Intellectual Property Rights and New Technology Development: How the Replacement Effect and Capabilities Influence Firm Investment Following a Reduction In IPR

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Version: June 28, 2021

Abstract: This study investigates a key question in the intellectual property rights (IPR) literature: will a reduction in IPR increase or decrease investments in technology development by firms already operating in an industry? We examine investments in the form of new phase 1 clinical trials by pharmaco-genetics firms before and after the invalidation of gene patents by the 2013 United States Supreme Court *Myriad* decision. We use a difference-in-differences design, with the European Union, where gene patents remained valid, as the control group. Fine-grained analysis reveals substantial differences between the US and the EU, depending on firms' presence in specific technological areas, defined along medical conditions, and on firms' capabilities. In aggregate, investments following *Myriad* neither increased nor decreased. However, when we investigated different categories of firms, including pre-shock startups and pre-shock established firms, with distinct strengths of technological and complementary capabilities, we found three differences. First, pre-shock startups decreased investments while pre-shock established firms as a group did not change their total activity. Second, pre-shock established firms reduced investments in home technological areas and increased investments in medically-related new areas, indicating what the literature calls a replacement effect: in this case, from prior investment targets to new related targets. Third, possession of strong technological and generic complementary capabilities reinforced the replacement effect by incentivising pre-shock established firms to diversify into related new areas, while strong area-specific complementary capabilities attenuated the replacement effect by making firms more likely to maintain investments in home areas.

Keywords: Intellectual property rights; investment; diversification; replacement effect; capabilities

1. Introduction

A wide literature has examined how intellectual property rights (IPR) shape firms' incentives to invest in the development and commercialization of new technologies (Schumpeter 1950, Arrow 1962, Teece 1986, Levin et al. 1987, Cohen et al. 2000). Two streams of research with conflicting predictions dominate the debate. On the one hand, strong IPR may encourage investment because they protect innovators against imitation (Teece 1986, Mitchell 1989, Arora et al. 2001, Gans et al. 2002, Gans and Stern 2003, Arora and Ceccagnoli 2006). This argument suggests that incentives to invest in new technology development will diminish if IPR weaken. By contrast, strong IPR environments may raise the cost of entry and deter new investments, thus leading to a low rate of subsequent innovation in the protected areas (Gilbert 2006, Cockburn and MacGarvie 2011, Khoshsokhan 2019, Lemley and Shapiro 2005, Nelson 2006). Within this perspective, weak IPR may encourage investment in technology development.

To date, the conversation lacks two key elements. First, prior studies have not considered contingencies related both to how firms' presence in a technological area of an industry and the capabilities they possess may influence how they respond to a change in the IPR regime. Second, research in this stream has struggled with the lack of counterfactuals where one observes firms' investments in regimes of strong versus weak IPR. In this exploratory study, we aim to fill these gaps in the literature by investigating how a change in an IPR environment affects the incentives of firms already operating in an industry to undertake additional investments. We do this in the context of a legal shock that allows us to compare investments in technological areas of an industry under both strong and weak IPR regimes.

We focus on two contingencies likely to shape the effect of unexpected shocks in the IPR environment on existing firms' investments in technology development. First, we consider the influence of firms' presence in a technological area. Firms with existing investments in a technological area are likely to be key players in ongoing innovation activity, yet we have only limited understanding of how changes in an IPR regime affect their subsequent investment incentives. We accordingly examine the impact of a shock in IPR on investments into existing areas of an industry separately for firms that were already present in specific technological areas prior to the IPR regime change and firms present in other areas in the same

industry. Second, we examine the role of capabilities in the strategic adaptation of investment behavior by firms operating in an industry after a shock in their IPR environment. We distinguish between two categories of firms with different levels of capabilities: pre-shock startups are young entrepreneurial firms that started their activities in the years soon before the shock, while pre-shock established firms are mature firms benefitting from a stronger foothold in the industry. We also assess variation in the strength of capabilities within the pre-shock established firms category to further disentangle the nuanced impact of capabilities.

Our focus on these two contingencies is motivated by two core literature streams. In examining how firms' presence in a technological area affects their incentives to undertake subsequent investments, we build on the literature initiated by Arrow (1962), who drew attention to the dilemma that incumbent firms face when investing in innovation. In his seminal work, Arrow argued that firms' incentives to innovate in areas where they are already present are subject to concerns about cannibalizing their profits from existing investments. This is referred to as the *replacement effect* (Tirole 1988), which might be particularly strong in weak IPR environments where innovations can be expropriated by imitating entrants (Gilbert and Newbery 1982, Katz and Shapiro 1987). Thus, in weak IPR environments, firms already present in an area have lower incentives to innovate in the area than entrants, which are not subject to the replacement effect. This may lead established firms to redeploy technology development efforts from home areas to new areas, rather than seek incremental expansion in an area that is now open to entrant attack following a reduction in IPR. Despite their strategic importance, the implications of the replacement effect for investments in home and new technological areas have received limited attention.

Our investigation of the role of firm capabilities in technology investment draws from a well-established research stream that has highlighted the importance of capabilities in technology commercialization (Penrose 1959, Teece 1986, Mitchell 1989, Tripsas 1997, Sosa 2013). Yet, we have a limited understanding of how the differences and the interplay between technological and complementary capabilities may affect the investment incentives of firms operating in environments with various levels of IPR (Teece 2006, Wang et al. 2020, Nerkar and Roberts 2004, Song et al. 2005). The literature on corporate

diversification has pointed out that technological capabilities may facilitate diversification in related areas (Tanriverdi and Venkatraman 2005, Miller 2006, Sakhartov and Folta 2014, Lieberman et al. 2017). A question remains regarding the relative impact of technological compared to complementary capabilities, including both generic and area-specific complementary capabilities. We aim to fill this gap by examining the separate role of complementary and technological capabilities in the relationship between the strength of IPR and investment in different technological areas within an industry.

Building on these theoretical concepts, we assess how existing firms in an industry adapt to unexpected changes in the strength of the IPR environment within their industry, focusing on whether such changes encourage or deter investments in technology development. We examine if the impact of the IPR environment differs depending on whether firms were present in a particular technological area within the industry. Further, we investigate whether complementary capabilities or technological capabilities are more likely to influence the IPR-investment relationship. As the logic for predicting how capabilities will affect technology development investments following changes in the IPR regime is complex and ambiguous, we adopt an exploratory research question approach rather than attempting to develop specific predictions.

We exploit a shock in the IPR environment of the pharmaco-genetics industry. Pharmaco-genetics firms develop drugs for medical conditions associated with specific genetic traits; these include general biopharmaceutical firms as well as specialist genetics firms. Our study examines technology development investments in the form of new phase 1 clinical trials before and after the invalidation of gene patents by the 2013 United States (US) Supreme Court *Myriad* decision. Gene patents inhibit competing firms from conducting research with the objective of developing drugs whose mechanism of action would specifically target the protein encoded by a gene. Gene patents thereby create a legal barrier to investments in medical condition areas associated with specific genes and their encoded proteins. By contrast with the US, gene patenting has remained valid in all European Union (EU) member countries because patent validity was upheld through regulation in 1998. The difference in the evolution of the legal regimes covering gene patenting in the US (treatment group) and in the EU (control group) allows us to develop a difference-in-differences empirical design to assess the impact of a sudden reduction in the strength of the IPR

environment on technology development investment dynamics.

We find substantial evidence that the effect of a reduction in the strength of the IPR environment depends on a firm's prior presence in a technological area as well as on the strength of its capabilities. We first show that the relaxation in IPR introduced by the Supreme Court decision did not have an aggregate impact on investments by existing firms but this apparent null result masks variation in the implications of the reduction in IPR for investments by different types of firms. Firms founded soon before the shock (pre-shock startups) considerably decreased investments following the *Myriad* decision while on average those with a more established prior base (pre-shock established firms) remained unaffected overall. In turn, the apparent lack of effect for established firms masks counter-acting influences based on the relatedness of new areas in which firms invest and on the strength of firms' capabilities. The more nuanced analysis shows that pre-shock established firms decreased investments in their home areas, while increasing investments in medically-related new areas. Moreover, strong technological capabilities, strong generic complementary capabilities, and weak area-specific complementary capabilities enhanced the tendency to reduce investment in home technological areas, thereby reinforcing the replacement effect.

This study contributes to the literature on IPR and technology development by uncovering how the effect of a shock in the IPR environment on investments by existing firms is contingent on these firms' presence in a technological area and the strength of their capabilities. Recent empirical research on the impact of IPR has mainly focused on their consequences for cumulative innovation and the direction of research (Huang and Murray 2009, Williams 2013, Galasso and Schankerman 2015, Murray et al. 2016, Sampat and Williams 2019). Moreover, prior studies have examined various innovation outcomes associated with policies increasing the strength of the IPR environment (Sakakibara and Branstetter 2001, Branstetter et al. 2006, Chaudhuri et al. 2006, Kyle and McGahan 2012, Duggan et al. 2016, Vakili and McGahan 2016, Chattopadhyay and Bercovitz 2020). Our paper provides novel insights on the specific impact of a sudden reduction in the strength of the IPR environment and extends prior work by studying the strategic implications of the IPR environment in order to advance the literature on technology commercialization (Teece 1986, Mitchell 1989, Arora et al. 2001, Gans and Stern 2003, Cockburn and

MacGarvie 2011, Khoshsokhan 2019). We help clarify the debate on the impact of the IPR environment on existing firms' incentives to invest in technology development and highlighting how this impact differs depending on firms' presence in a technological area and their capabilities.

