] and certify that a generic drug does not infringe upon a branded firm's patents that are listed in the Orange Book. Specifically, for each patent listed, an ANDA must claim one of the following four certifications: (i) a Paragraph I certification, declaring that the patent of interest has not been previously submitted to the FDA; (ii) a Paragraph II certification, stating that the patent has expired; (iii) a Paragraph III certification, declaring that the patent has not expired and that generic manufacturers will enter the market after it does; or (iv) a Paragraph IV certification, claiming that the listed patent either is invalid or will not be infringed by the generic drug.

Under Paragraph I and II certifications, the FDA can approve an ANDA immediately. With a Paragraph III certification, generic manufacturers may be granted "tentative approval." A Paragraph IV certification can be filed with the FDA only after the data exclusivity period ends. If successful, it can substantially reduce the branded firm's market

[7]To demonstrate therapeutic equivalence, a generic producer must prove that its product shares the same active ingredient, applies the same dosage form and strength, and uses the same route of administration as the brand-name drug.

exclusivity period (Higgins and Graham, 2009).

Once a generic drug manufacturer submits an ANDA to the FDA with a Paragraph IV certification asserting that the patent(s) contained in a given NDA is (are) invalid or uninfringed, it has 30 days to notify the brand-name drug producer of its ANDA filing. The latter then has 45 days to sue the generic drug manufacturer in the Federal District Court, initiating a thirty-month stay during which the FDA will not approve the generic's ANDA unless the generic drug manufacturer prevails in the litigation.[8] If a patent is held invalid by the Federal District Court, the brand-name drug manufacturer can appeal this court's decision to the Court of Appeals for the Federal Circuit (CAFC) in Washington, DC. If the latter reverses the judgment of the Federal District Court, the generic drug manufacturer must pay damages for patent infringement in case it has already entered the market (Voet, 2020). Thus, if a generic manufacturer launches its product before the CAFC's decision, it will have launched *at risk*, risking the loss of the Paragraph IV case (Drake et al., 2021). To avoid this risk, generic manufacturers typically launch their products after a decision by CAFC is made. This is an important point to note. In fact, branded manufacturers can delay generic entry by artificially extending litigation time. If a generic manufacturer's ANDA is approved by the FDA, that manufacturer receives a 180-day marketing exclusivity period, during which the FDA will not approve another generic version of the same drug (Voet, 2020).[9] De facto, this rule confers a duopoly power on the first generic filer for 180 days (Glass, 2021).

For our purposes, it is important to bear in mind that the FDA places no obligation on generic drug manufacturers to produce a Paragraph IV certification against patents that brand-name drug manufacturers add to an approved drug application after the filing of an ANDA. However, branded manufacturers can sue generic producers for infringing such

[8]Until 2003, branded manufacturers could initiate several thirty-month stay periods by adding patents to the Orange Book after a Paragraph IV challenge, but in 2003 the Hatch-Waxman Act was modified, and it now allows only one thirty-month stay (Federal Trade Commission, 2002).

[9]Branded manufacturers can market generic drugs, thereby increasing the level of competition and contributing to lower retail drug prices (Federal Trade Commission, 2009, 2011).

added patents. Importantly, branded manufacturers can substantially delay generic entry by requesting that a court examine whether a patent protecting a given drug, including a patent added to the Orange Book after FDA approval, is infringed by a generic manufacturer. This is a lengthy judicial procedure. Take, for example, the branded drug Aloxi, for which Helsinn Healthcare SA received FDA approval in 2003, and which was originally protected by US patent 5,202,333. On May 24, 2011, Helsinn Healthcare SA then listed patents 7,947,724, and 7,947,725 in the Orange Book. On May 27, 2011, all three patents were challenged by Dr. Reddys, Teva, and Sandoz. After the challenge, Helsinn Healthcare SA was granted US patent 7,960,424, which the firm listed in the Orange Book in June 2011 and which is a continuation of an initial patent application filed in 2005. During the first litigation case, which took place in August 2011, only US patents 5,202,333, 7,947,724, and 7,947,725 were asserted; the more recently granted continuation patent 7,960,424 was added in the second litigation case in September 2011. In 2015, the Federal District Court stated that all four patents-in-suit were valid. The generic manufacturers appealed, and, in 2017, the Court of Appeals for the Federal Circuit reversed the Federal District Court's decision, stating that all the asserted patents were invalid under the on-sale bar.[10] As this example demonstrates, adding a (continuation) patent in the Orange Book after the FDA approval of a drug can contribute to delaying generic entry for a considerable period of time through litigation.[11]

2.3 Data

We assembled our data from a variety of different sources. The first is the Orange Book, which is the FDA record of all approved small-molecule drugs in the United States. This source has been widely used by researchers investigating the pharmaceutical sector (for instance, Grabowski and Kyle (2007); Higgins and Graham (2009); Branstetter et al. (2016)).

[10] Figure A1 shows the timeline for this process.

[11] Besides litigation, another channel through which adding patents to the Orange Book can delay generic entry is by delaying Paragraph III entry.

The Orange Book lists NDAs, their approval dates and applicant names, the underlying products, and all the relevant patents protecting a given drug. We complement these data by manually matching the drugs in our sample with Anatomical Therapeutic Chemical (ATC) codes given in the Kyoto Encyclopedia of Genes and Genomes (KEGG), which lists all drugs approved in the US, Europe, and Japan.[12] The ATC classification, which is compiled by the World Health Organization, allows us to define a market for each drug. The dataset thus constructed encompasses 1,454 NDAs—of which 35.6% are for NCEs—belonging to 128 therapeutic classes and filed by 286 pharmaceutical companies between 1991 and 2016.

We enrich our data by adding the dates on which the patents were listed in a given NDA. The information was originally assembled by Williams (2018) from the historical archives of all Orange Book editions until 2016.[13] We further add the listed patents' application and grant dates, as well as their continuation status as given in the USPTO Patent Examination Research Dataset and PatentsView. Following Hegde et al. (2009), we consider the following three types of continuation applications: the "continuation application," the "continuation in part," and the "division."

Our information on Paragraph IV challenges brought against the approved drugs of branded manufacturers comes from the FDA's Office of Generic Drugs. Data on Paragraph IV challenges are available only starting from 2003, which explains why we start our sample in 1991. On average, Paragraph IV challenges take place 5.4 years after an FDA drug approval, so drugs approved before 1991 are rarely affected by the observed challenges. We complement these data with unique information on which Paragraph IV challenges led to litigation, from the Paragraph IV Report dataset (Glass, 2021), available at *paragraphfour.com*. This dataset also reports information on the branded manufacturers' complaints that initiated a litigation case against a generic manufacturer and the patents

[12]The data are available at https://www.genome.jp/kegg/.

[13]The data are available at https://www.nber.org/research/data/orange-book-patent-and-exclusivity-data-1985-2016. Williams constructed a digital version of the yearly Orange Book versions for the years 1985–2016.

that were asserted in litigation. Finally, we complete the dataset by matching our NDAs with the corresponding ANDAs, in cases of generic entry. These data are available from Drugs@FDA.

As Figure 2.1 shows, the number of NDAs approved by the FDA increased between 1990 and 1996 and remained stable afterward. Of the 286 pharmaceutical companies filing NDAs with the FDA, 147 filed only one. These companies' NDAs account for 10% of the total NDAs in our sample. Companies in the top 95th percentile in terms of NDAs filed have 25 NDAs or more. These NDAs account for 42% of the sample. Figure 2.2 additionally shows the increasing trend in the overall and at FDA approval average number of patents per NDA.

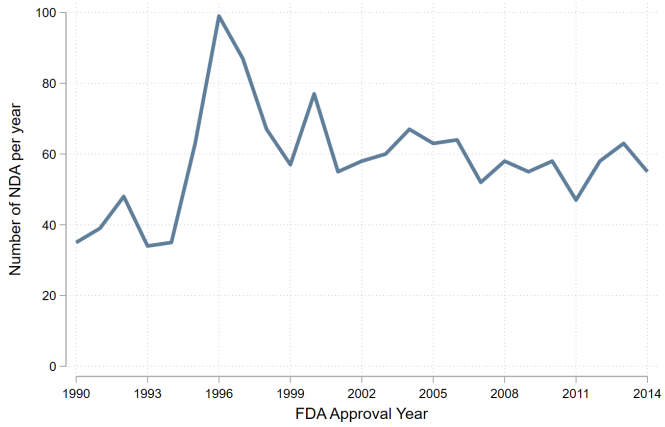


Figure 2.1: Number of NDAs by FDA approval year

Table 2.1 provides descriptive statistics for our sample NDAs. The majority of NDAs are concentrated in the Nervous System class (16%), followed by Alimentary Tract and Metabolism (14%), Anti-Infectives (12%), Cardiovascular System (11%), Dermatologicals (10%), and Cancer[14] (9%). The average number of patents listed in an NDA at FDA approval is 2.6. An NDA can cover multiple products, which differ in route of administration and/or drug strength. To introduce these products, branded manufacturers must file a supplemental NDA, that is, a supplement to an existing approved drug application. These

[14]This category corresponds to antineoplastic and immunomodulating agents in Table 1.

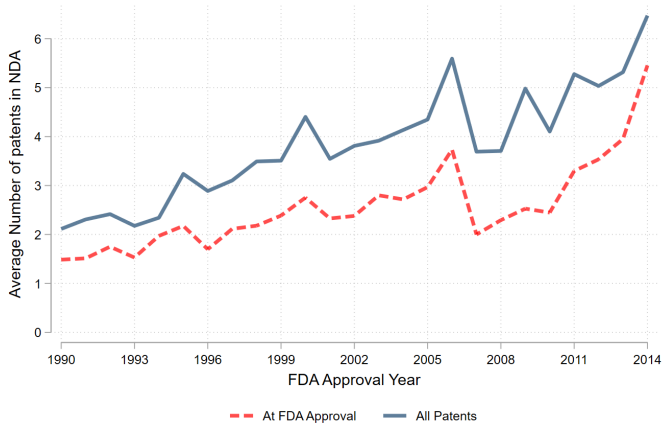


Figure 2.2: Number of patents per NDA at FDA drug approval by approval year

new products usually correspond to minor, new indications (Glass, 2021).[15] The FDA assigns a number to identify each product in an application.[16] Using these data, we show in Table 2.1 that the average number of products per NDA is 2.2.

During the period of our study, generic firms submitted a total of 894 Paragraph IV challenges. In line with studies by Krieger et al. (2021) and Jacobo-Rubio et al. (2020), Figure 2.3 shows that the number of Paragraph IV challenges per year increased over time up until 2008, and subsequently declined. Specifically, in our sample, we observe 580 challenged NDAs, of which litigation occurred for 470. Of the sample NDAs, 16% received two challenges, 4% received three challenges, and 3% received more than three. These challenges concern 153 brand-name drug manufacturers across 99 therapeutic classes. Among all the NDAs targeted by at least one Paragraph IV challenge, 27% belong to the Nervous System therapeutic class, 13% to the Alimentary Tract and Metabolism, 11% to the Cardiovascular System, 9% to Anti-Infectives, and 9% to Cancer. Not all Paragraph IV challenges lead to generic entry. Of the 580 observed challenged NDAs, generic entry occurs in 337 of the cases. On average, generic manufacturers enter the market 11 years after an NDA is

[15]For example, the HIV drug Biktarvy (NDA 210251) has two products with two different dosages, but these two products do not rise to the level of drug reformulation, which would imply a distinct NDA, with an additional three years of data exclusivity.

[16]https://www.fda.gov/drugs/drug-approvals-and-databases/orange-book-data-files.

Table 2.1: Summary statistics at the NDA level

	Panel A					
	Obs	Mean	Std. Dev.	Min	Max	Median
N. patents at FDA approval	1454	2.591	2.602	1	31	2
N. continuation patents at FDA approval	1454	1.069	1.843	0	20	0
N. patent claims at FDA approval	1454	54.818	77.264	1	693	11
N. of Intra-NDA Products	1454	2.205	1.722	1	14	2
Received paragraph-IV (0/1)	1454	0.399	0.490	0	1	0
Litigation in response to Paragraph-IV (0/1)	580	0.743	0.437	0	1	1
Time to first Paragraph IV (Years)	580	5.390	4.192	0	21	4
Time to generic entry (Years)	497	10.931	4.758	0	29	11
	Panel B					
Therapeutic class	ATC-1	NDA Count	%			
Alimentary tract and metabolism	A	207	14%			
Blood and blood forming organs	B	36	2%			
Cardiovascular system	C	164	11%			
Dermatologicals	D	141	10%			
Genito-urinary system and sex hormones	G	106	7%			
Other hormonal preparations	H	38	3%			
Anti-infectives for systemic use	J	178	12%			
Antineoplastic and immunomodulating agents	L	134	9%			
Musculo-skeletal system	M	38	3%			
Nervous system	N	230	16%			
Antiparasitic products	P	7	0%			
Respiratory system	R	84	6%			
Sensory organs	S	32	2%			
Various	V	59	4%			

granted FDA approval. As Figure 2.4 shows, the time elapsed between the approval of an NDA and the entry of the first generic manufacturer steadily decreased over time for both NCE drugs (solid line) and reformulations of existing drugs (dotted line).

Figure 2.3: Number of Paragraph IV challenges per year

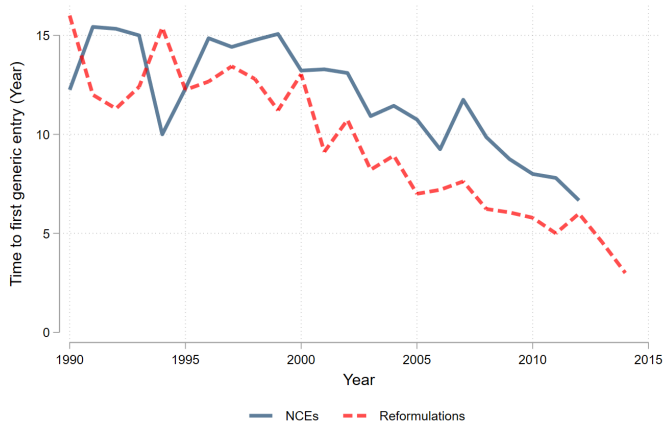


Figure 2.4: Average time to first generic entry, by year of NDA approval, distinguishing between NCE drugs and reformulations

2.4 The reaction to Paragraph IV generic entry threats

2.4.1 Empirical specification

Our goal is to evaluate the reaction of branded manufacturers to Paragraph IV generic entry threats affecting their drugs. Specifically, we want to assess whether branded manufacturers wait until the threat of competitor entry materializes to disclose full information about the intellectual property protecting their products. For this purpose, we estimate a staggered difference-in-differences model at the drug level, exploiting the differential timing of Paragraph IV challenges across challenged drugs. Since the reaction of a branded manufacturer to a subsequent Paragraph IV challenge is likely to be serially correlated with the reaction to a first challenge, we limit our analysis to initial Paragraph IV challenges.

This model rests on two main identification assumptions. First, the *timing* of the first Paragraph IV challenge is exogenous to challenged brand-name drug manufacturers. Grabowski and Kyle (2007) mention that generic entry affects both high-selling and low-selling branded drugs, so that it is hard to predict generic threats from drug sales. As Glass (2021) reports, a substantial portion of NDAs could have received Paragraph IV certifications but never did, because ANDA filers face manufacturing uncertainties involving,

among other things, production costs and methods to replicate branded drugs (Voet, 2020; Morton, 1999). These uncertainties also account for the fact that not all ANDAs are filed at the end of the data exclusivity period (when there is one). And it is worth noting that the 180-day marketing exclusivity period conferred on the first approved ANDA filer might induce generic producers to act sooner than an incumbent might predict.

Our interview with Gregory Glass, a practitioner with over 25 years of experience in the pharmaceutical industry and creator of the Paragraph IV Report,[17] confirmed the unpredictability of the timing of Paragraph IV challenges. As his *paragraphfour.com* website notes,

> "[W]hen a brand receives a Paragraph IV certification can be unpredictable as well. Since 2000, some brands have received a Paragraph IV certification within months of approval but at other times it may be years before it receives its first Paragraph IV certification".

Empirical evidence from our sample is consistent with this quote. Figure 2.5 reports the histogram for the timing of the first Paragraph IV challenge relative to a drug's FDA approval. Apart from a relative prevalence of Paragraph IV challenges in the fourth year of a drug's FDA approval, the year marking the end of the data exclusivity period for new chemical entities, there is substantial variation in the timing of remaining Paragraph IV challenges. More than 75% of the ANDAs are filed before or after the fourth year following approval.[18]

The second identification assumption we make is that, in the absence of a Paragraph IV challenge, challenged and unchallenged drugs would have been protected with a similar patent strategy by their manufacturers. To ensure that the challenged drugs are comparable

[17]The Paragraph IV Report is a database of Paragraph IV challenges, and it is available at paragraphfour.com.

[18]In the case of new chemical compounds, generic entry cannot occur during the data exclusivity period, which lasts five years from FDA approval. Thus, generic manufacturers can only file their ANDA starting from the fourth year. As a robustness check, we excluded Paragraph IV challenges that occurred during the fourth and fifth years since a new chemical entity was approved by the FDA. The results reported in Table A2 are qualitatively the same.

