Research Exemption and Pharmaceutical Innovation: Evidence from China*

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Abstract The patent laws of many countries have "research exemption" provisions that exempt certain research-related uses of proprietary materials from patent infringement. By limiting the rights of existing patent holders, such rules are meant to facilitate follow-on innovation and benefit latecomer firms, especially in the pharmaceutical industry. In this paper, we provide the first study of the impact of the research exemption, exploiting unique features of the institutional setting in China. Using firm-level data from 2007 to 2018 and a difference-in-differences (DID) strategy, we find that the research exemption in China leads to a large increase in firms' R&D inputs. However, there is no evidence that the research exemption leads to more patents or improved productivity on average. Further analysis reveals that it only causes an increase in patents for few firms with large market power. Overall, our findings highlight the importance of understanding the relationship between firms' innovation and imitation strategies for the design of innovation policies.

Keywords: research exemption, R&D and innovation, imitation, generic drugs, pharmaceutical industry

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1 Introduction

A central issue in the design of innovation policies is to provide firms with the proper incentives to innovate. For follower firms, limiting the monopoly rights of incumbent patent holders makes it easier to catch up in the technology race. This paper studies the so-called "research exemption" (or "experimental-use exemption") rules that exist in the patent laws of many countries. Such rules exempt certain research-related uses of proprietary information and technology from patent infringement, and in general, they are intended to encourage follow-on innovation and benefit latecomers. Also known as the Bolar exemption in the pharmaceutical context (after the court case *Roche v. Bolar* in the U.S.), they are often specifically intended to facilitate generic drug production.[1] Under a research exemption, pharmaceutical firms can use patent-protected materials and methods for their own product R&D, and by doing so, they can shorten the development cycle of generic drugs and follow-on medicines. As generic drugs are often economical substitutes for brand-name medicines and crucial to public health (Haas *et al.*, 2005; Gothe *et al.*, 2015), understanding the impact of the research exemptions on pharmaceutical manufacturing is vitally important, especially in times of global health crisis (Service, 2020; Rogosnitzky *et al.*, 2020). In the U.S., the issue of whether to codify a broadly applied research exemption has also been the subject of heated debate (see, e.g., Mueller, 2004; Short, 2016b). Despite the importance of the research exemption, empirical evidence of its impact remains scant. In fact, as noted by Short (2016b), "[t]o date, [...] no studies have attempted to measure how the implementation or codification of a research exemption—whether general or subject matter-specific, whether in the United States or elsewhere—influences research expenditures or proxies for innovation outcomes (like new drug applications) [...]" In this paper, we aim to partially fill this gap by providing the first evidence of the causal impact of the research exemption law. In particular, we examine how the introduction of the research exemption affects both R&D inputs and

[1] For accounts of the Bolar exemption and the related 1984 Hatch-Waxman Act in the U.S., see, e.g., Kelly (2011) and Short (2016a).

innovation outputs in China's emerging pharmaceutical sector.

While it is generally expected that the research exemption would provide incentives for follow-on firms to invest in R&D, the nature and results of such R&D activities are often not well understood. In pharmaceuticals, generic R&D is a form of imitation—that is, developing a product similar or functionally identical to an existing one—rather than innovation, which involves developing something entirely novel. Therefore, depending on the strategic relationship between imitation and innovation, providing R&D incentives to firms may have different effects on innovation outcomes. On the one hand, the "knowledge spillover" view emphasizes the learning aspect of R&D (Cohen and Levinthal, 1989): imitation can allow firms to acquire the knowledge necessary for cumulative innovation and thus serves a complementary role. For instance, the process of generic research and manufacturing can lead to technology upgrading and innovation in peripheral areas, such as basic chemical substances and manufacturing techniques; in Section 2, we include an account of Lopinavir—an HIV-treating drug recently considered for treating COVID-19 (Cao *et al.*, 2020)—that has had many related patent applications in China made before the expiry of the patents on its core substances. On the other hand, if imitation and innovation are independent or substitutable strategies for latecomer firms, generic R&D may not lead to—and may even crowd out—genuine innovation. These considerations can be crucial for the design of innovation policies, especially in less developed economies whose industries predominantly comprise follower firms, because policies may "make it more likely that a society will be trapped [...] and fail to converge to the world technology frontier" (Acemoglu *et al.*, 2006).

China's pharmaceutical industry provides an ideal setting for us to investigate these different possibilities. First, along with India, China's pharmaceutical sector has become increasingly important in the global supply chain. Traditionally, China has been a major supplier of low-cost medicines to low-income and developing countries (Hafner and Popp, 2011). In recent years, China and India are responsible for 80% of the supply of active pharmaceutical ingredients (APIs)—the basic chemical compounds for drug manufacturing—

in the U.S. (Huang, 2020), and China's supply alone accounts for 40% of all APIs used around the world (Horner, 2020). At the same time, 90% of China's pharmaceutical firms are generic drug producers.

Second, the unique institutional setting in China gives us a rare opportunity to tackle the common empirical challenge of finding causal relationships. In October 2009, China introduced a pharmaceutical-specific research exemption as part of its third patent law amendment, and a series of acts that were previously considered illegal and frequently challenged in court in China became exempt from patent infringement (Zhuang, 2014). Along with the research exemption, there have been several other reforms, such as higher patentability standards and increased infringement penalties. To isolate the impact of the research exemption from other contemporaneous effects, we take advantage of the presence of traditional Chinese medicine (TCM) firms in China. TCM firms are pharmaceutical manufacturers that use modern technology to produce medical products based on alternative theories of medicine. In our sample of publicly listed firms, they are large enterprises that serve sizable domestic markets and have average characteristics similar to those of mainstream drug producers. Figure 1 shows that TCM firms and other drug producers have similar average R&D levels before 2010. However, TCM firms typically do not engage in R&D and production related to generic drugs or follow-on products based on modern pharmacology, and the sector in general lacks cumulative innovation (Pan *et al.*, 2011; Qin and Dong, 2016); therefore, these firms should not be susceptible to the new research exemption law. This distinct feature is in sharp contrast to the practice of mainstream drug producers—which we refer to as biochemical firms in this paper—that are predominantly manufacturers of chemical ingredients and generic drugs. To establish causal evidence, our empirical difference-in-differences (DID) strategy thus relies on the comparison of the outcome variables of biochemical firms to those of TCM firms before and after the introduction of the research exemption law in China. Using our dataset of publicly listed firms from 2007 to 2018, we show that biochemical and TCM firms are largely comparable in terms of average pre-reform R&D growth and

other firm-level characteristics (see Table 2). To further assess the appropriateness of our comparison, we use the synthetic control method (Abadie *et al.*, 2010) to generate an artificial comparison group from a pool of TCM firms and out-of-sample chemical manufacturing firms, targeting the pre-reform characteristics of the treatment firms. We show that the automated procedure assigns disproportionately high weights to TCM firms in forming the synthetic controls, thus lending additional support to our research design. In Section 4, we describe our DID strategy in detail and present further evidence to support our identification assumptions.

Our estimation results based on firm-year observations show that after the introduction of the research exemption, on average, China's biochemical firms spend CNY53.9 million (US$8 million) more on R&D, and their R&D intensity increases by approximately 30%, compared with TCM firms. As our results pass a series of tests for parallel trends, placebo effects, and robustness, we consider the estimates to have a causal interpretation. In addition, the research exemption leads to a large increase in firms' in-house R&D employment. Our findings provide the first piece of evidence for the strong positive effects of the research exemption in inducing pharmaceutical R&D.

At the same time, using various measures related to firms' patent status and total factor productivity (TFP), we find that the research exemption has no significant impact on future innovative outputs in China's pharmaceutical sector. Our results are robust to additional checks, in which we consider alternative variables, use more restrictive sample construction rules, and control for international trade factors. Overall, our findings suggest that in the Chinese context, the increased R&D investments brought by the research exemption law did not lead to innovation or productivity improvement on average. They are consistent with the theoretical argument that stresses the substitutability between imitation and innovation.

To further explore firm heterogeneity in treatment effects, we show that firms with large market power—measured by firms' market share in their home provinces—have larger increases in their R&D spending and future patents after the research exemption law; however,

such differential effects do not exist with regard to measures of firm size. This finding highlights the important role of market concentration in shaping policy effects on the innovation incentives of firms.

This paper contributes to our understanding of the effects of intellectual property (IP) protection and innovation policies. While there is no existing evidence to our knowledge of the impact of the research exemption,[2] Moschini and Yerokhin (2008) present the only theoretical analysis of this subject. They compare private incentive and social welfare under the research exemption vis-à-vis full patent protection in a model of sequential innovation. Relatedly, there is an important empirical literature on the effects of IP protection and patents (see Williams (2017) for a recent review). For instance, Williams (2013) finds that the IP protection of human genome sequences significantly reduces subsequent research by 20–30%; however, in a subsequent study, Sampat and Williams (2019) find that patents on human genes have no effect on follow-on innovation. Galasso and Schankerman (2015) show that the removal of patent rights through court invalidation has a positive impact on follow-on innovation in information technology (IT) industries but not in pharmaceutical and chemical industries. In this paper, we examine how the relaxation of pre-existing patent rights affects both the R&D inputs and innovative outputs of follower firms. Using a novel design for identification, our study confirms the positive effect of the research exemption on pharmaceutical R&D. We also point out that increases in R&D may not lead to truly innovative outputs or enhanced productivity.

This paper is closely related to several strands of the large literature on innovation. The knowledge spillover effect of R&D is stressed by Cohen and Levinthal (1989) and has been considered an important source for economic growth since Grossman and Helpman (1991) and Aghion and Howitt (1992). In addition, the dichotomy between innovation and imitation has been emphasized by, for instance, Benoit (1985) and Katz and Shapiro (1987) in industrial organization and Acemoglu *et al.* (2006) in macro development. Our

[2] Iles (2005) presents country-level descriptive statistics in a discussion of the possible effects of research exemptions.

empirical investigation builds on their important insights to understand the effects of the research exemption law in a specific industry setting. Our market power-based explanation of firm heterogeneity in treatment effects is related to a long-standing debate about the relationship between market concentration and innovation incentives, following the classic works of Schumpeter (1942) and Arrow (1962), as surveyed by Cohen (2010). Our findings support Schumpeters argument by showing that only very firms with large market power generate more innovation outputs following the implementation of the research exemption in China.

