

# HOW RELIABLE IS THE MARKET FOR TECHNOLOGY?

Vincenzo Palermo, Matthew J. Higgins, and Marco Ceccagnoli\*

*Abstract*—Research has focused on why and when firms access external technology markets. Less is known about the reliability of patents attached to licensed technologies during litigation. Unreliable patents expose a firm to loss of downstream revenues. We address this by constructing a data set of patent litigation in the pharmaceutical industry and exploit a change in patent law that exogenously increased the probability of litigation. We find that licensed patents are more likely to fall during litigation. This effect is isolated to firms with fewer intellectual property capabilities and less patenting experience, suggesting that benefits from external technology are not shared equally.

## I. Introduction

**E**XPANDING markets for technology allow firms to boost their performance by combining different technological inputs acquired externally, such as through licensing. Recent research on this topic has focused on both the supply and demand side of the technology markets (Arora, Fosfuri, & Gambardella, 2001; Cassiman & Veugelers, 2006; Ceccagnoli, Higgins, & Palermo, 2014), highlighting the effect of externally acquired technologies on firm performance. This stream of literature, however, has focused on the technological value of new technologies, and it has overlooked the importance of underlying patent reliability or legal strength in the face of litigation.

Patents and their enforcement strategies have increasingly become a crucial component of firm competitive advantage, and patent enforcement has been identified as a fundamental strategic capability (Somaya, 2012). While firms can exploit internally or externally generated technol-

ogy to boost productivity and firm performance, the protection and value of a downstream product is limited by the uncertainty of patent litigation (Lemley & Shapiro, 2005). Little is known, however, about 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 at greater risk of being considered invalid during litigation, regardless of their technological quality, buyers can suffer from significant revenue shocks.

To fill this gap, we combine insights from the law and economics literature on patent litigation (Lanjouw & Schankerman, 2001; Lemley & Shapiro, 2005; Somaya, 2012) with research on markets for technology (Gambardella, Giuri, & Luzzi, 2007; Arora & Gambardella, 2010) to provide new evidence on the reliability of acquired patents during litigation. In particular, we analyze and compare litigation challenges and outcomes of internally developed and externally licensed patents, adopting an agnostic position on the quality of the underlying technology.

To answer our research question, we focus on the U.S. pharmaceutical industry and the early entry of generic products through a specific regulatory mechanism called a Paragraph IV (Para-IV) challenge. In the United States, 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 Para-IV challenge with the FDA, which usually results in litigation.<sup>1</sup> We exploit a change in patent law by the U.S. Supreme Court that had a profound (and unanticipated) impact on Para-IV litigation. In short, we find that this shock caused Para-IV litigation to increase and made it more likely that challenged patents would fall because of invalidity, allowing early generic entry. Such litigation risk is substantial; we estimate an average Para-IV litigation loss of \$320 million.<sup>2</sup>

Surprisingly, we find that licensed patents were more likely to fall during litigation. In other words, they were less reliable than internal patents. This pattern, however, is not homogeneously distributed throughout our sample. The effects are isolated to pharmaceutical firms with below-average IP resources or capabilities *and* below-average patenting experience. This suggests that for these firms, future litigation risk is entering through either the due diligence process or underlying licensing relationship. Importantly, this suggests that the potential benefits of accessing external technology markets are not shared equally across firms.

Our findings complement the existing literature on licensing and licensing management. Many studies have shown

Received for publication April 15, 2015. Revision accepted for publication November 13, 2017. Editor: Philippe Aghion.

\* Palermo: Accenture; Higgins: Georgia Institute of Technology and NBER; Ceccagnoli: Georgia Institute of Technology.

We thank Rajshree Agarwal, Brent Bellows, Dan Breznitz, Chirantan Chatterjee, Chris Forman, Gregory Glass, Stuart Graham, Dietmar Harhoff, Lisa Higgins, Sherry Knowles, Daniel Spulber, Mike Stonebrook, Marie Thursby, Jerry Thursby, Arvids Ziedonis, and seminar participants at Georgia Institute of Technology, Washington University, CCC Doctoral Consortium (MIT), and the Academy of Management for helpful comments and suggestions. Research assistance by Mayank Jasiwal is gratefully acknowledged. We are grateful to two anonymous referees and Philippe Aghion for their constructive comments and reviews. We thank Deloitte ReCap for access to their data. We also thank IMS Health Incorporated for their generous support and access to their data. The statements, findings, conclusions, views, and opinions contained and expressed here are not necessarily those of IMS Health Incorporated or any of its affiliated or subsidiary entities. The statements, findings, conclusions, views, and opinions contained and expressed in this paper are based in part on data obtained under license from the following IMS Health Incorporated or affiliate information services: IMS MIDAS, June 1997 to December 2010, IMS Health Incorporated, or its affiliates. The statements, findings, conclusions, views, and opinions contained and expressed here are not those of Accenture or any of its affiliated or subsidiary entities. M.H. acknowledges funding from the Inlay Professorship and the Georgia Tech Center for International Business Education and Research. V.P. acknowledges funding from the Kauffman Dissertation Program Fellowship. The usual disclaimers apply.

A supplemental appendix is available online at [http://www.mitpressjournals.org/doi/suppl/10.1162/rest\\_a\\_00717](http://www.mitpressjournals.org/doi/suppl/10.1162/rest_a_00717).

<sup>1</sup> See Voet (2014) for a complete discussion of the Paragraph IV challenge process.

<sup>2</sup> Details of the event study and litigation loss is available in the appendix.

the importance of dedicated alliance or licensing capabilities and learning for the success of such deals (Gambardella et al., 2007). The firms in our sample are clearly “successful” in terms of identifying high-quality external technology and taking it to market. Our findings suggest that these capabilities previously identified in the literature may not be enough. Firms also need to have a complementary IP capability and sufficient experience that it allows them to potentially identify problematic patents and plan for the litigation risk they create.

## II. The Reliability of Externally Acquired Patents

In the past few decades, the importance of external technologies in boosting innovation has grown, and an extensive stream of literature has developed focusing on the role played by technology commercialization, especially through licensing (Arora et al., 2001; Arora & Ceccagnoli, 2006; Gambardella et al., 2007; Arora & Gambardella, 2010; Ceccagnoli et al., 2014). In many industries, firms use external innovation to maintain their competitive advantage, 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 discovered outside 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.

Existing research has extensively focused on either the role of external patents in boosting a firm’s innovative effort or on the conditions that facilitate technology transfer. Previous work comparing the quality of internally generated and externally acquired technology has assessed the importance of the “lemons problem” in affecting technology trade. In other words, it has focused on the intrinsic value and quality of the external technology. While empirical results to date are mixed, a recent review of this literature suggests the “lemons problem” has 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 & Gambardella, 2010).

Our work aims to extend this view and shifts the focus of the comparison downstream by evaluating the reliability of a focal technology’s patents as opposed to its underlying quality. Previous analyses on optimal patent policy have usually assumed that there is no uncertainty about the scope of patent protection (Gallini, 1984; Gallini & Winter, 1985). However, subsequent perspectives recognize that patent protection is imperfect until it successfully survives a challenge in court (Shapiro, 2003; Lemley & 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. 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 & Shapiro, 2005; Hemphill & Sampat, 2011).

Our focus is to empirically test the probabilistic view of patents, after the technology is integrated in commercialized products. The argument behind this logic is that the reliability of patents acquired through the markets for technology may differ in quality from patents drafted 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 & Higgins, 2011). When these firms acquire patents in the external technology markets, they undergo significant due diligence.

However, does this due diligence process ensure less reliable patents are not acquired? While this may be the goal, the process is more nuanced and opaque. For example, during due diligence, counsel for the licensee (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 & Higgins, 2011). Compounding these issues is often the limited supply of licensable drug leads within highly disaggregated markets. As such, pharmaceutical companies may acquire “assets with warts” (Knowles & 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.<sup>3</sup>

Moreover, suppliers of technology such as smaller research-intensive firms may not have any experience with Hatch-Waxman generic litigation (i.e., Para-IV challenges) or global litigation scenarios. The licensor may have only limited research assets and little commercial experience. Often these companies are resource constrained, and patents are drafted by outside counsel who themselves may have limited experience in these issues (Knowles & Higgins, 2011). Finally, in this setting, patent prosecution rights are usually kept by the licensor, while the obligation to defend those decisions falls on the licensee, which may be resource constrained. Licensor firms will often make short-term decisions to hit a milestone payment, for example, but create longer-term litigation risks for the licensee. Ultimately, how the licensing relationship is managed can have important downstream implications.

<sup>3</sup> 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. In this respect, our paper builds on Arora et al. (2009) and suggests that the relative strength of the underlying patents appears to differ in a way that will have a significant impact on the commercialization of the drug.