We first uncover how the replacement effect pushes firms to diversify into related new areas and to reduce investments in their home areas, allowing them to adapt to the threat of technology expropriation. We thereby extend this literature by highlighting the broader consequences of the replacement effect at the level of an industry comprised of multiple technological areas (Arrow 1962, Gilbert and Newbery 1982, Katz and Shapiro 1987). By comparing the impact of technological capabilities and two types of complementary capabilities, generic and area-specific, on the relationship between IPR and technological area entry, we respond to a call for more granular theoretical and empirical research on the role of firms' capabilities in technology commercialization (Teece 2006, Anand et al. 2010, Arora and Nandkumar 2012, Wang et al. 2020). Our study demonstrates that the IPR environment influences firms' positioning across areas within their industry and brings new insights to the literature on resources redeployment by highlighting IPR as a factor driving the redeployment of capabilities (Penrose 1959, Helfat and Eisenhardt 2004, Levinthal and Wu 2010, Wu 2013, Sakhartov and Folta 2014, Folta et al. 2016, Lieberman et al. 2017, Sakhartov 2017, Dickler and Folta 2020). Finally, our paper extends recent work on the impact of IPR on innovation (Sampat and Williams 2019, Khoshsokhan 2019) by focusing on the consequences of a shock in the IPR environment for firms that were already present in the industry at the time of the shock. The strategic behavior of existing firms in reaction to IPR disruption holds important implications for industry evolution and competitive dynamics.

The paper is organized as follows. Section 2 summarizes the theoretical perspectives that may shape the relationship between a sudden reduction in the strength of the IPR environment and technological investment dynamics. Section 3 describes the empirical setting and methods. Section 4 presents the main analyses and results. Section 5 discusses our findings and concludes.

2. Theory

2.1 Strong vs. weak IPR regimes

A wide stream of literature suggests that IPR hold considerable strategic implications for technological firms by shaping their ability to profit from their innovations (Schumpeter 1950, Arrow 1962, Teece 1986, Levin et al. 1987, Cohen et al. 2000). Prior research has shown how firms may align their strategies with the industry's IPR environment to successfully commercialize new technological products, either independently or through cooperation (Teece 1986, Arora et al. 2001, Gans et al. 2002, Gans and Stern 2003, Arora and Ceccagnoli 2006). The effect of IPR on incentives to invest in technology development nevertheless remains unclear in the literature, especially in the context of a sudden reduction in the strength of the IPR environment requiring existing firms to adapt.

On one hand, a stream of studies has shown that a weak IPR environment may inhibit investments in the development of new technologies, as few firms will be willing to undertake investments that might be appropriated by follower-imitator firms (Teece 1986, Mitchell 1989). According to these studies, strong IPR environments are expected to incentivize investments by providing a monopolistic competitive advantage to firms developing novel products. Moreover, IPR protection provides technological firms with the time needed to acquire capabilities required to enter the product market (Teece 1986). Recent work has for instance shown that strong IPR environments benefit startups by improving their access to funding (Hsu and Ziedonis 2013) and increasing their capacity to grow (Farre-Mensa et al. 2020).

By contrast, other studies suggest that strong IPR tend to significantly reduce the rate of investments and to mostly benefit incumbents (Cockburn and MacGarvie 2011, Boldrin and Levine 2013, Khoshsokhan 2019). The theoretical economics literature has shown that potential competitors often have little to gain from competing against incumbents in their home areas if incumbents remain active in R&D (Nelson 2006, Gilbert 2006). Another justification for this reduction in investment may lie in the role played by IPR in facilitating technology commercialization through cooperation with incumbent firms, such as via licensing contracts (Arora et al. 2001, Gans and Stern 2003). These considerations reinforce the dominant position of incumbents and explain why other firms have diminished incentives to carry out major investments in environments with strong IPR.

2.2 Prior presence in a technological area: The replacement effect

The impact of IPR on firms' investments in technology development may depend on whether they were present in a specific technological area. These considerations were first discussed by Arrow (1962) and are referred to in the literature as the replacement effect (Tirole 1988). The logic behind the replacement effect compares incumbents' and entrants' profits from the development of a superior innovation. Simply stated, payoffs will tend to be higher for entrants to an area, whereas area incumbents will have to bear the cost of cannibalizing profits derived from an older technology. In strong IPR environments, incumbents have incentives to develop and commercialize superior technologies to preempt new entrants as they risk losing their entire profits if a new entrant is the first to commercialize a superior technology (Gilbert and Newbery 1982). Nevertheless, in weak IPR environments, a new entrant and an incumbent would be able to imitate each other and could both commercialize a superior product independently of which of these firms would be the first to develop it. Their respective payoffs are likely to be influenced by the strength of their complementary and technological capabilities (Teece, 1986) but, holding such capabilities constant, an incumbent's relative payoffs should generally be lower than those of a recent entrant's because incumbents are subject to the replacement effect (Katz and Shapiro 1987). Established firms might accordingly have lower incentives to commercialize new technologies in their home areas and higher incentives to diversify into new areas where they will not be subject to a replacement effect and the cannibalization of their existing profits in weak IPR environments.

The replacement effect is reinforced because the resources required to invest in technological areas often are non-scale free in nature and investment in new technological areas accordingly is likely to require their inter-temporal redeployment from old to new areas (Penrose 1959, Helfat and Eisenhardt 2004, Levinthal and Wu 2010). For example, a corporate laboratory would have to redeploy its attention from a technological area currently under investigation to a new technological area following the firm's investment in that area as at least some of the laboratory's scientists and research instruments may not be able to be used contemporaneously in both technological areas. Such inter-temporal redeployment of capabilities provides an explanation for the decrease in firms' investment in home technological areas likely to be

associated with an increase in their investment in new technological areas due to the replacement effect.

Furthermore, the literature on corporate diversification has offered useful insights on strategic opportunities arising from the redeployment of capabilities in new technological areas. Drawing from the resource-based view of the firm, studies in this literature underline that capabilities can create value when they are applied in related technological industries (Rumelt 1982, Wernerfelt 1984, Barney 1986, Montgomery and Hariharan 1991, Peteraf 1993, Robins and Wiersema 1995, Silverman 1999, Diestre and Rajagopalan 2011). A complementary stream of research has found this relationship to hold at the market or area level (Tanriverdi and Venkatraman 2005, Miller 2006, Sakhartov and Folta 2014, Lieberman et al. 2017). The replacement effect may thus push established firms to prioritize investments in related technological areas that are new to them following a reduction in IPR.

2.3 Technological and complementary capabilities

The replacement effect taking place in weak IPR environments opens intriguing questions regarding the types of capabilities that may facilitate firms' diversification process in related new areas. Prior literature has underlined that the strength and type of capabilities owned by firms are likely to influence the impact of the IPR environment on their investment decisions (Teece 1986, Arora et al. 2001, Gans and Stern 2003). Recent research has called for more attention to differences between types of capabilities and, in particular, to the difference between technological capabilities and complementary capabilities (Teece 2006, Wang et al. 2020, Nerkar and Roberts 2004, Song et al. 2005). A limited set of studies has addressed this topic. Anand, Oriani, and Vassolo (2010) examined the impact of technological and complementary capabilities on market entry following a technological discontinuity. Arora and Nandkumar (2012) have studied how complementary and technological capabilities shape firm performance across environments that differ in terms of the resources that firms can access via markets for technology. We aim to fill a gap in the literature by assessing how the effect of the IPR environment on technology development investments by existing firms is conditioned by the strength of their technological and complementary capabilities. Moreover, we intend to assess the potential interactive effect of technological and complementary capabilities on firms' investments, where there is little empirical

evidence (Arora and Nandkumar 2012).

Technological capabilities have been defined as the set of routines involving physical assets, knowledge, and competencies that are intrinsic to the engineering and manufacturing of a product (Mitchell 1992, Anand et al. 2010). In the pharmaco-genetics industry, advanced expertise and equipment required to conduct R&D in an advanced scientific field, such as genomics, are relevant examples of comparatively advantageous technological capabilities. The literature on corporate diversification has highlighted how firms' technological capabilities may facilitate investment in related technological areas (Tanriverdi and Venkatraman 2005, Miller 2006, Sakhartov and Folta 2014, Lieberman et al. 2017).

In contrast with technological capabilities, complementary capabilities have typically been described as capabilities assisting in the commercialization of a technology, such as marketing, manufacturing, distribution, and after-sales support capabilities (Teece 1986). Extensive literature has highlighted their role in facilitating investments in technological industries (Mitchell 1989, Tripsas 1997, Sosa 2013). Such capabilities may be further decomposed into generic or area-specific complementary capabilities based on their level of interdependence within a given technological area. Generic complementary capabilities may be used in multiple technological areas while area-specific complementary capabilities are closely tied to the particularities of a given technological area and have limited use in other areas. For example, in the pharmaceutical industry, management and regulatory affairs departments experienced in the development and administration of large clinical trials would be considered generic while a sales department with connections to medical specialists in a particular medical condition area developed over multiple years would be considered area-specific.

Views on the roles of generic and area-specific complementary capabilities differ. Teece (1986) argued that, when IPR institutions are weak, area-specific complementary capabilities play a more important role relative to generic complementary capabilities in profiting from investments in technology development; his logic is that area-specific capabilities are more difficult to access on the market and require irreversible financial commitments while generic capabilities are more readily available on the market. Nevertheless, recent research has highlighted how the higher redeployability of generic complementary

capabilities may help established firms adapt to changes in their environment through diversification in settings with weak barriers to entry (Rothaermel and Hill 2005, Uzunca 2018). The redeployability of technological capabilities and generic complementary capabilities could thus play a role in facilitating the diversification process behind the replacement effect likely to occur in weak IPR environments.

The debate in the literature on the impact of the strength of the IPR environment on incentives to invest in technology development raises key research questions, which we examine in the context of a sudden reduction in the strength of the IPR environment. We focus on its consequences for firms already present within an industry. We first assess whether such a shock in the IPR environment is likely to have a positive or a negative effect on investments in technological areas of an industry and whether this effect will be different in areas in which firms already operated and in areas in which they are not yet present. We then draw from the literature on firm capabilities to uncover how technological and complementary capabilities tend to influence the impact of the IPR environment on investments.

3. Methods

3.1 Research setting

The Human Genome Project, an international research project launched in 1990 and completed in 2003, led to the sequencing and open publication of the first human genome. The project provided the basis to develop increasingly efficient and affordable sequencing tools and to use genomics research methods in the drug development process. Genomics has since led to the discovery that millions of gene microsections differ across individuals. A better understanding of the associations between specific genes and medical conditions is driving considerable changes in the practice of medicine and pharmaceutical R&D as these genes constitute clinically useful drug targets. Experts believe that medical care will eventually be adapted to each individual's unique genetic profile through the use of genomics technologies (Green et al. 2011).