By focusing on China's pharmaceutical sector, our study also adds to the economics literature on pharmaceutical markets (see Morton and Kyle (2011) for a review). Using data from 76 countries, Cockburn *et al.* (2016) show that patent protection helps new drugs to become commercially available in a country. In recent years, the importance of big emerging countries like China and India in the global pharmaceutical supply chain has been especially recognized. This study joins previous works that examine the policy factors affecting the pharmaceutical sector in developing countries, especially India (e.g., Chaudhuri *et al.*, 2006; Kyle and McGahan, 2012; Duggan *et al.*, 2016). In a recent study, Zhang and Nie (2021) use patent data to examine market size—a demand-side factor—and pharmaceutical innovation in China. Our study explores an important policy that affects supply-side incentives for pharmaceutical R&D. Our results suggest that, in the context of a large developing economy with follower firms, the research exemption law alone has limited effects in spurring innovation. An important factor to consider, especially for laggard countries, is the strategic relationship in firms between imitation and innovation.

The rest of this paper is organized as follows. In Section 2, we describe China's pharmaceutical industry, especially TCM firms, and the 2009 patent law reform. In Section 3, we describe our data and present the descriptive statistics. Section 4 describes our empirical methodology. Section 5 presents our empirical results. The final section states our conclusions.

2 Institutional Background

2.1 Research exemptions around the world and in China

Under research exemption laws, firms are able to use patented materials and information for their own product development before the expiration of the related patents. However, the form and scope of the research exemptions vary across countries. The term "Bolar exemption," often specific to the pharmaceutical industry, comes from the U.S. court case *Roche Products v. Bolar Pharmaceuticals* in which Roche sued the generic drug manufacturer Bolar for the infringing use of patented chemical substances. However, in the U.S., there is no broad statutory research exemption law (Iles, 2005), and the Bolar exemption specific to pharmaceuticals is included in the 1984 Hatch-Waxman Act, with the intention of benefiting generic drug manufacturers after the *Roche v. Bolar* case (Kelly, 2011; Short, 2016a). In contrast, Japan's patent law has a statutory research exemption, which generally applies to all patented products, not just medicines and medical products (Iles, 2005). European countries also have very different research exemption rules regarding pharmaceuticals and other industries (see Kupecz *et al.* (2015) for a review). The research exemption for pharmaceuticals has been adopted by major developing countries, such as Argentina, India, and Malaysia (Tridico *et al.*, 2014).

A pharmaceutical-specific research exemption was introduced in China as part of the third amendment to China's patent law, which was passed by the National People's Congress in 2008 and went into effect in October 2009.[3] The newly added item (5) in Article 69 of the patent law states that the acts of "producing, using or importing patented medicine or patented medicinal equipment for the purpose of providing the information as required for administrative examination and approval" are exempt from patent infringement. Previously, such acts were deemed patent infringement in China,[4] and there were numerous court cases

[3]See "Patent Law of the People's Republic of China (2008 Amendment)." `http://www.lawinfochina.com/display.aspx?id=7289&lib=law` (texts in English translation) and Zhuang (2014) for a review of China's patent system.

[4]See Article 13 of the second amendment of China's patent law; i.e., "Patent Law of the People's Republic

in which incumbent patent holders sued Chinese generic drug producers for the infringing use of patents—the first of such cases was *Glaxo Wellcome v. Southwest Pharmaceuticals*, in which the British multinational pharmaceutical company sued the Chinese producer for using its patents in the clinical trial of a new drug and eventually won.

The 2008/2009 amendment of China's patent law also brought several other significant changes, such as higher patentability standards, increased infringement damages, and clarified rules on patent joint ownership and double patenting (Zhuang, 2014). However, the research exemption was the only new law specific to the pharmaceutical industry. This institutional feature of the 2008/2009 amendment is important for our research design, to isolate the impact of the research exemption from the effects of other concurrent changes in the law.

2.2 Pharmaceutical innovation in China

Since the 1980s, the sales and production of pharmaceuticals in China have experienced double-digit growth. From 2008 to 2018, the total industry revenue increased from approximately CNY908 billion (US$130 billion) to CNY2,426 billion (US$350 billion), accounting for 2.6% of China's GDP.[5] In China, domestic pharmaceutical manufacturers typically engage in the production of generic drugs, chemical compounds, TCMs, and other medical products (Jiang *et al.*, 2001). In the early 2000s, there were approximately 5,000 firms in the industry, of which 90% were generic drug producers. Over time, the industry has become an important supplier of low-cost medicines and chemical ingredients to overseas markets, including low-income and developing countries (Hafner and Popp, 2011). For instance, it is reported that 90% of the U.S. supply of antibiotics, vitamin C, and a number of common medicines are imported from China (Huang, 2020), and China's supply alone accounts for 40% of all APIs used around the world (Horner, 2020).

of China (2000 Amendment)." `http://www.lawinfochina.com/display.aspx?id=4983&lib=law` (texts in English translation). In fact, according to China's National Intellectual Property Administration, prior to 2008/2009, corporate R&D and experiments were in generally not considered as research for scientific purposes (CNIPA, 2001).

[5] *Source*: China's National Bureau of Statistics. Also see Jiang *et al.* (2001), Sun *et al.* (2008), and Yu *et al.* (2010).

Despite the growing importance of China's pharmaceutical sector, until recently it was weak in R&D and lacked innovative capacity. Many drug manufacturers relied on small-scale production with outdated technology and management structure (Yu *et al.*, 2010). R&D intensity was also low. For instance, between 2005 and 2008, the ratio of R&D spending to sales revenue among pharmaceutical firms was 1% to 2% on average, whereas this ratio was around 15% to 18% for pharmaceutical companies in major developed countries (Sun *et al.*, 2008; DiMasi and Grabowski, 2012). Therefore, industrial policy and institutional reforms aimed at promoting R&D and innovation, such as the research exemption, are crucial for pharmaceutical innovation in China.

Over the past decade, the innovation level of China's pharmaceutical companies has increased. Figure 1 shows the average R&D spending of China's listed pharmaceutical companies from 2007 to 2018. Although in general China's pharmaceutical sector lacks groundbreaking innovations and proprietary products, through the process of imitation and learning, drug producers can make technical progress and incremental innovation based on their existing knowledge. For instance, research and manufacturing of a new generic drug can lead to innovation in a number of basic areas, such as chemical compounds and mixture, crystal structure, chemical intermediates, pharmaceutical preparations, and drug usage. An important example is Lopinavir, a drug used to treat HIV and recently considered as a candidate drug for treating the COVID-19 (see, e.g., Cao *et al.*, 2020), for which purpose it is sold under the brand name Kaletra. The patents on Lopinavir's basic substances were held by Abbott Laboratories and expired in 2016. However, as of 2014, 149 patent applications in China were related to Lopinavir from various applicants including big multinational firms (e.g., Pfizer, DuPont, and Schering-Plough) and domestic research institutions (e.g., Nanjing University and Shanghai Public Health Clinical Center) and firms; and these applications covered chemical intermediates, drug preparations, and medical usage (Yang *et al.*, 2015). Another example is Atorvastatin, a drug used to treat dyslipidemia and sold under the brand name Lipitor. Although the key patents on its basic substance are held by Pfizer, during

the 1996-2000 period, there were 59 related patent applications in China—among which 44 were filed by domestic firms—covering Atorvastatin-based preparation methods, chemical mixture, and compounds (Liu *et al.*, 2011). It has been documented that in China, the process from generic R&D to production typically takes around two to three years.[6] Patent applications can be made at different stages in the process. In fact, pharmaceutical innovators conventionally disclose information and file patent applications early in the research process, for both ethical and regulatory reasons (Lehman, 2003).

2.3 TCM in China

In comparison to mainstream biochemical firms, TCM firms in China have a very different mode of product development. Due to their cultural acceptance and inexpensiveness, TCMs are often popular alternatives for treating diseases and illnesses among Chinese people. In 2018, more than 52,000 hospitals and clinics specialized in TCMs, accounting for approximately 20% of all health facilities in China, and the total number of TCM outpatient visits was around 1 billion per year, representing 12% of all outpatient visits in China (National Administration of Traditional Chinese Medicine, 2019). Serving the strong domestic market demand, listed TCM firms in China are large enterprises; in fact, based on our sample, TCM and biochemical firms are on average comparable in terms of their size, total assets, and financial status (see Table 2).

TCM firms—especially the large ones that we examine in this study—use modern technology for production; however, their products are based on a set of alternative theories and principles, which include the use of Chinese herbal medicines (*zhongcaiyao*) and unique systems of medicine preparation (*paozhi*) and formulas (*fangji*) (Xu and Yang, 2009). Therefore, the mode and standards of TCM R&D and innovation differ significantly from those based on modern medicines and pharmacology (Pan *et al.*, 2011). According to the study of China's TCM patents by Qin and Dong (2016), during the 2003-2013 period, most in-

[6] See, e.g., China Bond Rating Coporation (2017)'s report on China's pharmaceutical industry.

ternational and domestic TCM patent applications from China were based on special TCM compounds (*zhongyao fufang*), of which many are generation-old, family-held formulas. In fact, 35% of the TCM-related patents in China in this period were held by individuals instead of pharmaceutical companies and research institutions.

Overall, previous studies indicate a lack of cumulative innovation in the TCM sector, partly because of TCM's somewhat outdated and opaque mode of R&D that often does not connect to modern pharmacology (Pan *et al.*, 2011; Qin and Dong, 2016).[7] Although on average, TCM firms in China have low R&D levels (Cao *et al.*, 2019), based on our sample of listed firms in China, we find that the R&D intensity of TCM firms was not significantly lower than that of other drug producers in 2009. As shown in Figure 2, the mean and median values for R&D intensity among biochemical firms are 0.039 and 0.036, respectively, while for TCM firms, the values are 0.030 and 0.025, respectively, which are only slightly smaller and largely comparable. Figure 1 shows that the average R&D spending of both biomedical and TCM firms has increased over time. However, the distribution of their R&D inputs shows clear differences in 2018 (i.e., the last year of our sample period). As previously stated, our study compares China's TCM firms and mainstream biochemical firms to disentangle the effects of the research exemption. Before explaining our estimation strategy, we describe our dataset in the next section.

[Figure 1 about here]

[7]For instance, according to Pan *et al.* (2011), "[t]he practice of TCM is mainly based on an empirical approach which has yet to be accepted in Western medicine. Despite the long history of use, the therapeutic application of [Chinese herbal medicines (CHM)] or their formulae needs to be validated by experimental and/or clinical evidence obtained from contemporary studies using appropriate methodologies. After all, the efficacy and toxicity of CHM need to be addressed by scientifically acceptable language in the 21st century."