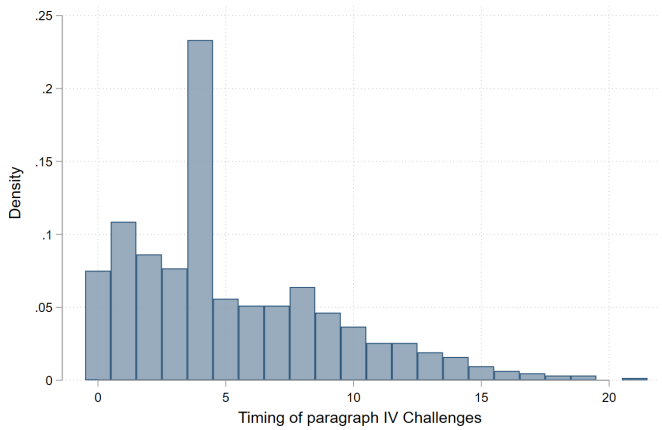


Figure 2.5: Histogram of the timing of first Paragraph IV challenges

to unchallenged drugs, we draw the latter from the population of unchallenged drugs that belong to the same ATC 3 therapeutic class as the challenged drugs. The equation we estimate is:

$$Y_{ijkt} = \beta PostParaIV_{ijkt} + \gamma_i + \delta_j + \tau_{it} + \omega_{kt} + \varepsilon_{ijkt}, \tag{2.1}$$

where Y_{ijkt} is, alternatively, (i) the number of company j's patents applied for in year t and whose content is highly similar to that of patents originally listed in drug i's approved application i, (ii) the number of patents listed in drug i's approved application by company j in year t and belonging to the ATC 3 therapeutic class k, (iii) and the share of continuation patents listed in the Orange Book in year t. Finally, we evaluate whether a Paragraph IV certification has any impact on modified products added to an approved NDA via a supplemental NDA (outcome (iv)). For this purpose, we modify the outcome in Eq. (1) and examine the likelihood that a modified product will be added to an approved drug application via a supplemental NDA, a process we call "intra-product NDA expansion."

By examining outcome (i), we want to assess whether branded manufacturers react to a threat of generic entry by applying for more patents. With outcome (ii), we evaluate whether branded firms respond to a Paragraph IV challenge by disclosing information

about their product-patent strategy. By exploring outcome (iii), we gauge whether branded manufacturers make disproportionate use of continuation patents to address generic entry threats. In analyzing the reaction of outcome (iv) to a Paragraph IV challenge, we finally assess whether branded manufacturers react to a Paragraph IV challenge by intensifying their innovation effort to differentiate from generic competitors.

$PostParaIV_{ijkt}$ is an indicator that takes the value one after drug i of company j in therapeutic class k receives a Paragraph IV challenge and zero otherwise. The coefficient of interest is β, which measures the change in Y_{ijkt} -in the years following a Paragraph IV challenge- that the drug affected by that challenge experiences, relative to the change experienced by other comparable unchallenged drugs. To address the possible concern that Paragraph IV certifications do not randomly target branded drugs, we saturate our model with a battery of relevant fixed effects. In particular, γ_i denotes the fixed effect for drug i, δ_j is branded manufacturer j's fixed effect, τ_{it} denotes the fixed effect for drug application i's age, and ω_{kt} is a fixed effect for ATC 3 therapeutic class by year.[19] As we show in Table A3, our results do not change when we substitute the 128 ATC 3 therapeutic classes with the more granular 291 ATC 4 classes. Finally, ε_{ijkt} is an idiosyncratic error term.

The inclusion of γ_i fully controls for fixed differences between drugs. Moreover, δ_j absorbs time-invariant heterogeneity across brand-name drug manufacturers. The fixed effect τ_{it} absorbs any differences in patent strategy due to a drug's age. Finally, ω_{kt} accounts for variations over time in market conditions that are common to drugs belonging to the same therapeutic class.

In the second part of the empirical analysis, we assess the effect of a Paragraph IV challenge concerning company j on the number of NDAs the company files in therapeutic class k. This analysis complements the one above as it is aimed at evaluating whether branded manufacturers react to the threat of generic entry by differentiating from the competition

[19] Like Myers and Pauly (2019), we face a tradeoff between the ability to control for market trends over time versus the heterogeneous effects of Paragraph IV challenges depending on the characteristics of a firm's portfolio of drugs in a given therapeutic area.

by introducing substantially new products. We estimate a difference-in-differences model, where the control group to a branded manufacturer's therapeutic class challenged in year t is the set of unchallenged therapeutic classes in the same year:

$$Y_{jkt} = \beta PostParaIV_{jkt} + \delta_j + \omega_{kt} + \varepsilon_{jkt}. \tag{2.2}$$

Y_{jkt} is the number of NDAs filed by company j in therapeutic class k at time t, which proxies a firm's inter-market expansion. $PostParaIV_{jkt}$ is an indicator variable that takes value the one after company j receives a first Paragraph IV challenge in therapeutic class k, and zero otherwise. As before, δ_j represents brand-name drug manufacturer j's fixed effect, while ω_{kt} is a fixed effect for ATC 3 therapeutic class by year, and ε_{jkt} is an idiosyncratic error term.

2.4.2 Descriptive statistics

Table 2.2 reports the descriptive statistics for our variables of interest. In Panel A of Table 2, the unit of observation is the NDA, in Panel B, the NDA-year, and in Panel C, the firm-therapeutic-class-year. These descriptive statistics offer a first glance at the phenomenon we study in this paper. As appears in Panel A, challenged and unchallenged NDAs do not differ significantly in the number of patents at the time of FDA approval. However, after FDA approval, challenged NDAs encompass more patents than non-challenged NDAs, as reported in Panel B. While there is no significant difference in the number of continuation patents at the FDA approval of a drug between challenged and unchallenged drugs (Panel A), in the years following a drug's FDA approval branded manufacturers list more continuation patents in their NDAs that are challenged by generic manufacturers (Panel B). Panel B additionally shows that the likelihood of adding a modified product to an existing NDA is higher for challenged than for unchallenged NDAs. Finally, Panel C shows that the number of NDAs in challenged therapeutic classes is larger than in unchallenged therapeutic

classes. These last descriptives confirm the importance of controlling for therapeutic-class-by-year fixed effects in our empirical models, as certain therapeutic classes are likely to experience more drug applications and more Paragraph IV challenges.

Table 2.2: Summary statistics continued

	(1) Para-IV Challenge=1		(2) Para-IV Challenge=0		(3)
	Panel A: NDA level				
	Mean	S. E.	Mean	S. E.	Diff.
N. patents at FDA approval	2.510	0.088	2.645	0.097	-0.135
N. continuation patents at FDA approval	1.057	0.063	1.077	0.069	-0.020
N. patent claims at FDA approval	53.593	2.599	55.630	2.897	-2.037
N. intra-NDA Products	2.407	0.073	2.071	0.057	0.336***
Observations	580		874		
	Panel B: NDA-year level				
	Mean	S. E.	Mean	S. E.	Diff.
N. patents	3.080	0.034	2.733	0.028	0.347***
N. continuation patents	1.488	0.027	1.173	0.020	0.315***
Listed a new product in NDA (0/1)	0.029	0.002	0.019	0.001	0.010***
Observations	5955		8686		
	Panel C: Firm-therapeutic-class-year level				
	Mean	S. E.	Mean	S. E.	Diff.
N. NDAs	0.166	0.009	0.049	0.005	0.117***
Observations	2357		2673		

Notes: In Panel A, the unit of observation is the NDA, in Panel B the unit of observation is the NDA-year, while in Panel C the unit of observation is the firm-therapeutic-class-year. Significance noted as: *p<0.10; **p<0.05; ***p<0.01.

2.4.3 Results

A Paragraph IV challenge may induce branded manufacturers to increase their patent production to protect their drugs. To check this possibility, we implemented a machine learning algorithm to assess whether the text of a branded manufacturer's patents (title, abstract, and claims) subsequently listed in the Orange Book resembles the text of patents initially listed in a given drug application. The details of this algorithm are reported in the Appendix. Building on the output of this algorithm, we examined the yearly number of (granted) patent applications whose similarity score relative to patents originally listed in drug appli-

cation i is in the 99th percentile of the distribution of similarity scores. The results from estimating Eq. (1) for this outcome are reported in column 1 of Table 3. Standard errors are clustered at the approved drug application level. Again, we control for drug application, firm, drug application age, and ATC3 therapeutic class by year fixed effects. We do not observe a significant increase in the number of patents a branded manufacturer applies for after a Paragraph IV challenge. That is, branded firms facing Paragraph IV challenges do not seem to increase their patent output in order to delay competitor entry.

We next assess the effect of a Paragraph IV challenge on the patents that branded manufacturers list in their approved drug applications. As we discussed earlier, branded manufacturers could pursue a strategy whereby they list all their intellectual property upfront to deter generic entry, or they could at least partially fragment such intellectual property, delaying its full disclosure until generic manufacturers have pursued their threats. While the upside of the first strategy is the monopoly rent branded manufacturers would continue to earn if successful, the downside is that their patents could be invalidated too early and no longer be used in litigation. This is a non-negligible opportunity cost. In fact, 21.1% of the patents listed in the Orange Book after the FDA approval of a drug and before a Paragraph IV challenge are used in multiple NDAs, and 9.3% in multiple litigation cases when these patents are not invalidated. For comparison, the corresponding figures for patents listed at the FDA approval of a drug are 25.5% and 11.9%, respectively. This evidence confirms that, indeed, there are opportunity costs from fully disclosing information on an incumbent's intellectual property too early as -if invalidated- patents cannot be used ex-post in litigation to protect a given drug or any follow-on innovation. Waiting until the threat of generic entry has materialized to disclose full information about a branded manufacturer's patent strategy has the advantage that the manufacturer can gather valuable information from the move of the generic competitor. However, the downside of this strategy is that post-Paragraph IV challenge, the burden of proof that a potentially infringed patent protects a challenged product falls on the branded manufacturer.

To assess the reactions of branded manufacturers, we estimate Eq. (1) for the number of patents that are listed in an approved drug application in year t. The results reported in column 2 of Table 2.3 show that following a Paragraph IV challenge, the number of patents listed in the Orange Book increases by 0.34, a 12% increase over the average number of patents listed in the Orange Book.[20] Table A2 shows that our findings hold when we exclude from the sample those Paragraph IV challenges that affected drugs in their fourth and fifth years after FDA approval, years in which our exogeneity assumption may not hold. Moreover, as we show in Table A3, the results still hold when we replace ATC 3 therapeutic class by year fixed effects with the finer grained ATC 4 therapeutic class by year fixed effects. Finally, Table A4 shows that the results do not change when we restrict the post-Paragraph IV period to the years just after a challenge.

As we mentioned earlier, branded manufacturers could split and fragment their intellectual property ex-ante before generic manufacturers have threatened to enter by using continuation patents. That way, they increase the uncertainty for generic competitors and at the same time, wait until these competitors have made their move to learn from it and resurface their intellectual property. Discussions with patent lawyers revealed that although the 1999 changes in US patent law mandated the publication of a large share of patent applications after 18 months, establishing the full link between a product and its protecting patents is still complicated for generic manufacturers. This is because incumbents' patent portfolios are large, continuation patents are applied for at different points in time, single patents can protect multiple products, and a single product can be protected by multiple patents. To verify whether branded manufacturers engage in opportunistic behavior by using continuations in patenting, we modify Eq. (1), evaluating the share of continuation patents listed in the Orange Book in year t. The results are reported in column 3 of Table 3. We find that a Paragraph IV challenge triggers an increase by 3.7 percentage points in the

[20] As we report in Table A1 of the Appendix, the results remain unchanged when we take the natural logarithm of the dependent variables. Moreover, we report in Figure A2 a placebo test showing that after we randomize the treatment across observation units, the likelihood that we obtain the estimates reported in Table 2.3 is less than 1%.

share of continuation patents listed in the Orange Book, equivalent to an 11% increase relative to the mean. By inspection, these are patents whose continuation application pre-dates a Paragraph IV challenge.

In Figure 2.6, we report the results of an event study where we inspect the presence of pre-trends. We want to exclude the possibility that branded manufacturers anticipate the entry of generic drug manufacturers and increase their patent listings before a Paragraph IV challenge. This analysis also allows us to verify whether uncontrolled factors, such as possible improvements in a drug over time, could drive the observed patent strategies that branded manufacturers implement around the time of a Paragraph IV challenge. Therefore, we modify Eq. (1) by replacing the $PostParaIV_{jkt}$ indicator with binary variables for each of the pre- and post-treatment years. This specification allows us to compare the patent protection that challenged drugs receive with that of unchallenged drugs in the same ATC 3 class, in each year before and after a Paragraph IV challenge. In Panel A, the outcome is the number of patents listed in the Orange Book in year t, while in Panel B, the outcome is the share of continuation patents. We detect three important patterns. First, there are no significant pre-existing trends regardless of the outcome examined. This result suggests that branded manufacturers do not act in anticipation of generic entry threats and that omitted variables do not drive our estimates. Second, the number of patents listed in an approved drug application significantly increases over the first three years after the submission of a Paragraph IV challenge, reaching a maximum in year 3. This graphical representation suggests that brand-name manufacturers react immediately after a Paragraph IV challenge, and their reaction levels off after approximately four years. Finally, we detect similar patterns when we examine the share of continuation patents as an outcome.

To dig deeper into the identified patent strategy, we proceed to characterize the source of the patents added to the Orange Book after a drug's FDA approval. We classify these patents as: i) patents granted by the USPTO no earlier than one year of their being listed in the Orange Book, ii) patents acquired from external sources, iii) patents previously listed in

Table 2.3: Approved drug application patents after a Paragraph IV challenge

	Number of Similar Patents	Number of Patents listed in the OB	Share of Continuation Patents listed in the OB
	(1)	(2)	(3)
Post Paragraph IV	0.077	0.341***	0.037***
Challenge	(0.100)	(0.109)	(0.013)
Firm FE	Yes	Yes	Yes
Drug FE	Yes	Yes	Yes
ATC-3 $\times$ Year FE	Yes	Yes	Yes
Drug Age FE	Yes	Yes	Yes
N	14,641	14,641	14,641

Notes: This table reports the results from estimating Eq. (1) for: the number of patents that were applied for in year t and are similar to those originally listed in the Orange Book (column 1), the number of patents listed in the Orange Book (OB) in year t (column 2), and the share of continuation patents (column 3). All the specifications control for drug, firm, drug application age, and ATC-3 therapeutic class by year fixed effects. Standard errors are clustered at the drug level. Significance noted as: *p¡0.10; **p¡0.05; ***p¡0.01.

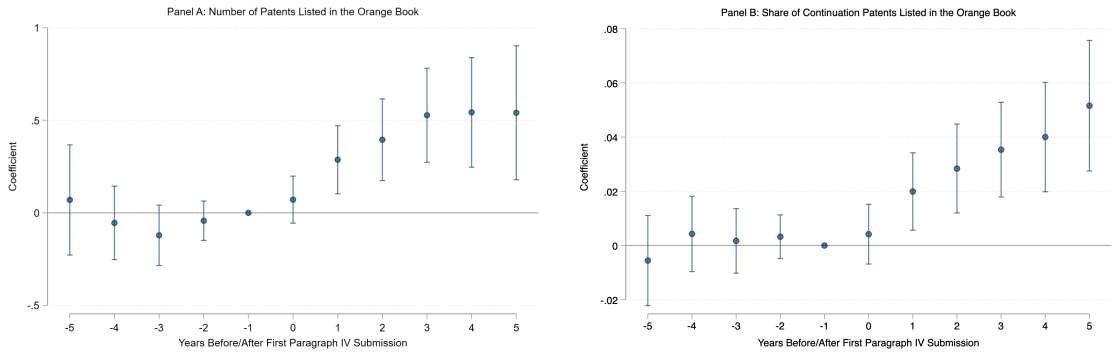


Figure 2.6: Event Study of Pharmaceutical Firm Patent Reaction to Paragraph IV Challenges

This figure shows how the number of patents added to the Orange Book in a given year changes after a Paragraph IV challenge. To generate this graph, we modified Eq. (1) in the main text by substituting the $PostParaIV_{jkt}$ indicator with binary variables for each of the pre- and post-treatment years. In Panel A, we report the coefficients for these variables when the dependent variable is the number of patents listed in the Orange Book. In Panel B, we use the share of continuation patents listed in the Orange Book as the dependent variable. The vertical lines represent 95% confidence intervals. The coefficient for the year immediately before a Paragraph IV challenge is set to 0 and displayed without a confidence interval because it is our baseline year.

another FDA-approved drug application. The results from estimating Eq. (1) for these three outcomes are reported in Table 2.4. They show that, following a Paragraph IV challenge, branded firms react by disproportionately adding recently granted patents to the Orange Book (column 1). This is to be expected, as patents granted after an NDA's approval must be listed in the Orange Book within 30 days of granting. Moreover, branded manufacturers neither acquire external patents (column 2 of Table 2.4 nor transfer patents from existing NDAs (column 3 of Table 2.4) to the challenged one in reaction to a Paragraph IV challenge.