In pharmaco-genetics, gene patents have received considerable attention in recent years as firms present in the industry have been able to maintain high prices for drugs targeting proteins covered by gene patents because of the wide protection from expropriation that these patents offer. Patents create barriers to

investments in medical condition areas associated with a gene by preventing competing firms from conducting research and developing a drug specifically targeting the protein produced by a patented gene. For example, Alzheimer's Institute of America, a firm created for the purpose of extracting value from a patent covering the APP695 gene (a specific mutation of the APP gene associated with early-onset Alzheimer's disease; also referred to as APPswe), asserted its gene-related patents against 18 defendants in a series of lawsuits initiated in 2003 (Bubela et al. 2015, Cook-Deegan et al. 2016). Some of these lawsuits involved the production by competing firms of transgenic mice with the APP695 gene for pharmaceutical R&D purposes. Furthermore, firms holding gene patents may also prevent competitors from conducting genetic testing to identify the presence of a patented gene in individuals' genomes in the context of research, as Myriad Genetics did against clinical researchers at the University of Pennsylvania (Carbone et al. 2010). Barriers to investments in areas associated with patented genes accordingly have important implications for the development of new drugs and the treatment of patients affected by genetic medical conditions. Appendix A provides a more detailed overview of the effect of gene patents on pharmaceutical R&D.

Our study relies on a shock that significantly reduced the strength of the IPR environment in the US pharmaco-genetics industry. In its 2013 decision *Association for Molecular Pathology v. Myriad Genetics, Inc.* (*Myriad*), the US Supreme Court put an end to a 30-year period during which court decisions established and then repeatedly confirmed the patentability of genes and gene-based diagnostic methods (USSC 2013, Sanzo 2016). The court stated that isolated gene sequences, referring to DNA sequences in a form outside the human body, do not constitute the type of subject matter that is eligible for patenting, rebutting Myriad Genetics' claims on the BRCA1 and BRCA2 genes. The Court based its decision on the fact that isolated gene sequences are the same as those which are found in nature (Feldman 2014). The decision accordingly allowed pharmaco-genetics firms to perform research as well as to develop and commercialize drug products using any gene and their associated proteins previously protected by IPR. While the decision had been long awaited in the biomedical community, its outcome was difficult to predict as the logic was founded on technical scientific details that were challenging to interpret in view of US IPR law. Thus, even though the Supreme Court decision was unanimous, *Myriad* involved an important degree

of ex ante uncertainty for firms involved in the pharmaco-genetics industry. Indeed, two lower courts that had heard the case before the Supreme Court, the Southern District Court of New York and the United States Court of Appeal for the Federal Circuit, had rendered opposing decisions.

IPR law is implemented within country jurisdictions and *Myriad* therefore does not apply outside the US. The EU harmonised IPR protection of biotechnological inventions in 1998, allowing patenting of genes associated with a potential industrial application in all member countries (EU 1998). Transposition of the directive in national legislation of EU countries was completed in 2007. The US and EU legal regimes governing the patentability of genes and the protection afforded by gene patents against infringement by competing firms evolved in parallel and were considered to include the same key principles up to the *Myriad* decision in 2013 (Lai 2015, Whitley 2015, Saw 2016, Liddicoat et al. 2019, Nicol et al. 2019).

This distinction in the rules of the IPR regime covering the patenting of genetic sequences in the US and EU thus offers an opportunity to test our hypotheses using a difference-in-differences empirical design. Our study is inspired by prior research having also relied on equivalent patents granted in the US and in the EU to develop a difference-in-differences approach (Hegde and Luo 2018, Hegde et al. 2019). The biomedical industry, which has been used in previous research on technology development investment dynamics, provides a useful setting for our study (Mitchell 1989, Sosa 2011, Sosa 2014).

3.2 Data

The data collection strategy, which is inspired by prior research by Jensen and Murray (2005), Huang and Murray (2009), and Sampat and Williams (2019), involved identifying relevant patents, related clinical trials and medical condition areas, and the firms that carried out the trials. We first identified all US patents mentioning genetic sequences in their claims section using the United States Patent and Trademark Office's (USPTO) PatFT database and retrieved the genetic sequences as well as bibliographic data. In order to build on methods relied upon in previous literature, we further identified equivalent EU patents using the European Patent Office's Open Patent Services database and retrieved bibliographic data. Equivalent patents are patents obtained for the same invention in different countries. Using the US National Center for Biotechnology Information's BLAST software to compare the patented genetic sequences

previously retrieved with the human genome, we subsequently identified the specific genes covered by the equivalent US and EU patents. This procedure allowed us to identify 1,805 pairs of equivalent US and EU patents with a total of 2,744 different genes mentioned in the claims section.

Once we had identified patents, we identified relevant clinical trials. We collected data on drugs targeting our sample of patented genes using the DrugBank database, a public database with unique and comprehensive information on genetic drug targets (Wishart et al. 2006). Based on Sampat and Williams' (2019) methods, we matched the drugs targeting proteins covered by patented genes identified in the previous step with global clinical trials data from Springer's AdisInsight database. To avoid biases introduced by how the success of initial trials influences investments in subsequent trials, we retained only phase 1 clinical trials submitted for the approval of a drug in the US or in the EU.

We then matched clinical trials with medical conditions to isolate distinct technological areas. In order to define medical condition areas, we matched medical conditions associated to each clinical trial with medical conditions listed in the 11th Revision of the World Health Organization's International Classification of Diseases (ICD). The ICD is the international standard for reporting medical conditions in clinical and research settings. As the ICD provides an extensive and highly granular list of medical conditions, we aggregated medical conditions in our sample to the third level of ICD's hierarchical structure. For example, following ICD's hierarchical structure, we defined all bacterial intestinal infections as part of a unique medical condition area given their pathological similarity. Our sample includes 351 distinct medical condition areas.

We next collected information on firms sponsoring clinical trials from Bureau van Dijk's Orbis database, adjusting the dataset to take into account historical ownership changes. Using this information, we assigned each clinical trial to the highest parent firm at the start of the clinical trial. We also assigned clinical trials of acquired firms to acquiring firms in the year that an ownership change took place in order to consider technology development investments made through mergers and acquisitions. In order to isolate the effect of the shock on investments by existing firms, we excluded clinical trials by firms that launched their first ever clinical trial after 2013, the year of the Supreme Court decision. Our final sample constitutes

a unique dataset connecting patented genes and commercialization outcomes at the international level. The data consist of 2,512 phase 1 clinical trials for 352 drugs targeting 158 genes patented in the US and in the EU and sponsored by a total of 258 firms.

This procedure established the set of relevant pharmaco-genetics firms that had experience in gene-related drug development prior to the US Supreme Court decision, which include both generalist pharmaceutical firms and specialist genetics firms. Many of the firms in our sample are active both in the US and in the EU and, given the considerable size of the US market, many European firms are also active in the US. We then classified firms in terms of their pre-shock experience and capabilities.

Based on prior literature and particularities of our empirical setting, we distinguish between pre-shock startups and pre-shock established firms. Pre-shock startups are young entrepreneurial existing firms that lack critical complementary and technological capabilities often considered to be necessary for sustained independent technology development investments. By contrast, pre-shock established firms generally possess complementary and technological capabilities developed over time during the course of their activities in the industry on which they may rely to develop and commercialize new technologies (Teece 1986, Mitchell 1989, Tripsas 1997, Sosa 2013).

We assigned clinical trials to pre-shock startups or pre-shock established firms categories according to the following criteria: 1) a clinical trial is assigned to the *pre-shock startups* category if the sponsoring firm had launched only one clinical trial prior to the US Supreme Court decision and the firm's first clinical trial (in any field) was launched within five years after its incorporation; 2) a clinical trial is assigned to the *pre-shock established firms* category if the sponsoring firm had launched more than one clinical trial prior to the US Supreme Court decision. This categorization allows us to distinguish the general effect of the IPR environment on categories of firms that tend to have different levels of capabilities. In addition, we distinguished between investments in areas in which firms were already present and investments in areas in which firms were not present at the time of the Supreme Court decision.

To further disentangle how technological and complementary capabilities shape the relationship between the strength of the IPR environment and investments in technology development, we split the

observations in the categories above in additional subcategories concerning capabilities. We developed these subcategories based on measures used in prior literature on technological and complementary capabilities (Tripsas 1997, Helfat 1997, Nerkar and Roberts 2004, Arora and Ceccagnoli 2006, Ceccagnoli 2009, Anand et al. 2010, Sosa 2011, Arora and Nandkumar 2012, Kapoor and Furr 2015, Moeen 2017). We rely on ownership of relevant patents and prior experience in fully bringing a drug to market to respectively classify firms in subcategories with strong or weak technological and complementary capabilities. We assigned clinical trials to subcategories with strong technological capabilities if the sponsoring firm owned at least one gene patent and to subcategories with weak technological capabilities for firms with no patents. In parallel, we assigned clinical trials to subcategories with strong generic complementary capabilities if the sponsoring firm had at least one marketed drug in its portfolio and to subcategories with weak generic complementary capabilities otherwise. In turn, we assigned clinical trials to subcategories with strong area-specific complementary capabilities if the sponsoring firm had at least two marketed drugs targeting the medical condition in the focal clinical trial and to subcategories with weak area-specific complementary capabilities otherwise. This more granular firm categorization allows us to improve the precision of our assessment of the role of technological and complementary capabilities as drivers of investment in technology development.

Finally, we relied on the ICD to define relatedness of medical condition areas. The ICD is composed of 26 chapters that structure the indexing of medical conditions. Each chapter focuses on a broad category of medical conditions that share similar pathological characteristics. For example, ICD chapters distinguish between diseases of the immune system; diseases of the nervous system; diseases of the circulatory system; and diseases of the respiratory system. As they are likely to share a common technological background, we consider clinical trials targeting medical conditions indexed within a same ICD chapter to be related. We created a variable indicating whether a clinical trial targets a medical condition related to a medical condition targeted by any of the sponsoring firm's prior clinical trials. We subsequently divided our samples of clinical trials by pre-shock established firms investing in new areas into subsamples with investments in related new areas and investments in unrelated new areas.