3 Data and Summary Statistics

3.1 Data Sources and Variable Construction

We use data on publicly listed pharmaceutical manufacturing firms (CSRC industry code C27) in China's A-share markets from 2007 to 2018. The primary data source is the China Stock Market and Accounting Research (CSMAR) database, a standard database for Chinese business research similar to Compustat in the U.S. The CSMAR data include firm-level information on R&D, patent applications and grants, and other financial variables. To avoid sample selection problems, we drop all firms that first appear in the database after 2009—our policy event year.

The main data are further augmented in two ways. First, we use additional information from another financial database, Choice Data, for selected variables (e.g., the number of employees). Second, we manually check firms' annual financial reports to add any information missing from the original database. The resulting dataset is an unbalanced panel of 141 Chinese pharmaceutical firms over 12 years.

In this research, we study the impacts of the research exemption at various stages of the pharmaceutical production and innovation process. First, to measure R&D inputs, we use both R&D spending and R&D intensity, which is the ratio of R&D spending to total sales. To construct the total R&D spending variable, we follow the finance literature (e.g., Acharya and Subramanian, 2009) and China's accounting standards to include both firms' R&D expenses (under the category "Administrative Expenses") and capitalized R&D expenditure (under "Intangible Assets"). To gauge firms' in-house R&D level, we also examine the number of R&D-related personnel in a firm.

For firms' long-term innovation, we use two measures. The first measure is the number of patents filed by a firm in a given year that are eventually granted. We use the patent application year as it better captures the actual time of innovation than the grant year (Griliches *et al.*, 1987). In China's patent system, any patent is one of three types: "invention," "utility

model," or "design." For our main empirical analysis, we only consider the first two types of patents as innovation outcomes. In Table A.3, we show that our main results are robust when we consider alternative patent measures. Our patent data are available from 2007 to 2017. Upon checking the patent statistics of listed pharmaceutical firms, we find that it takes 2.2 years on average for a successful patent application to be approved in China. Therefore, we only use the patent variable for the 2007-2015 period. The second measure we use is a firm's TFP. As a broader measure of innovation and technical progress, TFP is the part of output growth not explained by the relative contributions of common inputs, such as labor and capital. To calculate firm-level TFP, we follow the procedure of Giannetti *et al.* (2015), who analyze the same dataset from China (see Appendix Table A.1 for more details). In the main analysis, we examine firms' innovation outcomes in $t+2$, which is three years after the enactment of the research exemption. This is based on the observation that the development process for generic drugs in China takes about 2 to 3 years. Zhang and Nie (2021) recently find that the implementation of a public health insurance program has led to an immediate increase in disease-related patent applications in China. For robustness, we also check the effects in $t+1$ and $t+3$ and obtain similar results.

Following the innovation literature, we control for a set of firm characteristics that can affect innovation. The control variables include firm size, measured by the log of total assets ($LnAssets$) and the log of the total number of employees ($LnEmployee$); asset tangibility, $PPEAssets$, measured by net property, plant, and equipment divided by total assets; capital expenditure ratio, $CAPEXAssets$, measured by capital expenditures divided by the book value of total assets; LEV, the ratio of total liabilities to total assets; $CirSharesRatio$, the ratio of unlimited circulating shares to total share capital; growth opportunities, $TobinQ$; and corporate liquidity, $CashRatio$, measured by the ratio of corporate cash to current liabilities. For further details on variable construction, see Appendix Table A.1.

Lastly, central to our research design is the distinction between biochemical and TCM firms in China's pharmaceutical sector. We use the firm classification provided in the original

database. To verify whether the listed TCM firms are really not involved in generic drug research or production, we check their annual reports. We find that at least until 2010, none of the sample TCM firms reported any activities related to generic drugs. However, toward the end of the sample period, some TCM firms started to invest in generic drug research. Nonetheless, as Table A.3 indicates, our main qualitative results remain valid when we remove all TCM firms that reported generic-drug related investments in 2016.

3.2 Summary statistics

Table 1 provides the summary statistics of the 141 pharmaceutical firms in our sample. All observations are at the firm-year level. Overall, there are 93 biochemical firms and 48 TCM firms. The average R&D intensity of all listed firms in our sample is 4.3%, which is higher than the estimated 1% to 2% for all pharmaceutical manufacturers in China (Sun *et al.*, 2008) but well below the average intensity in developed countries (DiMasi and Grabowski, 2012). The standard deviation is 3.9%, which implies a large degree of dispersion in R&D intensity across firms. The average annual R&D spending of the sample is CNY80 million (approximately US$12 million), and the standard deviation is CNY147 million, implying an even greater variation in the total amount of R&D spending. The average number of successful patent applications is around 12, ranging from 0 to 493 successful patent applications filed in one year, with a standard deviation of about 31. Figure 2 shows the distribution of these variables for a pre-reform year (2009) and a post-reform year (2015 or 2018). The distribution is clearly skewed to the right. The patterns suggest that a relatively small proportion of firms are responsible for making large R&D investments and generating patents. Some other variables, such as *Employee* and *Assets*, also show considerably large variance. In the regression analysis, the numbers become more comparable when we take the log of these strongly right-skewed variables.

Figure 2 also shows that the R&D inputs and patent status of the biochemical and TCM firms in our sample are largely comparable before 2010 but visibly different toward at end

of the sample period. Especially in the first two panels, the blue bars—representing the R&D inputs of biochemical firms— clearly show a pattern shifted more to the right than the orange bars do, which represent TCM firms. In the next section, we describe the empirical strategy we use to test and quantify the differences between the two groups of firms.

[Table 1 and Figure 2 about here]

4 Empirical Strategy

The presence of TCM firms in China provides unique quasi-experimental variation in firms' dependence on earlier patents for product development and production. Our empirical design exploits this cross-firm variation to isolate the impacts of the research exemption on the innovation activities of pharmaceutical firms in China. In our thought experiment, the key difference is that unlike mainstream biochemical firms, TCM firms should not be substantially affected by the research exemption brought by the 2009 patent law amendment, due to their distinct product R&D mode based on traditional formulas (see Section 2). Thus, TCM firms serve as a natural comparison group. We then implement a DID strategy that compares the outcome variables of biochemical firms (i.e., the treatment group) to those of TCM firms (i.e., the control group) before and after the enactment of China's research exemption law in late 2009.

We use the following baseline specification to run OLS regressions:

$$y_{i,t+N} = \alpha + \beta(Treat_i * Post_t) + \gamma X_{i,t} + \theta_t + \omega_i + \varepsilon_{i,t}. \tag{1}$$

In equation (1), i and t are firm and year subscripts, respectively. The dependent variable $y_{i,t+N}$ is an outcome of interest (e.g., R&D inputs) of firm i in year $t+N$, where N denotes the time lag. The main explanatory variable, $Treat_i * Post_t$, is the interaction of the binary variables $Treat_i$ and $Post_t$. Specifically, $Treat_i$ equals one if the firm is a biochemical

pharmaceutical firm in the treatment group, and zero otherwise. $Post_t$ equals one only if the observation's year is *strictly* after 2009; in other words, the estimated effects captured by β are assumed to start in 2010, or one year after the law's enactment. $X_{i,t}$ is a set of firm-level control variables discussed in Section 3. θ_t captures time-fixed effects, and ω_i captures firm-fixed effects. Standard errors are clustered at the firm level.

4.1 Validity of the control group

Our estimate of the key coefficient of interest, β, has a clean causal interpretation when the treatment and control groups are randomly assigned. With a non-random assignment—as in most observational studies—one concern is that any difference in innovation activities between biochemical firms and TCM firms after the treatment event may be driven by differences in firm characteristics unrelated to the research exemption law. To address this concern, in Table 2, we present evidence showing that the treatment and control firms are not significantly different in terms of R&D growth and firm characteristics before 2010. In columns 1 and 2, we report the mean values of the annual compound growth rates of the key innovation variables and other control variables of the two groups. Columns 3 and 4 show the mean differences and p-values for significance testing, respectively. As we have an unbalanced panel, we compare the control and treatment groups for each of the three years before 2010. Biochemical firms have on average higher Tobin's Q ratios than TCM firms, while the average log employment of TCM firms is higher. However, based on column 4, except for $PPE/Assets$ in 2007, none of the mean differences between the treatment and control firms are statistically significant.

[Table 2 about here]

We perform another check to assess the appropriateness of our comparison choice by using the synthetic control method (Abadie *et al.*, 2010). The synthetic control algorithm creates an artificial comparison group that mimics the pre-intervention characteristics of the

treatment group, and it does so by calculating a weighted average of the units in the set of potential comparisons, where some units may receive zero weight. In principle, if TCM firms are indeed suitable comparisons for biochemical firms, the algorithm should give them higher weights in forming the synthetic control. To implement this, we pool together TCM firms and additional, out-of-sample firms in the chemical industry (CSRC industry code C26) and target at the average characteristics of biochemical firms for each of the pre-reform years.[8] We report the results in Appendix Table A.2. As expected, the synthetic control's observables closely resemble the average characteristics of the treatment firms in the pre-reform years. More importantly, TCM firms are indeed given disproportionately higher weights in forming the synthetic control. For instance, in 2008, TCM firms only account for 20% of all firms, but their cumulative weights exceed 40%; and in 2009, they account for one third of all firms but carry 75% of total weights. Overall, this exercise demonstrates that our control group is also likely to be chosen by the algorithm as qualified candidates for comparison if we use an alternative, data-driven approach.

To further support our causal interpretation, we examine the pre-treatment trends in the key innovation variables of the two groups. Specifically, we interact $Treat_i$ with the year dummy variables representing 1 and 2 years before the treatment event and add these terms to equation (1). We find no evidence of any pre-trend in firms' R&D inputs and patent status before 2010. The results are reported in Table 5 and discussed in the next section.

[8] We target the average characteristics of the treatment firms separately for each pre-reform year due to the data's unbalanced nature. To be clear, we do not (attempt to) use the synthetic control approach to estimate the treatment effects, as the synthetic control estimator is inadequate for our study, which has too few pre-reform years (Abadie, 2021).

