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ASSETS WITH "WARTS": HOW RELIABLE IS THE MARKET FOR TECHNOLOGY?

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ABSTRACT

Existing research has focused on why and when firms may choose to access the external technology market. Surprisingly, however, less is known about the reliability of the patents attached to these external technologies in the face of litigation. “Weak” external patents expose a firm to the potential loss of downstream revenues. To address this question we construct a novel dataset of patent litigation in the pharmaceutical industry. We exploit a change in U.S. patent law as a natural experiment to test whether external patents are more reliable than those developed internally. We find that acquired patents are more likely to fall during litigation; they are less reliable then internal technologies. Losses lead to an average reduction in market capitalization of $450 million. Overall, our results demonstrate the critical importance of the underlying reliability of external patents and provides a cautionary note to the potential benefits of accessing external technology markets.

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1. Introduction

The development of new technologies has become a process that often involves many firms in multiple stages (Arora *et al.*, 2001). Expanding markets for technology allow firms to boost their performance by combining different technological inputs acquired externally, such as through licensing or acquisitions. While much research on this topic has focused on the supply-side of the technology markets, recent work has begun to analyze the role of the demand-side of the technology markets (Cassiman and Veugelers, 2006; Laursen and Salter, 2006), highlighting the effect of externally acquired technologies on firm performance.

Patents and their enforcement strategies have also increasingly become a crucial component of firm competitive advantage and patent enforcement has been identified as a strategic capability (McGahan and Silverman, 2006; Somaya, 2012). Firms can exploit internally or externally generated technology to boost productivity and firm performance, but once a downstream product is commercialized its protection is limited by the uncertainty of patent litigation (Lemley and Shapiro, 2005). Little is known, however, on the role of acquired patents in case of litigation and their importance as a defensive strategy for protecting downstream revenues. Specifically, if acquired patents are more likely to be considered invalid during litigation, technology buyers can suffer from significant revenue losses. Therefore, it is strategically important to understand the differences between acquired and internally developed patents in the context of patent enforcement.

To fill this gap, we combine insights from the economics and law literature on patent litigation (Lanjouw and Schankerman, 2001; Lemley and Shapiro, 2005; Somaya, 2012) with research on markets for technology (Gambardella *et al.*, 2007; Arora and Gambardella, 2010) to provide new evidence on the reliability of acquired patents in litigation cases. In particular, we

analyze litigation challenges and outcomes of internally developed or externally acquired patents, including the impact of patent litigation on subsequent revenue loss if patents are held invalid.

To answer our research question, we focus on the pharmaceutical industry and on the early entry of generic products through a specific regulatory mechanism called a Paragraph IV certification or challenge.[1] In the U.S., new branded chemical-based drugs are granted data exclusivity that runs in parallel with patent protection. After the expiration of data exclusivity, generic manufacturers can challenge a branded product by filing a Paragraph IV challenge with the FDA that usually results in litigation.[2] This unique setting offers us the opportunity to compare internally generated and externally acquired patents and their ability to successfully defend their incumbent position through litigation. Our results suggest that external patents are more likely to fall during patent litigation. This loss is significant because it allows for early entry by generic manufacturers, negatively impacting a pharmaceutical firm's future revenues. We approximate this loss through the use of an event study and find that a litigation loss corresponds to a real reduction in firm market capitalization of between $446m and $451m.

Our results provide a note of caution to the benefits associated with external technology acquisition in boosting innovative performance. To our knowledge this is the first paper that separates and analyzes the effects of internal and external patents on the probability of litigation, final litigation outcomes and the resulting impact on firm market value. We contend that the

[1] Interestingly, and more generally, sophisticated investors have been using Inter Partes Review (IPR) petitions to challenge patents they feel should be invalidated. Investors appear to be searching for questionable patents, filing an IPR petition and concurrently selling short the company's stock. IPR petitions were created by Congress in 2011 to fight patent-trolls and are evaluated by a panel of three administrative judges. http://www.wsj.com/articles/hedge-fund-manager-kyle-bass-challenges-jazz-pharmaceuticals-patent-1428417408

[2] The interested reader can see Voet (2013) for a complete discussion of the Paragraph IV challenge process.

reliability of external patents during *ex post* litigation is as important as the value of external technology itself.

Our findings also call into question the due diligence process firms undertake prior to licensing a patent. If firms knowingly are licensing technologies with known patent deficiencies or "assets with warts" then our results suggest that firms may need to identify and license potential technologies *prior* to their initial patenting. In this manner, the licensing (pharmaceutical) firm would be able to direct (and fund) the writing of the focal patent. As we will discuss, these firms have more experience writing patents and greater resources to commit to the patenting process.

The paper is organized as follows: Section 2 reviews the current literature on external technologies and patent litigation. Section 3 describes our industry setting. We discuss our data and empirical findings in Sections 4 and 5, respectively. In Section 6, we quantify the economic value of a litigation loss and we discuss the implications of our findings and conclude in Section 7.

2. The reliability of externally acquired patents

In the last few decades the importance of external technologies in boosting innovative activity has grown dramatically and an extensive stream of literature has developed focusing on the role played by technology commercialization, especially through licensing (Teece, 1986; Arora *et al.*, 2001; Gans *et al.*, 2002; Chesbrough, 2003; Arora and Ceccagnoli, 2006; Gambardella *et al.*, 2007; Arora and Gambardella, 2010). In many industries, firms utilize and build on external innovation to maintain their competitive market position, suggesting that markets for technology are a key component of a firm's innovative effort. For instance, Scherer (2010) shows that a larger proportion of revenues for pharmaceutical companies are derived

from products that were discovered outside of the firm. Similarly, Ceccagnoli *et al.* (2010) support this finding in their sample of new drugs introduced into the market; almost half of the patents linked to new products were developed outside the firm.

Despite the positive effects related to external technologies, there are potential downsides that may affect the ability to realize the payoffs generated by technology acquisition. First, contractual uncertainties can undermine the supply of technologies. For example, uncertainty and opportunistic behavior may increase transaction costs thereby reducing technology transfer (Williamson, 1985). Second, the level of tacit knowledge may reduce the positive spillovers generated by the transfer. In fact, when knowledge is difficult to transfer, the incentive to acquire external technologies may be reduced (Kogut and Zander, 1993; Ceccagnoli and Jiang, 2013).

Previous analyses on optimal patent policy have usually assumed that there is no uncertainty about the scope of patent protection (Gallini, 1984; Gallini and Winter, 1985). However, subsequent perspectives recognize that patent protection is imperfect until it successfully survives a challenge in court (Shapiro, 2003; Lemley and Shapiro, 2005). As Lemley and Shapiro (2005) explain, the strength of patents is linked to the examination process and, in general, the structure of patent review favors the approval of weak patents. As a result, almost half of challenged patents are found invalid when litigated. For this reason, patents have been defined as "probabilistic" since they do not confer an absolute right to exclude imitators but they confer the right to try to exclude them through litigation (Lemley and Shapiro, 2005; Hemphill and Sampat, 2011).

Existing research has extensively focused on either the role of external patents in boosting a firm's innovative effort or on the determinants and conditions that facilitate technology transfer. However, there is no clear evidence of the reliability of acquired

technologies. Previous work comparing the quality of internally generated and externally acquired technology has focused on assessing the importance of the "lemons problem" in affecting technology trade. Asymmetric information between technology buyers and sellers could lead to lower-quality technology transactions, which would result in higher quality internally developed technology. While empirical results to date are scant and mixed, a recent review of this literature suggests the information problems have been overemphasized and that, especially in the context of licensing in the pharmaceutical industry, "…licensed compounds appear to be drawn from the same distribution as the internally generated compounds of the licensor" (Arora and Gambardella, 2010). While we do not directly contribute to this debate, our work shifts the focus of the comparison downstream by comparing the quality of internal and external technology from the point view of its legal strength rather than the technological quality (as measured by the probability of successful development).

Our focus is on the extent to which firms are able to appropriate the returns generated by external technologies once embedded in commercialized products. The argument behind this logic is that holding a patent in the early stages, and conditional on successful development, it may be easier to appropriate the economic rewards of the technology. If acquired technologies are more reliable, from a legal standpoint, than those developed internally, firms may reduce the litigation uncertainty and increase their ability to appropriate the monetary effects of innovation.

Patents acquired through the markets for technology may differ in quality than those developed internally. Large pharmaceutical companies typically have an in-house patent department that has a quality assurance program that emphasizes best practices in drafting and prosecution of patents (Knowles and Higgins, 2011). These in-house attorneys have been trained in potential pitfalls that could lead to invalidation and are kept closely up to date on the

company's own litigation experiences and those of similar companies. Patent attorneys can easily access research notebooks and data that can be discussed with the scientists. This fully transparent landscape is valuable to determine whether the final granted patent can be relied upon by the company to a hold a market (Knowles and Higgins, 2011). These large companies also have the resources to engage the most experienced, high quality external patent attorneys, if needed.