To test whether heterogeneous treatment effects, including dynamic effects, generate bias in our results, we next implement the decomposition by Goodman-Bacon (2021), which we report in Table A5. This analysis indicates that 87% of our estimates of the effect of a Paragraph IV challenge on the number of patents a branded manufacturer lists in the Orange Book are driven by "good" comparisons, that is, early-treated drug applications

Table 2.4: Approved drug application patents after a Paragraph IV challenge - by patent sources

	Number of Recently Granted Patents	Number of Acquired Patents	Number of Patents from existing NDAs
	(1)	(2)	(3)
Post Paragraph IV	0.091***	0.013	0.001
Challenge	(0.021)	(0.008)	(0.005)
Firm FE	Yes	Yes	Yes
Drug FE	Yes	Yes	Yes
ATC-3 $\times$ Year FE	Yes	Yes	Yes
Drug Age FE	Yes	Yes	Yes
N	14,641	14,641	14,641

Notes: This table reports the results from estimating Eq. (1) for: the number of US patents granted by the USPTO no earlier than one year of their being listed in the Orange Book, ii) patents acquired from external sources (column 1); the number of patents acquired from external sources and listed in the Orange Book in year t (column 2); and the number of patents that were listed in an NDA in year t and were previously listed in another approved drug applications (column 3). All the equation specifications control for drug, firm, drug application age, and ATC 3 therapeutic class by year fixed effects. Standard errors are clustered at drug level. Significance noted as: *p<0.10; **p<0.05; ***p<0.01.

versus later or never treated drug applications. We obtain similar results when the outcome is the share of continuation patents.

While the results so far can be interpreted as meaning that firms list more patents in the Orange Book to protect an attacked drug, an alternative explanation is also possible, namely that the added patents could be part of a product differentiation strategy whereby branded manufacturers introduce new, differentiated products within their existing markets. In particular, the added patents could protect new modifications of products listed in an existing drug application (that is, intra-product expansion) or lay a foundation for drug innovations that will subsequently be listed in new drug applications within the same therapeutic area as the initially attacked drug (that is, intra-market expansion). To explore these alternative explanations, we estimate Eq. (1) for the likelihood that a modified product is added to an approved drug application. We cluster standard errors at the drug level. The related results are reported in column 1 of Table 2.5. We further estimate Eq. (2) at the firm-therapeutic-class-year level for the number of NDAs. This time, standard errors are two-way clustered at the firm and the ATC 3 class levels. We display these results in column 2 of Table 2.5.

Column 1 shows that following a Paragraph IV challenge, challenged brand-name drug manufacturers do not introduce modified products within an existing drug application. Moreover, and in line with Branstetter et al. (2022), column 2 of Table 2.5 reports that these manufacturers react by producing fewer NDAs in a given ATC 3 class after a Paragraph IV challenge. This last finding suggests that manufacturers move away from those therapeutic classes that are at risk of generic entry once they receive a Paragraph IV challenge. On the whole, these results support our conjecture that the added patents do not protect intra-market or intra-product differentiation.

2.5 Litigation strategy to delay generic entry

Thus far, we have shown that branded manufacturers react to Paragraph IV challenges by listing more (continuation) patents in their approved drug applications. We now dig deeper

Table 2.5: Intra-product and intra-market expansion after a Paragraph IV challenge

	Intra-Product (NDA) Expansion	Intra-Market Expansion
	(1)	(2)
Post Paragraph IV	-0.006	-0.082***
Challenge	(0.007)	(0.025)
Firm FE	Yes	Yes
ATC-3 $\times$ Year FE	Yes	Yes
Drug FE	Yes	
Drug Age FE	Yes	
N	14,641	6,383

Notes: This table reports the results from estimating a branded manufacturer's reaction to a Paragraph IV challenge, in terms of (i) modified products added to an existing drug application (column 1), which we label as intra-product (NDA) expansion, and (ii) new drug applications in the same ATC-3 therapeutic class as the initially challenged drug (column 2), which we label as intra-market expansion. The results in column 1 are obtained from estimating Eq. (1) for the likelihood that a modified product is added to an approved drug application. Here, the regressor of interest is an indicator that takes value 1 after a drug application i by company j in therapeutic class k receives a Paragraph IV challenge and zero otherwise. We cluster standard errors at the drug level. The results in column 2 are obtained from estimating Eq. (2) for the number of NDAs at the firm-therapeutic-class-year level. This time, the regressor of interest is an indicator that takes value one if company j's therapeutic class k is affected by a first Paragraph IV challenge in year t. Standard errors are two-way clustered at the firm and ATC 3 class levels. Significance noted as: *p<0.10; **p<0.05; ***p<0.01.

into the reasons why they enact this strategy. As we mentioned earlier, branded manufacturers may wait until generic producers have revealed their moves to list their patents in the Orange Book so that they can sharpen their swords for litigation forcing generic producers

to prove that these patents are not infringed. If their aim is to delay competitor entry, we should observe that patents listed in the Orange Book after a Paragraph IV challenge: (1) are disproportionately asserted in litigation cases, (2) are disproportionately similar to the content of a Paragraph IV challenge, and (3) help delay market entry by generic manufacturers, especially in cases that reach litigation.[21]

To verify prediction (1), we first estimate a linear regression model applied to the patents listed in challenged drug applications. Specifically, we regress whether a patent is asserted in litigation over whether the patent is listed in the Orange Book after a first Paragraph IV challenge, controlling for firm, ATC-2-therapeutic-class,[22] and year-of-the challenge fixed effects. The results are reported in column 1 of Table 2.6. Patents listed after a Paragraph IV challenge are indeed disproportionately more likely to be used in litigation. In column 2 of Table 2.6, we dig deeper into the type of patents listed after a Paragraph IV certification, distinguishing between whether they are continuation patents or not and whether they were included in the initial patent infringement complaint filed by the branded manufacturer or after. We show that, while patents included after the initial complaint are less likely to be litigated, continuation patents listed after it are more likely to be litigated than non-continuation patents. This result suggests that continuation patents play an important role in the later stages of Paragraph IV lawsuits.

To assess prediction (2), we implement the same machine learning algorithm as the one used to produce the dependent variable of column 1 of Table 2.3, this time comparing the text of a branded manufacturer's patents (that is, title, abstract, and claims) with the text of the initial complaint filed by the branded manufacturer in response to a Paragraph IV chal-

[21] Note that the number of patents listed in the Orange Book protecting a challenged drug and the number of patents asserted in litigation may differ for two reasons. First, in some instances, generic manufacturers may challenge only some of the patents listed in the Orange Book and instead use the Paragraph III mechanism for the others. Second, a branded manufacturer may not assert a challenged patent in litigation because the patent protects another drug or has little enforcement power (Glass, 2021). In our sample, the number of asserted patents is 803, while the total number of patents protecting challenged drugs and listed in the Orange Book after FDA approval is 1,337.

[22] We control for ATC 2 instead of ATC 3 therapeutic class because focusing on challenged drug applications drastically reduces the sample size.

lenge. We distinguish between patents listed in the Orange Book before and after a Paragraph IV challenge. Data on initial complaints are available from the Paragraph IV Report dataset at *paragraphfour.com*. As Panel A of Figure 2.7 shows, the average similarity between patents and complaints is larger for patents listed after a Paragraph IV challenge than for patents listed before. The difference is significant at the 5% level, having controlled for branded manufacturer and drug fixed effects. A similar, although more accentuated, pattern appears in Panel B, where we specifically report the average similarity between the complaints and the continuation patents listed before and after a Paragraph IV challenge. These descriptive findings suggest that branded manufacturers tailor their patent responses to the information that becomes available from the generic manufacturers' moves.

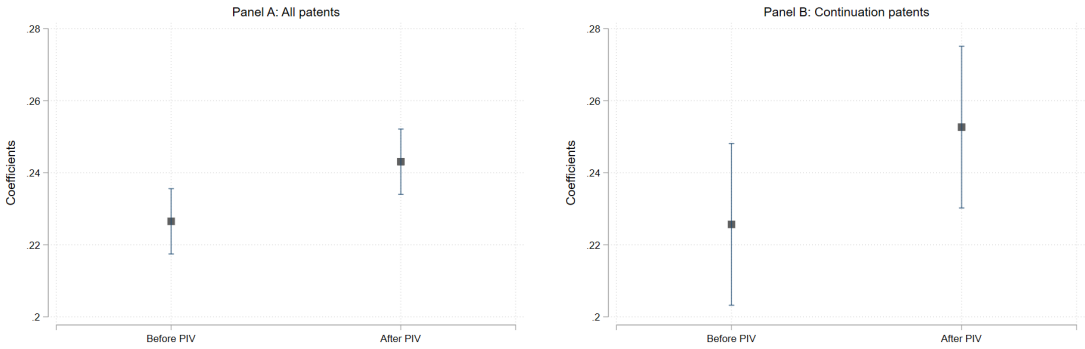


Figure 2.7: Similarity between a branded manufacturer's patents and the initial complaint it filed in response to a Paragraph IV challenge

To produce this figure, we implemented the same machine learning algorithm as the one used to produce the dependent variable of column 1 of Table 3, this time comparing the text similarity of a branded manufacturer's patents (that is, title, abstract, and claims) with the text of the initial complaint filed by the branded manufacturer in response to a Paragraph IV challenge. We distinguish between patents listed in the Orange Book before and after a Paragraph IV challenge, restricting the sample to drugs for which branded manufacturers listed patents before and after a Paragraph IV challenge. Data on initial complaints are available from the Paragraph IV Report dataset at *paragraphfour.com*. We report the coefficients from estimating a regression where the dependent variable is the similarity score for a given patent-complaint pair as a function of an indicator variable identifying whether a patent is listed after a Paragraph IV challenge. We control for branded manufacturer and drug fixed effects. In Panel A, we report the coefficients for the whole sample of patents. In Panel B, we restrict the sample to continuation patents. The squares represent the coefficient magnitudes, while the solid lines the 95% confidence intervals.

Table 2.6: Patents asserted in litigation

	Likelihood that a patent is litigated	
	(1)	(2)
Post Paragraph IV Challenge	0.083***	
	(0.003)	
Not in initial Paragraph IV Complaint		-0.661***
		(0.031)
Continuation Patent		-0.018
		(0.021)
Not in Initial Paragraph IV Complaint × Continuation Patent		0.078**
		(0.040)
ATC-2 FE	Yes	Yes
Paragraph IV Year FE	Yes	Yes
N	1,878	1,356

Notes: In column 1, we estimate a linear regression model applied to the patents listed in challenged drug applications. We regress whether a patent is asserted in litigation over whether the patent is listed in the Orange Book after a first Paragraph IV challenge, controlling for ATC 2 therapeutic class, and year of the Paragraph IV challenge fixed effects. In column 2, we use the subsample of patents listed in the Orange Book after the first Paragraph IV challenge. We distinguish patents according to whether they are continuation patents or not and whether they were included in the initial patent infringement complaint filed by the branded manufacturer or after. We replaced ATC 3 with ATC 2 therapeutic category fixed effects, given the small sample size. Robust standard errors are in parentheses. Significance noted as: *p¡0.10; **p¡0.05; ***p¡0.01.

We next move to evaluate prediction (3) and, thus, assess whether waiting gives branded manufacturers a second-mover advantage. To do so, we estimate a variant of Eq. (1) where the outcome is an indicator equal to zero in the years when generic manufacturers have not entered the market and equal to one in the first year when a drug's generic equivalent is sold in the market. We censor the sample in the year after the first generic sales. The regressors of interest are, as before, (i) an indicator that equals one from the year a branded manufacturer receives a Paragraph IV challenge, and, in addition, (ii) an indicator that is equal to one in each year when a branded manufacturer lists a patent in the Orange Book,

as well as an interaction (iii) between (i) and (ii). We use the same fixed effects as those included in Eq. (1), including drug fixed effects, which control for the drugs' differing propensities to attract generic competitors. The regressor of interest is (iii), which captures the effect of listing a patent in the Orange Book after a Paragraph IV challenge on the likelihood that the drug's generic equivalent is sold in the market in year t. The results are reported in column 1 of Table 2.7. Having restricted the sample to NDAs that received a Paragraph IV challenge, we show that listing patents after the challenge decreases the likelihood of observing a generic drug in year t by 3.2 percentage points, compared to a mean of 3.2 percentage points. Column 3 further shows that listing a patent after litigation starts decreases the likelihood of observing a generic drug by 3.6 percentage points, relative to a mean of 3.3 percentage points. As 75% of suits ended in settlements, these results suggest that adding patents in the Orange Book after a Paragraph IV challenge helps delay generic entry by increasing branded manufacturers' bargaining power in settlements.

In columns 2 and 4, we specifically delve into continuation patents. Here, we find that adding a continuation patent after a Paragraph IV challenge (column 2) or after litigation starts (column 4) is negatively associated with the presence of a generic drug in the market. The coefficient magnitudes are slightly larger than those reported in columns 1 and 3. These last results are important because they show that the usage of continuation patents to delay the full disclosure of a branded manufacturer's intellectual property is a useful strategy for retarding generic entry.

To bring our results full circle, we provide evidence that the effects we detect in Table 7 are substantial. To show this, we collected information on Medicare Part D spending by drug, available from the Center for Medicare & Medicaid Services for the years 2016-2020, to assess how branded drug revenues change with generic entry. Medicare Part D is a government-subsidized program of prescription drug insurance for Americans aged 65 and over; approximately 60% of seniors receive drug insurance through Part D (Friedman, 2009). While these data do not cover all spending for branded drugs, they represent a

Table 2.7: Delaying generic entry

	Generic Entry			
	Focus on Paragraph IV Challenges		Focus on Litigation	
	(*Any*)	(*Continuation*)	(*Any*)	(*Continuation*)
	(1)	(2)	(3)	(4)
New *(...)* Patent Listed in the OB	-0.000	0.003	-0.009	-0.011
	(0.008)	(0.013)	(0.010)	(0.014)
Post Paragraph IV	-0.012	-0.015		
Challenge	(0.011)	(0.011)		
New *(...)* Patent Listed in the OB x	-0.032*	-0.042*		
Post Paragraph IV Challenge	(0.017)	(0.023)		
Post Litigation			0.028	0.025*
			(0.014)	(0.013)
New *(...)* Patent Listed in the OB x			-0.036*	-0.044*
Post Litigation			(0.020)	(0.025)
Firm FE	Yes	Yes	Yes	Yes
Drug FE	Yes	Yes	Yes	Yes
ATC-3 × Year FE	Yes	Yes	Yes	Yes
N	4,201	4,201	3,710	3,710

Notes: We estimate a variant of Eq. (1) where the outcome is an indicator equal to zero in the years in which generic manufacturers have not entered the market and equal to one the first year we observe a drug's generic equivalent being sold in the market. We censor the sample in the year after the first generic sales. In columns 1 and 2, we distinguish between whether a patent is listed in the Orange Book before or after a Paragraph IV challenge. For this analysis, we restrict the sample to challenged drugs. In columns 3 and 4, we distinguish between whether a patent is listed in the Orange Book before or after a litigation case. For this analysis, we restrict the sample to challenged drugs for which we record a litigation case. The post-litigation period starts from the year a litigation case was filed. In columns 2 and 4, we specifically examine the listing of a continuation patent in the Orange Book. Standard errors are clustered at the drug level. Significance noted as: *p<0.10; **p<0.05; ***p<0.01.

considerable portion. Using these data, we regress the logarithm of government spending on a branded drug in a given year on an indicator variable for whether a generic equivalent becomes available in the market, controlling for drug, branded manufacturer, and year fixed effects. Like Saha et al. (2006), we show in Table A7 that when a generic drug becomes available in the market, spending for and quantities sold of branded drugs immediately drop by approximately 49%. Overall, these findings suggest that even relatively small delays in competitor entry can profoundly affect firm revenues.

2.6 Heterogeneity analysis

Having analyzed how branded manufacturers employ the patents they list after a Paragraph IV challenge to delay generic entry, we explore heterogeneity in the manufacturers' reaction to a Paragraph IV challenge. We begin by assessing whether the reaction of branded manufacturers varies depending on the number of drugs they have in the same ATC-3 mar-

ket as the drug challenged. If a company has only a few drugs in that market, it may be more inclined to react to an initial Paragraph IV challenge, as generic entry may jeopardize the company's entire profitability in that market. This conjecture is verified in columns 1 and 3 of Table 2.8. In Eq. (1) an interaction term between the $PostParaIV_{jkt}$ indicator and the number of a company's drugs, active in year t, that are in the same ATC-3 class as the focal challenged drug. The results are in line with our hypothesis. As column 1 shows, firms with an extra drug in a challenged market list 0.14 fewer patents in the Orange Book after a Paragraph IV challenge than other firms. Consistently, column 3 shows that the share of continuation patents is one percentage point lower for firms with an extra drug in a challenged market, post-Paragraph IV challenge.