5 Results

5.1 Baseline results

5.1.1 Effects on R&D inputs

Table 3 reports our baseline DID results. In columns 1 and 2, we examine the measures of R&D inputs. The estimated coefficients of $Treat * Post$ are positive and statistically significant at the 5% level. The regression model also fits the data well, as evidenced by the high R^2 (i.e., $R^2 > 0.60$). In column 1, our β estimate indicates that the average R&D intensity—measured by $R\&D/Sales$—of the biochemical firms increases by 1.3 percentage points after 2009, compared with the TCM firms. In the data, the average intensity of the biochemical firms is around 3.5% to 3.9% before the law's enactment. Given the causal interpretation of our estimate, this indicates that firms' R&D intensity increases by approximately 30% due to the research exemption, which represents a remarkably large impact.

Column 2 examines firms' total R&D spending. Our estimate shows that, on average, biochemical firms spend CNY53.9 million (US$8 million) more on R&D after 2009. Considering that the average R&D spending is around CNY30 million before the enactment of the law, this result indicates an even greater impact in terms of total spending. Figure 1 and Table 5 further support our causal interpretation by showing no pre-trend patterns for either measure of R&D inputs.

To further investigate the nature of those investments, we examine firms' R&D-related employment. R&D-related employment is an important indicator of in-house R&D. In Table 4, the estimated effects are large and significant—the research exemption drives up R&D employment in the treatment firms by more than 180% ($\approx e^{1.05} - 1$) and R&D employment as a fraction of total employment by 14%. This indicates that some of the new R&D activities have been conducted internally.

As most of the Chinese firms are generic drug producers, it is reasonable to say that those increased R&D investments are tied to generic drug development. In fact, the few Chinese

pharmaceutical firms known for genuine innovation became publicly listed only late in the past decade, and therefore they are not included in our sample.[9] Overall, we find that—as long expected by scholars and policy makers (Iles, 2005; Short, 2016b)—the research exemption has strong positive effects on pharmaceutical R&D in China.

[Tables 3 and 4 about here]

5.1.2 Effects on future innovation and productivity

We now turn to examine the impact on pharmaceutical innovation. *Ex ante*, the effect can be ambiguous, depending on the underlying complementarity or substitutability between imitation and innovation strategies. On the one hand, generic drug research and manufacturing may generate knowledge spillovers within firms and complement innovation in related areas, such as chemical ingredients and production technologies. In fact, there is scattered anecdotal evidence of such patentable outcomes in China (see Section 2). On the other hand, it is also likely that pouring resources into generic R&D crowds out genuinely innovative activities. In column 3 of Table 3, the outcome variable is the number of successful "invention" and "utility model" patents filed by a firm in year $t+2$ that are eventually granted. The coefficient estimate is negative—indicating a potential crowding-out effect on future patents—but not statistically significant (p-value = 0.303). The bottom line is that there is no evidence that the research exemption leads to more future patents by biochemical firms, compared with TCM firms. Figure 2, Panel C, which shows the yearly effects after $t+2$, further confirms this result by showing no significant impact on patents in the longer term. In column 4 examining firm productivity, we still do not find any significant impact, as the estimate is small and indistinguishable from zero. As shown in Table A.3, our main results are robust to an array of alternative measures, including other patent measures.

Put together, our results show that China's research exemption law does not lead to more patents or increased productivity in the pharmaceutical sector, although it evidently

[9] These listed pharmaceutical companies are Alphamab Oncology, BeiGene, Betta Pharmaceuticals, Chipscreen Biosciences and Innovent Biologics.

increases firms' R&D inputs. Previously, Galasso and Schankerman (2015) find that removing patent rights by court invalidation affects cumulative innovation in IT and electronics but has no effects on chemicals and pharmaceuticals. Our findings are consistent with theirs. As we observe both R&D inputs and outputs, this suggests that the increase in R&D brought by the research exemption did not generate sufficient knowledge spillovers to result in more patentable innovation or improved productivity. In fact, the estimated average treatment effect on future patents is negative (although not significant), suggesting a potential substitution effect between generic R&D and innovation activity.

5.2 Pre-trends and dynamic effects

One concern about our main findings is that the treatment firms that are more likely to be affected by the research exemption might already have been on a trajectory of higher R&D inputs. In the previous section, we showed that the average innovation growth and firm characteristics do not exhibit significant differences between the treatment and control groups. Here, we further strengthen this point by showing the pre-trend results in Table 5. If the treatment firms were on a different trajectory before 2010, the coefficients attached to the interactions of $Treat$ and the pre-treatment year dummies should be significant and positive or different from zero. In contrast, we find that all of the coefficients are small and not significant. There is clearly no pre-trend pattern in R&D inputs and patent status, which supports our causal interpretation of the main estimates.

[Table 5 about here]

Next, we perform a non-parametric event-study analysis of the dynamics of the impact of the research exemption. Formally, we run the following regression:

$$y_{i,t} = \alpha + \sum_{k=-2}^{8} \beta^k \, Treat_i * \mathbb{1}(t - 2010 = k) + \gamma X_{i,t} + \theta_t + \omega_i + \varepsilon_{i,t}, \tag{2}$$

where $\mathbb{1}(\cdot)$ is an indicator function equal to one if the observation's year minus the treatment year (i.e., 2010) is exactly equal to k. The coefficients of the interactions of $Treat$ and the yearly indicators, β_{-2}, β_{-1}, ..., β_8, range from two years before 2010 to eight years afterwards. The omitted year is 2007. We include the same set of control variables and fixed effects as in equation (1). In particular, this model does not impose any functional form restrictions on the pre- and post-treatment effects.

Figure 3 plots the estimated β_K coefficients and their 95% confidence intervals. It shows that the differences between the treatment and control firms for the three innovation-related variables are largely indistinguishable from zero, thus confirming our pre-trend results in Table 5. Panel (a) shows the effect on R&D intensity. The parallel trend in R&D intensity continues into the post-treatment years, but the positive difference becomes significant two years after the law's enactment and persistently increases over time. The magnitude of the effects is comparable to our main estimates in Table 3. Panel (b) plots the estimates for R&D spending. The qualitative pattern is similar, although the effects are less precisely estimated. In a separate regression not reported here, we treat both 2007 and 2008 as the baseline years, and the post-treatment effects are all positive and significant.

Panel (c) shows the effect on the number of patents. The differences are generally close to zero with large standard errors. The graph contrasts sharply with the other two graphs, which clearly show positive and upward post-treatment trends. This is consistent with our results in Table 3, indicating no significant impact of the research exemption on firms' patent outcomes.

[Figure 3 about here]

5.3 Robustness

In this section, we check the robustness of our main estimates.

Placebo tests. We previously showed in Table 5 that our results are not driven by concerns related to pre-trends. Here, we perform another placebo test to address any remaining con-

cern that our results may be driven by omitted factors unrelated to the research exemption. Specifically, we hold the policy year constant and randomly assign firms to the treatment or control group. This random assignment gives us a "fake" $Treat$ variable, which we use to re-estimate the main specification (1). For each of the dependent variables, we repeat the exercise 500 times and study the empirical distribution of the coefficients of $Treat * Post$. Figure 4 shows the distribution of the placebo estimates for R&D intensity. The average is very close to zero (i.e., -0.00002) and is far from the vertical red line representing our baseline estimate reported in Table 3. In fact, in only 2.2% of the random draws does the placebo test yield estimates that are statistically significant and greater than the baseline estimate. Similarly, for the effect on total R&D expenditure, the average placebo estimate is significantly closer to zero (4.15) than the original estimate (53.9) . In only 15% of the random draws, the placebo test yields estimates that are significant and greater than the baseline results. Overall, these findings indicate that the actual differences in firms' "treatment or control" status drive our main results. The placebo test further strengthens our confidence in the empirical strategy used.

[Figure 4 about here]

Sample construction. For our main analysis, we drop all firms that appear in the database after the treatment year. For robustness, we further trim our sample by removing all firms with missing outcome variables before or after 2009. Although this dramatically reduces the number of observations by more than 50% for the R&D variables, Panel A of Table A.3 shows that all of the estimated coefficients are quantitatively similar to the baseline results reported in Table 3.

A sharp DID design requires that the control firms not engage in any activity likely to be affected by the research exemption. Although we rely on a few sources to back this assumption, there may still be a concern. To address this issue, we manually check the annual financial reports of all TCM firms in our sample. We find that until 2010, none of the 48 TCM firms in our sample were involved in any generic-drug related activities. However, close to

the end of our sample period, in 2016, 16 TCM firms reported such activities. Following the logic of our research design, although including these firms will not harm the identification of the treatment effect around the policy event year, it may attenuate our estimates. As another robustness check, we remove these 16 firms and report the new estimates in Panel B. In columns 1 and 2, the coefficients for R&D inputs are larger than those reported in Table 3. For instance, they indicate that, on average, the research exemption law increases firms' R&D intensity by 2.1 points and total R&D spending by CNY86 million (US$12.6 million). In columns 3 and 4, the estimates remain negative but not statistically significant, and thus consistent with our original results for patents and TFP. As expected, removing the susceptible firms from the control group does not change our qualitative results.

Demand-side influences. An alternative explanation is that our main results may be driven by demand-side factors, such as increases in international trade. For instance, if there is a surge in demand in the global market for China's generic drugs contemporaneous to the 2009 patent law reform in 2009, this differential demand effect may also induce Chinese biochemical manufacturers to invest more in R&D relative to TCM firms. To account for this potential factor, in our main regressions, we also control for the firms' overseas sales revenue. As shown in Table A.3, Panel C, the new estimates are quantitatively similar to our earlier results.

Alternative outcome variables. In Panel D of Table A.3, column 1 uses a Poisson regression model to examine the count of patents. Column 2 examines the total number of all types of patents, including the "design" type. Columns 3 and 4 use the same definitions of patents and TFP as in Table 3 but examine the effects in $t + 3$. All of the coefficients show similar effects of the research exemption to our baseline estimates.

5.4 Market power and innovation responses

To explore firm heterogeneity in treatment effects, we focus on the role of market power in spurring innovation activities. Since Schumpeter (1942), it has been argued that the posses-

sion of *ex ante* market power—monopoly power in the extreme case—gives firms incentives to innovate. Another view held by Arrow (1962) and followers suggests that a monopolist has less incentive to incur the fixed cost of technology adoption, as it cannot amortize the cost with its restricted output. To test these competing arguments, we investigate whether the effects of the research exemption differ across firms with various degrees of market power. While we do not observe product-level information, we use a firm's sales share in its home province in 2009 to measure its market power, which is in line with Blundell *et al.* (1999). We interact this additional regressor with $Treat * Post$ in equation (1).