In contrast, suppliers of technology such as smaller research-intensive firms may not have any experience with Hatch-Waxman generic litigation (*i.e.*, Paragraph IV challenges) or global litigation scenarios. Moreover, the licensor may only have limited research assets and little commercial experience. Often these companies are resource constrained (Lerner *et al.*, 2003) and patents are drafted by outside counsel who themselves may have limited experience in these issues (Knowles and Higgins, 2011).

We know from conversations with senior industry executives that externally acquired patents go through a significant due diligence process. However does this selection process ensure lower quality patents are simply not acquired? While this may be the goal, the process is more nuanced and opaque. For example, during due diligence counsel for the licensee (large pharmaceutical company) may not be allowed to inspect notebooks or raw data before giving a binding offer. In some cases access to inventors may even be restricted during the negotiation phase, or important contracts or documents withheld or heavily redacted (Knowles and Higgins, 2011). Compounding these issues is often the limited supply of licensable drug leads within highly disaggregated markets. As such, pharmaceutical companies may knowingly license 'assets with warts' (Knowles and Higgins, 2011). The result of this complex, nuanced and often

opaque process is that internally generated patents may end up exceeding the average quality of externally acquired patents.[3]

In sum, due to the offsetting effects on the legal quality of internal and external patents highlighted above, answering the question of reliability of external patents is inherently empirical in nature. In what follows, we therefore turn to our empirical framework.

3. The pharmaceutical industry and its regulatory environment

The pharmaceutical industry provides a natural setting for our analysis. Because of the regulatory environment in the U.S., generic manufacturers can litigate the patents of a branded drug before they expire thereby potentially undermining the branded companies incumbent position. There is an extant literature on generic entry (Scott Morton, 2000; Reiffen and Ward, 2005; Grabowski and Kyle, 2007) along with an emerging literature relating this entry to competition and innovation (Branstetter *et al.*, 2011, 2014). An additional stream of research has discussed patent challenges and their role in affecting the length of market protection (Grabowski, 2004; Grabowski and Kyle, 2007; Hemphill and Sampat, 2011). In general, an increasing number of drugs are being challenged and those with larger sales attract more competitors (Scott Morton, 1999; Grabowski and Kyle, 2007; Hemphill and Sampat, 2011). Berndt *et al.* (2007) finds similar results on the increasing rate of Paragraph IV challenges. Despite their focus on the impact of authorized generics, which may reduce the incentive for entry by new firms, the authors conclude that the number of Paragraph IV challenges remains high.

[3] It is critical to note that a weak or 'bad' patent does not mean the drug molecule or underlying technology is 'bad'. In fact, from our field interviews we actually anticipate the opposite – a pharmaceutical company may license a weaker patent, the proverbial 'asset with warts', precisely because of the promise of the underlying molecule or technology. In this respect, our paper builds upon Arora *et al.* (2009). They focus on the differences between internally and externally developed drugs and show that external products are equally likely to succeed as internally developed molecules. However, that paper implicitly makes an assumption about the relative reliability of the internal and external patents. Equal success of clearing clinical trials and making it to market means less if the underlying patents are not reliable.

This last stream of literature suggests that generic challenges are driven by branded drug sales and as a consequence of this increase in competition, branded companies face an increased uncertainty over future revenues and reduction of R&D incentives. While results converge towards the role played by sales as an incentive for generic entry, there is little evidence on the role played by patents and their characteristics in the pre-entry decision and lawsuit outcome.[4] To our knowledge, Hemphill and Sampat (2011) provide the first attempt to link litigation initiated by generic manufacturers to patent characteristics. They find that conditional on sales and drug characteristics, "weaker patents", defined by citations and family size, are more likely to face Paragraph IV challenges. In a follow up study, Hemphill and Sampat (2012) expand their findings on Paragraph IV challenges confirming that patents that do not refer to the drug's active ingredient draw more challenges. They argue that these types of patents are often used by branded companies to extend the effective market life of a drug, however the disproportionate increase in challenges towards these patents limits the effectiveness of "evergreening".

Branded drug protection was fundamentally changed with the passage of the Drug Price Competition and Patent Term Restoration Act in 1984, informally known as the Hatch-Waxman Act (HW). HW was introduced with the intent to establish a balance between incentivizing innovative pharmaceutical research on the one hand and providing access to cheaper (generic) drugs on the other hand. Under HW once a drug is approved, pharmaceutical firms are required to list materially relevant patents in the FDA's Orange Book.[5] The FDA does not actively regulate the patents that are listed and only these identified patents can be used to protect the

[4] It should be noted that while product sales are important, we see a wide variance in the distribution of sales of those products that get challenged (Grabowski and Kyle, 2007).

[5] The FDA Orange Book Preface states the following: "*The patents that FDA regards as covered by the statutory provisions for submission of patent information are: patents that claim the active ingredient(s); drug product patents which include formulation/composition patents; use patents for a particular approved indication or method of using the product; and certain other patents as detailed on FDA Form 3542."* Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm

drug in case of litigation.[6] Since the FDA has not precisely defined "materially relevant" innovations, however, branded companies enjoy a certain level of freedom in selecting the patents to list.

HW introduced "data exclusivity" for branded drugs in parallel to patent protection. Data exclusivity is an exclusive marketing right granted upon approval and it runs concurrently with patent protection. It protects the ownership of the underlying clinical trial data and prevents the entry by generic manufacturers during that time period. It was intended to provide branded products monopoly protection should underlying patent protection be limited. The majority of chemical-based drugs receive 5 years of data exclusivity protection. Orphan drugs receive 7 years of protection while reformulations of an existing product receive only 3 additional years. Firms can gain an additional 6 months of data exclusivity for the addition of a pediatric indication. More recently, the GAIN Act provides an additional 5 years of data exclusivity for select antibiotics.

Data exclusivity was balanced by a system that facilitated generic entry. Under this system, the FDA can approve a new generic drug through an Abbreviated New Drug Application (ANDA). To be approved, generic manufacturers only have to demonstrate that their product is bioequivalent to a referenced NDA's branded product (as opposed to running their own costly clinical trials). While there are four 'certifications' that a generic manufacturer may claim in order to enter the market, our focus is in the fourth certification, Paragraph IV.[7] This is the only

[6] This lack of oversight has led to criticisms of potential gaming of patent listings (Bulow, 2004) and evergreening or attaching new patents in the FDA Orange Book after approval by the FDA (Hemphill and Sampat, 2012)

[7] Other certifications reflect a less competitive choice: under *Paragraph I and II*, patent protection has already expired therefore generic competitors can directly enter the market. Generic manufacturers apply for *Paragraph III* certifications when patent protection is still active, however the generic version of the drug can be commercialized only after patent protection has expired.

pathway that allows for the direct challenge of underlying branded patents prior to their expiration.

The process related to Paragraph IV challenges is not linear and it is conditioned by several strategic decisions. The process starts with the Paragraph IV challenge by a generic manufacturer. Paragraph IV applicants are required to list and identify all the patents they want to challenge. As part of the challenge, the ANDA filer has to notify the patent holder about the challenge and submit a detailed statement of the legal basis by which its product does not infringe on the listed patents or why the patents are invalid. A generic product may not infringe on the patent if the manufacturer has discovered a way to produce a bioequivalent drug through a different process, it has discovered a different structure of the same active ingredient, or it has adopted a different delivery mechanism. Alternatively, a patent may be considered invalid if it was wrongfully granted, it was anticipated by prior art, or if the invention was in public use for more than one year before the USPTO application (Herman, 2011).

Once a branded patent holder (pharmaceutical firm) receives notice, they have 45 days to initiate a suit. If an ANDA filer (generic manufacturer) wins the lawsuit, HW awards a 180-day exclusivity right to the first Paragraph IV applicant. It has been estimated that the 180-day exclusivity period generates potential revenues of approximately $60 million, more than compensating the generic challenger for the cost of litigation (Higgins and Graham, 2009). Figure 1 summarizes the Paragraph IV challenge process.

<Insert Figure 1 Here>

As described by (Knowles, 2010), the regulatory framework faced by pharmaceutical firms can be modified both by new legislation and by the courts that apply them. A change in the interpretation of patent law, for example, may alter the validity of patents (or vice versa). We

specifically focus on one such critical 2007 Supreme Court case, *KSR International Co. v. Teleflex Inc*. This case affected whether a patent was considered non-obvious based on existing prior art and involved the placing of a sensor on a fixed pivot point of the accelerator pedal of an automobile.[8] At first, the Court of Appeals for the Federal Circuit (CAFC) affirmed the validity of the patent using the "teaching, suggestion, or motivation" test (TSM test). Under this test, a patent is proved obvious only if there is some motivation or suggestion to combine prior art that can be already found in the prior art or in the knowledge of a person with ordinary skill in the art.