3.3 Variables

Due to the considerable time required to obtain final regulatory approval for the commercialization of a drug, we use phase 1 clinical trials as an indicator of a firm's technology development investment. Clinical trials provide a reliable indicator of investments in the development of new technologies as their management requires considerable funding, time, and attention on the part of firms involved. They also have the additional benefit of being directly connected to the patented genes in our sample. We excluded phase 2 and phase 3 clinical trials because these will be as much or more dependent on the success of phase 1 clinical trials than on IPR strength. We coded clinical trials as based in the US and/or in the EU in function of the country where they had been registered as part of a drug approval submission. The dependent variable for our analyses consists in a count of phase 1 clinical trials launched per medical condition area every year. In the main analysis, we started the post-shock count in 2014, about six months after the *Myriad* decision (June 13, 2013); as drug development and the launch of clinical trials require time to implement, we reproduced our analyses by setting the year of treatment to 2015 (i.e., about an 18-month lag), and obtained similar results. The main independent variable for all analyses is the post-*Myriad* treatment dummy for the two locations, which takes the value 1 for year observations after the invalidation of IPR in the US and 0 otherwise. We include year and medical condition fixed effects as controls.

3.4 Estimation

We estimated difference-in-differences using OLS regression on a jurisdiction-medical condition-year panel dataset. In this specification, the first difference is the jurisdiction, US or EU, and the second difference is the year of treatment, 2014 (2015 in sensitivity analysis). The panel only includes years after both US and EU equivalent patents have been granted. We used observations from 2009 to 2018, which provide comparable timeframes before and after the treatment. Table 1 reports descriptive statistics.

[Insert Table 1 about here]

4. Results

4.1 Main results

Overall average technology development investment

Model 1 in Table 2 reports results for the impact of a sudden reduction in the strength of the IPR environment on investments in technology development by all firms already present in the industry in the US or EU. The coefficient of the *US x Post-Myriad* interaction is statistically insignificant (Model 1: b=-0.088, n.s.). Thus, on average, the initial results suggest that the US Supreme Court decision did not have a major impact on investments overall. Intriguing though, subsequent investigation reveals that the apparent null results reflect offsetting positive and negative investment incentives for different types of firms.

[Insert Table 2 about here]

Pre-shock startups vs. pre-shock established firms

We then consider the impact of the reduction in the strength of the IPR environment on investments separately for pre-shock startups and pre-shock established firms. For pre-shock startups, the relevant coefficient is negative and statistically significant (Model 2: b=-0.024, $p<0.01$). For pre-shock established firms, the coefficient in Model 3 also is negative, in fact with greater magnitude than the coefficient in Model 2, but is not statistically significant (Model 3: b=-0.064, n.s.). Although the two coefficients do not differ statistically owing to high variance around the coefficient for established firms, the negative coefficient for pre-shock startups is meaningful. In turn, investigating the reasons for the high variance result in Model 3 reveals important differences that we disentangle in the subsequent analysis – i.e., the comparison of investments in home vs. new technological areas and of the role played by different types of capabilities. These results provide initial evidence indicating that pre-shock startups considerably decreased investments following the reduction in IPR. This suggests that firms most likely to have the smallest stock of capabilities – pre-shock startups – are deterred from making subsequent investments possibly because they do not own the capabilities needed to protect their initial area investments from competitors or are not able to attract subsequent funding due to the lack of key IPR.

Replacement effect: Home areas vs. new areas

We next assessed whether the Supreme Court decision weakening the IPR environment had a different effect on technology development investments in areas in which firms were already present at the

time of the decision (home areas) and in areas in which firms were not yet present (new areas). This investigates how the replacement effect might drive investment decisions by pre-shock established firms, as we discussed in the theory section. Because there are few occurrences of diversifying investments by pre-shock startups in new technological areas, we focused on pre-shock established firms.

Models 4 and 5 in Table 2 report results for pre-shock established firms: in home areas and in new areas, finding contrasting results. The coefficient of the interaction term is negative and statistically significant for pre-shock established firms in their home areas (Model 4: b=-0.242, p<0.01) and positive and statistically significant for pre-shock established firms in new areas (Model 5: b=0.178, p<0.01), demonstrating offsetting incentives and disincentives for investments in technology development (the two coefficients differ significantly). These results imply that pre-shock established firms increased investments into areas that were new to them in the US relative to in the EU following the *Myriad* decision while also decreasing investments in areas in which they were already present before the decision.

The differences are material. The results translate into an average of 60 additional phase 1 clinical trials launched by pre-shock established firms in new areas and 82 fewer clinical trials launched by pre-shock established firms in their home areas every year. These results provide initial evidence on how pre-shock established firms strategically adapt to a sudden reduction in the strength of the IPR environment: we find a replacement effect that pushes these firms to focus on new areas while reducing their presence in home areas. This replacement effect suggests that firms are more likely to seek new sources of profits in new areas than to incrementally seek to expand existing profits in home areas.

We next investigated whether the replacement effect after IPR invalidation is more likely to push pre-shock established firms to invest in related or unrelated new technological areas (Models 6 and 7 in Table 2). The coefficient of the interaction term is positive and statistically significant for investments in related new technological areas (Model 6: b=0.180, p<0.01) and positive but not statistically significant for investments in unrelated new technological areas (Model 7: b=0.026, n.s.); the two coefficients differ significantly. The results accordingly show that the replacement effect pushes firms to invest mainly in areas that are new to them but that share a common technological-market background.

Capabilities: Technological capabilities plus generic and area-specific complementary capabilities

In order to dig deeper into the effect of capabilities on the relationship between IPR and investments in technology development, we then considered investments in new and home areas by subcategories of pre-shock established firms: those with strong and weak technological, generic complementary, and area-specific complementary capabilities. As pre-shock startups in our sample have lower levels of capabilities, we focused our subsequent analyses on pre-shock established firms.

We report the results for three types of technological areas: related new areas, unrelated new areas, and home areas. Table 3a reports results for investments by each subcategory of pre-shock established firms in related new areas: 1) pre-shock established firms with strong technological capabilities; 2) pre-shock established firms with weak technological capabilities; 3) pre-shock established firms with strong generic complementary capabilities; 4) pre-shock established firms with weak generic complementary capabilities. Table 3b reports results for investments by each subcategory of pre-shock established firms in unrelated new areas. Table 4 reports results for investments by each subcategory of pre-shock established firms in their home areas, where we can also examine strong and weak area-specific complementary capabilities.

[Insert Tables 3a, 3b, and 4 about here]

We first consider new areas. Results for investments in related new areas, presented in Table 3a, show that the effect of the reduction in the strength of the IPR environment was considerably larger for pre-shock established firms with strong technological capabilities (Model 1: $b=0.154$, $p<0.01$) than for pre-shock established firms with weak technological capabilities (Model 2: $b=0.022$, $p<0.01$); the coefficients differ significantly. Pre-shock established firms with strong generic complementary capabilities were also more likely to make technology development investments after the reduction in IPR (Model 3: $b=0.130$, $p<0.01$) than firms with a weak level of these capabilities (Model 4: $b=0.046$, $p<0.01$); the coefficients again differ significantly. Stronger technological capabilities and generic complementary capabilities accordingly seem to have facilitated diversifying investment in related areas by pre-shock established firms.

By contrast, results for investments in unrelated new areas, presented in Table 3b, show that *Myriad* had at most a limited effect on investment for pre-shock established firms with either strong or weak levels

of technological capabilities and generic complementary capabilities. Only the effect of strong technological capabilities approaches significance (Model 1: b=0.032, p<0.10), with a substantially smaller coefficient than the comparable result for related diversification in Table 3a (Model 1: b=0.154).

Table 4 then considers home areas. Pre-shock established firms with higher levels of technological capabilities (Model 1: b=-0.219, p<0.01) and generic complementary capabilities (Model 3: b=-0.227, p<0.01) were significantly more likely to decrease investments in technology development in their home areas than firms with weak levels of technological capabilities (Model 2: b=-0.023, p<0.01) or generic complementary capabilities (Model 4: b=-0.015, p<0.01); both sets of coefficients differ significantly. Moreover, pre-shock established firms with strong area-specific complementary capabilities (Model 5: b=-0.044, n.s.) were not significantly affected by the reduction in IPR while firms with weak area-specific complementary capabilities (Model 6: b=-0.198, p<0.01) significantly reduced investments in their home areas; the coefficients differ significantly.

The results suggest an intriguing tension concerning firms' investment incentives in their home areas. Following the reduction in IPR, possession of strong technological and generic complementary capabilities seems to have driven the decrease in investments by pre-shock established firms in their home areas. By contrast, stronger area-specific complementary capabilities appear to have insulated pre-shock established firms from the negative effect of the shock. As we discuss in more detail later, our results suggest that weak IPR environments provide incentives for diversification into related areas by pre-shock established firms and that stronger technological and generic complementary capabilities push these firms to switch their focus from their home areas to related new areas, thereby reinforcing the replacement effect.

Possible interaction among types of capabilities

We subsequently investigated the potential interactive effect of technological and complementary capabilities on the relationship between IPR and technology development investments, finding little or no joint relationship. The question of which capabilities are substitutes and which capabilities are complements is a long-standing issue in the innovation strategy literature (Arora and Gambardella 1994; Cassiman and Veugelers 2006). Interactions between technological and complementary capabilities have sometimes been

seen in prior literature (Arora and Nandkumar 2012). We therefore examined investments in samples of pre-shock established firms with both strong or both weak technological capabilities and generic complementary capabilities as well as with both strong or both weak technological capabilities and area-specific complementary capabilities.