Table 2.8: Heterogeneous effects by the number of a branded manufacturer's drugs in a challenged market and by whether a challenged drug is an NCE

	Number of Patents Listed in the OB		Share of Continuation Patents Listed in the OB	
	(1)	(2)	(3)	(4)
Post Paragraph IV Challenge	0.679***	0.018	0.064***	0.031*
	(0.155)	(0.149)	(0.013)	(0.019)
Post Paragraph IV Challenge × Number of Drugs in same ATC-3	-0.137**		-0.011**	
	(0.057)		(0.005)	
Post Paragraph IV Challenge × Challenged Drug is NCE		0.630***		0.012
		(0.209)		(0.024)
Firm FE	Yes	Yes	Yes	Yes
Drug FE	Yes	Yes	Yes	Yes
ATC-3 × Year FE	Yes	Yes	Yes	Yes
Drug Age FE	Yes	Yes	Yes	Yes
N	14,641	14,641	14,641	14,641

Notes: In columns 1 and 2, the dependent variable is the number of patents listed in the Orange Book in year t, while in columns 3 and 4, the dependent variable is the share of continuation. In columns 1 and 3, we report the results having introduced in Eq. (1) an interaction term between the $PostParaIV_{jkt}$ indicator and the number of a company's drugs -active in year t- that are in the same ATC-3 class as the focal challenged drug. In columns 2 and 4, we report the results having added to Eq. (1) an interaction term between the $PostParaIV_{jkt}$ indicator and an indicator identifying drugs based on New Chemical Entities (NCE). Standard errors are clustered at the drug level. Significance noted as: *p<0.10; **p<0.05; ***p<0.01.

We further investigate how a branded manufacturer's reaction to a Paragraph IV chal-

lenge varies depending on whether the challenged drug is an NCE. As we mention above, NCEs not only are highly innovative but also can constitute a foundation for follow-on drugs, which reuse the same molecules for different medical indications. Given the strategic importance of NCEs, we should expect branded manufacturers to react more strongly when these drugs are challenged. To test this hypothesis, we modify Eq. (1) to include an interaction term between the $PostParaIV_{jkt}$ dummy and an indicator identifying NCE products. The results, reported in column 3 of Table 2.8, show that the positive effect of a Paragraph IV challenge on the number of patents that branded manufacturers list in the Orange Book is driven by NCEs. Column 4 shows that the share of continuation patents listed in the Orange Book post-Paragraph IV challenge is one percentage point higher for NCEs than for other drugs, although the difference is not statistically significant at conventional levels. [23]

Finally, the detected patent strategy might vary depending on the breadth of the patents listed in the Orange Book at the time of FDA approval. Following Gambardella (2013), we operationalize this distinction by classifying NDAs according to whether they are in the last quartile for the number of claims. The results are reported in Table 2.9. In column 1, we show that firms whose initially listed patents have fewer claims react to a Paragraph IV challenge by listing 0.45 more patents in the Orange Book. Conversely, the reaction is close to zero and insignificant (p-value=0.609) for firms whose initially listed patents are in the upper quartile for the number of claims. We report similar results in column 2, where the outcome is the share of continuation patents. In accord with the notion that some patents have "warts" (Palermo et al., 2019), these results provide evidence that firms derive more value from strategically protecting drugs following the materialization of a competitor threat when the initial patents are narrower.

[23] It is possible that the increase might be driven by the fact that NCEs are, on average, poorly protected by their patents. However, descriptive evidence shows that the average number of claims for patents protecting NCE drugs is 19.7, while the average number of claims for patents protecting non-NCE drugs is 20.7. These figures are very similar, suggesting that patents protecting NCE drugs are not narrower than patents protecting non-NCE drugs.

Table 2.9: Heterogeneous effects by the breadth of the patents listed in the Orange Book at a drug's FDA approval

	Number of Patents Listed in the OB	Share of Continuation Patents Listed in the OB
	(1)	(2)
Post Paragraph IV	0.451***	0.046***
Challenge	(0.110)	(0.015)
Post Paragraph IV Challenge	-0.559***	-0.043**
× High Number of Claims	(0.214)	(0.021)
Pharmaceutical FE	Yes	Yes
Drug FE	Yes	Yes
ATC-3 × Year FE	Yes	Yes
Age FE	Yes	Yes
N	14,641	14,641

Notes: In this table, we assess whether the branded manufacturer's patent reaction to Paragraph IV challenges varies depending on the breadth of the patents listed in the Orange Book at a drug's FDA approval. We report the results having introduced in Eq. (1) an interaction term between the $PostParaIV_{jkt}$ indicator and an indicator for whether the patents listed in the Orange Book at a drug's FDA approval are in the last quartile for the number of claims. In column 1, the dependent variable is the number of patents listed in the Orange Book in year t. In column 2, the dependent variable is the share of continuation patents listed in the Orange Book. Standard errors are clustered at the drug level. Significance noted as: *p<0.10; **p<0.05; ***p<0.01.

2.7 Discussions and conclusions

We take advantage of the unique features of the pharmaceutical industry, where -unlike other industries- we can observe the exact moment a competitor threat materializes, the product that is being threatened, the link between a product and its protecting patents, and the consequences of the incumbents' patent strategies. Leveraging these unique characteristics and exploiting plausibly exogenous variation in the timing of generic entry threats, we show that branded manufacturers react to these threats, which materialize via Paragraph

IV challenges, by disclosing more patents in the Orange Book. These are disproportionately continuation patents. These continuation patents are relatively more likely to be used in the later phases of litigation, and their text is similar to the initial complaints filed by branded manufacturers against generic producers after a Paragraph IV challenge. These findings show that branded manufacturers tailor their patent response to the information that becomes available from the generic threats. And this strategy pays off: it is positively associated with generic entry delay.

Our paper has clear managerial implications. When a threat of competitor entry materializes, incumbents often cannot simply respond by creating differentiated products, as doing so requires resources and time. As a result, they must optimize the use of strategic assets, such as patents, which can be deployed more flexibly. This paper shows that the marginal value of these assets can increase after a threat, especially if incumbents capitalize on the information revealed by potential entrants and tailor their responses accordingly.

Although we focused on the pharmaceutical industry, this industry is a crucial source of innovations and value creation (Higgins and Rodriguez, 2006b). Importantly, the relevance of our findings extends to any R&D-intensive industry, where intellectual property rights -including patents- are strategically used by firms either ex-ante as entry deterrents or ex-post in litigation against potential competitors. The use of continuation patents is widespread across these industries, and scholars have speculated that these patents may be deployed for opportunistic reasons (Allison et al., 2003). Our paper is one of the few providing large-scale empirical evidence of such strategic use.

A remarkable example of how our results could be extended outside of the pharmaceutical sector is Sonos's strategic response to the threat of entry by Google in the smart speaker market. Founded in 2002, Sonos became renowned for its patent-protected smart speakers, launched in 2005. Sonos had a monopoly on wireless in-home music systems until Amazon and Google entered that market. While Amazon specialized in low-end smart speakers, in 2017 Google launched the Google Home Max, a high-quality smart speaker

that began competing directly with Sonos's products. In response, in January 2020 Sonos sued Google before the International Trade Commission (ITC), claiming that Google had infringed five of its patents.[24]

Although Sonos had been granted 381 patents before entry by Google in 2017, it had virtually marked -and thus, explicitly disclosed- only 77 of them.[25] According to the 2011 Leahy-Smith America Invents Act, virtual patent markings (VPMs) are required for patent holders to be able to claim damages in case of patent infringement (Fromer, 2016). Therefore, it is remarkable that, despite this law requirement, Sonos selected only a portion of its portfolio patents for virtual marking. After Google entered the market in 2017, Sonos virtually marked 224 more patents and three of the five patents asserted by Sonos in the lawsuit derive from this second group. Like the pharmaceutical firms we examined, Sonos disproportionately listed continuation patents as VPMs in response to Google's threat; the percentage of continuation patents it listed rose from 32 before Google's entry to 63 afterwards, and four of the five patents for which Sonos claimed infringement are continuation patents. In January 2022, the ITC ruled in favor of Sonos, and Google was forced to remove the patent-infringing features from its products. This example supports the main finding of this paper, namely, that there is value in waiting to disclose the intellectual property protecting a given product and that continuation patents can be opportunistically used for this purpose.

Finally, our findings also have implications for policymakers. After policymakers recognized that branded manufacturers were initiating several thirty-month stay periods by adding patents in the Orange Book after a Paragraph IV challenge, the US Congress passed the Medicare Modernization Act in 2003, which allowed for only one such period (Bulow, 2004). We highlight a loophole that branded manufacturers continue to exploit despite this reform. Even though generic manufacturers are not required to produce Paragraph IV certi-

[24]The litigated patents are: US 9,219,460, US 9,344,206, US 9,967,615, US 10,469,966, and US 10,779,033.

[25]We manually collected virtual patent markings from historical archives of Sonos' website *www.sonos.com* using Wayback Machine.

fications for follow-on patents that are listed in the Orange Book after a drug is challenged, branded manufacturers can request the enforcement of these follow-on patents in court. Our finding that branded manufacturers game the ”openness” of the Orange Book, combined with evidence that the Paragraph IV mechanism is associated with increased welfare (Branstetter et al., 2016), suggests that policymakers should consider ”closing” the Orange Book (Hollis, 2001), preventing firms from adding patents after a drug is approved.

Beyond the pharmaceutical sector, our results unveil that although the 1999 changes in US patent law mandated the publication of patent applications after 18 months, incumbents continue to act opportunistically, relying on the fact that it is difficult for competitors to link a product to its protecting patents. This is a real concern. Our results suggest that while the 1999 changes might have had an impact on curbing firms' opportunistic behavior, more should be done to increase the transparency of product-patent linkages. Recent advances in machine learning techniques might help ease the task.

2.8 Appendix

2.8.1 A1: Similarity between a company's portfolio patents and those initially listed in a drug application

To determine how similar is a brand-name drug manufacturer's patent, unlisted in the Orange Book, to that manufacturer's patents listed in a given approved drug application, we implement a machine learning algorithm that determines the text similarity between patent pairs. In what follows, we describe the main steps of the algorithm.

We begin by identifying all patents owned by those pharmaceutical firms that have at least one FDA-approved drug listed in the Orange Book. To do so, we perform a fuzzy matching between pharmaceutical firm names and patent assignee names, using Python's library Dedupe.[26] Having applied this method, we identify 104,784 pharmaceutical patents.

For each patent, we generate a unique document that encompasses the patent's title, abstract, and International Patent Classification (IPC) description. We successively remove accents, special characters, and punctuation from the document. We next implement a vectorization step that uses the Term Frequency–Inverse Document Frequency (TF-IDF) procedure to turn each document into a vector where the entries are the TF-IDF scores assigned to the words in the document. A TF-IDF score is defined as the frequency with which a given word occurs in a certain document divided by the frequency with which that word is present in all patent documents (that is, the vocabulary). We then generate a matrix where each row corresponds to a given patent i and each column corresponds to a word j from the patents' entire corpus of words. Each cell in this matrix contains the TF-IDF score of word j, provided that it is present in patent i. If the word is not present in patent i, we assign the value zero.

Because the computed matrix is very large (104,784 x 238,379), we apply the Singular Value Decomposition (SDV) method to reduce dimensionality. SVD allows one to reduce

[26] Additional details about Fuzzy String Matching using Dedupe are provided at https://github.com/dedupeio/dedupe.

the dimension of a matrix, while retaining most of its properties. The matrix obtained after implementing SVD is a low-rank approximation of the original TF-IDF matrix, and it can be used as a substitute for the original TF-IDF matrix. Although the resulting matrix has only $1,000$ columns, the cumulative explained variance is 81.8%.

As the last step, we compute the text similarity between patent pairs using cosine similarity, which measures the cosine of the angle between the two vectors, each representing a patent. The output of this procedure is a similarity score, which is computed as:

$$sim_{patent_a, patent_b} = \frac{\langle patent_a, patent_b \rangle}{\|patent_a\| \cdot \|patent_b\|}$$

where $\langle \cdot, \cdot \rangle$ is the dot product between a patent a and a patent b and $\| \cdot \|$ is the Euclidean norm. The similarity score is bounded between 0 and 1, with values close to 0 representing dissimilar patents and values close to 1 representing highly similar patents. Since we calculate the similarity score for every patent pair, the final output is summarized in a symmetric matrix that contains the similarity scores between the patents listed in the rows and those listed in the columns.

2.8.2 A2: Figures & Tables

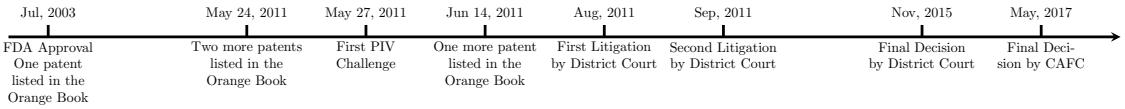


Figure A1: Case Study: Aloxi by Helsinn Healthcare SA

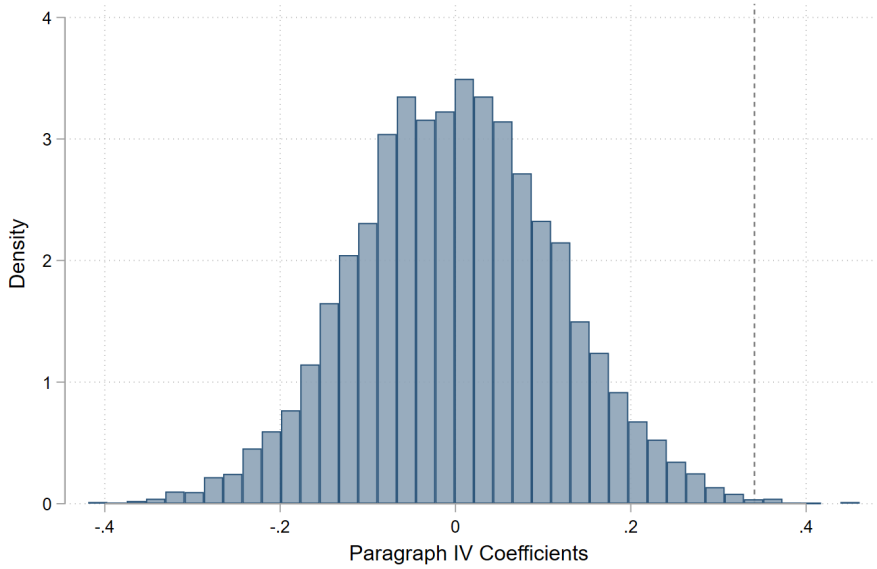


Figure A2: Placebo Test - Randomization of Treatment

This figure displays the distribution of Paragraph IV litigation coefficients derived from the model estimated in column 2 of Table 3 over 10,000 samples where we randomly assign the timing of the first Paragraph IV challenge. The vertical dotted line represents the baseline estimate from column 2 of Table 3. As shown, the likelihood that we obtain the estimate reported in Table 3 is less than 1%, implying that the magnitude of the coefficient displayed in column 2 of Table 3 is unlikely the result of chance.

Table A1. Approved drug application patents after a Paragraph IV challenge

	Number of Similar Patents (log)	Number of Patents Listed in the OB (log)
	(1)	(2)
Post Paragraph IV	0.015	0.085***
Challenge	(0.019)	(0.022)
Firm FE	Yes	Yes
Drug FE	Yes	Yes
ATC 3 $\times$ Year FE	Yes	Yes
Drug Age FE	Yes	Yes
N	14,641	14,641

Notes: This table reports the results from estimating Eq. (1) for: the number of patents that were applied for in year t and are similar to those originally listed in the Orange Book (column 1), and the number of patents listed in the Orange Book (OB) in year t (column 2). The dependent variables are expressed in *natural logarithm*. All the specifications control for drug, firm, drug application age, and ATC 3 therapeutic class by year fixed effects. Standard errors are clustered at the drug level. Significance noted as: *p¡0.10; **p¡0.05; ***p¡0.01.

Table A2. Approved drug application patents after a Paragraph IV challenge: Excluding drug applications that received a Paragraph IV challenge in years 4 and 5 from FDA Approval

	Panel A: Number of Patents listed in the OB			
	Excluding:			
	NCE Drugs PIV in $t = 4$	NCE Drugs PIV in $t = 4$ or $t = 5$	All Drugs PIV in $t = 4$	All Drugs PIV in $t = 4$ or $t = 5$
	(1)	(2)	(3)	(4)
Post Paragraph IV	0.269**	0.247**	0.281**	0.249*
Challenge	(0.114)	(0.117)	(0.123)	(0.130)
Firm FE	Yes	Yes	Yes	Yes
Drug FE	Yes	Yes	Yes	Yes
ATC-3 × Year FE	Yes	Yes	Yes	Yes
Drug Age FE	Yes	Yes	Yes	Yes
N	13,836	13,657	13,301	12,912
	Panel B: Share of continuation patents			
	(1)	(2)	(3)	(4)
Post Paragraph IV	0.036**	0.037**	0.034**	0.032**
Challenge	(0.014)	(0.015)	(0.016)	(0.016)
Firm FE	Yes	Yes	Yes	Yes
Drug FE	Yes	Yes	Yes	Yes
ATC-3 × Year FE	Yes	Yes	Yes	Yes
Drug Age FE	Yes	Yes	Yes	Yes
N	13,836	13,657	13,301	12,912

Notes: This table reports the results from estimating Eq. (1) for the number of patents listed in the Orange Book (OB) in year t. In column 1, we exclude NCE drug applications that received a Paragraph IV challenge in year 4 from the FDA approval of a drug. In column 2, we exclude NCE drug applications that received a Paragraph IV challenge in year 4 or year 5 from a drug's FDA approval. In column 3, we exclude all drug applications that received a Paragraph IV challenge in year 4 from a drug's FDA approval. In column 4, we exclude all drug applications that received a Paragraph IV challenge in year 4 or year 5 from a drug's FDA approval. In Panel A, the outcome is the number of patents listed in the Orange Book in year t. In Panel B, the outcome is the share of continuation patents. All the specifications control for drug, firm, drug application age, and ATC 3 therapeutic class by year fixed effects. Standard errors are clustered at the drug level. Significance noted as: *p¡0.10; **p¡0.05; ***p¡0.01.