We report the results in Table 6, Panel A. In columns 1 and 4 for R&D intensity and TFP, the estimated coefficients of the three-way interaction term are positive but largely indistinguishable from zero. In the literature, a non-linear, "U-shaped" relationship between R&D intensity and concentration is often observed empirically (Aghion *et al.*, 2005); it is therefore not surprising that our result does not show a larger impact on R&D intensity for firms with larger market power.

More importantly, in columns 2 and 3, the estimated coefficients of the three-way interaction are positive and significant at the 5% level; they indicate that the research exemption leads to a larger increase in R&D spending and future patents for firms with greater market share. In particular, given that the average market share is 7% in 2009, the average effects on R&D spending and patents are 76.25 $(2.768 + 0.07 * 1049.799)$ and -0.104 $(-0.256 + 0.07 * 2.162)$, respectively, which are comparable to the baseline estimates reported in Table 3. Based on these estimates, we can see that the research exemption actually translates into more future patents for firms with sufficiently large market share. For instance, in our sample, the market shares of the top 5% biochemical firms in 2009 were over 16%, so for these firms, our estimates suggest an increase of at least 9% ($\approx e^{-0.256+0.16*2.162} - 1$) in their future patents due to the research exemption. Nonetheless, this important heterogeneity could not be captured by our baseline DID results.

One alternative explanation of the above finding is that the research exemption simply

has larger effects for larger firms and that firm size is correlated with market share. In fact, the relationship between firm size and innovation is the theme of a large literature following the Schumpeterian tradition.[10] Relevant to our context, for instance, Cohen and Klepper (1996) argue that it is easier for larger firms to enjoy the benefit of process innovations (i.e., the improvement of manufacturing processes), which are less saleable in disembodied form. To test this, in Panels B and C, we interact $Treat * Post$ with two measures of firm size. Panel B uses a binary variable indicating whether a firm is officially classified as a large firm according to China's National Bureau of Statistics.[11] Panel C uses the continuous variable $LnAssets$. In both specifications, our estimates show that for large firms, the effects on R&D spending are greater (column 2 of Panels B and C); and these results echo the findings in the literature (e.g. Cohen, 2010), especially those of Grabowski (1968) and Henderson and Cockburn (1996) on firm size and pharmaceutical R&D. However, these differential effects are not statistically significant for the number of patents (see column 3 of Panels B and C). In fact, according to column 4 of Panel B, the estimated effect on TFP is positive only for small and medium-size firms but not for large firms. Overall, our results indicate that firm size cannot explain why firms with large market shares experience a larger increase in future patents after the enactment of the research exemption law.

Taken together, our evidence is consistent with Schumpeter's view on the relationship between market power and the incentive to innovate. For underlying mechanisms, first, the class Schumpeterian argument states that product market competition can reduce economic rents for successful innovators, rendering firms less incentivized *ex ante*. In our context, another possible explanation emerges: as more profitable firms often have more diverse product lines, the economy of scope or knowledge spillovers of imitation on innovation can be larger for firms that face less competition. Our findings demonstrate that market competition and innovation policies can generate important interactions in shaping the innovation incentives

[10] See Cohen (2010) for a survey of the literature

[11] The classification is industry-specific. For instance, in 2011, for manufacturing firms, a "large-size" firm needs to have at least 1,000 employees and CNY400 million sales revenue.

of follower firms.

6 Conclusion

Although it is generally believed that by limiting the patent rights of incumbent innovators, innovation policies like the research exemption can be crucial in promoting R&D and innovation activities among latecomer firms, there is a lack of causal evidence of its impact. This study is the first to examine the effects of the research exemption, exploiting the patent law reform and the unique institutional setting of the pharmaceutical industry in China. Using firm-level data from 2007 to 2018 and a novel DID design, we find that the research exemption law has had strong positive effects on pharmaceutical R&D in China. However, we do not find evidence that the research exemption has led to more patents or improved productivity on average. Our investigation of firm heterogeneity in treatment effects further reveals that the research exemption has led to more patents only for few firms with large market power in China.

Overall, our empirical findings have important implications for the pharmaceutical sector and for the design of innovation policies in general. First, we furnish clear evidence that the research exemption law has led to large increases in pharmaceutical R&D investments in China—which are very likely to have contributed to China's growing position over the past decade in the global supply chain of chemical ingredients and generic drugs. Second, regarding truly innovative outcomes, the research exemption has had limited impact. The lessons from China are particularly relevant for laggard countries whose manufacturing sector mostly consists of follower firms striving to catch up with the technological frontier. Using China's case, our study highlights the importance of understanding the strategic relationship between imitation and innovation for public policy design. Various external factors, such as market competitiveness, should also be considered by practitioners and policy makers in business planning and policy making, as they may generate significant interaction effects

with R&D incentives and innovation policies. Lastly, our empirical design can also help us to analyze other outcome variables in the Chinese context, such as the direction of R&D and product proliferation, with other suitable datasets. We leave these directions for future research.

References

Abadie, A. (2021): "Using Synthetic Controls: Feasibility, Data Requirements, and Methodological Aspects," *Journal of Economic Literature*, forthcoming.

Abadie, A., A. Diamond, and J. Hainmueller (2010): "Synthetic Control Methods for Comparative Case Studies: Estimating the Effect of California's Tobacco Control Program," *Journal of the American Statistical Association*, 105(490), 493–505.

Acemoglu, D., P. Aghion, and F. Zilibotti (2006): "Distance to Frontier, Selection, and Economic Growth," *Journal of the European Economic Association*, 4(1), 37–74.

Acharya, V. V. and K. V. Subramanian (2009): "Bankruptcy codes and innovation," *The Review of Financial Studies*, 22(12), 4949–4988.

Aghion, P., N. Bloom, R. Blundell, R. Griffith, and P. Howitt (2005): "Competition and innovation: An inverted-U relationship," *The Quarterly Journal of Economics*, 120(2), 701–728.

Aghion, P. and P. Howitt (1992): "A Model of Growth Through Creative Destruction," *Econometrica*, 60(2), 323–351.

Arrow, K. J. (1962): "Economic Welfare and the Allocation of Resources for Invention," in *The Rate and Direction of Inventive Activity: Economic and Social Factors*, 609–626.

Benoit, J.-P. (1985): "Innovation and Imitation in a Duopoly," *The Review of Economic Studies*, 52(1), 99–106.

Blundell, R., R. Griffith, and J. van Reenen (1999): "Market share, market value and innovation in a panel of British manufacturing firms," *Review of Economic Studies*, 66, 529–554.

Cao, B., Y. Wang, D. Wen, W. Liu, J. Wang, G. F. ..., and C. Wang (2020): "A Trial of Lopinavir–Ritonavir in Adults Hospitalized with Severe Covid-19," *The New England Journal of Medicine*, 382, 1787–1799.

Cao, Y.-D., R.-J. Gong, N. Chen, and W. Liu (2019): "Research on patent quality of Chinese listed traditional Chinese medicine enterprises from R&D investment perspective (in Chinese)," *China Journal of Chinese Materia Medica*, 44(6), 1284–1288.

Chaudhuri, S., P. K. Goldberg, and P. Jia (2006): "Estimating the effects of global patent protection in pharmaceuticals: a case study of quinolones in India," *American Economic Review*, 96(5), 1477–1514.

China Bond Rating Coporation (2017): *Special Topics Report No. 426 (in Chinese).*

CNIPA (2001): *Guide to the Newly Amended Patent Law (in Chinese)*, Intellectual Property Publishing House.

Cockburn, I. M., J. O. Lanjouw, and M. Schankerman (2016): "Patents and the global diffusion of new drugs," *American Economic Review*, 106(1), 136–64.

Cohen, W. M. (2010): *Handbook of The Economics of Innovation*, Elsevier, vol. 1, chap. Fifty Years of Empirical Studies of Innovative Activity and Performance, 129–213.

Cohen, W. M. and S. Klepper (1996): "Firm Size and the Nature of Innovation within Industries: The Case of Process and Product R&D," *Review of Economics and Statistics*, 78(2), 232–243.

Cohen, W. M. and D. A. Levinthal (1989): "Innovation and Learning: The Two Faces of R&D," *Economic Journal*, 99(397), 569–96.

DiMasi, J. A. and H. G. Grabowski (2012): "R&D Costs and Returns to New Drug Development: A Review of the Evidence," in *The Oxford Handbook of the Economics of the Biopharmaceutical Industry*, ed. by P. M. Danzon and S. Nicholson, Oxford University Press.

Duggan, M., C. Garthwaite, and A. Goyal (2016): "The market impacts of pharmaceutical product patents in developing countries: Evidence from India," *American Economic Review*, 106(1), 99–135.

Galasso, A. and M. Schankerman (2015): "Patents and cumulative innovation: Causal evidence from the courts," *The Quarterly Journal of Economics*, 130(1), 317–369.

Giannetti, M., G. Liao, and X. Yu (2015): "The brain gain of corporate boards: Evidence from China," *Journal of Finance*, 70(4), 1629–1682.

Gothe, H., I. Schall, K. Saverno, M. Mitrovic, A. Luzak, D. Brixner, and U. Siebert (2015): "The impact of generic substitution on health and economic outcomes: a systematic review," *Applied Health Economics and Health Policy*, 13(1), 21–33.

Grabowski, H. G. (1968): "The Determinants of Industrial Research and Development: A Study of the Chemical, Drug, and Petroleum Industries," *Journal of Political Economy*, 76(2), 292–306.

Griliches, Z., A. Pakes, and B. H. Hall (1987): "The Value of Patents as Indica- tors of Inventive Activity," in *Economic Policy and Technical Performance*, ed. by P. Dasgupta and P. Stoneman, Cambridge University Press, 97–124.

Grossman, G. M. and E. Helpman (1991): "Quality ladders in the theory of growth," *The Review of Economic Studies*, 58(1), 43–61.

Haas, J. S., K. A. Phillips, E. P. Gerstenberger, and A. C. Seger (2005): "Potential savings from substituting generic drugs for brand-name drugs: medical expenditure panel survey, 1997–2000," *Annals of Internal Medicine*, 142(11), 891–897.

Hafner, T. and D. Popp (2011): "China and India as suppliers of affordable medicines to developing countries," *NBER Working Papepr Series*, No. 17249.

Henderson, R. and I. Cockburn (1996): "Scale, Scope, and Spillovers: The Determinants of Research Productivity in Drug Discovery," *The RAND Journal of Economics*, 27(1), 32–59.