### III. The Pharmaceutical Industry and Its Regulatory Environment

The pharmaceutical industry provides a natural setting for our analysis. Because of the regulatory environment in the United States, generic manufacturers can litigate the patents of a branded drug before they expire, thereby potentially undermining the branded companies' incumbent position. Based on the literature on generic entry (Reiffen & Ward, 2005; Grabowski & Kyle, 2007), along with an emerging literature relating this entry to competition and innovation (Branstetter, Chatlerjee, & Higgins, 2016),<sup>4</sup> an increasing number of drugs are being challenged, and those with larger sales attract more competitors (Scott Morton, 1999; Grabowski & Kyle, 2007; Hemphill & Sampat, 2011).

While results converge toward the focal role played by sales, there is less evidence on the role played by patents in the preentry decision and litigation outcome.<sup>5</sup> 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 Para-IV challenges. In a follow-up study, Hemphill and Sampat (2012) expand their findings on Para-IV challenges, confirming that patents that do not refer to the drug's active ingredient draw more challenges.

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). Under HW, once a drug is approved, pharmaceutical firms are required to list materially relevant patents in the FDA's Orange Book.<sup>6</sup> HW also introduced "data exclusivity" for branded drugs in parallel to patent protection. Data exclusivity is an exclusive marketing right granted on approval, and it runs concurrently with patent protection. It protects the ownership of the underlying clinical trial data and prevents entry by generic manufacturers during that time period. It was intended to provide branded products monopoly protection should underlying patent protection be limited.<sup>7</sup>

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 on the fourth certification, Para-IV.<sup>8</sup> This is the only pathway that allows for the direct challenge of underlying branded patents prior to their expiration. Appendix figure 1 summarizes the Para-IV challenge process.

### IV. Empirical Strategy and Data

#### A. Empirical Strategy

As described by Knowles (2010), the regulatory framework that pharmaceutical firms face can be modified by both new legislation and 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 U.S. Supreme Court case, *KSR International Co. v. Teleflex Inc.*<sup>9</sup> In this case, the Court considered the Teleflex patent as obvious and invalid and in doing so introduced a broader definition of obviousness. While this case was not directly related to the pharmaceutical industry, this new standard of obviousness had implications for branded product patents.

In our context, *KSR* should be interpreted as an exogenous shock reducing the strength of a patent, as represented by the probability that a patent is declared invalid, conditional on a challenge. Moreover, post-*KSR*, it should be more likely that a generic firm initiates a Para-IV challenge because it is more likely to win the challenge. A recent report by PwC (2013) appears to bear this out; generic litigation jumped from forty three cases from 2001 to 2006 to seventy seven cases in the more recent post-*KSR* 2007–2012 time period. Outcomes favorable to generic firms also increased in the post-*KSR* period.

Our data support these same upward trends (see appendix figures 2 and 3). Prior to 2003, only twenty-four drugs were challenged. In the subsequent five years (2003–2007), this number increased to 124, with 58 of these challenges occurring in the final two years. The horizontal lines in appendix 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 Para-IV challenges. First, after the introduction of the Medicare Modernization Act in 2003, generic manufacturers embraced Para-IV challenges

<sup>4</sup> There exists an additional stream of research that has discussed patent challenges and their role in affecting the length of market protection (Grabowski, 2004; Grabowski & Kyle, 2007; Hemphill & Sampat, 2011).

<sup>5</sup> 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 & Kyle, 2007).

<sup>6</sup> The FDA does not actively regulate the patents that are listed, and only these identified patents can be used to protect the drug in case of litigation. This lack of oversight has led to criticisms of potential gaming of patent listings (Bulow, 2004) and evergreening in the FDA Orange Book after approval by the FDA (Hemphill & Sampat, 2012).

<sup>7</sup> Chemical-based drugs receive five years of data exclusivity protection. Orphan drugs receive seven years of protection, while reformulations of an existing product receive three additional years. Firms can gain an additional six months of data exclusivity for the addition of a pediatric indication.

<sup>8</sup> Other certifications reflect a less competitive choice: under Paragraphs I and II, patent protection has already expired, so 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.

<sup>9</sup> U.S. Supreme Court Case No. 04-1350, [http://www.supremecourt.gov/oral\\_arguments/argument\\_transcripts/04-1350.pdf](http://www.supremecourt.gov/oral_arguments/argument_transcripts/04-1350.pdf).

as a viable strategy due to lower litigation costs.<sup>10</sup> Second, we observe another shift in the number of drugs challenged after 2007. This 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.

We exploit the *KSR* decision as an exogenous temporal shock to estimate a difference-in-differences (diff-in-diffs) specification. We use two groups of observations. In the first group (treated) are patents granted in the United States and listed in the FDA Orange Book. Because *KSR* affects only the U.S. legal environment, our treated group is exposed to the exogenous shock in the post-2007 period but not in the pre-2007 period. The second group (control) is based on patents linked to the treated U.S. patents that have been extended from or to the EU. The control group is not exposed to the treatment in either period (see appendix figure 4).

Our identification strategy relies on the fact that both the Para-IV challenge and the European opposition are postgrant validity examinations but that the European oppositions remain unaffected by *KSR*. In Europe, the patent-granting process is subject to a unified postgrant revision that can be initiated by any third party interested in challenging the validity of the EU patent (Graham et al., 2003; Harhoff, Scherer, & Vopel, 2003; Harhoff & Reitzig, 2004; Harhoff, von Grevenitz, & Wagner, 2016).<sup>11</sup> Opponents can present evidence that the prerequisites for patentability were not fulfilled, and, as a consequence, the patent should be invalidated. At the end of the opposition procedure, the European Patent Office (EPO) may uphold the patent without any amendment, or it may approve partial modification to the patent or completely revoke it.

To build our control group, we collected information from the EPO-Espacenet website. For each of our U.S. patents, we matched the equivalent EU patent through the Patent Cooperation Treaty (PCT) application and priority date. Approximately 50% of our focal U.S. patents attached to FDA-approved drugs also have protection in Europe through the EPO. Below we discuss the technical similarities and differences between these two sets of patents and our controls for any differences. Next, we collected data on whether the validity of each EU patent was challenged through the opposition process. Finally, we recorded the name of opposing party and the outcome of the opposition. Specifically, we classify partial patent amendments and the revoking of a patent as a successful opposition.

Using a traditional diff-in-diffs approach, we start with the following model (controls and subscripts are omitted for simplicity):

$$y = \beta_0 + \beta_1 USA + \beta_2 Post-KSR + \beta_3 (USA \times Post-KSR) + u, \quad (1)$$

where  $y$  is the outcome of interest (either the probability of a challenge or the probability of a generic win). *Post-KSR* is a dummy variable for the posttreatment period represented by the *KSR* decision and captures aggregate factors that would cause changes in  $y$  even in the absence of the treatment. *USA* is a dummy variable and captures possible differences between the treatment and the control groups. The coefficient of interest is  $\beta_3$ , and it represents the impact induced by the *KSR* ruling on U.S. patents relative to EU patents.

After the analysis of the effect of *KSR* on the probability of challenge, we explore our primary research question by estimating the difference between internal and external patents in conditioning the effect of *KSR*. To accomplish this, we again use a traditional diff-in-diffs model but now include a triple interaction to compare estimates for these two different types of patents. We estimate the following model (controls and subscripts are omitted for simplicity):

$$y = \beta_0 + \beta_1 USA + \beta_2 Post-KSR + \beta_3 External + \beta_4 (USA \times Post-KSR) + \beta_5 (USA \times External) + \beta_6 (Post-KSR \times External) + \beta_7 (USA \times Post-KSR \times External) + u. \quad (2)$$

Equation (2) replicates the traditional diff-in-diffs model, equation (1), with the addition of the variable *External* and its interactions. Consequently, we can estimate the expected values of the Para-IV challenge and its outcome for both internal patents from the United States and external patents from the United States in the post-*KSR* period to identify the treatment effect on the two patent subgroups:

$$\begin{aligned} PM_I &= E(y|USA = 1, Post-KSR = 1, External = 0) \\ &= \beta_1 \times (USA = 1) + \beta_2 (Post-KSR = 1) \\ &\quad + \beta_3 (External = 0) + \beta_4 ((USA = 1) \\ &\quad \times (Post-KSR = 1)) + \beta_5 ((USA = 1) \\ &\quad \times (External = 0)) + \beta_6 ((Post-KSR = 1) \\ &\quad \times (External = 0)) + \beta_7 ((USA = 1) \\ &\quad \times (Post-KSR = 1) \times (External = 0)) \\ &= \beta_1 + \beta_2 + \beta_4, \end{aligned} \quad (3)$$

$$\begin{aligned} PM_E &= E(y|USA = 1, Post-KSR = 1, External = 1) \\ &= \beta_1 \times (USA = 1) + \beta_2 (Post-KSR = 1) \\ &\quad + \beta_3 (External = 1) + \beta_4 ((USA = 1) \\ &\quad \times (Post-KSR = 1)) + \beta_5 ((USA = 1) \\ &\quad \times (External = 1)) + \beta_6 ((Post-KSR = 1) \\ &\quad \times (External = 1)) + \beta_7 ((USA = 1) \\ &\quad \times (Post-KSR = 1) \times (External = 1)) \\ &= \beta_1 + \beta_2 + \beta_3 + \beta_4 + \beta_5 + \beta_6 + \beta_7, \end{aligned} \quad (4)$$

<sup>10</sup> The Medicare Modernization Act has limited the ability to stack multiple thirty-month periods of protection. This change forced pharmaceutical companies to make all their claims against a generic manufacturer in their initial lawsuit in response to a Para-IV challenge (Bulow, 2004).