However, the U.S. Supreme Court revised the CAFC decision and decided the TSM test was too narrow and rigid. It concluded that an innovation could be obvious even if prior art did not teach, suggest or motivate the innovation. The Supreme Court considered the Teleflex patent as obvious and invalid and in doing so introduced a broader (and vaguer) definition of obviousness. With this broader standard in place the obviousness of some branded product patents became questionable. Thus, *KSR* should make it more likely that a generic firm initiates a Paragraph IV challenge. A recent report by PwC (2013) appears to bear this out; generic litigation jumped from 43 cases during 2001-2006 to 77 cases in the more recent post-*KSR* 2007-2012 time period (PwC, 2013).

4. Data description and methodology

Our sample consists of all the new chemical entities approved by the FDA between 1995 and 2004 and their reported patents listed in the FDA Orange Book. Our analysis is limited to drugs approved up to 2004 in order to allow all our drugs to have the opportunity to be targeted

[8] U.S. Supreme Court Case No. 04-1350. http://www.supremecourt.gov/oral_arguments/argument_transcripts/04-1350.pdf

by a Paragraph IV challenge. Our final sample consists of 324 unique chemical-based drugs approved by the FDA between 1995 and 2004, covered by 773 unique patents.[9]

We linked the drugs and patents collected from the FDA Orange Book to several data sources. First, litigation data was gathered from The Paragraph Four Report. This data includes information on the number of Paragraph IV applicants, the products and patents being challenged, the status of pending court cases and the ultimate court decision. Next, we obtained drug level data on sales and promotion expenditure from IMS MIDAS™. Patent approval dates, number of claims, citations, and type were collected from Delphion™, IMS Patent Focus™ and the United States Patent and Trademark Office (USPTO). Finally, stock market data was obtained from the Center for Research in Security Prices (CRSP).

We identify whether a patent was acquired or internally developed through the reassignment database of the USPTO. We compared the original patent assignee with the company that commercialized the focal drug; if the two were different we defined that patent as externally developed. Descriptive statistics and correlations are provided in Table 1 and 2, respectively. All financial variables are converted into constant 2000 U.S. dollars and foreign currencies are converted by using their respective average twelve-month exchange rate against the U.S. dollar.

<Insert Table 1 and Table 2 here>

Our empirical approach relies on the adoption of a difference-in-difference (diff-in-diff) specification (Angrist and Pischke, 2008). The diff-in-diff estimator identifies the effect of an exogenous event on two groups of observations (*e.g.*, firms and state). The simplest set up includes two groups observed for two time periods. One of the groups is exposed to a treatment

[9] We exclude biologic-based drugs in our sample because they are not covered by the same HW procedures as chemical-based drugs. In short, there is not (currently) an equivalent Paragraph IV mechanism for biologic-based drugs.

(exogenous shock) in the second period but not in the first period. In a non-parametric approach, the average gain in the second (control) group is subtracted from the average gain in the first (treatment) group. This removes biases in second period comparisons between the treatment and control group that could be the result from omitted variables given differences between the two groups and it reduces biases from comparisons over time in the treatment group that could be the result of trends.

Practically, we exploit the 2007 *KSR* U.S. Supreme Court decision as an exogenous temporal shock to estimate the diff-in-diff model. We consider externally acquired patents as the treated group to be compared to the control group of internally developed patents. Our main reported results are from a linear probability model. We also show the results are robust to logit and probit formulations. This robustness confirms that there is typically little qualitative divergence between the different specifications (Angrist and Pischke, 2008).

First, we analyze the probability of Paragraph IV related litigation. Our intent is to understand whether the new legal environment (post-*KSR*) has an impact on the possibility of challenge after controlling for other important factors, such as drug sales. Second, conditional on being challenged, we estimate the diff-in-diff model on the lawsuit outcome to estimate the implications of the change in patent law on patent litigation. Finally, we conduct an event study on the firms whose drugs faced a Paragraph IV challenge in order to estimate the economic impact of litigation outcomes.

We follow McWilliams and Siegel (1997) to compute cumulative abnormal returns (CAR). First we estimate the market model using OLS over a period of 250 days prior to the event. The estimation equation is the following:

(1) $$R_{it} = \alpha_{it} + \beta_{it} * R_{mt} + \epsilon_{it}$$

where R_{it} is the return for firm *i* at time *t* and R_{mt} is the market return. The estimated OLS parameters represent the stock's "normal" return with respect to the market in a period prior to the event. The abnormal return (AR) is defined as the return during a time span that includes the event, in our case the generic challenge, minus the estimated return accounting only for the market effect. In other words, the abnormal return is the forecast error between the "actual" and the "normal" rate of returns. Empirically it is estimated as follow:

(2) $$AR_{it} = \epsilon_{it} = R_{it} - (\alpha_{it} + \beta_{it} * R_{mt})$$

After estimating the abnormal returns for each firm *i* at time *t*, the CAR variable is computed as the cumulative value of the standardized abnormal returns. The CAR equation is:

(3) $$CAR_i = \left(\frac{1}{k^{0.5}}\right) * \sum_{t=1}^{k} \frac{AR_{it}}{SD_{it}}$$

where AR_{it} is defined by Equation 2, SD_{it} is the abnormal return standard deviation and *k* represents the cumulative number of days. We consider different event windows as a robustness check for our analyses: we assume *k* equal to 3, 5 and 7 days. The event date is defined as *t*=0 and it represents the date of the litigation outcome.[10]

Finally, we multiple CARs by relevant firm market capitalization data. We argue that this monetized value of the abnormal return represents the potential change in the discounted value of future streams of revenues. For example, a negative outcome of a Paragraph IV challenge should elicit a negative CAR. When multiplied by a firm's market capitalization, the value should

[10] No confounding events were identified over any of the event windows tested.

reflect the discounted value of lost future revenues due to early generic entry. On the other hand, if branded patents survive a Paragraph IV challenge, generic manufacturers cannot enter the market. In this case, we expect no abnormal market response because there will be no unanticipated expected change in the level of market competition. In other words, a branded company that wins a Paragraph IV challenge will be expected to continue to generate the already anticipated future revenues.

4.1. Dependent variables

We rely on data from The Paragraph Four Report to create a dummy that equals one for a drug that was challenged in a given year between 1999 and 2010, and zero otherwise. We are able to identify a total of 264 unique Paragraph IV challenges. Among our drugs about 51% experience at least one Paragraph IV challenge; Figure 2 maps the trend in challenges on a yearly basis.

<Insert Figure 2 Here>

Prior to 2003 only 33 drugs were challenged. In the subsequent 5 years (2004-2008), however, this number increased to 132, with 99 of these challenges occurring in the final two years. The horizontal lines (Figure 2) represent the average number of challenges in three different periods. It is easy to visualize the impact of policy changes on the number of Paragraph IV challenges. Firstly, after the introduction of the Medicare Modernization Act in 2003, generic manufacturers embraced Paragraph IV challenges as a viable strategy due to lower litigation costs.[11] Secondly, we observe another shift in the number of drugs challenged after 2008. This

[11] The Medicare Modernization Act has limited the ability to "stack up" multiple 30-month periods of protection, a strategy known as *evergreening*. This changed forced pharmaceutical companies to make all their claims against a generic manufacturer in their initial lawsuit in response to a Paragraph IV challenge (Bulow, 2004).

increase is related to changes in patent law due to the *KSR* decision; the average number of challenges increased by 87% compared to the previous period.

Our first dependent variable is a patent level dummy, *Paragraph IV (patent level)*, that equals one if the ANDA generic filer challenges a focal patent in a given year, and zero otherwise. Out of the 773 unique patents, 356 of them were challenged at least once in our data. As shown in Figure 3, the distribution of patents per number of Paragraph IV challenges is skewed towards zero. About 17% of our patents (131 patents) received at least 2 challenges, and 29% (225 patents) were litigated only once. Among the 417 patents that were not litigated, 349 patents are listed for drugs that did not receive any Paragraph IV challenges while 68 were not challenged but listed under drugs that were litigated.

<Insert Figure 3 Here>

Our second dependent variable classifies the *Paragraph IV lawsuit outcome*. We identify two potential scenarios: first, the court decides on the validity of the litigated patents, and second, the companies can privately settle the case. For the latter, we collected data from companies' statements and SEC filings to identify the terms of the agreements. We categorized four different outcomes:

1. The court rules in favor of the Paragraph IV applicant (*i.e.*, generic manufacturer). One or more patents listed in the FDA Orange Book are considered either invalid or not infringed on by the generic product. It follows that the generic manufacturer can enter the market
2. The parties settled prior to trial and the agreement, in contrast to the previous case, allows generic manufacturers to enter as an "authorized generic". We coded this outcome as

favorable to generic manufacturers because the branded drugs market share will begin to diminish.