Table 5 presents results for investments in related and unrelated new technological areas. The results reported in Model 1 ($b=0.125$, $p<0.01$) vs. Model 2 ($b=0.020$, $p<0.01$) show that the effect of the reduction in IPR in related new areas is stronger for pre-shock established firms with both strong technological capabilities and generic complementary capabilities than pre-shock established firms with weak levels of both of these capabilities; the coefficients differ significantly. Moreover, the coefficient of the effect of the reduction in IPR on investments in related new areas by pre-shock established firms with both technological capabilities and strong generic complementary capabilities (Table 5, Model 1: $b=0.125$) is similar in magnitude to the coefficients reported in Table 3a for investments in related new areas by pre-shock established firms with strong technological capabilities (Table 3a, Model 1: $b=0.154$) and for investments by pre-shock established firms with strong generic complementary capabilities (Table 3a, Model 3: $b=0.130$). In turn, the results reported in Models 3 and 4 of Table 5 show that the reduction in IPR had insignificant relationships with investments in unrelated new areas by pre-shock established firms with either both strong or both weak technological capabilities and generic complementary capabilities. The lack of joint effect suggests that technological and generic complementary capabilities are substitutes (i.e., alternatives) in assisting diversification in weak IPR environments.

[Insert Table 5 about here]

We also considered potential interactions of types of capabilities in home areas, again finding no significant relationships. Table 6 presents results for technological investments by pre-shock established firms in their home areas: 1) with both strong technological capabilities and generic complementary capabilities; 2) with both weak technological capabilities and generic complementary capabilities; 3) with both strong technological capabilities and area-specific complementary capabilities; 4) with both weak technological capabilities and area-specific complementary capabilities.

[Insert Table 6 about here]

The results first show that pre-shock established firms with both strong technological capabilities and generic complementary capabilities were more likely to decrease investments than pre-shock established firms with weak levels of these capabilities (Table 6, Model 1: b=-0.208, p<0.01). Again, the magnitude of the coefficient for investments by pre-shock established firms with the combination of both strong technological and generic complementary capabilities is similar to the coefficients reported in Table 4 for investments by pre-shock established firms with strong technological capabilities (Table 4, Model 1, b=-0.219) and for investments by pre-shock established firms with strong generic complementary capabilities (Table 4, Model 3: b=-0.227). Technological capabilities and generic complementary capabilities accordingly seem to act as alternatives in driving the decrease in technology development investments by pre-shock established firms in their home areas following the Supreme Court decision.

The results presented in Table 6 show that pre-shock established firms with both strong levels of technological and area-specific complementary capabilities (Model 3: b=-0.040, n.s.) or weak levels of both types of capabilities (Model 4: b=-0.008, n.s.) are not affected by the reduction in IPR. Technological capabilities and area-specific complementary capabilities accordingly do not appear to play a complementary role in influencing investment by pre-shock established firms in their home areas after the reduction in IPR. Overall, we do not find evidence of a joint relationship between technological and complementary capabilities in weak IPR environments, whether in new or home areas.

4.2 Robustness checks

The parallel trends assumption is critical for the validity of difference-in-differences analysis results. We accordingly investigate whether this assumption holds in our empirical design. A common method in the literature to test whether this assumption holds is first to visually explore temporal trends in the data. Figures 1 and 2 show that technology investment dynamics of pre-shock established firms in new and home areas evolve similarly in the US and in the EU before the US Supreme Court decision *Myriad* was officially rendered in 2013 and that the rate of investments increased substantially in new areas and decreased considerably in home areas in the US relative to in the EU after 2013. The parallel trends

assumption thus holds for the relationship between the reduction in IPR strength and investments in technology development by pre-shock established firms in new areas and in their home areas.

[Insert Figures 1 and 2 about here]

Another common method to investigate whether the parallel trends assumption holds is to explore the difference between the treatment and control groups separately for each year before and after the causal event (Bertrand et al. 2004). The parallel trends assumption implies that before *Myriad* was delivered, the difference in investments in the US and EU was constant and not trending upward for pre-shock established firms in new areas or downward for pre-shock established firms in their home areas. The validity of our difference-in-differences specifications would otherwise be uncertain. Figure 3 presents a graphical version of this test for our analysis of investments by pre-shock established firms in new areas. The time-varying coefficients do not reveal significant evidence for an increase in investments in the US compared to in the EU before 2013. Figure 4 presents a graphical version of this test for our analysis of investments by pre-shock established firms in home areas. The time-varying coefficients do not show a significant decrease in investments in the US compared to in the EU before 2013. The evidence from these analyses reduces the concern that technology development investment dynamics of pre-shock established firms were different in the US and EU before the shock. The parallel trends assumption accordingly is supported in our analyses.

[Insert Figures 3 and 4 about here]

We also examined whether the increase in investments in new areas by pre-shock established firms that we observe following the reduction in the strength of IPR was driven by factors other than the invalidation of gene patents. To do this, we analyzed the impact of the *Myriad* decision on pre-shock established firms' reliance on genes that were previously protected by IPR to commercialize new drugs in related new technological areas. The dependent variable for this analysis is the number of new patented genes relied upon by pre-shock established firms per medical condition area. Table 7 shows that following the invalidation of the IPR protecting genes, pre-shock established firms started to rely on a higher number of genes previously protected by IPR when they invested in related areas that are new to them ($b=0.117$, $p<0.01$). The *Myriad* decision accordingly seems to have enabled firms in the pharmaco-genetics industry

to target genes that were previously inaccessible, thereby facilitating investments in related areas of the industry in which they were not previously present.

[Insert Table 7 about here]

5. Discussion and conclusion

5.1 Overview

We began by investigating a key question in the IPR literature: Will a sudden reduction in IPR increase or decrease incentives to invest in technology development of firms already operating in the industry? We find a nuanced answer. Both results hold, depending on firms' presence in particular technological areas, the relatedness of potential new areas, and the types of capabilities that firms possess. These results have striking implications for the existence of what the literature refers to as the replacement effect, in which firms have lower incentives to invest in technological areas in which they are already present and may eventually shift their activities from one area to another under certain conditions.

The results become increasingly nuanced. Initially, in aggregate, we found no evidence of an increase or decrease in technology development investments by existing area participants following the invalidation of gene patents by the *Myriad* decision. However, when we investigate different types of firms, comparing recent entrants from the pre-shock era to pre-shock established firms, we found two differences. First, pre-shock startups considerably decreased investments while pre-shock established firms overall remained unaffected. The second difference arises when we distinguish among established firms in terms of their expansion into new areas versus investments in their home areas. Pre-shock established firms reduce investments in home areas and increase investments in new areas that are related based on medical conditions, indicating a replacement effect that applies to diversification into areas with related technological-market characteristics to prior investments. Thus, the initial insignificant high variance impact for pre-shock established firms masks significant differences based on the nature of the firms present in the technological area and the relationship to prior home technological areas.

We next found differences based on the nature of firms' capabilities that provide a nuanced

understanding of the replacement effect. Ownership of strong technological capabilities and generic complementary capabilities reinforces the replacement effect, driving pre-shock established firms to further increase investments in related new areas and decrease investments in their home areas following the shock. We also found an attenuation of the replacement effect, in which pre-shock established firms with strong area-specific complementary capabilities retain incentives to maintain their presence in home areas.

5.2 Contribution

This study contributes to the literature on IPR and technology development by uncovering how the effect of a shock in the IPR environment on technology development investments by existing firms is contingent on these firms' presence within an area as well as on the strength of their capabilities. We address long standing conceptual tensions by using recent developments in the empirical research on the consequences of IPR for cumulative innovation and the direction of scientific research (Huang and Murray 2009, Williams 2013, Galasso and Schankerman 2015, Murray et al. 2016, Sampat and Williams 2019). Furthermore, we build on prior literature studying various innovation outcomes associated with policies increasing the strength of the IPR environment by focusing on the specific consequences of a sudden reduction in the strength of the IPR environment (Sakakibara and Branstetter 2001, Branstetter et al. 2006, Chaudhuri et al. 2006, Kyle and McGahan 2012, Duggan et al. 2016, Vakili and McGahan 2016, Chattopadhyay and Bercovitz 2020). In doing so, we extend prior scholarship focusing on the strategic implications associated with the strength of the IPR environment (Teece 1986, Mitchell 1989, Arora et al. 2001, Gans and Stern 2003, Cockburn and MacGarvie 2011, Khoshsokhan 2019). Our core contribution to the literature on technology commercialization strategy is to highlight how the strength of the IPR environment influences existing firms' strategic behavior across technological areas of an industry. The focus on firms already present in an industry at the time of a change in the IPR environment is motivated by the importance of their investment strategy for the evolution of competitive dynamics within the industry. This emphasis further distinguishes our paper from recent work in the area (Khoshsokhan 2019).

Our initial results suggest that the strength of the IPR environment does not have a significant effect on existing firms' investment incentives in aggregate. These aggregated findings contrast with prior studies

arguing that strong IPR environments may be necessary to provide incentives for investments in technology development (Teece 1986, Mitchell 1989, Arora et al. 2001, Gans and Stern 2003). Importantly, when we disaggregate the results based on firms' presence in a technological area and their capabilities, we find striking differences in the impact of the change in IPR.

We first show that pre-shock startups were negatively affected by the reduction in IPR. Indeed, only 18 percent of the pharmaco-genetic startups active in the US before the Supreme Court decision launched a new phase 1 clinical trial in the US after the decision (compared to 60 percent of pre-shock established firms). Prior literature argued that IPR are especially useful to startups as they provide protection from competition and the time needed to acquire capabilities required for innovative investments (Teece 1986). Our analyses provide empirical grounding for this argument, showing that pre-shock startups reduce commercialization investments in weak IPR environments in which they are at the mercy of competition from imitators. Our results suggest that pre-shock startups' more limited capabilities put them at a disadvantage relative to more experienced pre-shock established firms by constraining them from adapting to changes in the IPR environment. We extend literature by demonstrating that, in industries with weak IPR-related barriers to investments, pre-shock startups are likely to lose competitive opportunities to established competitors. This likely occurs because IPR often was the main resource of the startups.