Horner, R. (2020): "Why the world needs pharmaceuticals from China and India to beat coronavirus," *The Telegraph*, May 27, https://www.telegraph.co.uk/global–health/science–and–disease/world–needs–pharmaceuticals–china–india–beat–coronavirus.

Huang, Y.-Z. (2020): "The Coronavirus Outbreak Could Disrupt the U.S. Drug Supply," https://www.cfr.org/in–brief/coronavirus–disrupt–us–drug–supply–shortages–fda.

Iles, K. (2005): "A comparative analysis of the impact of Experimental Use Exemptions in patent law on incentives to innovate," *Northwestern Journal of Technology and Intellectual Property*, 4, 61–82.

Jiang, Y., Y. Wang, and X. Yan (2001): "Chinese pharmaceutical companies: An emerging industry." *Drug Discovery Today*, 6(12), 610.

Katz, M. L. and C. Shapiro (1987): "R&D Rivalry with Licensing or Imitation," *American Economic Review*, 77(3), 402–420.

Kelly, C. (2011): "The balance between innovation and competition: The hatch-waxman act, the 2003 amendments, and beyond," *Food and Drug Law Journal*, 66(3), 417–478.

Kupecz, A., K. Roox, C. Dekoninck, D. Schertenleib, M. Stief, F. Sanna, M. Orsingher, S. Miralles, E. Molina, T. Crosse, *et al.* (2015): "Safe harbors in Europe: an update on the research and Bolar exemptions to patent infringement," *Nature Biotechnology*, 33(7), 710–715.

Kyle, M. K. and A. M. McGahan (2012): "Investments in pharmaceuticals before and after TRIPS," *Review of Economics and Statistics*, 94(4), 1157–1172.

Lehman, B. (2003): "The Pharmaceutical Industry and the Patent System," http://www.integrityip.com/Patent–Library/Community/Other/PharmaPatents.pdf.

Liu, J., L. Dong, and J.-M. Gao (2011): "Analysis of atorvastatin patent application in China (in Chinese)," *Chinese Journal of New Drugs*, 20(15), 1372–1376.

Morton, F. S. and M. Kyle (2011): "Markets for pharmaceutical products," in *Handbook of Health Economics*, Elsevier, vol. 2, 763–823.

Moschini, G. and O. Yerokhin (2008): "Patents, research exemption, and the incentive for sequential innovation," *Journal of Economics & Management Strategy*, 17(2), 379–412.

Mueller, J. M. (2004): "The Evanescent Experimental Use Exemption from United States Patent Imfringement Liability: Implications for University and Nonprofit Research and Development," *Baylor Law Review*, 56, 917.

National Administration of Traditional Chinese Medicine (2019): *Yearbook of Traditional Chinese Medicine of China*, China Press of Traditional Chinese Medicine.

Pan, S.-Y., S.-B. Chen, H.-G. Dong, Z.-L. Yu, J.-C. Dong, Z.-X. Long, W.-F. Fong, Y.-F. Han, and K.-M. Ko (2011): "New perspectives on Chinese herbal medicine (Zhong-Yao) research and development," *Evidence-Based Complementary and Alternative Medicine*, 2011, 1–11.

Qin, Y. and L. Dong (2016): "Analysis of the current situation of the Chinese traditional medicine patent application in China and the corresponding suggestions (in Chinese)," *Chinese Journal of New Drugs*, 25(8), 841–860.

Rogosnitzky, M., E. Berkowitz, and A. R. Jadad (2020): "Delivering Benefits at Speed through Real-World Repurposing of Off-Patent Drugs: The COVID-19 Pandemic as a Case in Point," *JMIR Public Health and Surveillance*, 6(2), e19199.

Sampat, B. and H. L. Williams (2019): "How do patents affect follow-on innovation? Evidence from the human genome," *American Economic Review*, 109(1), 203–36.

Schumpeter, J. (1942): *Capitalism, Socialism and Democracy*, New York: Harper & Brothers.

Service, R. (2020): "Would-be coronavirus drugs are cheap to make," *Science*, April 10.

Short, N. (2016a): "The political economy of the Research Exemption in American patent law," *Fordham Intellectual Property, Media and Entertainment Law Journal*, 26, 573–623.

——— (2016b): "A Research Exemption for the 21st Century," *University of Michigan Journal of Law Reform Caveat*, 50(1), 1–17.

Sun, Q., M. A. Santoro, Q. Meng, C. Liu, and K. Eggleston (2008): "Pharmaceutical policy in China," *Health Affairs*, 27(4), 1042–1050.

Tridico, A., J. Jacobstein, and W. Leythem (2014): "Facilitating generic drug manufacturing: Bolar exemptions worldwide," *WIPO Magazine*, 3.

Williams, H. L. (2013): "Intellectual property rights and innovation: Evidence from the human genome," *Journal of Political Economy*, 121(1), 1–27.

——— (2017): "How do patents affect research investments?" *Annual Review of Economics*, 9, 441–469.

Xu, J. and Y. Yang (2009): "Traditional Chinese medicine in the Chinese health care system," *Health policy*, 90(2-3), 133–139.

Yang, Q., Q.-J. Ma, and X.-J. Wang (2015): "Suggestions for secondary innovations and generic development for drugsfrom the perspective of patent—taking HIV protease inhibitor lopinavir as an example (in Chinese)," *Journal of China Pharmaceutical University*, 46(4), 499–503.

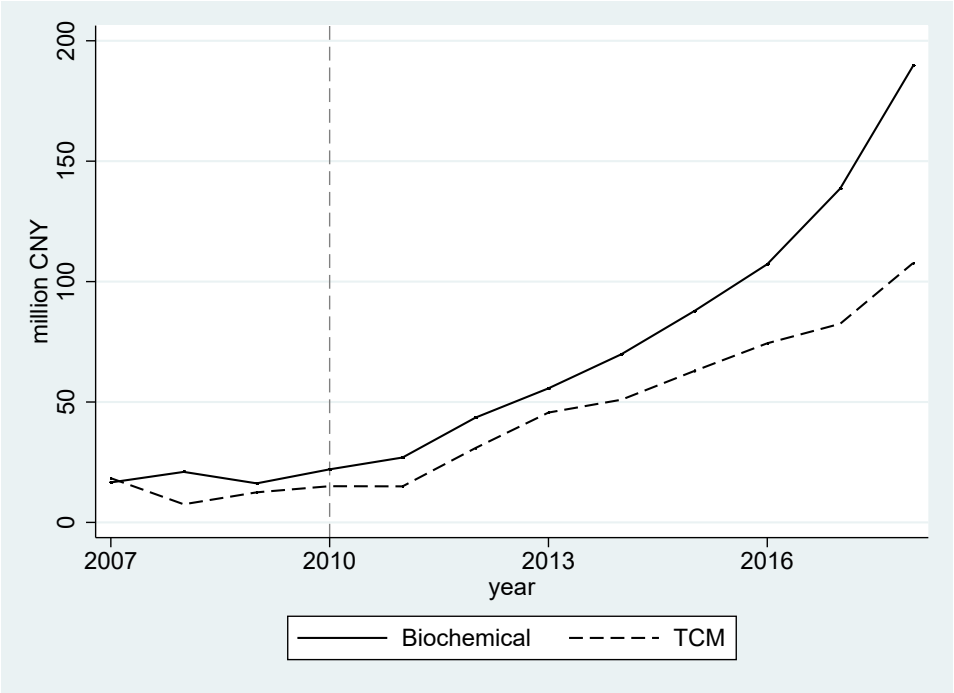
Yu, X., C. Li, Y. Shi, and M. Yu (2010): "Pharmaceutical supply chain in China: current issues and implications for health system reform," *Health Policy*, 97(1), 8–15.

Zhang, X. and H. Nie (2021): "Public health insurance and pharmaceutical innovation: Evidence from China," *Journal of Development Economics*, 148.

Zhuang, W. (2014): *Emerging Markets and the World Patent Order*, Edward Elgar, chap. Evolution of the patent system in China, 155–179.

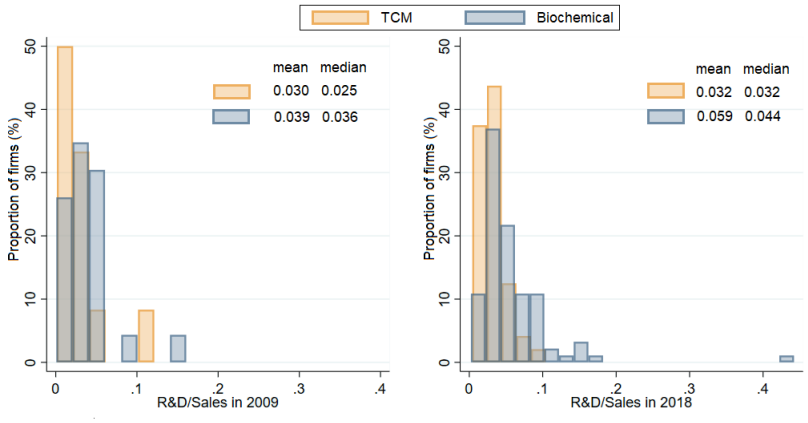
Figures

Figure 1: Average R&D spending over time: Biochemical vs. TCM firms

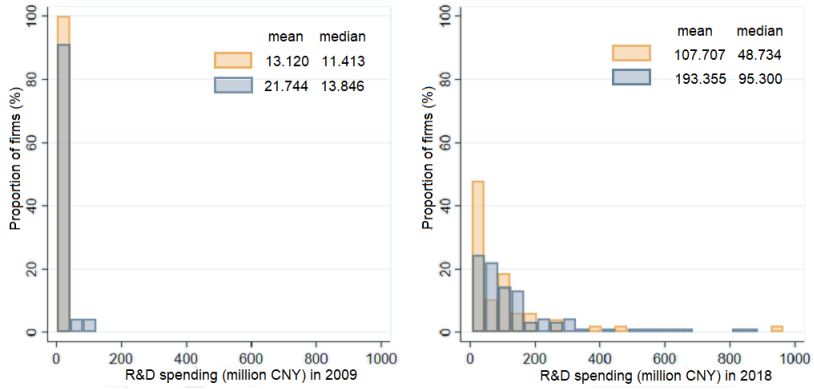


Notes: This figure plots the average R&D spending of biochemical pharmaceutical firms versus TCM firms in China.