<sup>11</sup> If no oppositions are filed within the nine-month period following the publication of the mention that a European patent has been granted, the validity of a European patent can also be challenged later in a national court.

where  $PM_I$  and  $PM_E$  are the expected values of the outcome of interest conditional on the focal patent being *Internal* or *External*, respectively. We will also test whether the difference between these two expected values, representing the marginal effect of *External* on the probability of a challenge or its outcome, equals 0. The test can be written as follows:

$$H_0 : PM_E - PM_I = 0 \text{ and } H_1 : PM_E - PM_I \neq 0.$$

where  $PM_E - PM_I$  reduces to

$$\begin{aligned} PM_E - PM_I &= \beta_3(External = 1) + \beta_5((USA = 1) \\ &\quad \times (External = 1)) + \beta_6((Post-KSR = 1) \\ &\quad \times (External = 1)) + \beta_7((USA = 1) \\ &\quad \times (Post-KSR = 1) \times (External = 1)) \\ &= \beta_3 + \beta_5 + \beta_6 + \beta_7. \end{aligned} \quad (5)$$

The test exploits the diff-in-diffs specification to identify differences between patents and their impact on Para-IV challenges and outcomes. A positive and significant test implies that in the post-KSR period, the expected value of a challenge or its outcome for external patents from the United States ( $PM_E$ ) is larger than the expected value of internal patents from the United States ( $PM_I$ ), thereby suggesting possible differences in the underlying legal strength of the two patent types. We report this test at the bottom of our tables.

### B. Selection

Because the models on the probability of a generic win are conditional on the probability of a challenge, there may exist a potential selection bias. From a theoretical point of view, generic manufacturers would challenge a drug if their expected revenues (their probability of winning a challenge times expected revenues) are greater than costs (e.g., litigation, manufacturing, distribution). On one hand, internal patents appear to be more valuable than external patents and attached to more valuable drugs.<sup>12</sup> On the other hand, U.S. patents may be more valuable because of a different market size or because the incentives to litigate due to a different regulatory environment are higher.<sup>13</sup> However, incentives to litigate a patent will be offset by their legal strength. As discussed previously, an external patent may be weaker, and EU patents may be characterized by differential legal strength as well.<sup>14</sup>

<sup>12</sup> Average sales of drugs comprising more than 50% of external patents were \$173 million, while drugs with less than 50% external patents had average sales of \$540 million.

<sup>13</sup> The average sales of EU drugs are \$245 million; for equivalent U.S. drugs, the counterpart is \$346 million, and the difference is statistically significant.

<sup>14</sup> Differences in the propensity to patent between the United States and EU are discussed in the appendix.

In sum, for an internal or U.S. patent, the expected probability of being challenged may be higher or lower ex ante. To the extent that a patent, whether internal versus external or from the United States versus the EU, has a different probability of success in the challenge may introduce a potential selection bias in our outcome estimates. This potential bias could change the proportion of patents (internal versus external or United States versus EU) in the sample of challenged patents. To overcome this potential bias, we adopt an alternative empirical approach that includes the inverse Mills ratio (IMR) in our estimates (Greene, 2017). To achieve identification, we include *Drug sales* in the selection equation that is a probit model where the dependent variable is *Challenge*. The IMR is defined as the ratio of the probability density function to the cumulative distribution function of the selection equation. The estimated IMR is then included in the outcome equation to account for possible selection bias.

### C. Data

Our sample consists of all new chemical entities (NCEs) approved by the FDA between 1995 and 2004, along with their reported U.S. patents listed in the FDA Orange Book and associated patents extended from or to the EPO.<sup>15</sup> Our analysis is limited to drugs approved up to 2004 in order to allow all our drugs to have the opportunity to be targeted by a Para-IV challenge.<sup>16</sup> Our final sample consists of 309 unique chemical-based drugs covered by 708 unique U.S. patents and 234 EU patents.<sup>17</sup>

We linked the drugs and patents collected from the FDA Orange Book to several additional data sources. First, Para-IV litigation data were gathered from the Paragraph Four Report for the time period 1999 to 2010. Next, we obtained drug-level data on sales and promotion expenditure from IMS MIDAS. Patent-level licensing information was obtained from Pharmaprojects. Patent approval dates, number of claims, citations, and type were collected from Delphion, IMS Patent Focus, and the U.S. Patent and Trademark Office (USPTO). Measures of patent quality and economic value were collected from the OECD Patent Database. Finally, EU patents and opposition data were collected from the EPO. Descriptive statistics and correlations are provided in table 1 and appendix table 1, respectively.

*Dependent variables.* We define our first dependent variable as a patent-level dummy, *Challenge*, that equals 1 if either a generic manufacturer challenges a focal patent in

<sup>15</sup> <http://www.accessdata.fda.gov/scripts/cder/ob/>.

<sup>16</sup> It is not possible to initiate a Para-IV challenge until at least five years after a new drug has been approved. Since our FDA Orange Book data start in 1995, our Para-IV data start in 1999.

<sup>17</sup> We exclude biologic-based drugs in our sample because they are not covered by the same regulatory procedures as chemical-based drugs.

TABLE 1.—DESCRIPTIVE STATISTICS

Variable	Number of Observations	Mean	SD	Minimum	Maximum
1. Challenge	8,597	0.066	0.249	0	1
2. Challenge outcome	4,126	0.051	0.2221	0	1
3. Post-KSR	8,597	0.410	0.492	0	1
4. External	8,597	0.443	0.496	0	1
5. Drug sales	8,597	10.44	3.389	0	15.922
6. Product patent	8,597	0.293	0.455	0	1
7. Drug delivery patent	8,597	0.125	0.331	0	1
8. Composition patent	8,597	0.333	0.471	0	1
9. Method of use patent	8,597	0.183	0.387	0	1
10. Claims	8,597	19.626	19.874	1	240
11. Backward citation	8,597	18.122	24.458	0	167
12. Forward citation	8,597	21.346	33.449	0	387
13. Newest patent	8,597	0.461	0.498	0	1
14. Patent per innovation	8,597	3.931	2.954	1	18
15. USA	8,597	0.877	0.327	0	1
16. OECD patent quality index	8,597	0.393	0.143	0.051	0.874
17. Patent family size	8,597	23.194	11.611	1	51
18. Patent scope	8,597	2.510	1.297	1	8
19. Total assets	8,597	49,603.42	55,267.15	5.296	797,769
20. Patenting activity	8,597	2,570.04	5246.79	0	44,615

All financial variables are converted into constant 2,000 U.S. dollars, and foreign currencies are converted by using their respective average twelve-month exchange rate against the U.S. dollar.

a given year or if a third-party initiates a European patent opposition, 0 otherwise. Out of the 708 unique U.S. patents, 339 of them were challenged at least once in our data. As shown in appendix figure 5, the distribution of patents per number of Para-IV challenges is skewed toward 0. About 18% of our patents (125 patents) received at least two challenges, and 30% (214 patents) were litigated only once. Among the 369 patents that were not litigated, 318 are listed for drugs that did not receive any Para-IV challenges; 51 were not challenged but listed under drugs that were litigated.

Our second dependent variable classifies the *Challenge outcome*. *Challenge outcome* is a dummy that equals 1 in the case of a favorable outcome for a challenger (either generic manufacturers in the case of a Para-IV challenge or third party in the case of the EU opposition), 0 otherwise. On average, a favorable outcome for generic manufacturers occurs in about 47% of the cases; among the U.S. patents, it is almost always equally divided between court decisions (63 occurrences) and settlement agreements (61 cases). Not surprisingly, the number of settlements more than doubled in the post-KSR period (see appendix figure 6).

With respect to Para-IV challenges, we categorized the following four outcomes and classify the first two cases as favorable to generic manufacturers (*Challenge outcome* = 1) and the last two cases as favorable to pharmaceutical companies (*Challenge outcome* = 0):

1. The court rules in favor of the Para-IV challenger, and a generic drug can enter the market.
2. The parties settled prior to trial or trial conclusion, and the agreement allows generic manufacturers to enter as an “authorized generic.”

3. The parties settled prior to trial or trial conclusion, but the agreement either delays (“pay-for-delay”) or blocks generic entry.<sup>18</sup>
4. The court rules in favor of the pharmaceutical company. No generics may enter the market until branded patents expire.