3. The parties settled prior to trial, but the agreement either delays or blocks generic entry. We coded this outcome as favorable to a pharmaceutical company.
4. The court rules in favor of the pharmaceutical company. Patents listed in the FDA Orange Book are considered either valid or infringed by the generic product and therefore, the generic manufacturer cannot enter the market.

To create the outcome dummy variable, we classify the first two cases as favorable to generic manufacturers and the last two cases as favorable to pharmaceutical companies. Therefore, *Paragraph IV outcome* is a dummy that equals one in case of favorable outcomes for generic manufacturers, and zero otherwise. On average, a favorable outcome for generic manufacturers occurs in about 47% of the cases and is almost always equally divided between court decisions (63 occurrences) and settlement agreements (61 cases).

4.2. Independent variables

External Patent is a dummy that takes a value of one if a patent was originally assigned to a different company than the pharmaceutical company that marketed the drug, and zero otherwise. With the available data we are not able to identify the method of procurement (*i.e.*, licensing or acquisition) because we can only track changes in patent assignees over time and compare the original assignee with the company that marketed the branded drug. The number of external patents does not significantly differ from internal patents; 383 patents in our sample (about 49%) represent external technologies. Additionally, only 41% of these patents (159 out of

383 external patents) are challenged compared to 50% of the internal patents (197 out of 390 internal patents).

To implement our diff-in-diff estimation strategy, we create a dummy (*2007 Dummy*) that equals one for all the observations after the 2007 *KSR* Supreme Court decision. The dummy variable identifies the time period after the Supreme Court decision, which we consider an exogenous event. While the case was known the final determination of the case was unknown as was its impact on the pharmaceutical industry. Ultimately, the case represented an important legal change that affected the outcome of Paragraph IV challenges.

Next, we define yearly branded product level sales, *Drug Sales*, as one of our drug-level independent variables. Our intent is to study whether higher revenue drugs influence the decision for entry by generic manufacturers since more profitable segments may attract more competitors. Prior literature has shown that more profitable drugs have a higher probability of being attacked (Grabowski and Kyle, 2007; Hemphill and Sampat, 2011). Similarly, Caves *et al.* (1991) ENREF 11 find that market share is a key determinant of generic entry.

To control for differences across types of patents we include a set of dummies, *Type of Patent*. We rely on data from the IMS Patent Focus™ database that describes the function and use of focal patents. Each patent is categorized into one of the following groups: product patent, compound patent, method of use patent, drug delivery system and "other", which includes process patents. Based on this classification, we create five dichotomous variables. In our sample approximately, 21% of the patents are products, 21% are classified as method of use patents, 34% of the patents protect the drug composition, and finally, 14% are drug delivery system patents. On average, we do not find significant differences in the distribution of patent types between internal and external technologies.

Based on prior research, we also include four variables to control for patent characteristics (Allison and Lemley, 1998; Lanjouw and Schankerman, 2001; Lemley and Shapiro, 2005). First, we collected data on both *Forward* and *Backward* citations. Forward citations are measured by cumulating the number of citations received by a patent from its grant year up to any given year and represent the impact of the focal patent on subsequent innovations. Patents with more forward citations may be more "important" due to their impact on future innovation. Additionally, the economic value of patents may be positively related to the number of times the patent is cited. Backward citations, on the other hand, equal the number of existing patents cited and denote how fundamental and innovativeness of a patent. Patents with significant numbers of backward citations extensively build on existing knowledge and therefore may be less innovative. Among the challenged patents in our sample, external technologies have significantly fewer backward citations than those developed internally.

Second, we use the numbers of *Claims* as a measure of patent quality (Lanjouw and Schankerman, 2004). The principal role of claims is to define and detail the novel features of the invention. We construct a variable that counts the total number of claims in all the patents in our sample. There are not any significant differences between internal and external patents.

Third, following Hemphill and Sampat (2011), we control for the positive effect that late expiring patents can have on the market life to the focal drug and that the timing of patenting may affect generic entry. *New Patent* dummy takes a value of one if, within the patent portfolio for a single drug, the grant date of a patent is the latest, zero otherwise. By doing so we are able to trace from a temporal point of view which patents for a specific drug have the latest grant date. Particularly in the pharmaceutical industry, the timing of technology patenting is not necessarily coincident with its commercialization.

Next, we add controls for drug specific characteristics. *Patent per innovation* controls for the total number of patents attached to the focal NDA in the FDA's Orange Book. By doing so, we take into consideration the different sizes of the set of patents protecting each drug. On average, drugs in our sample have four patents listed in the FDA Orange Book while the drug with the largest set has 18 patents attached.

Companies may also have different incentives in protecting their products. In particular, we control for the relative importance of a focal drug to a specific company. We define *Drug importance* as drug sales divided by firm sales in any given year. We control for the drug's relative importance because we assume that in case of a Paragraph IV challenge a company will be more likely to commit greater resources to their most valuable products.

Finally, we include a dummy to account for challenges that include Teva Pharmaceutical Industries (*Teva dummy*). Teva is the largest generic company and has been active with Paragraph IV challenges.[12] In our sample Teva is involved with about 25% percent of Paragraph IV cases (66 cases out of 264). We build a dichotomous variable that equals one if Teva is among the first group of challengers in a Paragraph IV challenge, zero otherwise.

5. Results

5.1. Probability of receiving a Paragraph IV challenge

In our first set of analyses, we estimate the probability of a Paragraph IV challenge at the patent level. Table 3 reports these estimates based on a variety of empirical specifications. Models 1 through 5 report the results computed with a linear probability model, Model 6 through 10 are estimated with a probit model while Models 11 through 15 are based on a logit model. We find no evidence of a difference between internal and external patents; the interaction terms

[12] http://www.tevapharm.com/en-US/About/Pages/AboutUs.aspx. Access 09/26/2011

between our primary dummies (*External Patents* and *2007 Dummy*) are never significant. These results should not be surprising given the common practice to challenge almost all patents listed in the FDA Orange Book.

<Insert Table 3 Here>

Consistent with prior findings, we find that drug sales drive most of the variation in explaining the probability of a generic challenge (Scott Morton, 1999; Grabowski, 2004; Grabowski and Kyle, 2007; Hemphill and Sampat, 2011). As demonstrated by Higgins and Graham (2009), the first generic producer to enter the market is granted 180 days of market exclusivity, which translates into approximately $60 million in profits. Therefore, there is more of an incentive to attack and focus on the most profitable drugs. In addition, it has also been shown that sales affect the intensity of challenges, conditional on a challenge occurring (Berndt *et al.*, 2007; Hemphill and Sampat, 2011).

We find a positive relationship between the 2007 *KSR* Supreme Court decision, *2007 Dummy*, and an increase in litigation. This suggests that generic manufacturers are increasing their Paragraph IV challenges in order to exploit the new post-*KSR* legal environment. Given the less restrictive validity test for patents, generic manufacturers may perceive the new legal environment as more favorable, thus creating more incentives to challenge branded drugs. This increase in Paragraph IV challenges was an unintended consequence of *KSR*. We could find no discussion of this feared development in the *KSR* decision or in any of the Amicus briefs filed in the Supreme Court case.

5.2. Paragraph IV outcomes

After generic manufacturers file a Paragraph IV challenge, entrance into a market is defined by either a positive outcome of the litigation or by a favorable settlement with the pharmaceutical firm.[13] Therefore, it is important to understand the role of patents in determining the litigation outcome for each challenge. We do so by estimating litigation outcomes using a diff-in-diff approach. Table 4 reports the estimated coefficient of this Paragraph IV outcome regression. The dependent variable equals one if a generic manufacturer is able to enter the market by either winning a challenge or by signing an agreement with a branded company to become an authorized generic. The variable equals zero when the court rules in favor of branded companies (*i.e.*, litigated patents are valid and/or infringed) or when pharmaceutical companies adopt a "pay-for-delay" strategy (Hemphill, 2006). We estimate our models through 3 different specifications: linear probability models (Models 1 to 5), probit models (Models 6 to 10) and logit models (Models 11 to 15).