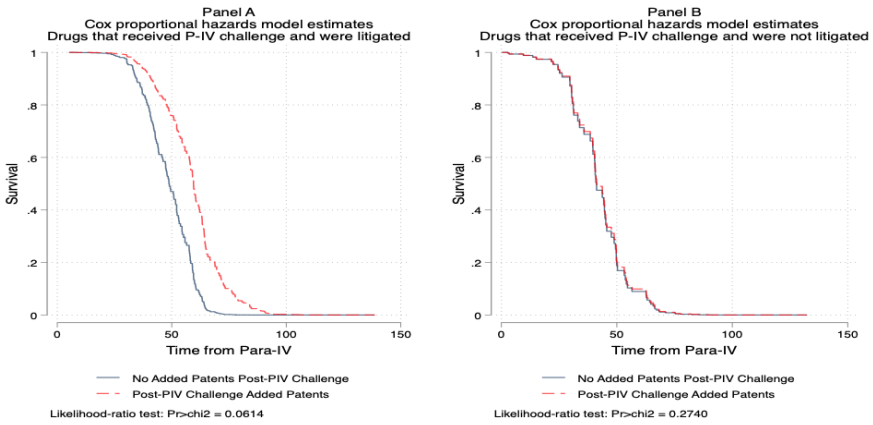


Figure A3: Cox Proportional Hazard Estimates of Time to Generic Entry

These figures display the Cox Proportional Hazard estimates of the number of years until generic entry distinguishing between those cases where patents were added after a Paragraph IV challenge (in red) and those where all the patents were added by the time a drug was challenged (in blue). Panel A displays the hazard of generic entry for drugs that received a Paragraph IV challenge followed by litigation. Panel B reports the results for those drugs that received a Paragraph IV challenge not followed by litigation.

Table A3. Approved drug application patents after a Paragraph IV challenge - With ATC 4 therapeutic class by year fixed effects

	Number of Similar Patents	Number of Patents listed in the OB	Share of Continuation Patents listed in the OB
	(1)	(2)	(3)
Post Paragraph IV	0.020	0.417***	0.052***
Challenge	(0.098)	(0.117)	(0.015)
Firm FE	Yes	Yes	Yes
Drug FE	Yes	Yes	Yes
ATC-4 $\times$ Year FE	Yes	Yes	Yes
Drug Age FE	Yes	Yes	Yes
N	13,347	13,347	13,347

Notes: This table reports the results from estimating Eq. (1) for: the number of patents that were applied for in year t and are similar to those originally listed in the Orange Book (column 1), the number of patents listed in the Orange Book (OB) in year t (column 2), and the share of continuation patents in the Orange Book (column 3). All the specifications control for drug, firm, drug application age, and ATC-4 therapeutic class by year fixed effects. Standard errors are clustered at the drug level. Significance noted as: *p¡0.10; **p¡0.05; ***p¡0.01.

Table A4. Approved drug application patents after a Paragraph IV challenge - Limiting the Post-Paragraph IV period

	Panel A: Number of Patents listed in the OB				
	$\leq$ 7 years	$\leq$ 5 years	$\leq$ 3 years	$\leq$ 2 years	$\leq$ 1 years
	(1)	(2)	(3)	(4)	(5)
Post Paragraph IV	0.336***	0.356***	0.348***	0.317***	0.273***
Challenge	(0.106)	(0.102)	(0.095)	(0.090)	(0.082)
Firm FE	Yes	Yes	Yes	Yes	Yes
Drug FE	Yes	Yes	Yes	Yes	Yes
ATC-3 $\times$ Year FE	Yes	Yes	Yes	Yes	Yes
Drug Age FE	Yes	Yes	Yes	Yes	Yes
N	14,155	13,589	12,779	12,287	11,680

	Panel B: Share of Continuation Patents listed in the OB				
	$\leq$ 7 years	$\leq$ 5 years	$\leq$ 3 years	$\leq$ 2 years	$\leq$ 1 years
Paragraph IV	0.038***	0.037***	0.036***	0.034***	0.030***
Submission	(0.013)	(0.012)	(0.011)	(0.010)	(0.009)
Firm FE	Yes	Yes	Yes	Yes	Yes
Drug FE	Yes	Yes	Yes	Yes	Yes
ATC-3 $\times$ Year FE	Yes	Yes	Yes	Yes	Yes
Drug Age FE	Yes	Yes	Yes	Yes	Yes
N	14,155	13,589	12,779	12,287	11,680

Notes: This table reports the results from estimating Eq. (1), conditioning the post-Paragraph IV period to up to 7 (column 1), 5 (column 2), 3 (column 3), 2 (column 4), and 1 (column 5) year(s) after the first Paragraph IV challenge. In Panel A, the outcome is the number of patents listed in the Orange Book in year t. In Panel B, the outcome is the share of continuation patents. All specifications control for drug, firm, drug application age, and ATC-4 therapeutic class by year fixed effects. Standard errors are clustered at the approved drug application level. Significance noted as: *p¡0.10; **p¡0.05; ***p¡0.01.

Table A5. Goodman-Bacon difference-in-differences decomposition

Panel A: Number of Patents listed in the Orange Book

DD Comparison	Weight	Avg. DD Estimation
Earlier Group Treatment vs. Later Group Control	0.041	-0.404
Later Group Treatment vs. Earlier Group Control	0.044	0.741
Treatment vs. Never Treated	0.827	0.731
Treatment vs. Already Treated	0.088	0.167

Panel B: Share of Continuation Patents listed in the Orange Book

DD Comparison	Weight	Avg. DD Estimation
Earlier Group Treatment vs. Later Group Control	0.041	0.051
Later Group Treatment vs. Earlier Group Control	0.044	0.030
Treatment vs. Never Treated	0.827	0.045
Treatment vs. Already Treated	0.088	0.081

Notes: Goodman-Bacon's decomposition for the difference-in-differences model described by Eq. (1). In Panel A, the dependent variable is the number of patents listed in the Orange book. In Panel B, the dependent variable is the share of continuation patents listed in the Orange Book.

Table A6: Delaying generic entry

	Number of Years Until Generic Entry (log)		
	Drugs with Paragraph IV Challenges	Drugs with Litigated Paragraph IV challenges	Drugs without Litigated Paragraph IV challenges
	(1)	(2)	(3)
Log (Number of New Patents added after PIV Challenge)	0.060**	0.090*	-0.039
	(0.027)	(0.043)	(0.083)
Firm FE	Yes	Yes	Yes
ATC-2 FE	Yes	Yes	No
Approval Year FE	Yes	Yes	Yes
Number of Patents at PIV FE	Yes	Yes	Yes
N	264	185	60

Notes: Columns 1 to 3 report the results from estimating linear regression models for the number of years elapsed from drug i's approval year until generic entry as a function of the number of patents listed in a drug application i after a first Paragraph IV challenge. In column 1, we restrict the sample to those NDAs challenged by a Paragraph IV. In column 2, we examine those challenged NDAs that resulted in litigation. In column 3 we analyze those challenged NDAs for which the branded pharmaceutical did not initiate a Paragraph IV litigation. In these columns, the number of observations is smaller than the number reported in Section 3 since we restrict our sample to NDAs for which a generic entry occurred during our sample period. Standard errors are multi-way clustered at the firm, drug's ATC 2 therapeutic class, and NDA approval year levels, except for column 3 where the small sample size only allows us to cluster standard errors at the at the firm and NDA approval year levels. Given the small sample size, we substituted ATC 3 with ATC 2 therapeutic category fixed effects. Significance noted as: *p<0.10; **p<0.05; ***p<0.01.

Table A7. Generic Entry and the Brand Name Drug Demand: Medicare Part D program

	All Sample		Generic entry only in 2019 or 2020	
	Drug Spending (log)	Dosage units sold (log)	Drug Spending (log)	Dosage units (log)
	(1)	(2)	(3)	(4)
Post Generic Entry	-0.691***	-0.666***	-0.586***	-0.537***
	(0.141)	(0.155)	(0.164)	(0.179)
Constant	13.299***	12.327***	13.107***	12.250***
	(0.023)	(0.025)	(0.001)	(0.001)
Firm FE	Yes	Yes	Yes	Yes
Drug FE	Yes	Yes	Yes	Yes
Year FE	Yes	Yes	Yes	Yes
N	25,028	25,028	21,003	21,003

Notes: To derive the results in this table, we collected information on Medicare Part D spending by drug available from the Center for Medicare & Medicaid Services for the 2016-2020 period to assess how branded drug revenues change with generic entry. Medicare Part D is a government subsidized program of prescription drug insurance for Americans aged 65 and over. Using these data, we regress the logarithm of government spending by branded drug in a given year (columns 1 and 3) and the logarithm of the number of dosage units sold (columns 2 and 4) as a function of an indicator variable for whether a generic equivalent becomes available in the market (*Post Generic Entry*), controlling for drug, branded manufacturer, and year fixed effects. In columns 1 and 2, we consider the 2016-2020 period, for which the data is available. In columns 3 and 4, we limit generic entry to the 2019-2020 period to assess whether there is an immediate drop in branded manufacturers' sales and dosage units following generic entry. We cluster standard errors at the drug level. Significance noted as: *p<0.10; **p<0.05; ***p<0.01.

Table A8: Approved drug application patents after a Paragraph IV challenge - by the age of the oldest patent

	Number of Patents Listed in the OB
Post Paragraph IV	0.588***
Challenge	(0.141)
Post Paragraph IV	
Challenge ×	-0.571**
Oldest patent expires in 9 rs.	(0.227)
Firm FE	Yes
Drug FE	Yes
ATC-3 × Year FE	Yes
Drug Age FE	Yes
N	14,328

Notes: In this table, we interact the $PostParaIV_{jkt}$ indicator with a dummy that takes value 1 if the oldest patent's protection term is greater than nine years. The nine years cut-off corresponds to both the mean and median of the age distribution of the oldest patent. Standard errors are clustered at the drug level. Significance noted as: *p<0.10; **p<0.05; ***p<0.01.

CHAPTER 3
THE ROLE OF EXTERNAL SOURCES OF INFORMATION IN FIRM SOURCING DECISIONS: EVIDENCE FROM PATENT PROSECUTION SERVICES

Leonardo Ortega

3.1 Introduction

When considering performance differences among firms, one important factor is related to the decision of what elements of the value chain firms should make internally and what elements they should buy in the market. The Transaction Cost Economics (TCE) theory predicts that under high uncertainty and asset specificity, boundedly rational firms making *make-or-buy* decisions should opt for internal provision. This is because of asymmetries of information and supplier's incentives for opportunistic behavior in market exchanges (Williamson, 1985).[1] Yet, the markets for knowledge-based services, an economic sector characterized by highly specialized human capital and challenging performance evaluations, have experienced an important expansion in recent years (Nooteboom, 1992).[2] This significant expansion in knowledge-based services has led many firms to outsource services like accounting, marketing, finance, human resources, legal, and R&D, among others (Goldschmidt and Schmieder, 2017; Mayer et al., 2012). Although outsourcing decisions of knowledge-based services are becoming an important element of firms' strategic management, there is limited empirical evidence on how firms deal with information asymmetry and reduce transaction costs of market-based solutions (Cuypers et al., 2021).

[1] See Macher and Richman (2008) and Cuypers et al. (2021) for a recent literature review on TCE.

[2] From 1997 to 2021, the U.S. GDP's value added by professional and scientific services grew 256%, while the value added in the manufacturing sector grew 85%. Following Mayer et al. (2012), I proxy the U.S. GDP's value added for knowledge-based services using the *NAICS 54: Professional, scientific, and technical services* sector.

To address this apparent discrepancy in the traditional TCE theory, previous studies have proposed additional factors that mitigate the negative effects of information asymmetry in market transactions. One approach is the use of plural sourcing, which simultaneously balances internal and external provisions, thereby reducing the risks associated with market transactions (Chondrakis et al., 2022; Puranam et al., 2013; Rothaermel et al., 2006). Another approach involves considering the dynamic aspects of transactions, such as the evolution of inter-firm relationships, which can provide valuable information for sourcing decisions (Gulati, 1995; Hoetker, 2005; Nooteboom, 1992; Sako et al., 2016).

Building on these previous studies, this paper proposes a new approach that emphasizes the role of external sources of information in reducing information asymmetry and transaction costs in market exchanges. Furthermore, this study explores how firms' ability to incorporate external sources of information into sourcing decisions is influenced by behavioral biases, such as overreactions. Answering these questions empirically is challenging due to the complexity of tracking how particular external sources of information trigger the observed strategic response by the firm in isolation from other sources of information. Moreover, detecting the presence of behavioral biases in sourcing decisions requires identifying empirical settings where firms' actions can be contrasted with an objective measure of the optimal decision-making process.

This paper addresses these empirical challenges by analyzing firms' sourcing decisions around one important knowledge-based service: the sourcing of patent prosecution services. Patenting firms typically employ highly-specialized patent attorneys to represent them in prosecuting their patents. These attorneys play a crucial role in drafting, applying, and negotiating with patent examiners at the patent office to obtain patent rights over the underlying technology. In doing so, they translate complex technical concepts into a set of claims that can be protected by patent law. The role of patent attorneys is not limited to obtaining patent rights, however. It is also critical to obtaining enforceable patent rights that can be defended in court (Reitzig, 2004; Somaya et al., 2007; Süzeroğlu-Melchiors

et al., 2017).[3]

The U.S. patent system is an ideal empirical setting to study how external information affects firms' sourcing decisions for three reasons. First, patent documents contain bibliographic information listing the patent attorneys who represented the patenting firm during the patent prosecution process. This allows for consistent documentation of when patenting firms switch from one prosecuting provider to another. Second, this study leverages exposure to patent litigation as an exogenous source of information from external sources (i.e., litigating patent attorneys) about the quality of the prosecuting service provided by the law firm that prosecuted the litigated patents. One of the key factors determining the success of patents in litigation is the extent to which their claims accurately translate the underlying technology (Trop, 1988), which largely depends on the performance of the prosecuting law firm (de Rassenfosse et al., 2021). During litigation, litigated patents undergo thorough scrutiny by litigating patent attorneys, inadvertently providing patenting firms with information about the quality of the prosecuting law firm. This information can help patenting firms reduce information asymmetries about the quality of the prosecuting law firm.[4]

Finally, the U.S. patent system is also well suited empirical setting for identifying potential behavioral biases in patent prosecution sourcing decisions. In this paper, I take advantage of the fact that when a firm is accused of patent infringement, it frequently argues that the litigated patent is invalid, with legal arguments for patent invalidity that are fairly standardized.[5] More importantly, these arguments against litigated patents vary in the level of involvement of the prosecuting law firm. In some cases, these arguments highlight patent weaknesses that are strongly related to actions taken either by the prosecuting law

[3]Ideally, a firm applying for a patent expects to get the patent granted. More importantly, the patenting firm also aims to obtain patent rights that can potentially be enforced to exclude other parties from using or accessing the underlying patented technology. Unfortunately, patent rights are a necessary condition but not sufficient for enforceability. Patenting firms have to implement strategies to achieve appropriability (Pisano, 2006), including having a litigation-effective patent that can be enforced in court.

[4]Reitzig and Wagner (2010) also found that patent litigation informs patent prosecution. They discovered that firms with patent litigation experience are more likely to handle their patent prosecution process internally, underscoring the knowledge complementarity between the two processes.

[5]A defendant could also argue that the patent is not infringed or that the patent is unenforceable because the patent owner tried to deceive the USPTO when prosecuting the litigated patent.

firm (e.g., anticipation, obviousness, indefiniteness, lack of enablement, etc.)[6] or by the patenting firm even before the patent application was drafted (e.g., public-use and on-sale bar).[7] If patent litigation informs patenting firms about the quality of their current prosecuting law firm, we should expect a stronger reaction from firms against their prosecuting law firm in litigation cases where the alleged infringer raises the former type of argument relative to the latter one. Observing similar reactions in both types of litigation cases would indicate that patenting firms may incorrectly interpret the information from patent litigation and overreact based on it.