With respect to the EU oppositions, there are three possible outcomes: (a) the patent is revoked, (b) the patent is amended (e.g., there is a change or reduction of the claims), or (c) the patent is maintained unaltered. We classify the first two cases as a successful opposition (*Challenge outcome* = 1). The third case is classified as a win for the pharmaceutical company (*Challenge outcome* = 0).<sup>19</sup>

*Independent variables.* In order to determine whether a patent attached to a product in the FDA Orange Book was

<sup>18</sup> Legal settlements between pharmaceutical companies and generic manufacturers are private, so we had to look at various sources to infer whether settlements belonged to group 2 or group 3. We do know, however, with certainty that a settlement occurred. These data are available on the Paragraph Four Report. Observations were placed into group 2 if (a) we observed a settlement and (b) generic entry prior to the end of market exclusivity as calculated by IMS Health. Generic entry had to be by the same firm that launched the Para-IV challenge. Observations were placed into group 3 if we observed a settlement and did not observe generic entry prior to the end of market exclusivity. In addition, we also searched public disclosures, on settlements, as well as actions brought by the FTC, class actions brought by consumers and research by legal experts. Given that group 2 was easier to identify than group 3, any overcounting of group 3 (or undercounting of group 2) would dampen our overall findings.

<sup>19</sup> In appendix figure 7, the percentages of successful generic or third-party outcomes (*Challenge outcome* = 1) conditional on challenge are presented for internal versus external patents, across the United States and EU and over the time periods pre-KSR and post-KSR. The figure demonstrates that results are being driven by increases in successful Para-IV challenges as opposed to a decline in European oppositions.

licensed, we used patent-level licensing data available in Pharmaprojects. We define the variable *External* as a dummy that equals 1 if a patent was identified as being licensed by the company marketing a branded product. Next, we used reassignment data from the USPTO to determine if a patent was originally assigned to a firm different from the company marketing the drug. We searched news stories for the subset of patents that were reassigned but were not identified as “licensed” by Pharmaprojects. Searches revealed whether patents were involved in a license that was not coded as such by Pharmaprojects. Finally, if a U.S. patent was designated as external, we kept that designation for any European counterpart.<sup>20</sup>

To implement our diff-in-diffs estimation strategy, we create a dummy (*Post-KSR*) that equals 1 for all the observations after the 2007 KSR decision. Next, we define *Drug sales* as the natural logarithm of the sum of yearly branded product level sales plus 1. Our intent is to control for any influence that higher-revenue drugs have on the entry decision by generic manufacturers. Prior literature has shown that more profitable drugs have a higher probability of being challenged (Grabowski & Kyle, 2007; Hemphill & Sampat, 2011).

To control for differences across types of patents, we include a set of dichotomous variables. 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 four groups: *Product patent*, *Compound patent*, *Method of use patent*, *Drug delivery patent*, and *Other*, which includes process patents. In our sample approximately, 28% of the patents are products, 18% are classified as method-of-use patents, 33% protect the drug composition, and 12% are drug delivery system patents.<sup>21</sup> On average, we do not find significant differences in the distribution of patent types between internal and external technologies.

Based on prior research, we include variables to control for patent quality and value from the OECD patent database (Lanjouw & Schankerman, 2001; Lemley & Shapiro, 2005). These variables include *Forward* and *Backward citations*, *Claims*, *Patent scope*, and *Family size*. Research has found a positive relationship between forward citations, technological importance, and economic value (Trajtenberg, 1990; Harhoff et al., 2003; Hall, Jaffe, & Trajtenberg, 2005). Backward citation, denote the innovativeness of a patent. Patents with significant numbers of backward citations build extensively on existing knowledge and therefore may be more incremental.

The principal role of claims is to define and detail the novel features of an invention (Lanjouw & Schankerman,

2004). It has been also been shown that the technological breadth or scope of patents significantly affected firm valuation and that broad patents were more valuable (Lerner, 1994). In addition, Harhoff et al. (2003) found that large international patent families were especially valuable, while Lanjouw and Schankerman (1999) found that value was associated with the number of jurisdictions in which patent protection had been sought. Appendix tables 2a and 2b present detailed descriptives and differences for these variables across periods (pre- and post-KSR), between internal and external patents, as well as between the United States and EU.

Following Hemphill and Sampat (2011), we control for the effect that late expiring patents can have on the market life of a focal drug and their impact on generic entry. The variable *Newest patent* is a dummy that equals 1 if, within the patent portfolio for a single drug, the grant date of a patent is the latest, 0 otherwise. From a temporal point of view, this variable allows us to trace which patents have the latest grant date. Particularly in the pharmaceutical industry, the timing of technology patenting is not necessarily coincident with its commercialization.<sup>22</sup>

Finally, 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 heterogeneity in the set of patents protecting each drug. On average, drugs in our sample have four patents listed in the FDA Orange Book.

## V. Results

### A. *The Impact of KSR on the Probability of Receiving a Paragraph IV Challenge*

We start with the first-order question of whether the change in nonobviousness standard affected the probability of receiving a Para-IV challenge. Table 2 (models 1 to 3) reports linear probability estimates (LPM) of the diff-in-diffs model described in equation (1). The dependent variable in all models is *Challenge*. Model 1 includes only controls, while model 2 adds market (ATC) fixed effects, and model 3 adds both market and firm fixed effects.<sup>23</sup> Standard errors are clustered by patent and drug.<sup>24</sup> Given the number of controls in the regression, we report our main independent variables in table 2; the full set of estimates of these three models is reported in appendix table 3.

Our coefficient of interest, associated with the interaction between *Post-KSR* and *USA*, is positive and significant across all models, including those with various sets of mar-

<sup>20</sup> The number of external patents does not significantly differ from internal patents; 319 patents in our sample (about 45%) represent external technologies. In addition, only 41% of these patents (143 out of 319 external patents) are challenged compared to 50% of the internal patents (197 out of 390 internal patents).

<sup>21</sup> We kept the same classification for the related EU “matched” patents.

<sup>22</sup> Again, we kept the same classification for the related European “matched” patents.

<sup>23</sup> Markets are defined according to the Anatomical Therapeutic Chemical (ATC) classification system: [http://www.whocc.no/atc\\_ddd\\_index/](http://www.whocc.no/atc_ddd_index/). We define our markets at the ATC1 level.

<sup>24</sup> It is possible that a patent is attached to more than one drug.

TABLE 2.—CHALLENGE REGRESSIONS

	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6
Post-KSR	-0.027*** (0.006)	-0.026*** (0.006)	-0.027*** (0.006)	-0.021*** (0.007)	-0.020*** (0.007)	-0.021*** (0.007)
United States	0.015** (0.008)	0.020*** (0.008)	0.025*** (0.009)	0.029*** (0.009)	0.029*** (0.009)	0.031*** (0.010)
External	-0.016** (0.007)	-0.021*** (0.007)	-0.021** (0.008)	0.028** (0.013)	0.010 (0.014)	0.000 (0.017)
Post-KSR × USA	0.078*** (0.009)	0.078*** (0.009)	0.080*** (0.009)	0.076*** (0.012)	0.076*** (0.012)	0.078*** (0.012)
Post-KSR × External				-0.020* (0.012)	-0.020 (0.012)	0.017 (0.013)
USA × External				-0.044*** (0.015)	-0.030* (0.016)	0.020 (0.018)
Post-KSR × USA × External				0.010 (0.019)	0.011 (0.019)	0.010 (0.019)
Controls	Yes	Yes	Yes	Yes	Yes	Yes
Market FE		Yes	Yes		Yes	Yes
Firm FE			Yes			Yes
Internal patent				0.114	0.117	0.117
<i>p</i> -value				0.000	0.000	0.000
External patent				0.089	0.089	0.090
<i>p</i> -value				0.000	0.000	0.000
Difference				-0.026	-0.028	-0.027
<i>p</i> -value				0.037	0.024	0.036

Linear probability model (LPM) estimates of the diff-in-diffs models described in equations (1) and (2). The dependent variable in all models is *Challenge*. Models 1 and 4 include only controls; models 2 and 5 add market fixed effects (FE); models 3 and 6 add market and firm fixed effects. Expected values of internal patents from the United States and external patents from the United States in the post-KSR period (equations [3] and [4], respectively) as well as a test of their difference (equation [5]) are reported on the bottom panel of models 4 to 6. Standard errors are clustered by patent and drug. The full set of regression estimates is reported in appendix tables 3 and 4. The number of observations in all models is  $N = 8,597$ . \* $p < 0.10$ , \*\* $p < 0.05$ , and \*\*\* $p < 0.01$ .

ket and firm fixed effects. It appears that KSR induced a near 8 percentage point increase in the probability of a Para-IV challenge in the United States relative to an EU opposition. Generic manufacturers in the United States appear to be exploiting the new post-KSR legal environment. Interestingly, this increase in challenges was an unintended consequence of KSR; we could find no discussion of this feared development in the decision or in any of the amicus briefs filed in the case.