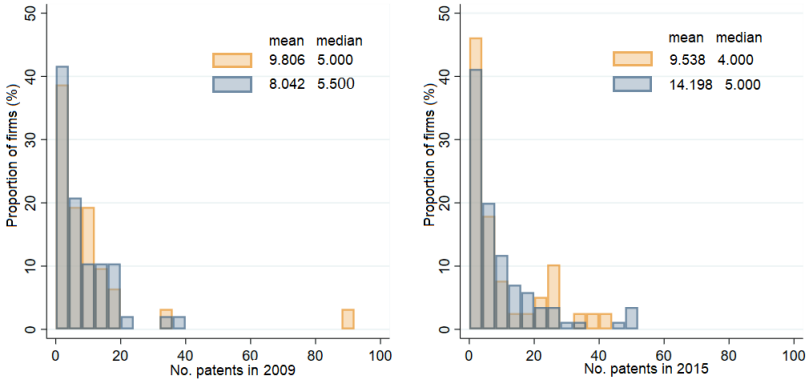
Figure 2: Distribution of the R&D and patent variables in selected years



(a) R&D intensity of biochemical and TCM firms in 2009 and 2018

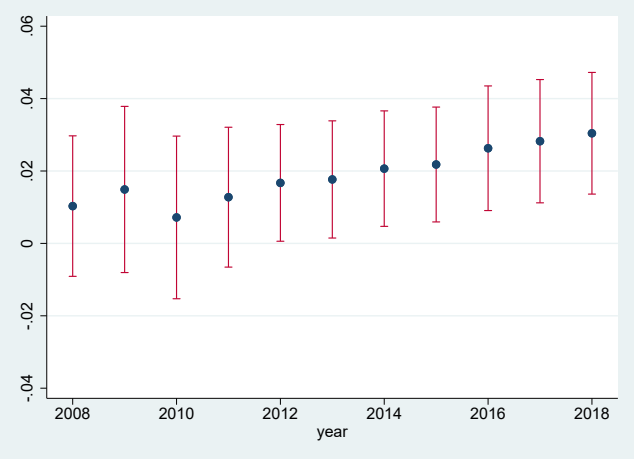


(b) Total R&D spending of biochemical and TCM firms in 2009 and 2018

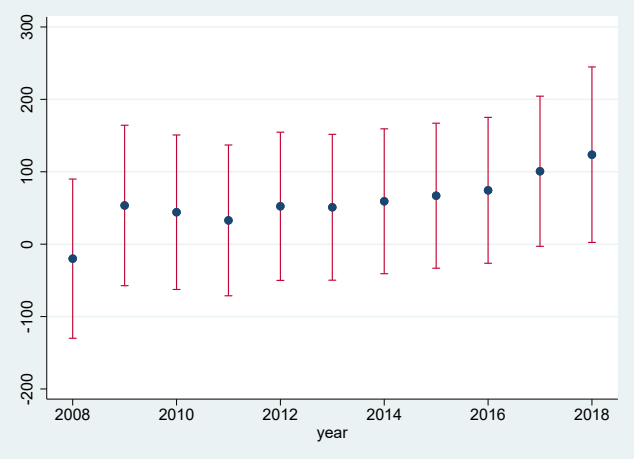


(c) No. successful patent applications by biochemical and TCM firms in 2009 and 2015

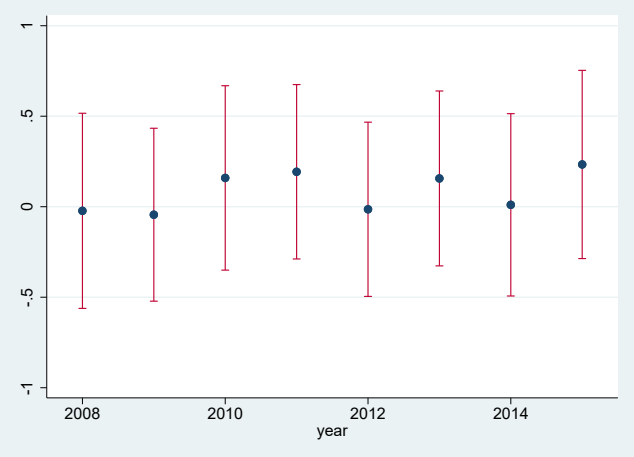
Figure 3: Parallel trends and dynamic effects



(a) The effects on $R\&D/Sales$



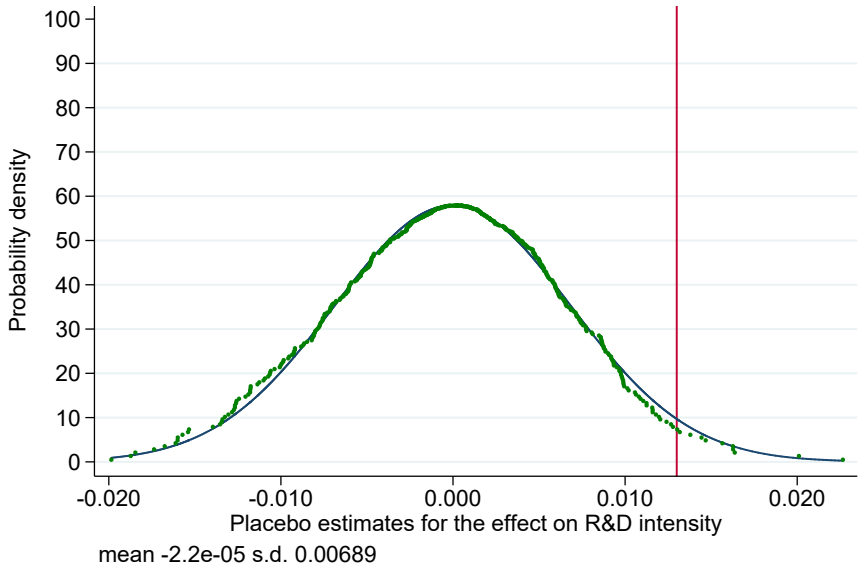
(b) The effects on $R\&DSpending$



(c) The effects on $LnPatent$

Notes: These figures plot coefficients and 95 percent confidence internals from the event study specification described in Section 5.2. The coefficients are estimates from OLS regressions, and the standard errors are robust and clustered at the firm level.

Figure 4: Placebo estimates



Notes: Density of the estimated coefficients from 500 simulations using random group assignments. The red vertical line represents the baseline estimate from Table 3. See Section 5.3 for more details.

Tables

Table 1: Summary statistics of main variables

	obs	mean	sd	min	25%	median	75%	max
$R\&D/Sales$	1106	0.043	0.039	0	0.024	0.037	0.052	0.526
$R\&DSpending$ (million CNY)	1112	80.042	147.724	0.088	15.35	36.532	82.692	2100.256
$Patent$	682	12.393	30.943	0	2	6	15	493
TFP	1187	4.370	1.195	1.478	3.375	4.179	5.449	7.359
$Assets$ (million CNY)	1467	3468.391	4955.194	101.651	878.136	1916.543	4018.803	58692.73
$Employee$	1467	3378.146	3856.32	24	1007	1881	4295	28848
$PPE/Assets$	1467	0.219	0.112	0	0.133	0.2	0.285	0.693
$CAPEX/Assets$	1467	0.057	0.048	0.001	0.025	0.044	0.077	0.384
$TobinQ$	1467	2.774	1.831	0.809	1.589	2.168	3.278	16.864
LEV	1467	0.338	0.212	0.008	0.177	0.314	0.463	1.893
$CashRatio$	1467	0.02	0.062	-0.044	0.003	0.006	0.016	1.675
$R\&DStaff$	544	352.551	423.238	6	131	228	414	4464
$R\&DStaffRatio$	536	0.112	0.069	0.0004	0.06	0.108	0.146	0.433

Notes: This table reports the descriptive statistics for the variables used in the baseline regressions, based on the sample of publicly listed pharmaceutical firms in China from 2007 to 2018. Observations are at the firm-year level. The variable *Patent* is for 2007–2015 only. Variable definitions are in Appendix Table A.1. All money values are in 2018 Chinese *yuan* (CNY).

Table 2: Comparison of the treatment and control groups before the research exemption law

variable	treatment mean (1)	control mean (2)	diff (3)	p-value (4)
R&D/Sales growth	-0.488	-0.5	0.012	0.928
R&D spending growth	-0.454	-0.489	0.035	0.802
Patent growth	0.217	0.234	-0.017	0.869
		Year 2007		
lnAssets	20.625	20.475	0.150	0.474
lnEmployee	7.286	7.403	-0.117	0.651
PPE/Assets	0.282	0.229	0.053	0.026**
CAPEX/Assets	0.057	0.049	0.008	0.553
TobinQ	3.336	2.713	0.623	0.165
LEV	0.398	0.427	-0.029	0.558
CashRatio	0.007	0.008	-0.001	0.562
		Year 2008		
lnAssets	20.700	20.604	0.096	0.636
lnEmployee	7.271	7.467	-0.195	0.430
PPE/Assets	0.263	0.232	0.031	0.184
CAPEX/Assets	0.064	0.054	0.01	0.484
TobinQ	2.03	1.722	0.308	0.285
LEV	0.395	0.399	-0.004	0.933
CashRatio	0.010	0.011	-0.001	0.756
		Year 2009		
lnAssets	20.834	20.708	0.126	0.516
lnEmployee	7.297	7.516	-0.218	0.346
PPE/Assets	0.242	0.212	0.03	0.211
CAPEX/Assets	0.059	0.047	0.012	0.302
TobinQ	3.313	2.787	0.526	0.187
LEV	0.374	0.379	-0.005	0.933
CashRatio	0.017	0.016	0.001	0.875

Notes: This table reports the univariate comparisons between the treatment and control firms' characteristics and their corresponding p-values in the pre-reform years (2007–2009). Annualized growth rates are reported for R&D and patent variables. All money values are in 2018 Chinese *yuan* (CNY).