<Insert Table 4 Here>

Across all specifications, the interaction between *External Patents* and *2007 Dummy* is always positive and significant. This result suggests that acquired patents are less reliable than those drafted internally. More specifically, after 2007 (post-*KSR*), external patents are more likely to be considered invalid thus allowing for increased generic entry via Paragraph IV challenges. Our findings suggest that there may be patent validity risk associated with the acquisition of external patents and it supports the IP validity risk described by Knowles and Higgins (2011). Pharmaceutical firms may very well be acquiring 'assets with warts'. The shift

[13] Generic manufacturers can enter the market before court ruling. However, generic producers must weigh the benefits and risks of an "at-risk launch" to minimize possible downstream risk in case the court rules in favor of the pharmaceutical company.

in patent law as a result of *KSR* reveals that external patents, on the margin, were more sensitive to the change in non-obviousness.

Over the last few decades the pharmaceutical industry has increasingly turned to the external technology markets to obtain new drug candidates and novel technologies (Arora *et al.*, 2001; Chesbrough, 2003; Cassiman and Veugelers, 2006; Ceccagnoli *et al.*, 2014). However, the external technology market is not a homogenous field of patenting capabilities. Firms may very well be acquiring patents from companies with limited patenting experience. Few small, research-intensive firms have the resources to hire high quality IP firms. And while a firm may receive a patent, the deficiencies in the process and construction may ultimately affect its reliability during litigation.

On the demand side, pharmaceutical companies have extensive experience in the external technology markets and conduct a due diligence process that should reduce the risk of acquiring non-optimal patents (Arora *et al.*, 2009). However, in practice the licensing decision is often driven by a specific technology need to refill the R&D pipeline and whose supply may be very limited. Such circumstances can create situations, as discussed earlier, where patent attorneys may not have access to clinical notebooks or key scientific personnel during the due diligence process (Knowles and Higgins, 2011). In extreme cases, potential licensors are required to make a binding offer prior to having access to these items (Knowles and Higgins, 2011). Consequentially, the decision to acquire external patents may rely on an imperfect set of information and reduce the ability to evaluate the validity of a patent. In essence, pharmaceutical firms may knowingly acquire 'assets with warts', a very different outcome than previously assumed in the markets for technology literature.

Finally, while we are unable to control for other lawsuit variables as suggested by Allison and Lemley (1998) we are able to proxy for the "willingness to protect" a drug by focusing on its relative importance to overall firm sales. We assume that pharmaceutical firms would adopt a more aggressive defensive strategy (and committing more resources) to those drugs that represent high volume of sales or have benefited from significant sunk costs, such as detailing or considerable downstream investments. As expected, our results confirm that pharmaceutical companies tend to allocate more resources to the defense of those drugs that are more important to the firm.

6. Economic Impact

Successful Paragraph IV challenges have detrimental economic consequences for branded companies that lose their monopoly market position due to early generic entry. An unanticipated loss of market position and resulting revenues should elicit a negative equity response. We estimate the potential impact of successful Paragraph IV challenge (loss for the branded pharmaceutical firm) with an event study at the time of the litigation decision.

Following McWilliams and Siegel (1997), we make the following assumptions. First, we assume that markets are efficient. The efficient market hypothesis implies that capital markets are effective in incorporating all relevant information available to traders into the stock price of a firm. Under this assumption, equities should respond when new relevant information is revealed. Given our empirical setting, we argue that the litigation outcome of a Paragraph IV challenge represents precisely such an event.

Second, it is important that events are publicly announced so that markets may digest the news. These types of suits are regularly reported in the general news as well as practitioner publications and websites. Because of the probabilistic nature of patents (Lemley and Shapiro,

2005), it is rarely obvious which firm will prevail during court. In case of a pharmaceutical win, markets will gain no new information from the announcement that would influence equity price. The market position of the branded product will remain intact as will the flow of already anticipated future revenues. If current equity price reflects discounted future cash flows, then nothing from a pharmaceutical win will disturb this calculation. In the context of the event study we would expect not to see any abnormal response since there is no unanticipated value being created or destroyed.

On the other hand, in case of successful challenge by a generic manufacturer, early entry of new competitors in the market will dramatically erode branded product sales. This loss in future revenues should negatively impact equity price. In terms of our event study, this unanticipated negative shock should be reflected in a negative CAR value. Moreover, the monetized value of this abnormal response should reflect the value of the lost future revenue.

Table 5 reports CARs for two subsamples, cases where the pharmaceutical company wins and cases where the pharmaceutical company loses, for three different event windows encompassing the Paragraph IV litigation decision date. In contrast to Panattoni (2011), across all event windows we find no significant CAR in the case where the pharmaceutical firm wins the case. If we assume that markets are efficient then this result should not be surprising; there is no reason to expect an *abnormal* market response. While a "win" might be unexpected, the resulting market position of the branded drug will not change nor will the already anticipated stream of future revenues, which should already be reflected in equity prices.

However, in case of loss, we find significant negative cumulative abnormal returns suggesting that the legal outcome was an unanticipated negative shock. In these cases pharmaceutical companies lose their incumbent position due to early generic entry, suffering

significant loss of future revenues. Across the three event windows, the CAR is significant for our two longer event windows. As we have correctly accounted for any potential confounding events, this difference suggests that there may be a leakage of information prior to the announcement date.

<Insert Table 5 here>

In order to quantify the actual loss in firm value we collected firm's market capitalization for the same month and year of our events. For our sample of losses, we estimate the average market capitalization and multiply this by the estimated CARs. For our two significant windows we find losses between $446m and $451m, respectively. The decline in firm value, representing the loss in future revenues, is significant for a pharmaceutical company when compared to the average cost of developing a new approved drug, which in the early 2000s, was equal to $1.2B (DiMasi *et al.*, 2003). This negative response represents about 30% of the R&D cost necessary to develop a new drug. In line with Branstetter *et al.* (2014) ENREF 9, these results provide one mechanism (*i.e.*, decline in revenues) as to why early generic entry may reduce the incentive for new drugs within a specific therapeutic market.

7. Discussion and conclusion

We use a unique patent litigation dataset to examine the relative reliability of external patents. Our empirical context is the pharmaceutical industry and litigation arises from Paragraph IV challenges filed by generic manufacturers. This paper expands our understanding of the importance of acquired patents in protecting future downstream revenues. It is commonly accepted that acquired technologies can increase innovative productivity, generate knowledge

spillovers and create unique synergies with existing internal competences (Arora *et al.*, 2001; Gans *et al.*, 2002; Cassiman and Veugelers, 2006; Ceccagnoli *et al.*, 2014). However the benefits in terms of future revenue streams are not guaranteed from these activities. Instead, those revenue streams will only be protected if the externally acquired patents are reliable during litigation.

By relying on the markets for technology and patent litigation literatures, our study provides novel insights on the role that acquired patents play during *ex post* litigation. In our research setting we find evidence that external patents are *less reliable* than those developed internally. In fact, our results suggest that external patents increase the possibility that generic manufacturers are able to successfully win their Paragraph IV challenges. Assuming that the market is correctly discounting lost future revenues, we estimate these losses at between $446m and $451m.

It has been argued that pharmaceutical companies can effectively select patents available in the market (Arora *et al.*, 2009). However, the legal shift induced by the Supreme Court in *KSR* (from the "TSM test" to a broadly defined "common sense" test) that we exploited in our analysis suggests that firms may very well be selecting some 'assets with warts'. On the margin, external patents in the post-*KSR* era were more likely to fall during litigation, suggesting that their reliability was more tenuous to begin with. Our findings suggest, contrary to prior belief, that the due diligence process is not summarily looking past weaker patents.

Why would a pharmaceutical firm knowingly acquire 'assets with warts'? Our field interviews, consistent with prior work (Knowles & Higgins, 2011), seem to provide two explanations. Firstly, pharmaceutical companies have the financial resources and experience to craft higher quality patents, taking into consideration broader IP strategies. However, smaller,

research-intensive firms are often resource constrained and as a result patents are written by attorneys with more limited experience or familiarity with pharmaceutical litigation, including Paragraph IV challenges (Knowles and Higgins, 2011). Therefore, the reliability of these patents, on average, during litigation may be lower.

Secondly, firms acquire external technologies to create synergies with internal capabilities (Cassiman and Veugelers, 2006; Ceccagnoli *et al.*, 2014) and to refill product pipelines (Higgins and Rodriguez, 2006). At times the need of the pharmaceutical firm may be great (and the supply of technology more limited) such that they knowingly take on this reliability risk. More broadly, our results do suggest that if firms are going to acquire external technologies they should do so *prior* to external patent construction so that the larger, acquiring firm can put their considerable IP resources to work writing a more reliable patent.

There are other reasons that may lead to this outcome. For example, it is often the case that a licensor will retain prosecution control while the licensee must defend the prosecution decisions during litigation. The licensor may also make short-term motivated decisions in prosecution to accomplish a quick patent grant, which can add to longer-term litigation risk (Knowles and Higgins, 2011). Such a nuanced distribution of control rights calls for an explicit analysis of licensing contracts, a more clear understanding of how rights are distributed and, ultimately, their effect on litigation outcomes.