In addition, it may be possible that the change in legal environment has affected the expected probability of a successful challenge (this result is confirmed in our estimates in table 3). As a consequence, if we define the probability of a challenge as a function of the expected probability of a successful outcome and the expected value of a win, it is not surprising that generic manufacturers are more likely to initiate Para-IV challenges given the higher likelihood of a positive litigation outcome.<sup>25</sup> On a similar note, we stress that the magnitude of the coefficient of *Post-KSR* × *USA* should be positively correlated with the net expected benefits of a challenge of a U.S. patent relative to an EU patent. This is plausible since Hatch-Waxman provides exclusivity benefits to a generic manufacturer in term of sales for a successful challenge, and the U.S. market tends to be larger in size.

Given that the overall probability of receiving a Para-IV challenge has increased, we now test whether there is a difference between internally generated patents versus

<sup>25</sup> We are grateful to an anonymous referee for this suggestion. For simplicity, we assume that the cost of a challenge remains unchanged over time.

TABLE 3.—OUTCOME OF PARA-IV LITIGATION

	Model 1	Model 2	Model 3	Model 4
Post-KSR	-0.004 (0.006)	-0.003 (0.006)	-0.003 (0.006)	0.000 (0.005)
USA	0.016*** (0.006)	0.016** (0.006)	0.017** (0.007)	-0.001 (0.015)
Post-KSR × USA	0.113*** (0.013)	0.112*** (0.013)	0.111*** (0.013)	0.109*** (0.013)
External	0.003 (0.007)	0.001 (0.007)	0.003 (0.008)	0.006 (0.009)
Controls	Yes	Yes	Yes	Yes
Market FE		Yes	Yes	Yes
Firm FE			Yes	Yes
Inverse Mills ratio				Yes
Observation	4,126	4,126	4,126	4,126

Linear probability model (LPM) estimates of the diff-in-diffs model described in equation (1). The dependent variable in all models is *Challenge outcome*. Model 1 includes only controls, while model 2 includes market and firm fixed effects (FE). Model 3 includes both market and firm fixed effects. Model 4 includes market and firm fixed effects, along with the inverse Mills ratio to control for selection. The selection equation is estimated with a probit model that includes all variables from the outcome equation, plus *Drug Sales*. Standard errors are clustered by patent and drug. The full set of regression estimates is reported in appendix table 5. \* $p < 0.10$ , \*\* $p < 0.05$ , and \*\*\* $p < 0.01$ .

licensed patents. Table 2 (models 4 to 6) reports linear probability estimates of the diff-in-diffs model with a triple interaction described in equation (2). The dependent variable in all models remains *Challenge*. Model 4 includes only controls, while model 5 adds market fixed effects and model 6 adds both market and firm fixed effects. Standard errors are clustered by patent and drug. The expected values of a challenge conditional on an internal patent from the United States or an external patent from the United States in the post-KSR period (equations [3] and [4], respectively), as well as a test of their difference (equation [5]), are reported on the bottom panel of table 2. Again, we report our main independent variables in the table, while the full

set of estimates of these three models is reported in appendix table 4.

In our fully specified model, model 6, the expected values of a challenge in the post-*KSR* period ( $Post\text{-}KSR = 1$ ) for U.S. patents ( $USA = 1$ ) are both positive for internal (11.7%) and external (9.0%) patents. Results suggest that internal patents are 2.7 percentage points more likely than external patents to be challenged in the United States relative to the EU. This result is consistent with the underlying descriptive statistics suggesting that, on average, among the challenged drugs in the United States, 58% of the patents are internal. In addition, the descriptives also suggest that internal patents are, on average, slightly more valuable than external patents and associated with more valuable drugs. This implies that the potential profits that can be earned from challenging internal patents will be greater; hence, we should expect a relatively larger increase in the challenges of internal patents.

### B. Has *KSR* Had an Impact on the Outcome of Paragraph IV Litigation?

Having established the first-order impact of the change in the nonobviousness standard on the probability of receiving a Para-IV challenge, we now examine how, if at all, this change has affected actual Para-IV litigation outcomes. *Ceteris paribus*, such a change should increase the probability that a patent protecting an FDA-approved drug is found invalid. We examine this question by presenting estimates of equation (1) in table 3, where the dependent variable in all models is *Challenge outcome*. Standard errors are clustered by patent and drug. We report the full set of estimates in appendix table 5.

Model 1 includes only controls, while model 2 includes market fixed effects. Model 3 includes both market and firm fixed effects, while model 4 includes both market and firm fixed effects along with the IMR to control for selection. The selection equation is estimated with a probit model that includes all variables from the outcome equation plus *Drug sales*. The dependent variable in the selection equation is *Challenge*. Across all models, the coefficient associated with the interaction ( $Post\text{-}KSR \times USA$ ), is positive and significantly different from 0. The probability that generic manufacturers win after *KSR* increases by approximately 11 percentage points in the United States relative to the EU.

The direction of the result should not be surprising as it confirms the existence of heterogeneity in patent drafting, construction, and prosecution. Changes in the nonobviousness standard will have an impact on the validity of the subset of patents that were closest to the existing bar of nonobviousness. Knowles (2010) cautioned about precisely this kind of impact when patents written under one set of patent law were adjudicated under a different set of law. The question now becomes how this increase in generic manufacturer “win” is distributed across internal and external patents.

TABLE 4.—OUTCOME OF PARA-IV LITIGATION WITH TRIPLE INTERACTION

	Model 1	Model 2	Model 3	Model 4
Post- <i>KSR</i>	0.013* (0.007)	0.013* (0.007)	0.013* (0.007)	−0.001 (0.007)
United States	0.035*** (0.008)	0.031*** (0.008)	0.033*** (0.008)	0.009 (0.016)
External	−0.001 (0.005)	−0.005 (0.006)	0.003 (0.009)	0.001 (0.013)
Post- <i>KSR</i> × USA	0.074*** (0.017)	0.074*** (0.017)	0.074*** (0.017)	0.086*** (0.017)
Post- <i>KSR</i> × External	−0.003 (0.010)	−0.002 (0.010)	−0.003 (0.010)	0.003 (0.011)
USA × External	−0.025*** (0.009)	−0.020** (0.009)	−0.025** (0.011)	−0.019 (0.014)
Post- <i>KSR</i> × USA × External	0.061** (0.025)	0.059** (0.025)	0.061** (0.025)	0.056** (0.026)
Controls	Yes	Yes	Yes	Yes
Market FE		Yes	Yes	Yes
Firm FE			Yes	Yes
Inverse Mills ratio				Yes
Observations	4,126	4,126	4,126	4,126
Internal patent	0.129	0.128	0.126	0.118
<i>p</i> -value	0.000	0.000	0.000	0.000
External patent	0.161	0.160	0.162	0.160
<i>p</i> -value	0.000	0.000	0.000	0.000
Difference	0.033	0.032	0.036	0.041
<i>p</i> -value	0.085	0.093	0.066	0.041

Linear probability model (LPM) estimates of the diff-in-diffs model with triple interactions described in equation (2). The dependent variable is *Challenge outcome*. Model 1 includes controls but no fixed effects (FE). Model 2 includes market fixed effects, while model 3 includes market and firm fixed effects. Model 4 includes the inverse Mills ratio, along with market and firm fixed effects. The expected values of internal patents from the United States and external patents from the United States in the post-*KSR* period (equations [3] and [4], respectively), as well as a test of their difference (equation [5]), are reported in the bottom panel. Standard errors are clustered by patent and drug. The full set of regression estimates is reported in appendix table 6. \* $p < 0.10$ , \*\* $p < 0.05$ , and \*\*\* $p < 0.01$ .

### C. Externally Acquired Patents

*How Reliable Are Externally Acquired Patents?* While internal patents were more likely to be challenged than external patents, we now examine whether, conditional on being challenged, there is a difference between internal and external patents when it comes to outcomes. We report results from our diff-in-diffs model with the triple interaction (equation [2]) in table 4. The dependent variable remains *Challenge outcome*, and standard errors are clustered by patent and drug. The expected values of *Challenge outcome* conditional on the focal patent being internal and from the United States versus external and from the United States in the post-*KSR* period (equations [3] and [4], respectively), as well as a test of their difference (equation [5]), is reported on the bottom panel of table 4. Again, the full sets of estimates are reported in appendix table 6.