Table 3: Effects of the research exemption on R&D inputs and innovation outputs

dependent variable	$R\&D/Sales_t$	$R\&D_t$	$LnPatent_{t+2}$	TFP_{t+2}
	(1)	(2)	(3)	(4)
$Treat * Post$	0.013**	53.904**	-0.138	0.033
	(0.006)	(25.747)	(0.134)	(0.040)
$LnAssets$	-0.000	54.953***	-0.089	0.065*
	(0.003)	(11.284)	(0.163)	(0.036)
$PPE/Assets$	0.002	20.328	0.154	-0.025
	(0.011)	(36.059)	(0.610)	(0.108)
$LnEmployee$	-0.003	-4.704	0.240**	-0.117***
	(0.002)	(10.710)	(0.100)	(0.024)
LEV	0.001	8.741	-0.524	-0.021
	(0.009)	(20.434)	(0.380)	(0.085)
$TobinQ$	0.001	7.846**	-0.034	0.027***
	(0.001)	(3.188)	(0.037)	(0.008)
$CashRate$	-0.003	74.165	-1.646***	-0.066
	(0.008)	(59.936)	(0.346)	(0.090)
$CAPEX/Assets$	0.062***	7.292	-0.885	-0.563***
	(0.019)	(64.289)	(0.907)	(0.215)
Constant	0.061	-1.1e+03***	2.370	3.827***
	(0.050)	(235.627)	(3.275)	(0.719)
Year fixed-effects	Yes	Yes	Yes	Yes
Firm fixed-effects	Yes	Yes	Yes	Yes
N	1106	1112	679	1187
Adj. R^2	0.639	0.632	0.596	0.965

Notes: This table reports the regression results for the impact of the research exemptions. The variable definitions are in Appendix Table A.1. Robust standard errors clustered by firm are displayed in parentheses. Significance at * 10%, ** 5%, and *** 1% levels.

Table 4: Effects on the number of R&D personnel

dependent variable	$LnR\&DStaff$	$R\&DStaffRatio$
	(1)	(2)
$Treat * Post$	1.050*	0.143***
	(0.562)	(0.051)
Constant	1.155	0.028
	(2.776)	(0.176)
Controls	Yes	Yes
Year fixed-effects	Yes	Yes
Firm fixed-effects	Yes	Yes
N	544	536
Adj. R^2	0.922	0.876

Notes: Robust standard errors clustered by firm are displayed in parentheses. Significance at * 10%, ** 5%, and *** 1% levels.

Table 5: Pre-trend results

dependent variable	$R\&D/Sales_t$	$R\&D_t$	$LnPatent_t$
	(1)	(2)	(3)
2 years before reform	0.010	-21.514	-0.024
	(0.010)	(56.304)	(0.274)
1 year before reform	0.016	58.266	-0.047
	(0.012)	(56.512)	(0.243)
$Treat * Post$	0.023***	75.216	0.012
	(0.008)	(51.971)	(0.207)
Controls	Yes	Yes	Yes
Year fixed-effects	Yes	Yes	Yes
Firm fixed-effects	Yes	Yes	Yes
N	1106	1112	892
Adj. R^2	0.639	0.632	0.557

Notes: This table reports the results of the pre-trend test with two pre-treatment yearly dummies representing 1 and 2 years before the law change added to the main regressions. For the results of an extensive event-study analysis, see Figure 3. Robust standard errors clustered by firm are displayed in parentheses. Significance at * 10%, ** 5%, and *** 1% levels.

Table 6: Heterogeneous effects

dependent variable	$R\&D/Sales_t$	$R\&D_t$	$LnPatent_{t+2}$	TFP_{t+2}
	(1)	(2)	(3)	(4)
		Panel A		
$Treat * Post$	0.010	2.768	-0.256**	0.023
	(0.007)	(20.628)	(0.144)	(0.043)
$Treat * Post * MarketShare$	0.058	1049.799**	2.162**	0.179
	(0.045)	(449.643)	(1.037)	(0.327)
N	1106	1112	679	1187
Adjusted R^2	0.639	0.637	0.598	0.965
		Panel B		
$Treat * Post$	0.001	-21.683	-0.022	0.197***
	(0.011)	(19.988)	(0.237)	(0.068)
$Treat * Post * Largesize$	0.014	91.202***	-0.134	-0.201***
	(0.010)	(24.932)	(0.228)	(0.064)
N	1106	1112	679	1187
Adjusted R^2	0.640	0.634	0.595	0.965
		Panel C		
$Treat * Post$	-0.153***	-1.4e+03***	-2.369	0.353
	(0.038)	(312.893)	(1.776)	(0.461)
$Treat * Post * LnAssets$	0.008***	65.247***	0.102	-0.015
	(0.002)	(14.958)	(0.082)	(0.021)
N	1106	1112	679	1187
Adjusted R^2	0.643	0.652	0.596	0.965
Controls	Yes	Yes	Yes	Yes
Year fixed-effects	Yes	Yes	Yes	Yes
Firm fixed-effects	Yes	Yes	Yes	Yes

Notes: This table reports additional results for the heterogeneous effects of the research exemption. $MarketShare$ is a firm's sales revenue share in its home province in 2009. $Largesize$ is a dummy variable indicating whether a firm is officially classified as a large-size firm by China's National Bureau of Statistics. Other variable definitions are in Appendix Table A.1. All regressions include firm-level controls, year fixed effect and firm fixed effect. Robust standard errors clustered by firm are displayed in parentheses. Significance at * 10%, ** 5%, and *** 1% levels.

A Appendix

A.1 Variable definitions

variable	definition
$R\&D/Sales$	The firm's R&D expenditure scaled by total revenue in a given year;
$R\&DSpending$	The firm's R&D expenditure after inflation adjustment;
$LnPatent$	Natural log of one plus the firm's total number of "invention" and "utility model" patent applications filed in a given year that are eventually granted;
TFP	Total factor productivity computed as the residual from the following cross-sectional regression estimated for each year, following Giannetti *et al.* (2015): $$y_{it} = \alpha_t + \beta_t l_{it} + \gamma_t k_{it} + \delta_t m_{it} + \varepsilon_{it}$$ where y_{it} is the natural log of one plus firm i's total revenue (in CNY) in year t, l_{it} is the natural log of firm i's employment (in persons), k_{it} is the natural log of the total assets, and m_{it} the natural log of the total expenditures on labor and capital goods;
$LnAssets$	Natural log of the book value of the firm's total assets measured at the end of fiscal year t after inflation adjustment;
$LnEmployee$	Natural logarithm of the total number of employees;
$PPE/Assets$	Net property, plant, and equipment divided by the book value of the firm's total assets;
$CAPEX/Assets$	Capital expenditure scaled by the book value of the firm's total assets;
$TobinQ$	The firm's market-to-book ratio, calculated as [the market value of equity plus the book value of assets minus the book value of equity minus balance sheet deferred taxes] divided by the book value of the firm's total assets;
LEV	The book value of the firm's debt divided by the book value of total assets;
$CashRatio$	The ratio of the firm's cash and cash equivalents to its current liabilities;
$LnR\&DStaff$	Natural log of the number of R&D-related personnel, which includes employees who directly participate in R&D project activities, R&D project management personnel, and personnel who provide materials, equipment maintenance and other direct services for R&D activities;
$R\&DStaffRatio$	The number of R&D personnel divided by the total number of employees.

Table A.1: Variable definitions

A.2 Assessing TCM firms using synthetic controls

We use the synthetic control method (Abadie *et al.*, 2010; Abadie, 2021) to create a synthetic control group from a pool of TCM firms and out-of-sample firms in the chemical industry, targeting at the average characteristics of treated firms for each of the pre-treat years. Table A.2 below shows the mean characteristics of the treatment and synthetic control groups for each year. It also shows the cumulative regression weights that the synthetic control algorithm assigns to TCM firms.

variable	treated	synthetic control
	Year 2007	
% TCM firms: 42.8%	Total weights of TCM firms: 44.9%	
$lnAssets$	28.004	28.050
$lnEmployee$	7.807	7.541
$PPE/Assets$	0.279	0.269
$CAPEX/Assets$	0.053	0.061
$TobinQ$	3.336	3.229
LEV	0.421	0.438
$CashRatio$	0.006	0.003
	Year 2008	
% TCM firms: 20%	Total weights of TCM firms: 40.3%	
$lnAssets$	28.026	27.589
$lnEmployee$	7.785	7.710
$PPE/Assets$	0.270	0.276
$CAPEX/Assets$	0.062	0.085
$TobinQ$	2.030	1.533
LEV	0.403	0.405
$CashRatio$	0.009	0.008
	Year 2009	
% TCM firms: 33.3%	Total weights of TCM firms: 75%	
$lnAssets$	28.160	28.146
$lnEmployee$	7.779	7.691
$PPE/Assets$	0.245	0.256
$CAPEX/Assets$	0.055	0.062
$TobinQ$	3.313	2.814
LEV	0.384	0.385
$CashRatio$	0.016	0.017

Table A.2: Comparison of biochemical firms and synthetic controls before the enactment of the research exemption law

A.3 Robustness results

	(1)	(2)	(3)	(4)
	Panel A: Removing firms w/ missing obs. before or after 2009			
dependent variable	$R\&D/Sales_t$	$R\&D_t$	$LnPatent_{t+2}$	TFP_{t+2}
$Treat * Post$	0.012**	55.333**	-0.084	0.032
	(0.005)	(26.311)	(0.134)	(0.040)
N	456	456	525	1123
Adj. R^2	0.650	0.591	0.574	0.965
	Panel B: Removing TCM firms w/ reported generic drug activities			
dependent variable	$R\&D/Sales_t$	$R\&D_t$	$LnPatent_{t+2}$	TFP_{t+2}
$Treat * Post$	0.021***	86.500***	-0.162	-0.010
	(0.007)	(32.731)	(0.170)	(0.052)
N	978	984	595	1051
Adj. R^2	0.631	0.625	0.583	0.963
	Panel C: Controlling for overseas sales			
dependent variable	$R\&D/Sales_t$	$R\&D_t$	$LnPatent_{t+2}$	TFP_{t+2}
$Treat * Post$	0.012**	49.778*	-0.135	0.036
	(0.006)	(25.982)	(0.134)	(0.040)
N	1106	1112	679	1187
Adj. R^2	0.641	0.636	0.595	0.965
	Panel D: Other outcome variables			
dependent variable	$Patent_{t+2}$ (Poisson reg.)	$LnAllPatent_{t+2}$	$LnPatent_{t+3}$	TFP_{t+3}
$Treat * Post$	-0.218	0.005	-0.144	0.002
	(0.241)	(0.131)	(0.149)	(0.040)
N	675	679	555	1047
Adj. R^2	–	0.606	0.560	0.962

Notes: This table reports the robustness results. See Section 5.3 for more details. All regressions include firm-level controls and year and firm fixed effects. Robust standard errors clustered by firm are displayed in parentheses. Significance at * 10%, ** 5%, and *** 1% levels.

Table A.3: Robustness results