We next uncover a replacement effect that pushes established firms to diversify into related new technological areas and reduce investments in their home technological areas. The replacement effect occurs because existing firms' expected profits from investments in weak IPR environments are larger in new areas than in areas where they are already present. Prior literature suggests that an area incumbent may have incentives to preempt new entrants in strong IPR environments because it risks losing much of its profits if a new entrant is the first to commercialize a superior technology that is protected by IPR (Gilbert and Newbery 1982). Nevertheless, in weak IPR environments, a new entrant and an area incumbent would be able to imitate each other and could independently commercialize a new superior technology. Thus, an area incumbent's incentives for innovative investments will be lower than those of a new entrant as it will uselessly cannibalize its own profits given that its technology is likely to be imitated by competitors (Katz

and Shapiro 1987). A new entrant would benefit from its investment despite its inability to appropriate the entire value of its superior technology due to the lack of IPR protection as it will avoid cannibalizing its own profits. In industries with weak IPR-related barriers to entry allowing for the redeployment of assets from one technological area to another, firms are accordingly likely to turn their attention from areas in which they are already present to areas in which they are not yet present. Our results demonstrate that established firms have lower incentives to commercialize new technologies in their home area and higher incentives to diversify into new areas in weak IPR environments than in strong IPR environments.

Prior literature on the replacement effect has focused on competition for profits between firms at the technological area level (Arrow 1962, Gilbert and Newbery 1982, Katz and Shapiro 1987). We extend this literature by highlighting implications at the industry level. We show that the replacement effect influences a firm's investment behavior in areas of the industry in which it did not already operate. By bridging the literature on strategic technology commercialization with the literature on the replacement effect, our study demonstrates that the IPR environment holds considerable strategic implications for the positioning of firms across technological areas within their industry, thus influencing industry evolution.

We further show that pre-shock established firms prioritize investment in new technological areas that are related to their initial home technological areas in some combination of technology and market opportunity. The study extends prior literature on corporate diversification by highlighting how changes in the IPR environment influence the direction of established firms' diversification activities (Rumelt 1982, Wernerfelt 1984, Barney 1986, Montgomery and Hariharan 1991, Peteraf 1993, Robins and Wiersema 1995, Silverman 1999, Tanriverdi and Venkatraman 2005, Miller 2006, Diestre and Rajagopalan 2011, Sakhartov and Folta 2014, Lieberman et al. 2017). Technologically dynamic industries, such as pharmaco-genetics, require considerable R&D investments and the success of R&D projects in such industries is often difficult to predict. In weak IPR environments where imitation is likely, established firms thus have incentives to invest in related new technological areas in order to minimize financial risks and adjustment costs associated with the internal development or acquisition of capabilities required to invest in unrelated new technological areas (Helfat and Eisenhardt 2004, Sakhartov and Folta 2014).

Our study also builds on the growing literature on the redeployment of resources by showing how changes in the strength of the IPR environment may drive capabilities redeployment (Helfat and Eisenhardt 2004, Wu 2013, Sakhartov and Folta 2014, Lieberman et al. 2017, Sakhartov 2017, Dickler and Folta 2020). Indeed, the non-scale free nature of some types of capabilities translates into the need for firms to redeploy capabilities from their home technological areas to new technological areas in which they invest, thereby leading to a concurrent decrease in investment in firms' home technological areas (Penrose 1959, Helfat and Eisenhardt 2004, Levinthal and Wu 2010). Such redeployment of capabilities changes competitive dynamics within the industry as new entrants in a technological area are likely to face less competition from firms retreating from their home areas. A reduction in the strength of the IPR environment levels the playing field among industry competitors by providing incentives for diversification and facilitating investment in new areas. This change in competitive dynamics highlights the importance of the redeployability of capabilities that contribute to firms' ability to diversify (Penrose 1959, Folta et al. 2016).

We respond to a call for more detailed theoretical and empirical research on the role of firms' capabilities in technology development and commercialization and compare the impact of technological capabilities as well as of two types of complementary capabilities, generic and area-specific, on the relationship between IPR and technology development investments (Teece 2006, Anand et al. 2010, Arora and Nandkumar 2012). We demonstrate that stronger technological and generic complementary capabilities tend to reinforce the replacement effect occurring in weak IPR environments, while stronger area-specific complementary capabilities attenuate the replacement effect. Extending prior literature, our results suggest that technological and generic complementary capabilities are more easily redeployable from one area to another and accordingly facilitate diversification at the expense of firms' presence in their home areas (Folta et al. 2016). Area-specific complementary capabilities are more closely aligned with the particularities of a given area and thus less likely to be useful in a new area, thereby providing further incentives for existing firms to maintain investments in their home areas.

Finally, we build on recent research on the complementarity of different types of capabilities (Arora and Nandkumar 2012). We show that technological capabilities and generic complementary capabilities

play substitutable roles in technology development as possessing both strong technological and generic complementary capabilities does not provide established firms with a superior advantage relative to possessing a strong level of only one of these types of capabilities. Indeed, having a strong level of only one of these types of capabilities allows established firms to expand their activities in new technological areas in environments with weak IPR-related barriers to investments. Facing a disruption in the IPR environment, established firms may leverage either existing technological assets (such as their advanced expertise in genomics) or generic complementary capabilities (such as experienced marketing, sales, and regulatory affairs departments), to adapt to the loss of IPR protection through diversification. We extend prior literature on capabilities by underlining that the absence of complementarity between types of capabilities mitigates the need for firms to concurrently develop multiple types of capabilities in anticipation of potential changes in the appropriability environment.

5.3 Limitations and future research

The limitations associated to natural experiments apply despite the plausibility of the shock on which we rely in this study. The US Supreme Court decision *Myriad* has been rendered recently and its effect on pharmaceutical R&D and the drug commercialization process is likely to persist and potentially vary in the next decades. It will be important in the future to revisit the issues addressed in this paper with a longer time frame in order to unpack the long-term effects of the invalidation of IPR on investments in technology development. Another issue concerns generalizability and the specificities of the setting that we selected, the pharmaco-genetics industry. Our difference-in-differences empirical design helps alleviate concerns regarding the impact of external environmental factors but the invalidation of IPR might hold different implications in other industries relying on gene patents, such as the genetic testing industry. We also focused on a type of technology development investment specific to our research setting, clinical trials, and future research could examine whether our findings apply to other types of investment.

Our study demonstrates that changes in the IPR regime have nuanced influences on investments in technology development, being contingent on firms' presence in a technological area as well as on the type and strength of their capabilities. Future research on the impact of IPR on investments could attempt to

highlight additional contingencies likely to influence the impact of IPR in order to provide a more nuanced understanding of the specific contexts in which IPR incentivize innovative investments and of which types of firms are most likely to benefit. New research is needed to better understand how industry specificities interact with IPR to facilitate or inhibit investments in technological areas. Future research could also examine the performance implications of the replacement effect leading firms to diversify within their industry uncovered in this study. Moreover, we have focused on the implications of an unexpected disruption in the strength of the IPR environment for firms already present within the affected industry at the time of the disruption. Future research should thus attempt to bring light on the consequences of a disruption in the IPR environment for diversifying entrants that previously operated outside of the industry or for new entrepreneurial firms launching their activities after the IPR shock.

Overall, the study demonstrates that the impact of reduced IPR on technology development investments by existing firms is influenced by firms' presence in an area and the strength of their capabilities. Although we initially find that a reduction in the strength of the IPR environment appears to have no significant effect on investments in aggregate, a more fine-grained investigation reveals a significant decrease in investments by pre-shock startups while pre-shock established firms remain unaffected as a group. We then demonstrate that pre-shock established firms are subject to a replacement effect pushing them to increase diversifying investments into related new areas and decrease investments in their home areas. Finally, we find that possessing stronger technological capabilities and generic complementary capabilities reinforces the replacement effect, while ownership of stronger area-specific complementary capabilities attenuates replacement. The work provides a base for ongoing research.

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Table 1. Descriptive statistics

	Mean	Std. dev.	Minimum	Maximum	No. of observations
Medical condition-Year	2,013.5	2.87	2,009	2,018	7,020
1(US)	0.50	0.50	0	1	7,020
1(Post-Myriad)	0.50	0.50	0	1	7,020
Clinical trials	0.87	2.66	0	44	7,020

Notes. This table presents descriptive statistics for variables used in the analyses. All firms are included in the sample. *Post-Myriad* refers to all years after 2013 until 2018. *US* refers to the jurisdiction affected by the invalidation of IPR.

Table 2. Impact of the invalidation of IPR on technology development investments

(Dependent variable: Number of clinical trials per technological area per year)

	(1) All pre-shock firms	(2) Pre-shock startups	(3) Pre-shock established firms	(4) Pre-shock established firms in home technological areas	(5) Pre-shock established firms in new technological areas	(6) Pre-shock established firms in related new technological areas	(7) Pre-shock established firms in unrelated new technological areas
US × *Post-Myriad*	-0.088	-0.024***	-0.064	-0.242***	0.178***	0.180***	0.026
	(0.089)	(0.006)	(0.087)	(0.079)	(0.030)	(0.026)	(0.021)
Year fixed effects	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Medical condition fixed effects	Yes	Yes	Yes	Yes	Yes	Yes	Yes
R-squared: within	0.007	0.011	0.006	0.010	0.023	0.044	0.008
R-squared: between	0.779	0.0702	0.781	0.780	0.774	0.795	0.715
R-squared: overall	0.558	0.166	0.558	0.567	0.252	0.246	0.176
Observations	7,020	7,020	7,020	7,020	7,020	6,060	6,060

Notes. This regression estimates the difference in the impact of the invalidation of IPR in the US on technology development investments in the United States and in the European Union across categories of firms before and after *Myriad* in a difference-in-differences framework using OLS. *Post-Myriad* refers to all years after 2013 until 2018. *US* refers to the jurisdiction affected by the invalidation of IPR. Standard errors are clustered at the medical indication level (shown in parentheses).
* $p < 0.10$; ** $p < 0.05$; *** $p < 0.01$

Table 3a. Impact of the invalidation of IPR on technology development investments by pre-shock established firms with strong or weak technological capabilities and generic complementary capabilities: Related new technological areas

(Dependent variable: Number of clinical trials per technological area per year)

	(1) Pre-shock established firms with strong technological capabilities	(2) Pre-shock established firms with weak technological capabilities	(3) Pre-shock established firms with strong generic complementary capabilities	(4) Pre-shock established firms with weak generic complementary capabilities
US × *Post-Myriad*	0.154***	0.022***	0.130***	0.046***
	(0.024)	(0.007)	(0.020)	(0.012)
Year fixed effects	Yes	Yes	Yes	Yes
Medical condition fixed effects	Yes	Yes	Yes	Yes
R-squared: within	0.039	0.007	0.035	0.013
R-squared: between	0.811	0.549	0.835	0.576
R-squared: overall	0.240	0.098	0.220	0.138
Observations	6,060	6,060	6,060	6,060