We report results across four different models. Model 1 includes our full set of controls but no fixed effects. Model 2 includes market fixed effects, and model 3, our fully specified model, includes market and firm fixed effects. Model 4 includes the IMR to control for selection, along with market and firm fixed effects. In models 3 and 4, we see a 3.6 to 4.1 percentage point difference between internal and external patents, with the difference significant at the 5% significance level in the fully specified model (model 4). In other words, while internal patents may have a greater probability of being challenged, licensed patents have a greater

probability of leading to a generic manufacturer “win” in the post-*KSR* period in the United States relative to the EU. While statistical significance is weak across models 1 to 3, it nonetheless appears that regardless of technological value, licensed patents are less reliable or, more specifically, have greater obviousness risk, than those patents drafted internally.

Why might this be the case? In the absence of adjudication of every pharmaceutical patent or a postpatent review decision, we can only conjecture as to what might be going on.<sup>26</sup> It is possible that *KSR* represents something more than just an increase in the nonobviousness threshold, but a more fundamental shift in the enforcement of the nonobviousness requirement. In fact, it has been recently argued that the *KSR* decision is the “first substantive return to the non-obviousness requirement since the Federal Circuit’s advent” (Lunney & Johnson, 2012, 43). They further argue that “the Court both rejected some of the key restrictions the Federal Circuit had placed on the obviousness doctrine and broadened the circumstances under which obviousness could be found.” The authors also provide evidence suggesting that in the three-year window preceding *KSR*, only 5% of federal circuit decisions unfavorable to patent holders were based on nonobviousness, hardly detectable at all. In a world where nonobviousness is hardly enforced, we would not expect any difference between internal and external patents based on their obviousness. After 2007, however, we would expect a difference in the ability of internal and external patents to hold up during Para-IV challenges.

It may also be that licensed patents were written in a way or covered material that made them more sensitive to changes in the nonobviousness standard relative to internal patents. For example, the number of claims significantly increased in the post-*KSR* period. Given that the structure of patent fees is generally based on the number of claims, it has been suggested that larger patent documents reflect greater technological breadth (Lanjouw & Schankerman, 2001, 2004). However, in a legal regime where the standard for nonobviousness was just increased (post-*KSR*), this wider breadth provides more opportunities for invalidity.

Furthermore, technology suppliers are often small, resource-constrained firms. As such, it is not implausible to believe that there will be greater variance in the legal quality that firms receive. In many cases, patent prosecution is done by a third party that may or may not have experience with Para-IV litigation or other expected litigation scenarios. Certainly there are high-quality law firms willing to provide legal work in return for equity stakes. However, if we think about patent prosecution in terms of a distribution, these law firms would be affecting the right tail of the quality distribution. To the extent that these patents have an impact on our results, we would expect them to be written in a manner that makes them less sensitive to changes in the

TABLE 5.—OUTCOME REGRESSIONS BASED ON FIRM CAPABILITIES

	(1) Below Mean	(2) Above Mean	(3) Below Mean	(4) Above Mean
Post- <i>KSR</i>	0.001 (0.019)	0.024* (0.013)	−0.006 (0.021)	0.008 (0.012)
USA	0.033*** (0.010)	0.049** (0.021)	−0.012 (0.019)	0.024 (0.035)
External	0.025** (0.012)	−0.021 (0.014)	0.031** (0.013)	−0.032 (0.022)
Post- <i>KSR</i> × USA	0.072*** (0.026)	0.071** (0.032)	0.075*** (0.027)	0.084*** (0.031)
Post- <i>KSR</i> × External	0.017 (0.025)	−0.013 (0.014)	−0.003 (0.022)	0.009 (0.016)
USA × External	−0.033** (0.013)	−0.034 (0.028)	−0.029** (0.015)	−0.014 (0.030)
Post- <i>KSR</i> × USA × External	0.028 (0.038)	0.084* (0.048)	0.052 (0.036)	0.062 (0.048)
Controls	Yes	Yes	Yes	Yes
Market FE	Yes	Yes	Yes	Yes
Firm FE	Yes	Yes	Yes	Yes
Inverse Mills ratio			Yes	Yes
Observations	2,568	1,246	2,568	1,246
Internal patent	0.107	0.153	0.089	0.144
<i>p</i> -value	0.000	0.000	0.000	0.000
External patent	0.145	0.168	0.140	0.167
<i>p</i> -value	0.000	0.000	0.000	0.000
Difference	0.038	0.016	0.050	0.024
<i>p</i> -value	0.136	0.642	0.051	0.507

Linear probability model (LPM) estimates of diff-in-diffs with triple interactions described in equation (2). The dependent variable is *Challenge outcome*. The sample is split above and below the mean of total assets. The expected values of internal patents from the United States and external patents from the United States in the post-*KSR* period (equations [3] and [4], respectively) as well as a test of their difference (equation [5]) are reported on the bottom panel. Standard errors are clustered by patent and drug. The full set of regression estimates is reported in appendix table 7. \* $p < 0.10$ , \*\* $p < 0.05$ , and \*\*\* $p < 0.01$ .

nonobviousness standard. As such, their presence in the sample should dampen our overall effects.

*Firm capability regressions.* Another possible explanation may be that acquired patents could have higher variance because there are economies of scale in drafting, prosecuting, and adjudicating patents.<sup>27</sup> This suggests that legal resources, capabilities, and experience of technology buyers may matter. Data do not exist on the size of internal IP departments or the split among patent, transactional, and litigation attorneys. Data also do not exist to verify the presence or use of joint IP-steering committees or IP-related expenditures. In the absence of such data, we must proxy for these resources and capabilities and do so by a firm’s total assets. In addition, we proxy for a firm’s patenting experience through their cumulative patenting activity.

In table 5, we split our sample above and below the mean of pharmaceutical firm IP resources or capabilities (i.e., total assets) and report results from equation (2). In table 6, we split our sample above and below the mean of pharmaceutical firm cumulative patenting. Firm patent stocks are constructed in two different ways. First, we cumulate firm patents from 1975 until the year prior to the application year of the focal patent. Second, we cumulate firm patents for the five years prior to application year of the focal

<sup>26</sup> The USPTO started inter partes reviews in 2012.

<sup>27</sup> We thank an anonymous referee for suggesting this point.

TABLE 6.—OUTCOME REGRESSIONS BASED ON FIRM PATENTING EXPERIENCE

	(1) Below Mean	(2) Above Mean	(3) Below Mean	(4) Above Mean
Post-KSR	0.015* (0.009)	0.022* (0.014)	0.002 (0.008)	0.004 (0.014)
USA	0.047*** (0.010)	0.020 (0.015)	0.034* (0.017)	-0.028 (0.024)
External	0.010 (0.009)	-0.018 (0.012)	0.013 (0.013)	-0.031* (0.018)
Post-KSR × USA	0.069*** (0.020)	0.069** (0.029)	0.080*** (0.021)	0.088*** (0.029)
Post-KSR × External	-0.007 (0.011)	-0.012 (0.015)	-0.001 (0.012)	-0.002 (0.017)
USA × External	-0.039*** (0.013)	-0.009 (0.016)	-0.039** (0.015)	0.009 (0.019)
Post-KSR × USA × External	0.066** (0.028)	0.067* (0.034)	0.062** (0.028)	0.056* (0.035)
Controls	Yes	Yes	Yes	Yes
Market and firm FE	Yes	Yes	Yes	Yes
Inverse Mills ratio			Yes	Yes
Observations	3,014	2,241	3,014	2,241
Internal patent	0.130	0.131	0.124	0.120
<i>p</i> -value	0.000	0.000	0.000	0.000
External patent	0.160	0.159	0.159	0.153
<i>p</i> -value	0.000	0.000	0.000	0.000
Difference	0.031	0.028	0.035	0.033
<i>p</i> -value	0.150	0.271	0.113	0.207

Linear probability model (LPM) estimates of diff-in-diffs with triple interactions described in equation (2). The dependent variable is *Challenge outcome*. The sample is split above and below the mean of patenting experience. The expected values of internal patents from the United States and external patents from the United States in the post-KSR period (equations [3] and [4], respectively), as well as a test of their difference (Equation [5]) are reported on the bottom panel. Standard errors are clustered by patent and drug. The full set of regression estimates is reported in appendix table 8. \* $p < 0.10$ , \*\* $p < 0.05$ , and \*\*\* $p < 0.01$ .

patent. Results remain robust to either measure so we use the first method in our reported results. In each table, models 1 and 2 include our full set of controls along with market and firm fixed effects. Models 3 and 4 control for selection with the inclusion of the IMR along with market and firm fixed effects. The dependent variable remains *Challenge outcome*, and standard errors are clustered by patent and drug. The expected values of *Challenge outcome* for both internal and external patents from the United States, in the post-KSR period (equations [3] and [4], respectively), as well as a test of their difference (equation [5]), is reported on the bottom panel of the table. The full set of regression estimates is reported in appendix tables 7 and 8.