Using the information on a sample of U.S. patents applied for between 1982 to 2018, I estimate a staggered difference-in-difference model to compare changes in patenting firm-prosecuting law firm relationships for exposed and unexposed patenting firms before and after patent litigation. The results show that, on average, firms that are exposed to patent litigation tend to weaken their relationship with the law firm that prosecuted the litigated patent relative to unexposed firms working with the same prosecuting law firm. Specifically, patenting firms react to information from patent litigation by reducing the workload of the exposed prosecuting law firm and are more likely to terminate the inter-firm relationship. This suggests that patenting firms utilize information from patent litigation to reduce information asymmetries when considering prosecution sourcing decisions. Additionally, the results indicate that there is no difference in firms' reactions to litigation cases with high or low involvement of prosecuting law firms. This suggests that firms may overreact by reducing the workload of their prosecuting law firm or by terminating their firm-supplier relationship even when the main arguments used in court against the patent are traced back

[6] Anticipation refers to the situation where a patent claim covers an invention that was already disclosed to the public before the patent application was filed. Obviousness refers to the situation where a patent claim is considered too obvious to be granted. Indefiniteness refers to the situation where a patent claim is too vague or ambiguous to determine its scope. Lack of enablement refers to the situation where a patent claim is not enabled in a way that someone skilled in the art could make and use the invention without undue experimentation. Public-use and on-sale bar refer to public-use and commercial-sale activities that may preclude a patent from being granted.

[7] The public-use bar refers to a situation where an invention has been publicly used by the inventor or someone else for more than one year before filing a patent application. The on-sale bar refers to a situation where the invention has been sold or offered for sale for more than one year before filing a patent application.

to actions taken by the patenting firm. This result supports the argument that firms collecting external information to reduce information asymmetries in market exchanges are also at risk of behavioral biases. Furthermore, descriptive evidence suggests that firms that start a new relationship with a prosecuting law firm face longer time-to-grant periods and a higher number of examiner's actions. Thus, if a firm misinterprets signals from patent litigation and overreacts, it is at risk of paying the adaptation costs of establishing a relationship with a new provider without necessarily enjoying better prosecution services. This is consistent with previous research by Leiblein et al. (2002), who found that governance misalignment can have a negative impact on performance.

My contribution to the literature is threefold. First, previous research on management of sourcing relationships has identified that firms mitigate the negative effects of asymmetric information and the difficulties in measuring and evaluating supplier's performance by using several information mechanisms such as prior contracting experience (Fabrizio, 2012), prior transaction experience with the same supplier (Leiblein and Miller, 2003; Gaulé, 2018; Hoetker, 2005), and internal evaluations (Chondrakis et al., 2022; Puranam et al., 2013; Sako et al., 2016). This paper contributes to the existing literature by examining how external sources of information can be utilized to reduce transaction costs associated with uncertainty in market exchanges. It particularly isolates the impact of a single external source, thereby providing valuable insights into the effectiveness of this method for reducing information asymmetry.

Second, this paper contributes to the literature that studies the extent to which bounded rationality affects governance decisions. Several studies have focused on how firms differ in the perception of potential opportunistic behavior (also known as *behavioral uncertainty*) (Buckley and Chapman, 1998; Puranam and Vanneste, 2009). For instance, Conner and Prahalad (1996) highlight that decision-makers exhibit bounded rationality by miscalculating the possibility of opportunistic behavior by suppliers, while Gulati (1995) highlights that trust in inter-firm relationships moderates the perceived opportunistic behavior. Other

studies instead, focus on elements of bounded rationality related to differences across firms in the costs of collecting and analyzing information (Weber and Mayer (2014) propose the term *interpretative uncertainty*) (Ghani et al., 2014; Nooteboom, 1992). This paper contributes to the literature by focusing on how firms' ability to analyze and translate external sources of information into useful information for governance decisions. Although external sources of information could inform firms about suppliers' performance, it also demands firms' capabilities to correctly interpret the expert's position. This contribution is in line with expanding our understanding of how firms make governance decisions by integrating insights from behavioral decision-making into our theoretical and empirical frameworks (Cuypers et al., 2021).

Finally, this study also contributes to the emerging literature that studies patent litigation as an overall information-transmission mechanism. Previous studies have found that patent litigation generates useful information for competitors or potential competitors. For instance, patent litigation can signal reputation for toughness patent enforcement (Agarwal et al., 2009), spills over information about the underlying technology (Awate and Makhija, 2021), helps the time to entry decision (Choi, 1998; Onoz and Giachetti, 2021), provides incentives for rival's R&D investments (Mezzanotti, 2021), and can induce resource imitation (Polidoro and Toh, 2011). This paper contributes to this literature by arguing that patent litigation can also be an important information-transmission mechanism for patenting firms to improve their understanding of the overall quality or enforceability of their patent rights.

3.2 Background

This paper focuses on sourcing decisions of patent prosecution services. Given the importance of enforceable patent rights to sustain knowledge-based competitive advantages, patenting firms are sensitive to miscalculations in sourcing decisions of patent prosecution services (Mayer et al., 2012). In this section, I describe the main elements of the U.S. patent

prosecution and litigation processes.

3.2.1 Patent Prosecution Process in the U.S.

In the U.S., patent applicants are not obligated to file for a patent under the guidance of a patent counselor. However, almost all patents are drafted, applied for, and prosecuted by a patent attorney in representation of the patenting firm. The main reason for this pattern is that patent prosecution is a technically and legally complex process.[8] In fact, patent prosecution in the U.S. is a specialized area of the law that requires patent attorneys to certify their knowledge of intellectual property right law by passing a USPTO patent bar.

The role of patent attorneys is key, not only for obtaining patent rights, but also for the enforceability of the granted patent rights (Hattenbach et al., 2010). The main task of a prosecuting patent attorney is to translate the underlying technology into a legal document to be granted patent rights. This process usually involves several interactions with the inventors in order to better understand the invention and to prepare the initial patent application (Reitzig, 2004). After the initial patent application is submitted to the USPTO, the patent attorney, in representation of the patent applicant's interest, bargains with the patent examiner over the scope and breadth of the claimed invention to grant patent rights. Ideally, issued patents should protect inventions that are novel, non-obvious, and useful. However, actions taken by the patenting firm, the patent attorney, and the patent examiner may affect the enforceability of the patent rights.

Firms choose the sourcing of patent prosecution services based on their technical expertise, costs, and strategic importance. In some cases, firms may choose to outsource the legal services because that way they can access better and more specialized attorneys in a cost-effective way (Goldschmidt and Schmieder, 2017; Mayer et al., 2012). In some other cases, the unpredictable and variable demand for intellectual property (IP) legal ser-

[8] Gaudry (2012) finds evidence that suggests that patents filed by inventors alone (also known as "pro se" applications) are more likely to be abandoned compared to patents filed using the services of a registered patent attorney.

vices makes having an internal legal department too expensive (Coates et al., 2011). When patent rights are of superior strategic importance for business performance, firms may opt for prosecuting their patents using the services of an internal legal department. For example, internal prosecution is prevalent in the pharmaceutical industry because a small set of patents protect multimillion-dollar drugs. In general in the U.S., patents are prosecuted by an external patent attorney, while patenting firms frequently switch prosecuting providers or simultaneously work with multiple providers.

Sourcing decisions of patent prosecution services is an suitable empirical setting to study how firms cope with unfavourable market exchange conditions due to information asymmetries. This is mainly because the majority of patenting firm-prosecuting law firm relationships are project-based and patenting firms oftentimes have the opportunity to reevaluate their sourcing decisions (Chondrakis et al., 2022; Mawdsley and Somaya, 2018; Moeen et al., 2013). Moreover, firms usually conduct annual reviews of the performance of the law firm providers (Sako et al., 2016).

3.2.2 Patent Litigation Process in the U.S.

As highlighted by Lemley and Shapiro (2005b), patent rights are a particular type of property right. Even after a patent is granted, the right to exclude others from using the patented invention has to be tested in court. While many court decisions are in favor of the patenting firm, sometimes the patenting firm can lose patent rights if the patent is declared invalid or unenforceable. In the U.S., there are two types of patent litigation. The most common one is *patent infringement* lawsuits, where a patenting firm asserts its patent rights against a potential infringer. The other type of patent litigation is known as a *declaratory judgment* (DJ) action, where a party asks a federal court to assert whether or not a particular portfolio of patents is being infringed (Rudy and Black, 2018).

The process of litigating a patent generates information about the asserted patent. In particular, the patenting firm can be informed about how well the litigated patent was writ-

ten. There are at least two reasons why this is the case. First, patent litigation involves patent scrutiny by two highly specialized counseling parties. Similar to patent prosecution, patent litigation is a specialized area of the law. However, it requires a higher degree of specialization and extensive experience beyond the required by the patent bar. Attorneys who specialize in patent litigation usually combine technical expertise in the technological area related to the litigated patent with legal experience in IP lawsuits. Litigating attorneys may also complement their expertise in IP lawsuits with some experience in the jurisdiction the litigation is taking place or against the opposing counseling party.

Second, during the patent lawsuit, these highly specialized attorneys representing both parties would analyze the claimed invention in order to make strong arguments in favor of their clients. For instance, as part of the regular litigation process, both litigating parties work on a pre-trial process known as *claim construction* where they agree and set the scope of each asserted claim. They establish the meaning of the words used in each asserted claim based on the language used in the claim, the overall description of the patent, and even the prosecution history of the asserted patent. After claims have been constructed, both parties present their evidence in favor and against the asserted patent while the court evaluates whether the alleged infringer indeed infringes the patent, the patent is not infringed or the patent is invalid or unenforceable.

In general, the party arguing against the asserted patent will claim invalidity or non-infringement using one of the following arguments. Prior art arguments include anticipation and obviousness arguments. That is, the alleged infringing party argues that there exist prior art references that precede the patented invention. The argument of lack of enablement refers to cases where the patent does not fully describe the invention. Indefiniteness refers to cases where patent claims are too broad. Patents can also be attacked by arguing that the patenting firm tried to omit and/or deceived the USPTO in order to obtain its allowance. Finally, a patent can be attacked in court if the patenting firm offered the invention for sale or it was described publicly at least more than a year before the patent was

filed. An unintended consequence of the patent litigation process is that it reveals clear and objective information on how well was written the patent, and ultimately, it will inform the patenting firm about the quality of the prosecution services received by the law firm that wrote the litigated patent.

3.3 Data

I study how innovative firms react in terms of their sourcing of patent prosecution services when exposed to patent litigation. I assemble a firm-prosecuting law firm-year data set that contains the first patent infringement litigation case for each firm-prosecuting law firm pair from 1982 to 2018. I combine this information with outcomes from firms that have not been exposed to infringement litigation and that access patent prosecution services from the law firms that prosecuted the litigated patents.

The main source of information about patent applications and patent allowance in the U.S. comes from PatentsView. Even though PatentsView performs an initial disambiguation process for patent assignees, several variations in firms' names are found. For this reason, I implement additional standardization and disambiguation techniques. I run standardization routines from the Patent Data Project.[9] These routines perform extensive changes in firm names to avoid non-alphanumeric characters or punctuation. It also conducts a standardization of legal denominations (i.e. 'Incorporated' and 'INC'). After this standardization process, I run two different algorithms that perform fuzzy string matching techniques for disambiguation. I use the Stata command *matchit* that performs a vector decomposition of the assignee names to manually identify different variations of the firm name. I complement this fuzzy matching by using *dedupe*, a python library that uses supervised machine learning techniques for fuzzy matching. After this cleaning process, I identify all patents at the firm level and collect information on their application and grant date, main technology class, and patent attorney.

[9] Available at https://sites.google.com/site/patentdataproject

Exploiting the richness of the bibliographic information included in the U.S. patent applications, I use the name of the patent attorney that prosecuted the patent before the USPTO and match it with the workplace information of all active patent practitioners maintained by the USPTO's Office of Enrollment and Discipline (OED). Periodically, the OED office publishes a repository document known as "Attorneys and Agents Registered to Practice Before the U.S. Patent and Trademark Office". Given that patent attorneys and law firms have incentives to maintain this information up to date[10], I use the closest version of the EOD report relative to patent application to ensure the quality of the patent attorney-law firm match. Additionally, this source allows me to distinguish between in-house or external patent counseling as well as the number of patents prosecuted for each law firm, while keeping track of any change in the workplace for a particular patent attorney. Since most firms outsource their patent prosecution services, I focus on firm-law firm pairs that involved external prosecuting attorneys.

Finally, I complement my data with information on patent litigation by combining two sources of information. First, I access all Federal District Court cases that involved patent infringements from LexisNexis. From the court decision document, I extract the name of the parties involved in the litigation, the type of lawsuit (i.e., infringement or declaratory judgment), the litigated patents, the docket number, and the decision date. From the text of the decision document, I also extract the arguments against the asserted patents. The most common ones are anticipation, obviousness, statutory bars (on-sale and public-use bars), enablement, and indefiniteness. I complement this information with the litigation filing date using the Federal Judicial Center Integrated Database (IDB).[11]

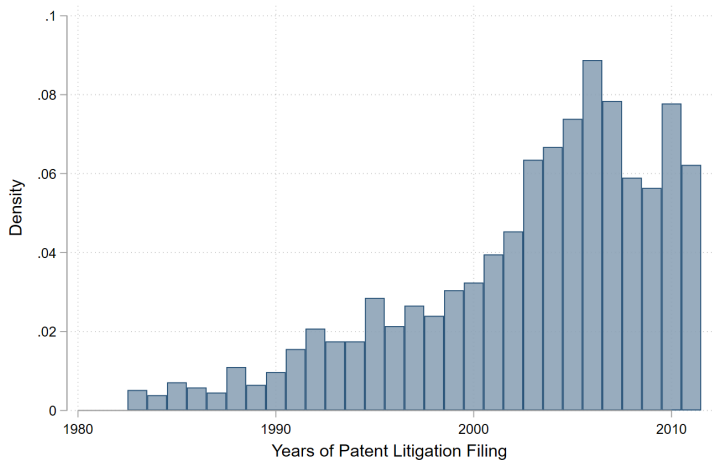
The final sample includes 17,052 unique firm-prosecuting law firms, out of which 1,564 pairs are exposed to patent litigation between 1983-2011. As reported in Figure 3.1, most of the patent litigation cases in-sample occur after 2000. This pattern has corresponded

[10]The USPTO regularly audits the information provided by patent attorneys and law firms in order to ensure the reliability of the information. In case the information is not accurate, patent attorneys are subject to fines and temporary suspensions of the patent bar (Somaya et al., 2007)

[11]Available at https://www.fjc.gov/research/idb/civil-cases-filed-terminated-and-pending-sy-1988-present

with an increase in the overall number of patent litigation cases.

Figure 3.1: Distribution of the Timing of Patent Litigation Cases



Notes: This figure shows the distribution of patent litigation cases from 1983-2011 that are included in the sample. I only consider the first time a patenting firm-prosecuting law firm dyad is exposed to patent litigation.

Table 3.1 shows that the number of prosecuting law firms has increased in the last 50 years. Moreover, the number of unique technology classes in patents has also increased in the last decades following a similar trend as the average number of issued patents per decade.[12] Taken together, I find suggestive evidence that the market for patent prosecution services has grown in the number of alternatives and technological complexity. Additionally, the average number of prosecuting law firms hired per patenting firm has increased over time, but the average length of the client-law firm relationship has declined significantly in the 2010s. This suggests that besides working with more prosecuting law firms, switching law firms is becoming a more prevalent phenomenon.

[12]The number of different technology classes per year is calculated as the number of unique main section, class, and sub-class (up to two technology codes) in patents applied for in that year with at least 10 patents.

Table 3.1: Descriptive Statistics.

	Decades				
	1970s	**1980s**	**1990s**	**2000s**	**2010s**
Average Number of Prosecuting Law Firms per year	456	645	1,118	1,911	1,697
Average Number of Patents per year	11,362	21,938	58,231	116,458	120,303
Average Number of Technological Class Mix per year	510	908	1,430	2,112	4,145
Average Number of Prosecuting Law Firms per Patent Owner	1.5	1.8	2.1	2.7	2.9
Average Tenure in Firm - Prosecuting Law Firm Relationships	16.5	13.9	10.6	9.6	4.8

3.4 Empirical Strategy

Outsourcing firms scour the market in search for the best available supplier given the specific firms' needs. This search becomes significantly difficult for knowledge-based services because of the asymmetric distribution of relevant information about suppliers' capabilities and performance. The supplier have more knowledge about the quality of its services than the buyer. Therefore, firms have to infer this quality based on available (public and private) information.

My goal is to evaluate how firms deal with information when making outsourcing decisions and to what extent they are subject to behavioral biases when making those decisions. In particular, I am interested in understanding to what extent firms exposed to new information about the quality of their current prosecution law firm refine their subsequent sourcing decisions. Tackling this empirical question has several challenges. First, firms may simultaneously access many public and private information sources about the quality of their current prosecution law firm provider. Hence, it is difficult to disentangle the effect of new information on sourcing decisions. Second, we need to consider an empirical setting that allows us to judge the rationality of the observed firm's decisions: do firms over/under-react to new information about the quality of their current prosecution law firm?

I address these empirical challenges by exploiting the patent litigation process as an information-transmission mechanism for the quality of prosecution services. This empirical setting has good coverage of the prosecution quality of economically important patents.