Notes. This regression estimates the difference in the impact of the invalidation of IPR in the US on technology development investments in the United States and in the European Union across categories of firms before and after *Myriad* in a difference-in-differences framework using OLS. *Post-Myriad* refers to all years after 2013 until 2018. *US* refers to the jurisdiction affected by the invalidation of IPR. Standard errors are clustered at the medical indication level (shown in parentheses).
* $p < 0.10$; ** $p < 0.05$; *** $p < 0.01$

Table 3b. Impact of the invalidation of IPR on technology development investments by pre-shock established firms with strong or weak technological capabilities and generic complementary capabilities: Unrelated new technological areas

(Dependent variable: Number of clinical trials per technological area per year)

	(1) Pre-shock established firms with strong technological capabilities	(2) Pre-shock established firms with weak technological capabilities	(3) Pre-shock established firms with strong generic complementary capabilities	(4) Pre-shock established firms with weak generic complementary capabilities
US × *Post-Myriad*	0.032*	-0.002	0.018	0.012
	(0.019)	(0.008)	(0.018)	(0.010)
Year fixed effects	Yes	Yes	Yes	Yes
Medical condition fixed effects	Yes	Yes	Yes	Yes
R-squared: within	0.010	0.003	0.010	0.005
R-squared: between	0.710	0.615	0.711	0.646
R-squared: overall	0.159	0.100	0.150	0.148
Observations	6,060	6,060	6,060	6,060

Notes. This regression estimates the difference in the impact of the invalidation of IPR in the US on technology development investments in the United States and in the European Union across categories of firms before and after *Myriad* in a difference-in-differences framework using OLS. *Post-Myriad* refers to all years after 2013 until 2018. *US* refers to the jurisdiction affected by the invalidation of IPR. Standard errors are clustered at the medical indication level (shown in parentheses).
* $p < 0.10$; ** $p < 0.05$; *** $p < 0.01$

Table 4. Impact of the invalidation of IPR on technology development investments by pre-shock established firms with strong or weak technological capabilities, generic complementary capabilities, and area-specific complementary capabilities: Home technological areas

(Dependent variable: Number of clinical trials per technological area per year)

	(1) Pre-shock established firms with strong technological capabilities	(2) Pre-shock established firms with weak technological capabilities	(3) Pre-shock established firms with strong generic complementary capabilities	(4) Pre-shock established firms with weak generic complementary capabilities	(5) Pre-shock established firms with strong area-specific complementary capabilities	(6) Pre-shock established firms with weak area-specific complementary capabilities
US × *Post-Myriad*	-0.219***	-0.023***	-0.227***	-0.015***	-0.044	-0.198***
	(0.078)	(0.007)	(0.078)	(0.005)	(0.047)	(0.051)
Year fixed effects	Yes	Yes	Yes	Yes	Yes	Yes
Medical condition fixed effects	Yes	Yes	Yes	Yes	Yes	Yes
R-squared: within	0.010	0.013	0.009	0.009	0.005	0.009
R-squared: between	0.781	0.597	0.782	0.721	0.768	0.790
R-squared: overall	0.565	0.145	0.562	0.209	0.513	0.522
Observations	7,020	7,020	7,020	7,020	7,020	7,020

Notes. This regression estimates the difference in the impact of the invalidation of IPR in the US on technology development investments in the United States and in the European Union across categories of firms before and after *Myriad* in a difference-in-differences framework using OLS. *Post-Myriad* refers to all years after 2013 until 2018. *US* refers to the jurisdiction affected by the invalidation of IPR. Standard errors are clustered at the medical indication level (shown in parentheses).

* $p < 0.10$; ** $p < 0.05$; *** $p < 0.01$

Table 5. Impact of the invalidation of IPR on technology development investments by pre-shock established firms with strong and weak technological capabilities and generic complementary capabilities: Related and unrelated new technological areas

(Dependent variable: Number of clinical trials per technological area per year)

	Related new technological areas		Unrelated new technological areas	
	(1) Pre-shock established firms with strong technological capabilities and generic complementary capabilities	(2) Pre-shock established firms with weak technological capabilities and generic complementary capabilities	(3) Pre-shock established firms with strong technological capabilities and generic complementary capabilities	(4) Pre-shock established firms with weak technological capabilities and generic complementary capabilities
US × *Post-Myriad*	0.125***	0.020***	0.021	0.004
	(0.020)	(0.007)	(0.017)	(0.006)
Year fixed effects	Yes	Yes	Yes	Yes
Medical condition fixed effects	Yes	Yes	Yes	Yes
R-squared: within	0.034	0.006	0.011	0.004
R-squared: between	0.837	0.547	0.706	0.649
R-squared: overall	0.220	0.101	0.148	0.113
Observations	6,060	6,060	6,060	6,060

Notes. This regression estimates the difference in the impact of the invalidation of IPR in the US on technology development investments in the United States and in the European Union across categories of firms before and after *Myriad* in a difference-in-differences framework using OLS. *Post-Myriad* refers to all years after 2013 until 2018. *US* refers to the jurisdiction affected by the invalidation of IPR. Standard errors are clustered at the medical indication level (shown in parentheses).
* $p < 0.10$; ** $p < 0.05$; *** $p < 0.01$

Table 6. Impact of the invalidation of IPR on technology development investments by pre-shock established firms with strong and weak technological capabilities and generic complementary capabilities or area-specific complementary capabilities: Home technological areas

(Dependent variable: Number of clinical trials per technological area per year)

	(1) Pre-shock established firms with strong technological capabilities and generic complementary capabilities	(2) Pre-shock established firms with weak technological capabilities and generic complementary capabilities	(3) Pre-shock established firms with strong technological capabilities and area-specific complementary capabilities	(4) Pre-shock established firms with weak technological capabilities and area-specific complementary capabilities
US × *Post-Myriad*	-0.208***	-0.004	-0.040	-0.008
	(0.076)	(0.003)	(0.047)	(0.005)
Year fixed effects	Yes	Yes	Yes	Yes
Medical condition fixed effects	Yes	Yes	Yes	Yes
R-squared: within	0.009	0.006	0.005	0.005
R-squared: between	0.782	0.609	0.769	0.613
R-squared: overall	0.560	0.123	0.509	0.102
Observations	7,020	7,020	7,020	7,020

Notes. This regression estimates the difference in the impact of the invalidation of IPR in the US on technology development investments in the United States and in the European Union across categories of firms before and after *Myriad* in a difference-in-differences framework using OLS. *Post-Myriad* refers to all years after 2013 until 2018. *US* refers to the jurisdiction affected by the invalidation of IPR. Standard errors are clustered at the medical indication level (shown in parentheses).
* $p < 0.10$; ** $p < 0.05$; *** $p < 0.01$

Table 7. Impact of the invalidation of IPR on the number of genes relied upon by pre-shock established firms in related new technological areas

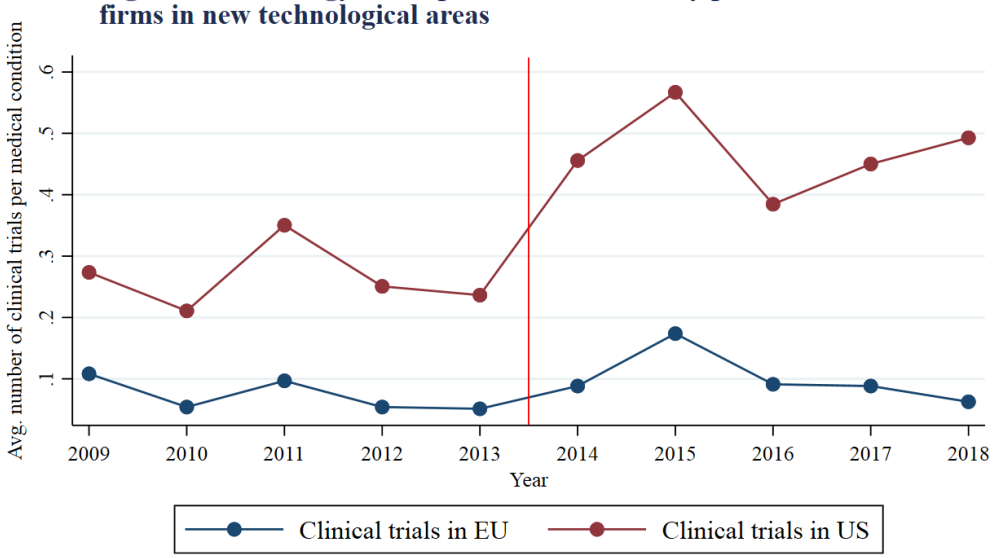
(Dependent variable: Number of new patented genes relied upon by a firm per technological area per year)

	(1) Pre-shock established firms
US × *Post-Myriad*	0.117*** (0.022)
Year fixed effects	Yes
Medical condition fixed effects	Yes
R-squared: within	0.025
R-squared: between	0.802
R-squared: overall	0.203
Observations	6,060

Notes. This regression estimates the difference in the impact of the invalidation of IPR in the US on the number of new genes relied upon by a firm in the United States and in the European Union before and after *Myriad* in a difference-in-differences framework using OLS. *Post-Myriad* refers to all years after 2013 until 2018. *US* refers to the jurisdiction affected by the invalidation of IPR. Standard errors are clustered at the medical indication level (shown in parentheses).