Interesting patterns emerge in both cases. In table 5, we see that for the sample of pharmaceutical firms with below-mean IP resources or capabilities (models 1 and 3), external patents from the United States were about 3.8 to 5 percentage points more likely to fall than internal patents from the United States in the post-KSR period. Likewise, in table 5, (models 1 and 3), we see that for firms with below-mean cumulative patenting experience, external patents from the United States were 3.1 to 3.5 percentage points more likely to fall than internal patents from the United States in the post-KSR period. In both tables, there was no statistically significant difference between internal and external patents for firms with above-mean assets or above-mean cumulative patenting (models 2 and 4 in both tables 5 and 6,

respectively). The difference is instead statistically significant at the 5% level for firms with below-mean assets and close to statistical significance ( $p$ -value = 0.113) for firms with below-mean cumulative patenting. Combined these results begin to suggest that our effect is driven by firms with fewer IP resources or capabilities *and* those with less patenting experience.

To test this conjecture, we create a 2-by-2 matrix with total assets and cumulative patenting. Quadrants are defined above and below the mean of the respective variables. In table 7, we split the sample across the four possible quadrants and again report results from equation (2). All models control for selection with the inclusion of the IMR and also include market and firm fixed effects. The full results are reported in appendix table 9. Of particular interest is model 1, which is defined by the quadrant of below-mean IP resources or capabilities and below-mean cumulative patenting experience. It is the only model where we have a highly statistically significant difference ( $p$ -value = 0.001) between internal and external patents. For this subsample of firms, U.S. external patents are 8.5 percentage points more likely to fall than U.S. internal patents in the post-KSR period.

These results suggest that firms with a combination of both below-average IP resources or capabilities and below-average patenting experience are more susceptible to having a licensed patent fall. There are several possible explanations for this result. First, these firms may have smaller, less experienced in-house patent departments that may not be conducting adequate enough due diligence prior to the acquisition of an external patent. This implies that external patents in the distribution of those close to the legal bar of nonobviousness were more likely to end up at these firms. Because these firms are able to prosecute their own internal patents, it would suggest they have adequate patent drafting experience but lack transactional experience with sufficient litigation scenario planning capabilities.

Second, there exists a nuanced relationship between licensee and licensor. In our research setting, the licensor usually retains prosecution control while the licensee is stuck defending the prosecution decisions during litigation (Knowles & Higgins, 2011; Haeussler & Higgins, 2014). A licensor may make short-term motivated decisions in prosecution to accomplish a quick grant, possibly to reach a milestone payment, but at the cost of adding longer-term litigation risks—for example, the failure to disclose a reference that could be considered material because the licensor might get a final office action that it thinks could affect deal terms (Knowles & Higgins, 2011). In our context, this suggests that these firms with below-average IP resources or capabilities and below-average patenting experience may be either ceding too many rights to licensors or constructing their deals in a way that is creating conflicts of interest. That is, the deal structure may be inducing the licensor to focus on the short term while the licensee is focused on the long term, thereby potentially creating future litigation risks.

TABLE 7.—OUTCOME REGRESSIONS BASED ON IP CAPABILITIES AND PATENTING EXPERIENCE

	(1) Low Capabilities and Low Experience	(2) High Capabilities and Low Experience	(3) Low Capabilities and High Experience	(4) High Capabilities and High Experience
Post-KSR	0.009 (0.021)	-0.001 (0.018)	0.013 (0.014)	0.046** (0.022)
USA	0.023 (0.022)	-0.030 (0.025)	0.016 (0.032)	0.004 (0.039)
External	0.016 (0.015)	-0.038** (0.018)	0.013 (0.020)	-0.001 (0.018)
Post-KSR × USA	0.038 (0.029)	0.100*** (0.036)	0.084** (0.037)	0.069 (0.056)
Post-KSR × External	-0.008 (0.022)	0.004 (0.020)	-0.014 (0.017)	-0.044* (0.024)
USA × External	-0.030* (0.018)	0.015 (0.019)	-0.069** (0.029)	-0.020 (0.040)
Post-KSR × USA × External	0.107*** (0.035)	0.045 (0.041)	0.061 (0.042)	0.079 (0.059)
Control	Yes	Yes	Yes	Yes
Market and firm FE	Yes	Yes	Yes	Yes
Inverse Mills ratio	Yes	Yes	Yes	Yes
Observations	2,669	2,331	2,414	1,980
Internal patent	0.079	0.130	0.150	0.141
<i>p</i> -value	0.001	0.000	0.000	0.000
External patent	0.164	0.155	0.141	0.154
<i>p</i> -value	0.000	0.000	0.000	0.000
Difference	0.085	0.025	-0.009	0.013
<i>p</i> -value	0.001	0.379	0.788	0.728

Linear probability model (LPM) estimates of diff-in-diffs with triple interactions described in equation (2). The dependent variable is *Challenge outcome*. Quadrants are defined above and below the mean of the respective variables. The expected values of internal patents from the United States and external patents from the United States in the post-KSR period (equations [3] and [4], respectively) as well as a test of their difference (equation [5]), are reported on the bottom panel. Standard errors are clustered by patent and drug. The full set of regression estimates are reported in appendix table 9. \* $p < 0.10$ , \*\* $p < 0.05$ , and \*\*\* $p < 0.01$ .

It is also common practice for pharmaceutical firms to create joint IP steering committees with licensor firms where IP issues can be elevated should the need arise. In almost all cases, the commercializing entity holds the tie-breaking vote. Their creation is contractual and again relates to how rights are allocated within these deals. It may be the case that for this subsample of firms, these committees are not being formed or utilized, possibly due to a lack of resources or internal expertise. If they do exist, however, they do not appear to be mitigating the kinds of issues that lead to the litigation risk we are observing.<sup>28</sup>

## VI. Discussion and Conclusion

This paper expands our understanding of the importance of acquired patents in protecting future downstream revenues and commercialized products. 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; Cassiman & Veugelers, 2006; Ceccagnoli et al., 2014). However, the benefits associated with acquired technologies can be uncertain due to the probabilistic nature of patents. As a consequence, future revenue streams may not be guaranteed. Instead, those revenue streams will be protected only if the externally acquired patents are reliable

during litigation. In other words, regardless of technological value, external patents should be carefully evaluated based on their current and future legal ability to hold up during litigation and alternative litigation scenarios.

By relying on the law and economics and markets for technology literatures, our study provides novel insights on the role that acquired patents play during litigation. We find evidence that licensed patents are less reliable than those developed internally, suggesting that their legal quality is more variable than those developed internally. Our results were not, however, homogeneously distributed across our sample firms. The effects were isolated to the subsample of firms with below-average IP resources or capabilities and below-average patenting experience.

Two questions arise. First, why do some external patents have what appears to be greater variability or sensitivity to changes in validity? Second, why does this subsample of technology buyers appear to be more sensitive to these litigation risks? On the first question, our field interviews seem to provide the most consistent explanation. Pharmaceutical companies have the financial resources and experience to craft more reliable patents, taking into consideration broader IP strategies and litigation scenarios. Smaller, research-intensive firms, however, are often resource constrained, and as a result, patents may be written by attorneys with limited experience. More important, most of these attorneys will not be involved in the nuances of pharmaceutical litigation, including Para-IV challenges. There are high-quality law firms that will accept IP cases on a contin-

<sup>28</sup> In appendix table 10, we present robustness tests exploring whether generic manufacturers systematically target weaker patents.

gency basis, but to the extent that these types of patents exist in our data, they would be in the right tail of the quality distribution and dampening our overall average effects.

On the second question, knowing that this variance exists within the external technology markets, firms should conduct robust enough due diligence to identify these litigation risks. Across the distribution of our sample firms, they appear to be doing just that. However, for firms with below-average IP resources or capabilities and below-average patenting experience, this process appears to be failing. For these firms, we think one of two things may be going on.

First, these results could be pointing to errors in the due diligence process itself. Firms appear to be able to select high-quality technology, as evidenced by the fact that these licensed patents were part of a branded product. The shift in the nonobviousness standard exposed these external patents to invalidity under new patent law. This implies that what was missing from these firms was an effective and robust transactional and litigation scenario planning capability. There is a second reason that may lead to this outcome. It is often the case that a licensor will retain prosecution control while the licensee must defend the prosecution decisions during litigation. As such, a licensor may make short-term motivated decisions in prosecution to accomplish a quick patent grant, which can possibly add to longer-term litigation risk to the licensee (Knowles & Higgins, 2011).

Unfortunately, in the absence of more disaggregate data, we are unable to disentangle these two effects. Nonetheless, our findings still complement the existing literature on licensing and licensing management. Many studies have shown the importance of dedicated alliance or licensing capabilities and learning for the success of such deals (Gambardella et al., 2007). Our findings suggest that these capabilities may not be sufficient. Firms also need to have a complementary IP capability so they can potentially identify less reliable patents or generate a more robust defense. For all of our sample firms, having a licensed technology as part of a branded product clearly suggests firms have the capabilities to select high-quality technologies, but for our subsample of firms with fewer IP resources or capabilities and less patenting experience, our findings suggest this second capability is lacking.