Moreover, I argue that patent litigation is an exogenous variation in the information about the quality of the asserted patents. This exogenous variation in the exposure to information allows us to identify the effect of new information on sourcing decisions after controlling for other sources of information. The underlying identification assumption is that patent litigation is exogenous to sourcing decisions because it is mostly motivated by enforcing existing patent rights, instead of by getting information about the quality of the prosecution services provided by the law firm that prosecuted the asserted patents. In fact, patent litigation can be interpreted as bargaining deals that failed between two parties working on the same technological space (Bessen and Meurer, 2005).

The empirical strategy uses temporal variation in the exposure to the first patent litigation for patenting firm-prosecuting law firm dyads to identify its effect on the relationship between the exposed patenting firm and the law firm that prosecuted the asserted patents. Specifically, I estimate the following equation:

$$Y_{ijt} = \beta LitigationDummy_{ijt} + \gamma_i + \tau_t + \lambda_j + \varepsilon_{ijt} \tag{3.1}$$

where Y_{ijt} is an outcome variable that measures the relationship between firm i and prosecuting law firm j at period t. $LitigationDummy_{ijt}$ is a dummy variable that takes the value 1 after the year in which a patent litigation was filed for the first time for the (i, j) pair and it is equal to 0 otherwise. I consider the filing year of the litigation instead of the decision year as the cutoff because most of the information flow from litigation occurs during the litigation process and not after the court decision has been reached. The coefficient of interest is β which measures the changes in patent prosecution outcomes for the (i, j) pair after it is exposed to a patent litigation case for the first time relative to unexposed patenting firm- prosecuting law firm pairs $(-i, j)$.

I include firm fixed effects (γ_i) to capture firm-specific characteristics that affect the prosecution sourcing decisions. I also include year fixed effects (τ_t) to factor in aggregate

changes in the demand for patent prosecution services over time. Finally, I include patent prosecuting law firm fixed effect (λ_j) to control for differences in law firm characteristics that may affect the patenting firm sourcing decisions. To reduce the impact of other sources of information about the quality of prosecution services of law firm j, I only include untreated patenting firm-prosecuting law firms pairs that work with a law firm exposed to litigation, having an active relationship around the same time and in the same technology class as the patenting firm exposed to litigation.

Interestingly, this empirical setting allows me to identify behavioral biases in sourcing decisions. I exploit the fact that among the fairly standardized set of arguments used in court by the alleged infringing party against the asserted patent, there is variation in the role played by the law firm that prosecuted the asserted patents. Some legal arguments like anticipation (i.e., there is some relevant prior art), indefiniteness (i.e., the terms of the claims are too broad), or lack of enablement (i.e., the written description of the underlying technology is not good enough for a person of ordinary skill in the art to replicate it) can be attributed to the quality of prosecuting law firm. Some other arguments like public-use bar (i.e., the underlying technology was publicly used more than a year before the patent application was filed) or on-sale bar (i.e., the underlying technology was offered for sale more than a year before the patent application was filed) are less related to actions taken by the prosecuting law firm and more related to actions taken by the patenting firm before the patent application was drafted. Under rational behavior, we should expect that exposure to patent litigation has a weaker effect on sourcing decisions in cases of public-use and on-sale bar relative to anticipation, indefiniteness, and lack of enablement cases.

3.5 Results

Outsourcing firms scour the market in search for the best available supplier given the specific firms' needs. This search becomes significantly difficult for knowledge-based services because of the asymmetric distribution of relevant information about suppliers' capabilities

and performance. The supplier have more knowledge about the quality of its services than the buyer. Therefore, firms have to infer this quality based on available (public and private) information.

The main objective is to identify how firms react when new information about prosecution quality arises from patent litigation. In general, firms can react by either reducing work given to the law firm that prosecuted the litigated patent or by terminating the law firm relationship and switching to another counseling source (Coates et al., 2011). In order to capture changes in both margins, I use the following main dependent variables. The first dependent variable refers to changes in the share of prosecuted patents by the law firm that prosecuted the litigated patent. The second dependent variable aims to identify situations in which the firm terminates the law firm relationship. In particular, I calculate a dummy variable that identifies whether the law firms do not prosecute patents for the litigated firm in a given year.

3.5.1 Do Firms Learn from Patent Litigation?

I start by analyzing to what extent patent litigation serves as an information-transmission mechanism for patenting firms in terms of the quality of the patent prosecution of their current provider. I estimate the effects of patent litigation exposure on the relationship between the patenting firm and the law firm that prosecuted the litigated patent in Table 3.2. Column 1 shows that for patenting firms exposed to patent litigation, the share of patents prosecuted by the law firm that prosecuted the litigated patent drops by 7% after patent litigation relative to the share the same law firm represents for non-exposed patenting firms. Similarly, column 2 shows that patenting firms are 12% more likely to terminate the relationship with the law firm that prosecuted the litigated patent relative to non-exposed patenting firms. These results suggest patenting firms weaken their relationship with their current source of patent prosecution services as a result of being exposed to patent litigation.

In Figure 3.2, I check for the presence of pre-trends by performing an event study.

Table 3.2: Changes in the Sourcing of Patent Prosecution as a reaction to Patent Litigation.

	Share of Prosecuted Patents by the Litigated Firm	Likelihood of Termination of the Litigated Law Firm
Patent Litigation	-0.071***	0.122***
Dummy	(0.007)	(0.009)
Mean	0.15	0.80
Patent Owner FE	Yes	Yes
Prosecuting Law Firm FE	Yes	Yes
Year FE	Yes	Yes
N	365,743	365,743

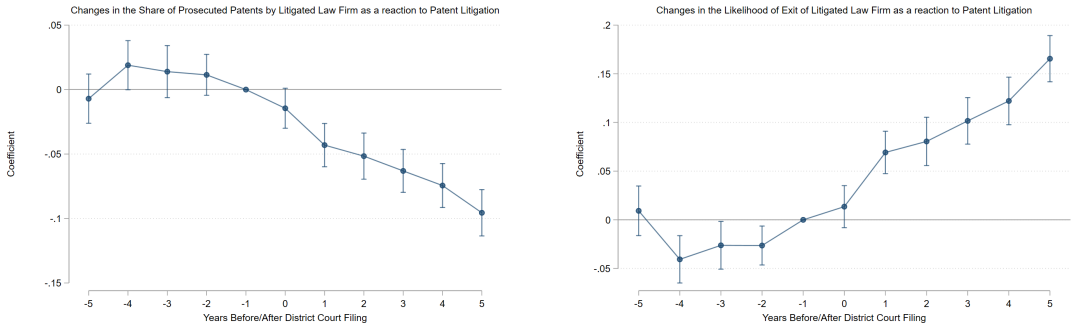
Notes: This table examines the effect of patent litigation exposure on the relationship between patent owners and the law firm that prosecuted the litigated patent. In column 1, I measure changes in the patent owner-prosecuting law firm relationship by using as dependent variable the annual share of prosecuted patents by the focal prosecuting law firm, while column 2 uses as dependent variable the likelihood of termination of the patent owner-prosecuting law firm relationship. The coefficient of -0.071 in column (1) suggests that patent owners exposed to patent litigation reduce the workload of the exposed prosecuting law firm by 7.1%. The coefficient of 0.122 in column (2) indicates that patent owners exposed to patent litigation are 12.2% more likely to terminate their relationship with the exposed prosecuting law firm relative to unexposed patent owners working with the same law firm. All specifications control for *patent owner*, *prosecuting law firm*, and *year* fixed effects. Standard errors clustered at the patent owner and prosecuting law firm level are shown in parentheses. *** p<0.01, ** p<0.05, * p<0.1.

It could be possible that patenting firms were weakening their relationship with the law firm that prosecuted the litigated patent even before the patent litigation occurred. This would reduce the role of patent litigation as a key source of information in the sourcing of patent prosecution services. In Panel A of the figure, we examine changes in the share of prosecuted patents by the law firm that prosecuted the litigated patent, while in Panel B we examine changes in the likelihood the patenting firm terminates its relationship with the exposed law firm. In both cases, no significant pre-trend is detected. Additionally, we observe a significant drop in the share of prosecuted patents (Panel A) and a significant rise in the likelihood of termination a year after the patent litigation is filed. Moreover, this effect is amplified over time.

3.5.2 Heterogeneity Analysis

After showing that patent litigation works as an information-transmission mechanism on the quality of prosecution services for patenting firms, I explore the presence of hetero-

Figure 3.2: Event Study: Changes in the Sourcing of Patent Prosecution as a reaction to Patent Litigation



Notes: These figures examine the effect of patent litigation exposure on the relationship between patenting firms and the law firm that prosecuted the litigated patent. To generate these graphs, I modified equation Equation 3.1 by substituting the $LitigationDummy_{ijt}$ variable with indicator variables for each of the pre-and post-treatment years. I plot the coefficient of these indicator variables using as the dependent variable the annual share of prosecuted patents by the focal prosecuting law firm (left) and the likelihood of termination of the patenting firm-prosecuting law firm relationship (right). The vertical lines indicate the 95% confidence interval. The baseline year is the year previous to the filing of the focal patent litigation. All specifications include the full set of fixed effects as in Table Table 3.2.

geneity effects in the identified reaction. To better understand which type of litigation is more prone to inform patenting firms about the quality of the prosecution services provided by the exposed law firm, I estimate a modified version of equation Equation 3.1 where an indicator dummy that identifies declaratory judgment cases and its interaction with the litigation dummy are added as independent variables. Based on the results in Table 3.3, I find evidence suggesting that which party initiated the patent litigation case has no significant role in the role of patent litigation as an information-transmission mechanism for patenting firms.

I also explore the role of firm characteristics in the effect of patent litigation on the sourcing of prosecution services. First, I evaluate the role of firm size. I proxy firm size by using the *small entity* status recorded by the USPTO. Patent applicants that report having less than 500 employees received the *small entity* status and enjoy a discount on USPTO patent application fees. I define a firm as small if at least 50% of its patent applications received the small entity status by USPTO. In Table 3.4, I add a small firm dummy and its interaction with the patent litigation dummy as independent variables. The results sug-

Table 3.3: Changes in the Sourcing of Patent Prosecution as a reaction to Patent Litigation, by type of Litigation Case.

	Share of Prosecuted Patents by the Litigated Firm	Likelihood of Termination of the Litigated Law Firm
Patent Litigation	-0.072***	0.128***
Dummy	(0.007)	(0.010)
Declaratory Judgment	0.024	0.057
Case Dummy	(0.048)	(0.100)
Patent Litigation	0.006	-0.033
Dummy × Declaratory Judgment	(0.018)	(0.022)
Case Dummy		
Mean	0.15	0.80
Patent Owner FE	Yes	Yes
Prosecuting Law Firm FE	Yes	Yes
Year FE	Yes	Yes
N	365,743	365,743

Notes: This table examines the role of the type of patent litigation on the patent owner's reaction to the exposure of patent litigation. I modify equation Equation 3.1 by including an indicator variable (and its interaction with the $LitigationDummy_{ijt}$ variable) that identifies declaratory judgement cases as independent variables. In column 1, I measure changes in the patent owner-prosecuting law firm relationship by using as dependent variable the annual share of prosecuted patents by the focal prosecuting law firm, while column 2 uses as dependent variable the likelihood of termination of the patent owner-prosecuting law firm relationship. All specifications control for *patent owner*, *prosecuting law firm*, and *year* fixed effects. Standard errors clustered at the patent owner and prosecuting law firm level are shown in parentheses. *** p<0.01, ** p<0.05, * p<0.1.

gest that small firms have a stronger reaction in terms of work reduction, while I find no significant difference in terms of terminations.

The next firm characteristic I explore is patenting experience. I proxy for patenting experience by the total number of patents granted by patenting firms during the sample period. I classify patenting firms based on the quartile of the distribution and create a dummy variable for each quartile. Firms with the lowest patenting experience will be captured by the *Experience Q1* dummy variable, while the firms with the most experience in patenting will be captured by the *Experience Q4* dummy variable. In Table 3.5, I add an interaction term for quartiles 2, 3, and 4, leaving firms with the least experience as the reference category. The results suggest that although there is no significant difference in reaction for the share of prosecuted patents by the litigated firm, firms with the most patenting experience have a stronger reaction when terminating the law firm relationship.

Finally, I explore whether the tenure in the patenting firm-prosecuting law firm relation-

Table 3.4: Changes in the Sourcing of Patent Prosecution as a reaction to Patent Litigation, by Firm Size.

	Share of Prosecuted Patents by the Litigated Firm	Likelihood of Termination of the Litigated Law Firm
Litigation Dummy	-0.066***	0.123***
	(0.007)	(0.010)
Litigation Dummy	-0.032*	-0.010
× Small Firm Dummy	(0.018)	(0.021)
Mean	0.15	0.80
Patent Owner FE	Yes	Yes
Prosecuting Law Firm FE	Yes	Yes
Year FE	Yes	Yes
N	365,743	365,743

Notes: This table examines the role firm size on the patent owner's reaction to the exposure of patent litigation. I identify as small all firms with at least 50% of their patents having the *Small Entity* status at USPTO which benefits firms with least than 500 employees. I modify equation Equation 3.1 by including an interaction of a small firm dummy with the $LitigationDummy_{ijt}$ variable as independent variables. In column 1, I measure changes in the patent owner-prosecuting law firm relationship by using as dependent variable the annual share of prosecuted patents by the focal prosecuting law firm, while column 2 uses as dependent variable the likelihood of termination of the patent owner-prosecuting law firm relationship. All specifications control for *patent owner*, *prosecuting law firm*, and *year* fixed effects. Standard errors clustered at the patent owner and prosecuting law firm level are shown in parentheses. *** p<0.01, ** p<0.05, * p<0.1.

ship affects the response to exposure to patent litigation. I proxy the length in the patenting firm-prosecuting law firm relationship by calculating the difference between the first patent application involving the focal dyad and the litigation filing date. I created three groups: i) short tenure relationships (i.e., less than 3 years of relationship); ii) medium tenure relationships (i.e., between 3 and 7 years of relationship); iii) long tenure relationships (i.e., more than 7 years of relationship). I estimate a modified version of equation Equation 3.1 where the interaction term of medium and long tenure relationships are included in the equation, leaving short tenure relationships as the baseline category. The results in Table 3.6 show that the reaction identified in Table 3.2 is primarily driven by patenting firm-prosecuting law firm relationships with at least 3 years of tenure.

Table 3.5: Changes in the Sourcing of Patent Prosecution as a reaction to Patent Litigation, by Patenting Experience.

	Share of Prosecuted Patents by the Litigated Firm	Likelihood of Termination of the Litigated Law Firm
Patent Litigation	-0.075***	0.078***
Dummy	(0.016)	(0.017)
Patent Litigation	0.004	-0.001
Dummy × Experience Q2	(0.026)	(0.028)
Patent Litigation	-0.028	0.041
Dummy × Experience Q3	(0.023)	(0.025)
Patent Litigation	0.014	0.058***
Dummy × Experience Q4	(0.018)	(0.021)
Mean	0.15	0.80
Patent Owner FE	Yes	Yes
Prosecuting Law Firm FE	Yes	Yes
Year FE	Yes	Yes
N	365,581	365,581

Notes: This table examines the role of patenting experience on the patent owner's reaction to the exposure of patent litigation. I measure patenting exposure by defining the quartile distribution of the total number of patents per patent owner in the sample period. Based on this, I create the indicator variables *Experience Q1*, *Experience Q2*, *Experience Q3*, and *Experience Q4*. I modify equation Equation 3.1 by including the interaction of the top three quartile dummy variables with the $LitigationDummy_{ijt}$ variable as independent variables, leaving *Experience Q1* as the reference category. In column 1, I measure changes in the patent owner-prosecuting law firm relationship by using as dependent variable the annual share of prosecuted patents by the focal prosecuting law firm, while column 2 uses as dependent variable the likelihood of termination of the patent owner-prosecuting law firm relationship. All specifications control for *patent owner*, *prosecuting law firm*, and *year* fixed effects. Standard errors clustered at the patent owner and prosecuting law firm level are shown in parentheses. *** p<0.01, ** p<0.05, * p<0.1.

3.5.3 Overreaction in the Sourcing of Patent Prosecution Services

So far, I find that firms exposed to patent litigation are more prone to reduce or terminate their relationship with the law firm that prosecuted the litigated patent. However, to fully understand the rationality of this firm behavior it is important to characterize whether the firm reacts or overreacts to the litigation signal. In order to identify whether the firms rationally react to the litigation signal, I test the firm's ability to disentangle the source of the potential invalidity.

As suggested by Mann and Underweiser (2012), the validity of a patent mainly depends

Table 3.6: Changes in the Sourcing of Patent Prosecution as a reaction to Patent Litigation, by the Tenure of the Patent Owner-Law Firm Relationship.