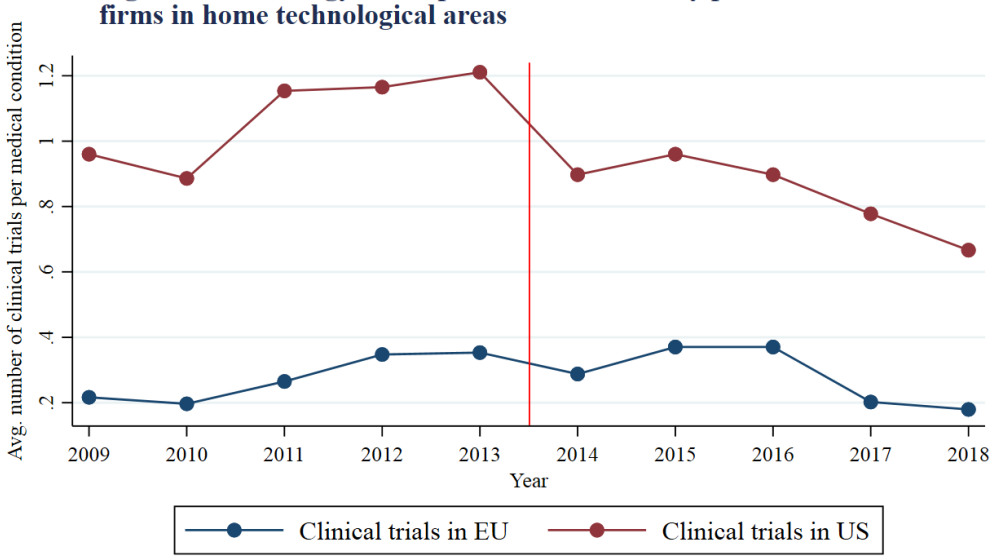
* $p < 0.10$; ** $p < 0.05$; *** $p < 0.01$

Figure 1. Technology development investments by pre-shock established firms in new technological areas



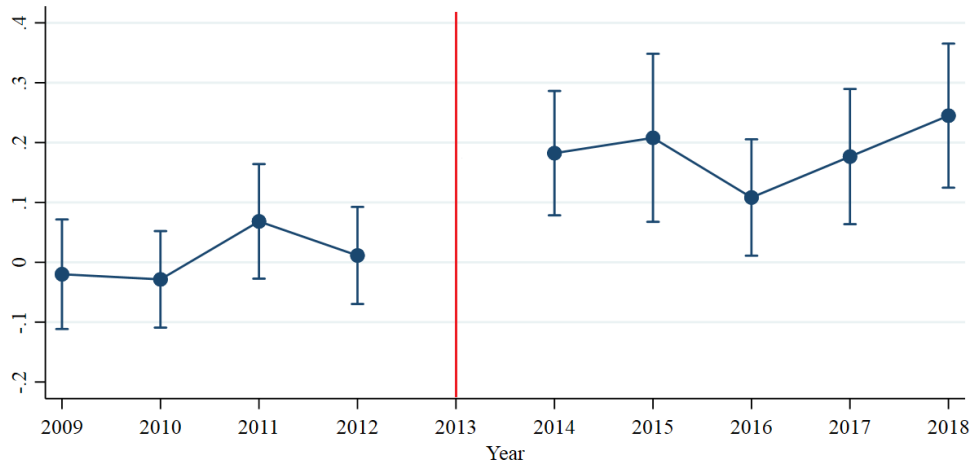
Notes. The figure presents the average number of clinical trials launched per medical condition by pre-shock established firms in new technological areas each year before and after *Myriad*.

Figure 2. Technology development investments by pre-shock established firms in home technological areas



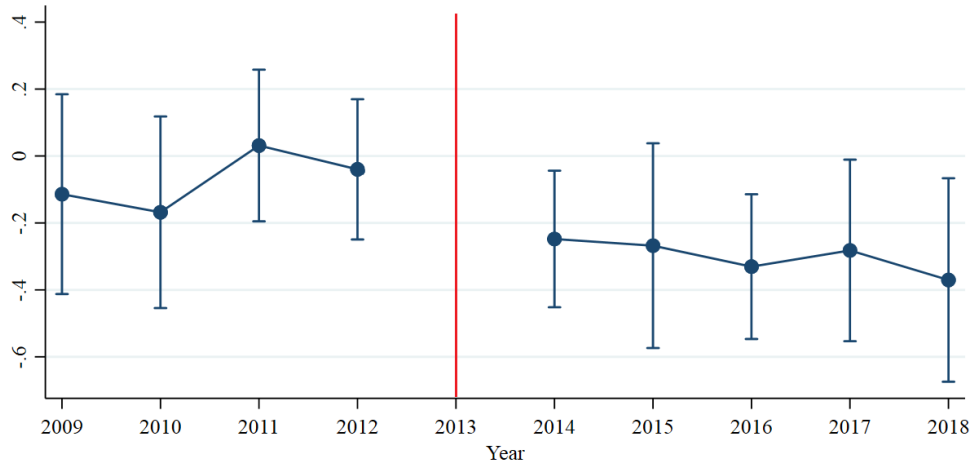
Notes. The figure presents the average number of clinical trials launched per medical condition by pre-shock established firms in home technological areas each year before and after *Myriad*.

Figure 3. Time-varying estimates of the impact of Myriad on technology development investments by pre-shock established firms in new technological areas



Notes. The figure plots coefficients and 95% confidence intervals from our difference-in-differences specification. The reference year is 2013, the year the US Supreme Court decision *Myriad* was rendered. The coefficients are estimates from OLS models and the dependent variable is the number of clinical trials per medical condition in a given year.

Figure 4. Time-varying estimates of the impact of Myriad on technology development investments by pre-shock established firms in home technological areas



Notes. The figure plots coefficients and 95% confidence intervals from our difference-in-differences specification. The reference year is 2013, the year the US Supreme Court decision *Myriad* was rendered. The coefficients are estimates from OLS models and the dependent variable is the number of clinical trials per medical condition in a given year.

APPENDIX A: Overview of the effect of gene patents on pharmaceutical R&D

Numerous legal scholars have claimed that gene patents may pose obstacles to pharmaceutical R&D both in the US and in the EU (Heller and Eisenberg 1998, Rai 1999, Caulfield et al. 2000, Rai 2001, Rai 2002, Jackson 2003, Paradise et al. 2005, Paradise and Janson 2006, Carbone et al. 2010, Cook-Deegan and Heaney 2010, Lauer 2011, Bubela et al. 2015, Cook-Deegan et al. 2016). It is standard for gene patents to claim proteins encoded by the patented genes (Scherer 2002, Huys et al. 2012) and these proteins may constitute actionable drug targets in the context of drug development. As explained by the then-head of the Biotechnology Examination Unit of the USPTO, John Doll (1998), gene patents extend to any future use of the gene, including uses not disclosed in the patent. Gene patents accordingly provide the ability to control following uses of encoded proteins and patent holders may legally prevent other firms from conducting research with the aim of developing a drug that would target such proteins.

At the turn of the century, firms, such as Incyte and Human Genome Sciences, whose business model was to widely patent genes part of the human genome and commercialize access to these genes for pharmaceutical R&D purposes emerged in parallel with the advancement of the Human Genome Project. In reaction, academic scientists mobilised through various projects to release gene sequences in the public domain. Pharmaceutical firms also attempted to secure their access to genes and proteins, which constitute critical pharmaceutical R&D inputs, through collaborative projects with academic laboratories possessing the necessary expertise. For example, Merck & Co. subsequently launched the Merck Gene Index Project in collaboration with the University of Washington at Saint Louis, one of the largest genomics sequencing center at the time, to identify and release in the public domain important coding regions of the human genome (Cook-Deegan and Heaney 2010).

Prior research identified multiple cases of litigation involving the enforcement of a gene patent against the use of the covered gene or associated protein with the objective of developing a useful drug compound (Holman 2007, Bubela et al. 2015, Cook-Deegan et al. 2016). For example, Alzheimer's Institute of America, a firm created for the purpose of extracting value from a patent covering the APP695 gene (a specific mutation of the APP gene associated with early-onset Alzheimer's disease; also referred to as APPswe), asserted its gene-related patents against 18 different defendants in a series of lawsuits that started in 2003. Some of these lawsuits even involved the production by competing firms of transgenic mice with the APP695 gene for pharmaceutical R&D purposes. Furthermore, gene patent holders may also prevent competing firms from conducting genetic testing to identify the presence of a patented gene in individuals in the context of research as *Myriad* notoriously did against clinical researchers at the University of Pennsylvania (Carbone et al. 2010). Litigation related to a patent granted in 2002 to Harvard, the Massachusetts Institute of Technology and the Whitehead Institute for Biomedical Research covering genes and their associated proteins part of the NF-kB pathway (i.e. NFKB1, NFKB2, REL, RELA, and RELB) provides another example of the effect of gene patents in pharmaceutical R&D (Salzberg 2012). The NF-kB pathway is tied to multiple genes having been found to play a role in the development of important medical conditions, such as cancer or inflammatory reactions, and controls their expression. The universities licensed their NF-kB genes patent to Ariad Pharmaceuticals, which subsequently sued Eli Lilly for the commercialization of drugs targeting proteins covered by the patent. A judge awarded 65.2 million USD and a percentage of future drug sales to Ariad Pharmaceuticals in 2006 before the decision was eventually overturned on appeal in 2010 as the court considered that the patent did not fulfill the written description requirement. A policy document produced by the US National Research Council's Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation (2006) as well as the report prepared for the Committee by John P. Walsh, Charlene Cho, and Wesley M. Cohen (2005) have also provided initial evidence that while academic scientists are not substantially affected by gene patents, the barriers they pose in the context of drug development to scientists operating in pharmaceutical firms are substantially stronger.

Gene patents accordingly pose considerable obstacles to pharmaceutical R&D. These obstacles were lifted in the US by the *Myriad* decision in 2013. In recent developments, a bipartisan group of senators introduced a bill proposal that, if eventually adopted, would overturn the *Myriad* decision and reinstate the patentability of genes. The pharmaco-genetics industry actively participated in the discussion leading to the drafting of the bill through the involvement of individuals as well as of some of its main trade groups, such as the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Innovation Organization (BIO). The bill was discussed at length in three congressional hearings that took place in 2019 and involved 45 expert witnesses. In the context of these hearings, multiple legal scholars testified that the proposed bill would reinstate gene patentability and impose obstacles to pharmaceutical R&D. The American Civil Liberties Union, involved in the *Myriad* case, also submitted a letter to the Congress along with more than 100 signatories, including large academic research centers, patient organisations, and firms, claiming that the new bill allowing for gene patenting would hinder pharmaceutical R&D.

Appendix References

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