There is an alternative explanation for our results. It is plausible that what we are observing is some sort of pecking order in the external technology markets. In this scenario, our subsample of pharmaceutical firms (below-average IP resources or capabilities and below-average patenting experience) may be selecting from “leftovers” in the market. We know from the alliance literature that smaller firms will try to ally with larger pharmaceutical firms as a signal of quality (Nicholson, Danzon, & McCullough, 2005). A similar dynamic may be unfolding in the licensing market. Smaller, research-oriented technology suppliers try to connect with the highest-quality firm possible. This is not to suggest there is a lemons problem in the external technol-

ogy market since all of these patents in our sample are attached to branded products. It does suggest, however, that a more complex decision is occurring. High-quality technologies with superior patent reliability went to licensees with above-average IP resources or capabilities and above-average patenting experience. These firms are probably also those that would be deemed higher quality or have higher reputations. The exploration of the existence (or not) of such a pecking order is beyond the scope of this project, so we leave it for future work.

This underappreciated aspect of the external technology markets may also have implications for 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, 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 toward external technologies. Such calls, however, need to recognize the importance of the complementary capabilities needed to select and manage new technologies and the IP resources or capabilities needed to ensure that revenue streams will be protected.

Finally, whether the price paid by technology buyers reflects possible future litigation risks remains an open question. This question is critical because if the price paid does not reflect the “warts” or potential litigation risks, then it suggests a possible inefficiency in the markets for technology. However, if technology buyers were able to adjust price to reflect these issues, then no inefficiency would exist. Unfortunately, with our data, it is not possible to get at these questions. As with all research, much remains to be done.

#### REFERENCES

- Arora, A., and M. Ceccagnoli, “Patent Protection, Complementary Assets, and Firms’ Incentives for Technology Licensing,” *Management Science* 52 (2006), 293–308.
- Arora, A., A. Fosfuri, and A. Gambardella, *Markets for Technology: The Economics of Innovation and Corporate Strategy* (Cambridge, MA: MIT Press, 2001).
- Arora, A., and A. Gambardella, “Ideas for Rent: An Overview of Markets for Technology,” *Industrial and Corporate Change* 19 (2010), 775–803.
- Arora, A., A. Gambardella, L. Magazzini, and F. Pammolli, “A Breath of Fresh Air? Firm Type, Scale, Scope, and Selection Effects in Drug Development,” *Management Science* 55 (2009), 1638–1653.
- Branstetter, L. G., C. Chatterjee, and M. J. Higgins, “Regulation and Welfare: Evidence from Paragraph IV Generic Entry in the Pharmaceutical Industry,” *RAND Journal of Economics* 47 (2016), 857–890.
- Bulow, J., “The Gaming of Pharmaceutical Patents” (pp. 145–187), in Adam B. Jaffe, Josh Lerner, and Scott Stern, eds.), *Innovation Policy and the Economy* (Chicago: University of Chicago Press, 2004).
- Cassiman, B., and R. Veugelers, “In Search of Complementarity in Innovation Strategy: Internal R&D and External Knowledge Acquisition,” *Management Science* 52 (2006), 68–82.
- Ceccagnoli, M., S. J. H. Graham, M. J. Higgins, and J. Lee, “Productivity and the Role of Complementary Assets in Firms’ Demand for

- Technology Innovations," *Industrial and Corporate Change* 19 (2010), 839–869.
- Ceccagnoli, M., M. J. Higgins, and V. Palermo, "Behind the Scenes: Sources of Complementarity in R&D," *Journal of Economics and Management Strategy* 23 (2014), 125–148.
- Gallini, N. T., "Deterrence by Market Sharing: A Strategic Incentive for Licensing," *American Economic Review* 74 (1984), 931–941.
- Gallini, N. T., and S. G. Winter, "Licensing in the Theory of Innovation," *RAND Journal of Economics* 16 (1985), 237–252.
- Gambardella, A., P. Giuri, and A. Luzzi, "The Market for Patents in Europe," *Research Policy* 36 (2007), 1163–1183.
- Grabowski, H., "Are the Economics of Pharmaceutical Research and Development Changing? Productivity, Patents and Political Pressures," *PharmacoEconomics* 22 (2004), 15–24.
- Grabowski, H. G., and M. Kyle, "Generic Competition and Market Exclusivity Periods in Pharmaceuticals," *Managerial and Decision Economics* 28 (2007), 491–502.
- Graham, S. J. H., B. H. Hall, D. Harhoff, and D. C. Mowery, "Patent Quality Control: A Comparison of US Patent Re-Examinations and European Patent Oppositions," in W. Cohen and S. Merrill, eds., *Patents in the Knowledge-Based Economy* (Washington, DC: National Academy Press, 2003).
- Greene, W. H., *Econometric Analysis*, 8th ed. (Boston: Pearson, 2017).
- Haeussler, C., and M. J. Higgins, "Strategic Alliances: Trading Ownership for Capabilities," *Journal of Economics and Management Strategy* 23 (2014), 178–203.
- Hall, B. H., A. Jaffe, and M. Trajtenberg, "Market Value and Patent Citations," *RAND Journal of Economics* 36 (2005), 16–38.
- Harhoff, D., and M. Reitzig, "Determinants of Opposition against EPO Patent Grants: The Case of Biotechnology and Pharmaceuticals," *International Journal of Industrial Organization* 22 (2004), 443–480.
- Harhoff, D., F. M. Scherer, and K. Vopel, "Citations, Family Size, Opposition and the Value of Patent Rights," *Research Policy* 32 (2003), 1343–1363.
- Harhoff, D., G. von Graevenitz, and S. Wagner, "Conflict Resolution, Public Goods and Patent Thickets," *Management Science* 62 (2016), 704–721.
- Hemphill, C. S., and B. N. Sampat, "When Do Generics Challenge Drug Patents?" *Journal of Empirical Legal Studies* 8 (2011), 613–649.
- "Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals," *Journal of Health Economics* 31 (2012), 327–339.
- Higgins, M. J., and S. J. H. Graham, "Balancing Innovation and Access: Patent Challenges Tip the Scales," *Science* 326, 5951 (2009), 370–371.
- Knowles, S. M., "Fixing the Legal Framework for Pharmaceutical Research," *Science* 327 (2010), 1083–1084.
- Knowles, S. M., and M. Higgins, "Vertical Disintegration in the Pharmaceutical Industry and the Role of IP," *Intellectual Asset Management* 45 (2011), 10–15.
- Lanjouw, J. O., and M. Schankerman, "The Quality of Ideas: Measuring Innovation with Multiple Indicators," NBER working paper 7345 (1999).
- "Characteristics of Patent Litigation: A Window on Competition," *RAND Journal of Economics* 32 (2001), 129–151.
- "Patent Quality and Research Productivity: Measuring Innovation with Multiple Indicators," *Economic Journal* 114 (2004), 441–465.
- Lemley, M. A., and C. Shapiro, "Probabilistic Patents," *Journal of Economic Perspectives* 19 (2005), 75–98.
- Lerner, J., "The Importance of Patent Scope: An Empirical Analysis," *RAND Journal of Economics* 25 (1994), 319–333.
- Lunney, G. S., and C. T. Johnson, "Not So Obvious After All: Patent Law's Nonobviousness Requirement, KSR, and the Fear of Hindsight Bias," *Georgia Law Review* 47 (2012), 41–111.
- Morgan Stanley, "Pharmaceuticals: Exit Research and Create Value" (Morgan Stanley, 2010).
- Nicholson, S., P. Danzon, and J. McCullough, "Biotech-Pharmaceutical Alliances as a Signal of Asset and Firm Quality," *Journal of Business* 78 (2005), 1433–1464.
- PwC, "Patent Litigation Study: Big Cases Make Headlines, While Patent Cases Proliferate" (PwC, 2012–2013).
- Reiffen, D., and M. R. Ward, "Generic Drug Industry Dynamics," this REVIEW 87 (2005), 37–49.
- Scherer, F. M., "Pharmaceutical Innovation," in B. H. Hall and N. Rosenberg, eds., *Handbook of the Economics of Innovation* (Amsterdam: North-Holland, 2010).
- Scott Morton, F. M., "Entry Decisions in the Generic Pharmaceutical Industry," *RAND Journal of Economics* 30 (1999), 421–440.
- Shapiro C., "Antitrust Limits to Patent Settlements," *RAND Journal of Economics* 34 (2003), 391–411.
- Somaya, D., "Patent Strategy and Management: An Integrative Review and Research Agenda," *Journal of Management* 38 (2012), 1084–1114.
- Trajtenberg, M., "A Penny for Your Quotes: Patent Citations and the Value of Innovations," *RAND Journal of Economics* 21 (1990), 172–187.
- Voet, M. A., *The Generic Challenge: Understanding Patents, FDA and Pharmaceutical Life-Cycle Management*, 4th ed. (Boca Raton, FL: BrownWalker Press, 2014).