	Share of Prosecuted Patents by the Litigated Firm	Likelihood of Termination of the Litigated Law Firm
Patent Litigation	0.060***	-0.077***
Dummy	(0.012)	(0.016)
Patent Litigation	-0.105***	0.146***
Dummy × Tenure	(0.018)	(0.023)
3-7 years		
Patent Litigation	-0.173***	0.269***
Dummy × Tenure	(0.015)	(0.019)
more than 7 years		
Mean	0.15	0.80
Patent Owner FE	Yes	Yes
Prosecuting Law Firm FE	Yes	Yes
Year FE	Yes	Yes
N	365,581	365,581

Notes: This table examines the role of the tenure of the patent owner-prosecuting law firm relationship on the patent owner's reaction to the exposure of patent litigation. My proxy for tenure is the difference between the first patent application and the filing year of the first patent litigation involving the focal dyad. Using this information, I create three indicator dummies identifying relationships with short tenure (less than 3 years), medium tenure (between 3 and 7 years), and long tenure (more than 7 years). I modify equation Equation 3.1 by including the interaction of the medium and long tenure dummy variables with the $LitigationDummy_{ijt}$ variable as independent variables, leaving the short tenure as the reference category. In column 1, I measure changes in the patent owner-prosecuting law firm relationship by using as dependent variable the annual share of prosecuted patents by the focal prosecuting law firm, while column 2 uses as dependent variable the likelihood of termination of the patent owner-prosecuting law firm relationship. All specifications control for *patent owner*, *prosecuting law firm*, and *year* fixed effects. Standard errors clustered at the patent owner and prosecuting law firm level are shown in parentheses. *** p<0.01, ** p<0.05, * p<0.1.

on the nature of the invention, the prosecuting law firm and examiner efforts. For instance, if the patent is granted by a lenient examiner, it is more likely to be found invalid on the grounds of obviousness or prior art. Also, if the patent application is poorly written, it is likely to be found invalid if it is litigated. Thus, patent litigation serves as an information mechanism about the quality of the prosecution service as long as the weakest element of the asserted patent is related to the role played by the prosecuting law firm. In order to evaluate the firm's rationality of the sourcing decisions after being exposed to patent litigation, I focus on cases where the role played by the applicant or the patent examiner against the enforceability of the asserted patent is stronger and evaluate whether firms have

a weaker reaction in those cases.

I start by testing whether patenting firms behave rationally when the main argument against the litigated patent is related to actions taken by the patenting firm even before the patent application was filed at the USPTO. I exploit the fact that in patent litigation cases, the alleged infringer party uses a fairly set of standardized arguments against the asserted patent. Some of those arguments are closely related to the role played by the prosecuting law firm. Some other cases are strongly related to the role played by the patenting firm. This is the case of the arguments of *on-sale* and *public-use* bars. These arguments refer to cases where the alleged infringer counseling argues that the patenting firm offered the underlying technology for sale or publicly described it at least a year before the patent application. In these cases, we should expect patenting firms to have a weaker reaction against the prosecuting law firm because the patenting firm's actions are the key to the weak enforceability of the litigated patent, while the role of the prosecuting law firm is weaker in these litigation cases. In Table 3.10, I estimate a modified version of equation Equation 3.1 where an indicator dummy that identifies litigation cases in which the arguments of on-sale and public-use bar were raised against the litigated patent is added as independent variables. I also include an interaction term with the litigation dummy.

The results for both dependent variables suggest that firms exposed to patent litigation do not have a weaker reaction in litigation cases where the information about the quality of prosecution services is limited. Although statistically insignificant, the sign of the coefficient goes in the opposite direction of a weaker response. I interpret these results as evidence that firms exposed to patent litigation exhibit behavioral bias and overweight the negative signals from litigation when deciding the source of prosecution for subsequent patents.

Next, I check whether patenting firms react by taking some actions against inventors when the litigated patent is attacked using *public-use* litigation cases. In this type of litigation, inventors may have caused the weak enforceability of the patent by publishing a

Table 3.7: Changes in the Sourcing of Patent Prosecution as a reaction to Patent Litigation, by the type of arguments used in court against the litigated patent.

	Share of Prosecuted Patents by the Litigated Firm	Likelihood of Termination of the Litigated Law Firm
Litigation Dummy	-0.070***	0.121***
	(0.007)	(0.009)
Litigation Dummy	-0.052	0.027
× On-Sale/Public-use	(0.063)	(0.073)
Bar Dummy		
Firm FE	Yes	Yes
Law Firm FE	Yes	Yes
Year FE	Yes	Yes
N	365,743	365,743

Notes: This table examines the presence of behavioral biases in the patent owner's reaction to the exposure of patent litigation. I create an indicator variable identifying patent litigation cases where the defendant party uses *on-sale* and *public-use* bar as the main argument against the litigated patent. I modify equation Equation 3.1 by including an interaction term of the *on-sale/public-use* bar dummy variable with the $LitigationDummy_{ijt}$ variable as independent variables. In column 1, I measure changes in the patent owner-prosecuting law firm relationship by using as dependent variable the annual share of prosecuted patents by the focal prosecuting law firm, while column 2 uses as dependent variable the likelihood of termination of the patent owner-prosecuting law firm relationship. All specifications control for *patent owner*, *prosecuting law firm*, and *year* fixed effects. Standard errors clustered at the patent owner and prosecuting law firm level are shown in parentheses. *** p<0.01, ** p<0.05, * p<0.1.

peer-review article or by participating in a specialized conference and publicly exposing the underlying technology before the patenting firm decides to protect the invention by applying for a patent. If this happens to be the case, it would not be surprising if the patenting firm limits the involvement of exposed inventors in subsequent inventions, and therefore, the number of patents listing them as inventors may decline over time. I check this hypothesis by calculating the number of patents per inventor for all inventors whose patent is exposed to litigation where the public-use bar is used as an argument against the patent. Table 3.8 shows that patenting firms do not react against the exposed inventors in cases where there is a reaction against the prosecuting law firm as shown by Table 3.10.

Finally, I assess the patenting firm's reaction in cases where the litigated patent is

Table 3.8: Changes in the Number of Patents per Inventor as a reaction to Patent Litigation.

	Number of Patents per Inventor	
	(1)	(2)
Litigation Dummy	0.088	0.089
	(0.152)	(0.154)
Litigation Dummy		-0.086
× On-Sale Bar Dummy		(0.183)
Mean	0.44	0.44
Patent Owner FE	Yes	Yes
Prosecuting Law Firm FE	Yes	Yes
Year FE	Yes	Yes
N	860,764	860,764

Notes: This table examines the presence of behavioral biases in the patent owner's reaction to the exposure of patent litigation. I create an indicator variable identifying patent litigation cases where the defendant party uses the *public-use* bar as the main argument against the litigated patent. I modify equation Equation 3.1 by including an interaction term of the *public-use* bar dummy variable with the $LitigationDummy_{ijt}$ variable as independent variables and by using the number of patents per inventor exposed to litigation as the dependent variable. All specifications control for *patent owner*, *prosecuting law firm*, and *year* fixed effects. Standard errors clustered at the patent owner and prosecuting law firm level are shown in parentheses. *** p<0.01, ** p<0.05, * p<0.1.

granted by a relatively lenient examiner. Patents granted by a lenient examiner are more likely to be litigated (Feng and Jaravel, 2020) and invalidated mainly because a lenient examiner is more likely to overlook relevant prior art or to grant overly broad claims. Thus, similar to in the cases of patent litigation with on-sale or public-use bar, the role played by the prosecuting law firm in patent litigation cases where the asserted patent was granted by a lenient examiner may be limited.

I calculate the examiner's leniency following Gaulé (2018).[13] The leniency rate is a continuous variable ranging from -1 and 1 and it captures the difference in the patent granting rate of the patent examiner and the average granting rate of all examiners in the

[13] See Appendix subsection 3.7.1 for more details.

same art unit as the focal examiner. Thus, a positive (negative) leniency rate means that the focal examiner has a higher (lower) patent allowance rate than the average examiner in the same art unit at USPTO. I modify equation Equation 3.1 by adding the leniency rate and its interaction with the litigation dummy as independent variables. Table 3.9 show the regression results. These results suggest that the firm reaction against the prosecuting law firm does not depend on the leniency of the examiner that granted the asserted patent.

Table 3.9: Changes in the Sourcing of Patent Prosecution as a reaction to Patent Litigation, by the examiner's leniency rate.

	Share of Prosecuted Patents by the Litigated Firm	Likelihood of Dropping the Litigated Law Firm
Litigation Dummy	-0.040***	0.089***
	(0.009)	(0.011)
Leniency Rate	0.208	-0.672
	(0.203)	(0.474)
Litigation Dummy	0.038	-0.057
$\times$ Leniency Rate	(0.063)	(0.088)
Mean	.16	.79
Patent Owner FE	Yes	Yes
Prosecuting Law Firm FE	Yes	Yes
Year FE	Yes	Yes
N	240,720	240,720

Notes: This table examines the role of examiner leniency on the patent owner's reaction to the exposure of patent litigation. I calculate the examiner's leniency rate as the annual difference in the granting rate of the examiner that granted the litigated patent and the average examiner in the art unit of the focal examiner. This continuous variable range between -1 and 1, where a leniency rate of 1 means the examiner is extremely lenient. I modify equation Equation 3.1 by including the leniency rate variable and its interaction with the $LitigationDummy_{ijt}$ variable as independent variables. In column 1, I measure changes in the patent owner-prosecuting law firm relationship by using as dependent variable the annual share of prosecuted patents by the focal prosecuting law firm, while column 2 uses as dependent variable the likelihood of termination of the patent owner-prosecuting law firm relationship. All specifications control for *patent owner*, *prosecuting law firm*, and *year* fixed effects. Standard errors clustered at the patent owner and prosecuting law firm level are shown in parentheses. *** p<0.01, **

Taken together with the results in Table Table 3.10, these results suggest that firms do not fully consider the source of information from patent litigation when deciding the sourcing of patent prosecution. Firms overreact by over-weighting the negative signals

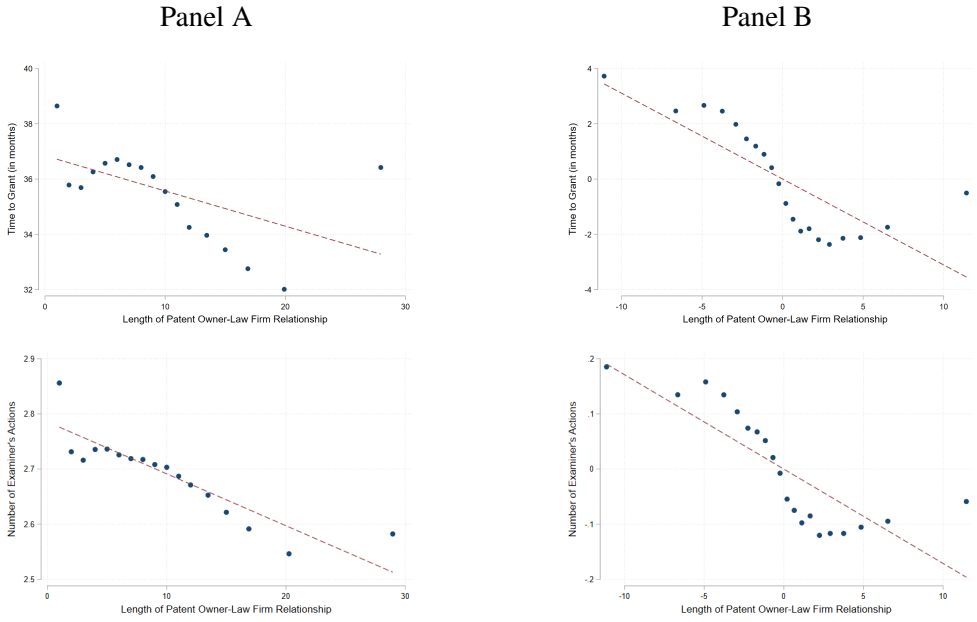
from patent litigation over the source of weakness in the enforceability of the asserted patents.

But, what are the costs of overreacting? When a firm replaces one prosecuting law firm with a new one, it faces the following tradeoff. The switching could improve the quality of the patents if the new prosecuting law firm has a better performance for the firm needs. On the other hand, besides the search costs, there is a short-term adaptation cost that the patenting firm faces whenever it starts a relationship with a new prosecuting law firm. The new law firm has to get to know the patenting firm's technological space and strategic positioning in the market. Also, the prosecuting law firm has to establish a close connection with the inventors involved in the patenting firm technologies. Getting to know the firm and finding synergies between the firm and the law firm could take some time. Hence, a firm will switch to a new prosecuting law firm if the benefits exceed the costs of initiating a new client-law firm relationship. When a firm is overreacting to a negative signal on the quality of its current prosecution source, it is at risk of facing the search and adaptation costs without necessarily improving its current prosecution services.

In Figure 3.3, I show a snapshot of the short-term costs of hiring a new prosecuting law firm. Panel A shows the raw binscatter plot between different patent outcomes and the length of the patenting firm-prosecuting law firm relationship. Panel B shows the same plot after controlling for patenting firm, year, and technology fixed effects. From the two figures on the top, we can notice that the younger a patenting firm-prosecuting law firm relationship is, the more time takes for patents to be granted by the USPTO. Similarly, the bottom figures suggest that the younger is a patenting firm-prosecuting law firm relationship, the more interactions with the USPTO are needed to get a patent granted. While the first evidence suggests that short-tenure relationships are associated with delays in patent protection, the second one points out that it takes more effort to get a patent granted, and therefore it increases the counseling costs to patenting firms to get patent protection. For firms overreacting to information emerging from patent litigation, this would mean that on

average, their subsequent patents would take longer to get granted, while their prosecution services would cost more.

Figure 3.3: Patent Outcomes by patenting firm-Prosecuting Law firm Tenure



3.6 Concluding Remarks

The markets for knowledge-based services have grown continuously in the last decades. When firms are making sourcing decisions, they usually collect information to choose the best available option given the particular needs of the firm. Firms' ability to correctly interpret new information about the quality of the different sources will determine the quality of supplied service. This paper makes an important contribution to the literature that studies firms' sourcing decisions by considering the role of external experts in coping with information asymmetries and by evaluating whether decision-makers exhibit behavioral bias when making sourcing decisions.

By exploiting patent litigation as an exogenous source of information from experts (i.e., litigating patent attorneys) about the quality of the law firm that prosecuted the litigated patents, I find that, on average, patenting firms exposed to patent litigation weaken

their relationship with the exposed prosecuting law firm. Moreover, this reaction seems to be robust to the type of information from patent litigation. That is, firms exhibit a similar behavior even in cases where the information from patent litigation points out that prosecuting law firms may have played a limited role in the alleged lack of enforceability of the patent. I interpret these results as evidence of overreaction to negative information from patent litigation about the quality of the prosecuting law firm.

My findings have clear managerial implications. Firms may access several internal and external sources of information to determine the quality of their current service supplier. Experts' opinions seem to help firms to achieve this task. However, when firms are rethinking their sourcing of knowledge-based services, it is important to separate noise from information. In absence of this, firms are at risk of changing their current sources in situations where they should not do it, or they maintain a relationship with a current source in situations where it is best to switch to another source. Making such mistakes may translate into search and adaptation costs of finding a new service provider without guaranteeing a better service.

3.7 Appendix

3.7.1 Leniency Rates

I calculate the examiner's leniency rate following Gaulé (2018). This is a leave-one-out measurement that considers the grant rate of an examiner relative to the average grant rate of her/his art unit. The examiner and average art unit grant rate is calculated as follows:

$$ExaminerRate_{ijt} = \frac{numberofgrants_{ijt} - 1}{numberofapplications_{ijt} - 1}$$
$$ArtUnitRate_{jt} = \frac{numberofgrants_{jt} - 1}{numberofapplications_{jt} - 1}$$

where examiner i, working for the art unit j in year t has a grant rate $Examiner\ Rate_{ijt}$ based on the fraction of patent applications processed by this examiner in year t that were granted. Similarly, the average grant rate by the art unit, $Art\ Unit\ Rate_{jt}$, is based on the fraction of patent applications received by the art unit j in year t that were granted. In order to reduce the likelihood that patent examiners with a short career at USPTO introduce some noise in the leniency rate measurement, I only consider examiners working with at least 10 patent applications during their role as patent examiners.

Thus, the net leniency rate of examiner i in year t is given by:

$$Leniency_{ijt} = ExaminerRate_{ijt} - ArtUnitRate_{jt}$$

A negative value for $Leniency_{ijt}$ indicates that examiner i is a strict examiner because she/he has a lower grant rate compared to her/his art unit. Similarly, a positive value for $Leniency_{ijt}$ indicates that examiner i is a lenient examiner because she/he has a higher grant rate compared to her/his art unit.

3.7.2 Robustness Test

Table 3.10: Changes in the Sourcing of Patent Prosecution as a reaction to Patent Litigation

	Share of Prosecuted Patents by the Litigated Firm	Likelihood of Termination of the Litigated Law Firm
Litigation Dummy	-0.068***	0.118***
	(0.007)	(0.010)
Litigation Dummy	-0.023	0.029
× On-Sale or Public-use	(0.022)	(0.029))
Bar Dummy		
Patent Owner FE	Yes	Yes
Prosecuting Law Firm FE	Yes	Yes
Year FE	Yes	Yes
N	365,743	365,743

Notes:

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