A natural question to ask, if our findings are correct, is whether this litigation risk is accurately reflected in the price of the license. Our conversations with industry practitioners seem to indicate that this risk is not fully appreciated. If this is the case, are firms, on average, overpaying for external technologies that are already covered by patents? Another area for future research would to explore a more complete valuation model that includes litigation risk.

Disaggregate data, at least for the pharmaceutical industry, exists such that it would be possible to explore these issues.

Ultimately, this heretofore-underappreciated aspect of the external technology markets has profound implications on future R&D expenditures and innovation. For example, some have called for the movement away from a traditional R&D model to one of "S&D" or "search and develop" (Morgan Stanley, 2010). That is, large pharmaceutical firms should focus their capabilities on development (clinical trials) while at the same time acquiring all their drug candidates. And while not this extreme, we do see some companies, such as Glaxosmithkline allocating close to 50% of their R&D budget towards externally acquired technologies. Such calls need to be dampened, we believe, and take into account not just the technologies (which may be superb) but also their associated patents (which may be poor). Given that future innovation and current R&D are paid for from existing product sales the importance of stable and reliable future revenue streams cannot be understated. If internal productivity within the industry has slowed and externally acquired patents may not reliable, the answer to the industry's overall productivity crisis becomes more complex.

Finally, recent work is beginning to document the longer-term impacts of generic penetration into markets on pharmaceutical innovation (Branstetter *et al.*, 2011). The authors are agnostic about how generic entry occurs (whether via Paragraph III or Paragraph IV) but rather focus on how quickly generics penetrate into a market. Our work complements that paper because we explain what might be occurring behind the scenes via Paragraph IV challenges, especially as it relates to externally acquired patents. They demonstrate that as a result of entry pharmaceutical firms appear to be shifting away from chemical-based products towards biologics-based products. The rotation is logical given that the current legislative framework

created under Hatch-Waxman is not applicable to biologic-based drugs; exclusivity periods are longer and no mechanism comparable to a Paragraph IV (for chemical-based drugs) exists. Future work should explore whether the rotation documented by (Branstetter *et al.*, 2011) _ENREF_8into biologics is also occurring with respect to externally acquired patents. Ultimately, we need to understand how this rotation and changing nature of innovation impacts overall welfare and the balance between access and innovation that Hatch-Waxman tried so hard to create. As with all research much remains to be done.

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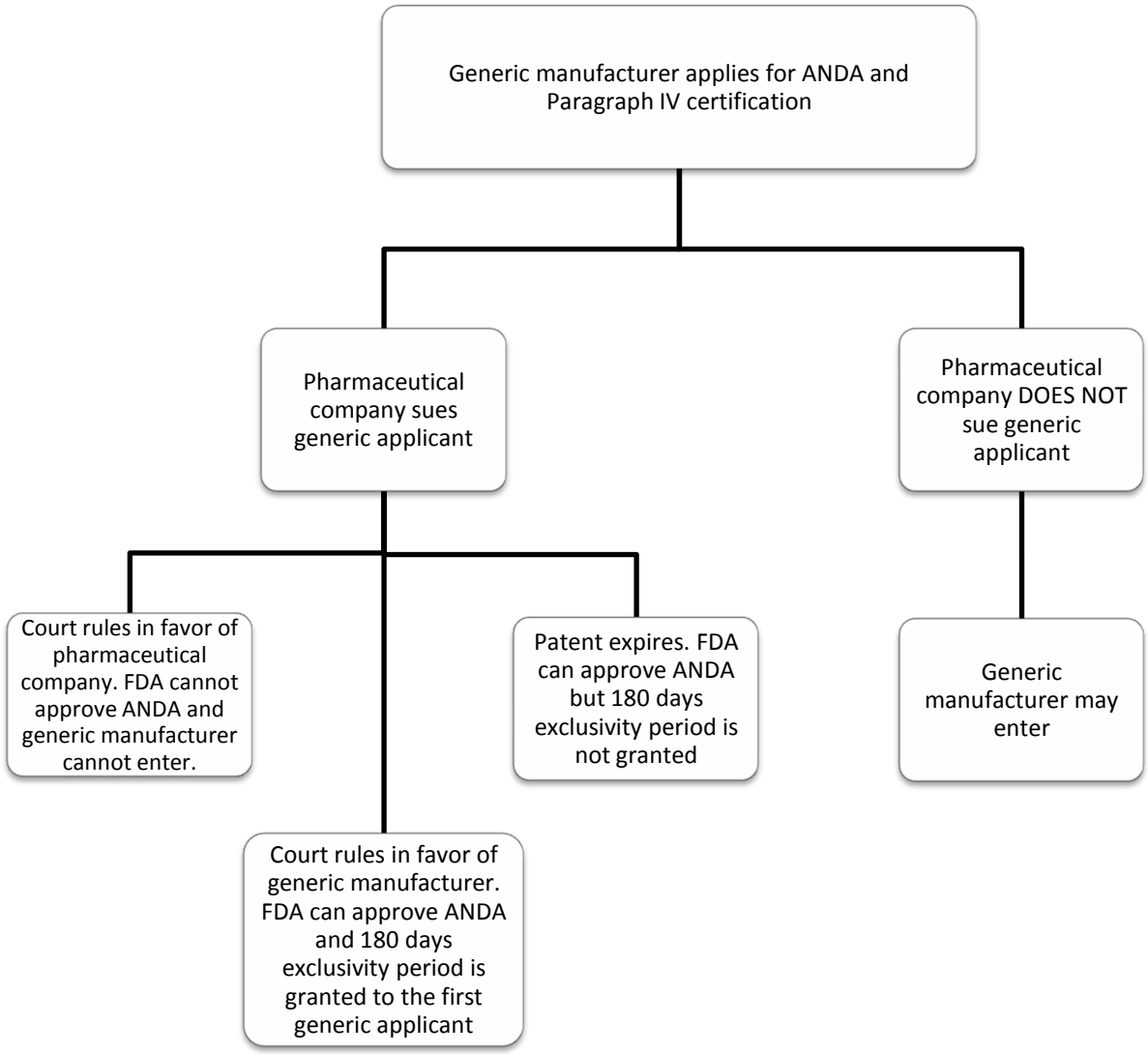

Figure.1 Paragraph IV challenge description
Source: Re-adapted from Bulow (2004)

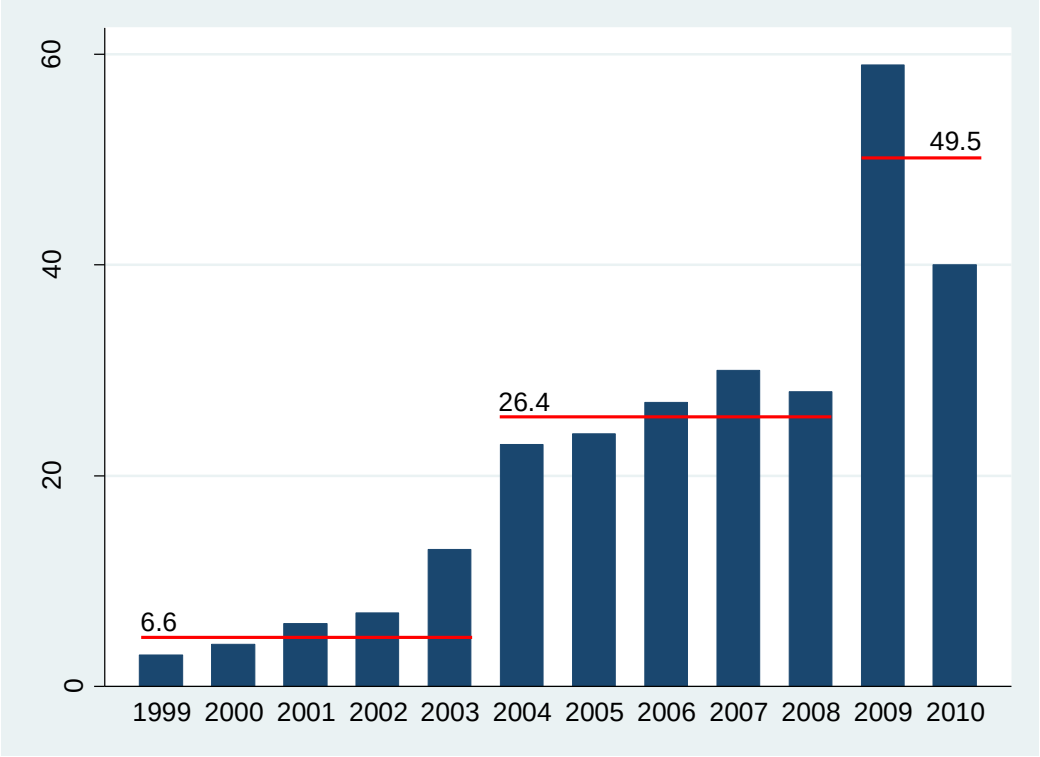

Figure 2. Number of unique drugs challenged per year

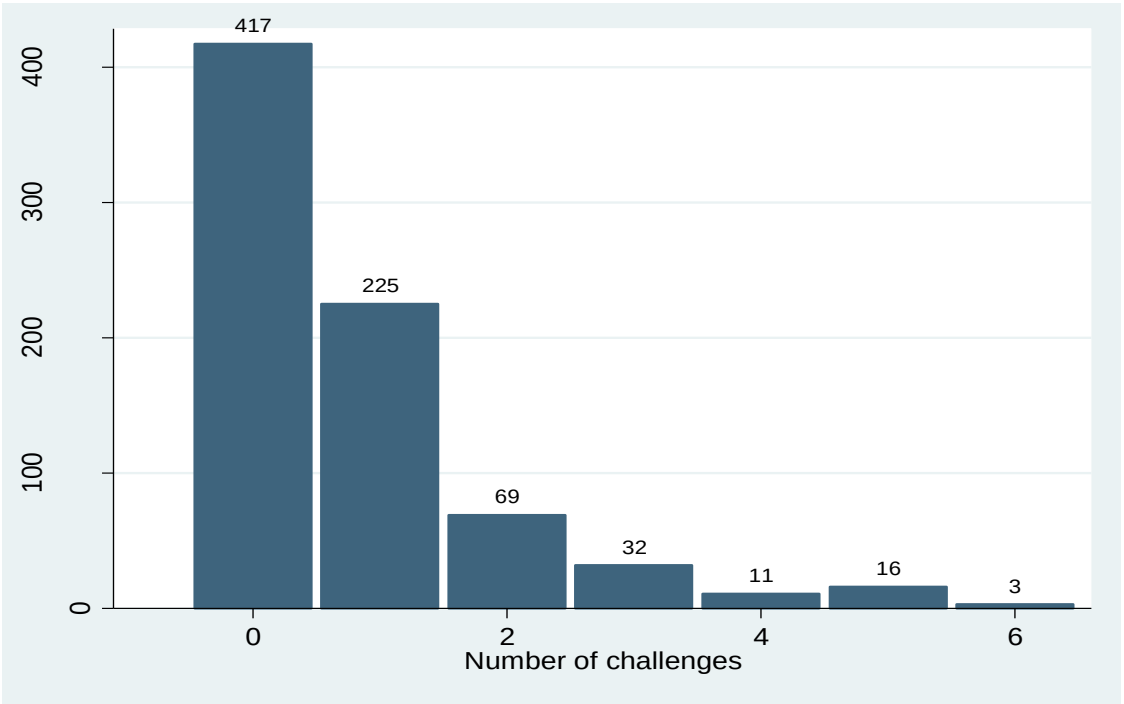

Figure 3. Distribution of patents per number of Paragraph IV challenges

Table 1. Descriptive statistics

Variable	Obs.	Mean	Std. Dev.	Min	Max
Paragraph IV (patent level)	7013	0.083131	0.2761	0	1
Paragraph IV outcome	676	0.491124	0.500291	0	1
2007 Dummy	7013	0.41751	0.493184	0	1
External Patent	7013	0.499216	0.500035	0	1
Ln(1+Sales)	7013	10.76971	3.099298	0	15.92163
Product Patent	7013	0.25082	0.433516	0	1
Drug Delivery patent	7013	0.136318	0.343151	0	1
Composition patent	7013	0.344218	0.475146	0	1
Method Patent	7013	0.206189	0.404596	0	1
Claims	7013	19.82105	22.02607	1	396
Backward citation	7013	15.49209	32.7743	0	276
Forward citation	7013	9.204477	19.72723	0	428
Newest patent	7013	0.48182	0.499705	0	1
Patent per Innovation	7013	4.079281	3.044918	1	18
Drug importance (Sales)	6805	0.118691	0.234041	0	1
Teva	7013	0.028091	0.165244	0	1

Table 2. Correlation Table

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1.Paragraph IV (patent level)	1															
2.Paragraph IV outcome	-0.0199	1														
3.2007 Dummy	0.1315*	-0.1653*	1													
4.External Patent	-0.0527*	-0.0176	0.0007	1												
5.Ln(1+Sales)	0.1814*	-0.0549	0.1000*	-0.1913*	1											
6.Product Patent	-0.0265*	-0.0364	-0.0476*	0.0229	0.0820*	1										
7.Drug Delivery patent	0.0143	-0.0233	0.0260*	0.1211*	-0.0475*	-0.2299*	1									
8.Composition patent	0.0003	-0.0056	0.0092	-0.0733*	-0.0520*	-0.4192*	-0.2878*	1								
9.Method Patent	0.0380*	0.0511	0.0073	0.0128	0.021	-0.2949*	-0.2025*	-0.3692*	1							
10.Claims	0.0383*	-0.0669	0.0451*	0.0482*	-0.0733*	-0.1173*	0.0869*	0.0232	0.0260*	1						
11.Backward citation	0.0484*	-0.0282	0.0589*	-0.0109	-0.0936*	-0.1530*	0.1835*	0.0017	-0.0815*	0.3161*	1					
12.Forward citation	0.0200	-0.0222	0.1655*	0.006	0.0852*	0.1013*	0.0106	-0.011	-0.1081*	0.0794*	-0.0047	1				
13.Newest patent	-0.0144	0.033	-0.0664*	-0.0239*	-0.0555*	-0.0688*	0.0186	0.0666*	0.0185	-0.0182	-0.0341*	-0.2076*	1			
14.Patent per Innovation	0.0685*	0.1621*	0.1362*	-0.0445*	0.1799*	-0.0864*	-0.0484*	-0.0660*	0.0663*	0.1128*	0.2000*	0.0668*	-0.3887*	1		
15.Drug importance (Sales)	0.0804*	-0.0126	0.0499*	0.0906*	0.1177*	-0.0392*	-0.0272*	-0.0408*	0.1513*	-0.0094	-0.0374*	-0.0406*	-0.0401*	0.1207*	1	
16.Teva	0.4583*	-0.0635	0.0748*	-0.0334*	0.1252*	0.0191	-0.0223	0.0003	0.0115	0.0062	-0.0233	0.0226	-0.0275*	0.0534*	0.0561*	1

* Indicates that the correlation is significant at the 5%level

Table 3. Patent Level: Challenge

	Linear Probability Model					Probit					Logit				
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)	(15)
2007 Dummy	0.069***	0.065***	0.058***	0.074***	0.069***	0.524***	0.499***	0.492***	0.509***	0.519***	1.012***	0.965***	0.941***	0.945***	0.931***
	(0.008)	(0.008)	(0.008)	(0.013)	(0.012)	(0.057)	(0.058)	(0.055)	(0.081)	(0.075)	(0.115)	(0.118)	(0.110)	(0.159)	(0.148)
External Patent	-0.030***	-0.034***	-0.017**	-0.026***	-0.007	-0.221***	-0.245***	-0.030	-0.232**	0.005	-0.437***	-0.486***	-0.053	-0.516***	-0.069
	(0.009)	(0.009)	(0.008)	(0.010)	(0.009)	(0.065)	(0.065)	(0.059)	(0.095)	(0.088)	(0.126)	(0.126)	(0.114)	(0.198)	(0.184)
2007 Dummy*				-0.018	-0.023				-0.022	-0.061				0.047	0.026
External Patent				(0.016)	(0.016)				(0.114)	(0.111)				(0.231)	(0.223)
Product Patent		0.050***	0.043**	0.049***	0.043**		0.432**	0.334*	0.432**	0.335*		0.886**	0.739**	0.886**	0.738**
		(0.019)	(0.018)	(0.019)	(0.018)		(0.197)	(0.187)	(0.198)	(0.188)		(0.405)	(0.376)	(0.404)	(0.376)
Drug Delivery		0.063***	0.063***	0.063***	0.063***		0.512**	0.576***	0.512**	0.577***		1.055***	1.298***	1.055***	1.298***
patent		(0.021)	(0.020)	(0.021)	(0.020)		(0.201)	(0.197)	(0.201)	(0.197)		(0.409)	(0.387)	(0.409)	(0.387)
Composition		0.059***	0.059***	0.058***	0.059***		0.480**	0.508***	0.480**	0.509***		0.985**	1.073***	0.985**	1.073***
patent		(0.019)	(0.018)	(0.019)	(0.018)		(0.195)	(0.188)	(0.195)	(0.188)		(0.400)	(0.373)	(0.399)	(0.373)
Method Patent		0.082***	0.077***	0.082***	0.077***		0.661***	0.616***	0.661***	0.618***		1.319***	1.287***	1.318***	1.287***
		(0.020)	(0.019)	(0.020)	(0.019)		(0.198)	(0.189)	(0.198)	(0.189)		(0.404)	(0.375)	(0.404)	(0.375)
Claims		0.000	0.001	0.001	0.001		0.002	0.001	0.002	0.001		0.004	0.002	0.004	0.002
		(0.001)	(0.001)	(0.001)	(0.001)		(0.002)	(0.001)	(0.002)	(0.001)		(0.004)	(0.003)	(0.003)	(0.003)
Backward		0.001	0.001**	0.001	0.001**		0.002	0.002**	0.002	0.002**		0.003*	0.003***	0.003*	0.003***
citation		(0.001)	(0.001)	(0.001)	(0.001)		(0.001)	(0.001)	(0.001)	(0.001)		(0.002)	(0.001)	(0.002)	(0.001)
Forward		0.001	0.001	0.001	0.001		0.001	-0.001	0.001	-0.001		0.002	-0.002	0.002	-0.002
citation		(0.001)	(0.001)	(0.001)	(0.001)		(0.001)	(0.001)	(0.001)	(0.001)		(0.003)	(0.002)	(0.003)	(0.002)
Newest patent		-0.017*	-0.010	-0.017*	-0.010		-0.097	-0.017	-0.097	-0.017		-0.177	0.014	-0.177	0.014
		(0.009)	(0.009)	(0.009)	(0.009)		(0.065)	(0.060)	(0.065)	(0.060)		(0.128)	(0.114)	(0.128)	(0.114)
Ln(1+Sales)			0.014***		0.014***			0.211***		0.211***			0.474***		0.474***
			(0.001)		(0.001)			(0.028)		(0.027)			(0.045)		(0.045)
Constant	0.072***	0.010	-0.146***	0.006	-0.152***	-1.721***	-2.211***	-4.680***	-2.218***	-4.700***	-3.107***	-4.110***	-9.731***	-4.097***	-9.725***
	(0.007)	(0.021)	(0.022)	(0.021)	(0.022)	(0.061)	(0.203)	(0.411)	(0.207)	(0.408)	(0.125)	(0.417)	(0.689)	(0.425)	(0.687)
Obs.	7,013	7,013	7,013	7,013	7,013	7,013	7,013	7,013	7,013	7,013	7,013	7,013	7,013	7,013	7,013

Clustered Standard errors in parentheses

* $p < 0.11$, ** $p < 0.05$, *** $p < 0.01$

Table 4. Patent Level: Outcome

	Linear Probability Model					Probit					Logit				
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)	(15)
2007 Dummy	-0.165***	-0.178***	-0.166***	-0.239***	-0.226***	-0.560***	-0.600***	-0.579***	-0.854***	-0.834***	-0.949***	-1.023***	-0.991***	-1.464***	-1.434***
	(0.041)	(0.042)	(0.042)	(0.052)	(0.053)	(0.147)	(0.153)	(0.155)	(0.214)	(0.217)	(0.254)	(0.268)	(0.272)	(0.379)	(0.383)
External Patent	0.013	0.033	0.037	-0.055	-0.049	0.041	0.090	0.106	-0.230	-0.215	0.070	0.156	0.182	-0.393	-0.370
	(0.043)	(0.044)	(0.045)	(0.065)	(0.064)	(0.147)	(0.146)	(0.152)	(0.221)	(0.222)	(0.248)	(0.248)	(0.259)	(0.379)	(0.382)
2007 Dummy*				0.145*	0.141*				0.531*	0.539*				0.910*	0.926*
External Patent				(0.084)	(0.085)				(0.293)	(0.299)				(0.506)	(0.517)
Product Patent		-0.081	-0.074	-0.089	-0.083		-0.240	-0.239	-0.278	-0.273		-0.403	-0.400	-0.471	-0.463
		(0.134)	(0.132)	(0.138)	(0.136)		(0.462)	(0.468)	(0.487)	(0.489)		(0.779)	(0.790)	(0.825)	(0.830)
Drug Delivery		-0.040	-0.042	-0.042	-0.045		-0.098	-0.115	-0.107	-0.125		-0.165	-0.192	-0.180	-0.210
patent		(0.141)	(0.139)	(0.145)	(0.142)		(0.479)	(0.486)	(0.502)	(0.507)		(0.807)	(0.822)	(0.849)	(0.860)
Composition		-0.038	-0.035	-0.048	-0.045		-0.103	-0.106	-0.143	-0.144		-0.169	-0.175	-0.238	-0.239
patent		(0.132)	(0.129)	(0.136)	(0.134)		(0.454)	(0.459)	(0.479)	(0.481)		(0.764)	(0.774)	(0.810)	(0.815)
Method Patent		-0.066	-0.048	-0.077	-0.059		-0.165	-0.128	-0.214	-0.174		-0.274	-0.210	-0.357	-0.286
		(0.133)	(0.130)	(0.137)	(0.135)		(0.461)	(0.465)	(0.486)	(0.488)		(0.776)	(0.785)	(0.823)	(0.827)
Claims		-0.001*	-0.001**	-0.001**	-0.001**		-0.004*	-0.005*	-0.005*	-0.005**		-0.007*	-0.008*	-0.008*	-0.009*
		(0.001)	(0.001)	(0.001)	(0.001)		(0.003)	(0.003)	(0.003)	(0.003)		(0.004)	(0.004)	(0.004)	(0.005)
Backward		0.001	0.001	0.001	0.001		0.001	0.001	0.001	0.001		0.002	0.002	0.002	0.002
citation		(0.001)	(0.001)	(0.001)	(0.001)		(0.001)	(0.002)	(0.001)	(0.002)		(0.002)	(0.003)	(0.002)	(0.003)
Forward citation		0.001	0.001	0.001	0.001		0.001	0.002	0.001	0.001		0.002	0.003	0.002	0.003
		(0.001)	(0.001)	(0.001)	(0.001)		(0.003)	(0.003)	(0.003)	(0.003)		(0.005)	(0.006)	(0.005)	(0.006)
Newest patent		0.074	0.076	0.072	0.075		0.267*	0.277*	0.267*	0.279*		0.448*	0.466*	0.449*	0.471*
		(0.047)	(0.048)	(0.047)	(0.048)		(0.159)	(0.166)	(0.164)	(0.170)		(0.270)	(0.281)	(0.279)	(0.289)
Patents per		0.028***	0.030***	0.027***	0.030***		0.099***	0.108***	0.100***	0.110***		0.167***	0.184***	0.170***	0.188***
Innovation		(0.007)	(0.008)	(0.008)	(0.008)		(0.027)	(0.029)	(0.028)	(0.030)		(0.047)	(0.050)	(0.049)	(0.052)
Teva		0.042	0.057	0.041	0.056		0.015	0.079	0.030	0.091		0.055	0.165	0.084	0.190
		(0.045)	(0.045)	(0.045)	(0.045)		(0.173)	(0.181)	(0.179)	(0.186)		(0.300)	(0.316)	(0.312)	(0.327)
Drug importance			-0.187*		-0.185*			-0.622*		-0.647*			-1.071*		-1.114*
(Sales)			(0.101)		(0.099)			(0.356)		(0.358)			(0.618)		(0.623)
Constant	0.587***	0.478***	0.486***	0.530***	0.535***	0.303**	-0.080	-0.046	0.110	0.142	0.512**	-0.145	-0.088	0.180	0.236
	(0.038)	(0.139)	(0.137)	(0.147)	(0.145)	(0.136)	(0.477)	(0.485)	(0.514)	(0.519)	(0.233)	(0.802)	(0.816)	(0.870)	(0.878)
Obs.	676	676	662	676	662	676	676	662	676	662	676	676	662	676	662

Clustered standard errors in parentheses
* $p < 0.11$, ** $p < 0.05$, *** $p < 0.01$

Table 5. Event study results divided by subsample

Pharmaceutical wins subsample

Time Window (days)	N	CAR	Z-statistics
(-1, +1)	75	-0.01%	-0.818
(-3, +1)	75	-0.02%	-0.818
(-5, +1)	75	-0.09%	-0.125

Pharmaceutical loses subsample

Time Window (days)	N	CAR	Z-statistics
(-1, +1)	69	-0.53%	0.487
(-3, +1)	69	-0.82%	-1.519*
(-5, +1)	69	-0.83%	-2.001**

The symbols *, **, and *** denote statistical significance at the 0.10, 0.05, 0.01 levels, respectively. Time windows are with respect to the event date set as t=0