

Competition and R&D Financing: Evidence from the Biopharmaceutical Industry*

Richard T. Thakor[†] and Andrew W. Lo[‡]

Forthcoming, *Journal of Financial and Quantitative Analysis*

Abstract

The interaction between product market competition, R&D investment, and the financing choices of R&D-intensive firms on the development of innovative products is only partially understood. To motivate empirical hypotheses about this interaction, we develop a model which predicts that as competition increases, R&D-intensive firms will: (1) increase R&D investment relative to assets in place that support existing products; (2) carry more cash; and (3) maintain less net debt. Using the Hatch-Waxman Act as an exogenous shock to competition, we provide causal evidence which supports these hypotheses through a differences-in-differences analysis that exploits differences between the biopharma industry and other industries, and heterogeneity within the biopharma industry. We also explore how these changes affect innovative output, and provide novel evidence that increased competition causes companies to increasingly “focus” their efforts, i.e., there is a decline in the total number of innovations, but an increase in their economic value.

Keywords: Healthcare Finance; Pharmaceutical Industry; Biotechnology Industry; Capital Structure; R&D Investments; Cash Holdings; Competition; Innovation

JEL Classification: G31, G32, L11, L12, L25, L65, O32

*We thank Jarrad Harford (the editor), Raj Iyer, Danmo Lin, Debbie Lucas, Andrey Malenko, Stew Myers, Matt Rhodes-Kropf (discussant), an anonymous referee, and participants at the *American Finance Association* Meetings for helpful comments and discussions. We also thank Nicholas Anaya, Christian Vilanilam, and Yuwei Zhang for research assistance, and Jayna Cummings for editorial assistance. Research support from the MIT Laboratory for Financial Engineering is gratefully acknowledged. The views and opinions expressed in this article are those of the authors only and do not necessarily represent the views and opinions of any other organizations, any of their affiliates or employees, or any of the individuals acknowledged above.

[†]University of Minnesota - Carlson School of Management, and MIT LFE. 321 19th Avenue South, 3-255, Minneapolis, MN 55455. Phone: (612) 626-7817. E-mail: rthakor@umn.edu

[‡]MIT Sloan School of Management, CSAIL, and NBER, 100 Main Street, E62-618, Cambridge, MA 02142. E-mail: alo-admin@mit.edu

1 Introduction

The question of how competition affects innovation has long been of interest to economists and policymakers, going back to Schumpeter (1942), and continuing to the more recent important contributions of Aghion, Bloom, Blundell, Griffith, and Howitt (2005), among others. However, the predicted relationship between competition and innovation has not been clear-cut. Theoretical and empirical studies alike have sometimes shown greater competition to be beneficial for innovation, and sometimes for it be deleterious. This effect has also depended on whether one focuses on the outputs of innovation, e.g., patents and products, or the inputs of innovation, e.g., research and development (R&D) efforts.¹ Additionally, R&D investments require funding to produce innovation, funding that often must be externally financed, given the large scale of such investments.² This introduces the influence of competition on the firm’s ability to finance, as well as the potential impact of frictions in external financing on the innovation process (e.g., Hall and Lerner (2010), Cornaggia, Mao, Tian, and Wolfe (2013), Lin (2017)).³ Thus, competition, innovation, and the financing choices of firms are inextricably linked. This raises the question: how does product market competition affect innovation and the choices of financing mix that firms make to fund innovative activities?

The primary goal of this paper is to answer this question empirically. While previously these issues have been studied separately, we are unaware of any prior empirical examination of the interactive relationship between competition, innovation, and financing in a setting

¹See Cohen and Levin (1989), Ahn (2002), and Aghion, Akcigit, and Howitt (2014) for reviews. Also see, for example, Chernyshev (2017) for a discussion and model demonstrating how the responses of innovative output and R&D may differ when the competition changes.

²For example, see DiMasi, Grabowski, and Hansen (2016) for evidence of the large costs of R&D in drug development, costs that have been steadily increasing over time.

³Understanding the effects of competition is important because they expose the process of innovation to theoretically and empirically documented frictions that are inherent to raising external financing. These effects vary depending on the particular financing source (e.g., debt or equity), with important downstream implications for investment decisions (e.g., Jensen and Meckling (1976), Myers and Majluf (1984)). For example, if innovative firms are driven to tap into particular financial markets, and these markets are exposed to some type of fragility or systemic risk, then this has potentially crucial implications for policy.

that overcomes concerns about endogeneity.⁴ The interaction effects and concerns about endogeneity are especially important because theory suggests that not only competition affects incentives to innovate, but also that innovation can affect competition as well (see, e.g., Aghion, Bechtold, Lassar, and Herz (2010) and Thakor (2012)), generating an endogenous effect in addition to the exogenous drivers of changes in competition.

In our analysis, we begin by developing a model we use to motivate empirically testable hypotheses on the relationship between competition, R&D investment, and financing. We then confront these hypotheses with data from the biopharmaceutical (biopharma) industry, using the Hatch-Waxman Act of 1984, which relaxed barriers to entry for generic drugs, as an exogenous shock to competition. We also provide novel evidence about their ultimate effects on innovation output.

Our choice of the biopharma industry is motivated by three considerations. First, it is an economically significant industry, intimately tied to healthcare (a sector that is now one-fifth of the U.S. economy), for which R&D is the lifeblood, where spending on R&D often dwarfs spending on property, plant, and equipment. Second, the biopharma industry has become increasingly competitive over time. This has taken place for a variety of reasons, including changes in regulation, lower costs of entry, and the expiration of patents combined with the high development costs of new therapeutics (e.g., Caves, Whinston, and Hurwitz (1991), Grabowski and Vernon (1992), among others). These factors have squeezed the margins from existing products associated with biopharma assets in place, with notable consequences for R&D investments in new products and the choice in capital structure of these firms. Third, a major regulatory change, the Hatch-Waxman Act, gave a shock to competition in the biopharma industry. We use this change as part of our identification strategy to overcome endogeneity concerns in a causal test of the effect of competition. These factors make the

⁴Moreover, these firms make decisions related to capital budgeting and financing for R&D that depart sharply from those made for other capital projects, due to the high risk, staged nature of R&D investment and the absence of observable post-investment cash flows for many years. This makes it difficult to simply extrapolate insights about investment and financing choices from other kinds of firms to R&D-intensive firms. See Myers and Howe (1997), who lay out these issues for the pharmaceutical industry.

biopharma industry well-suited for the study of the question posed above.

We develop a theoretical model to generate testable hypotheses about an R&D-intensive firm’s decisions regarding how much to invest in R&D versus assets in place, capital structure, and cash to carry, and how these decisions are affected by the mediating influence of its competitive environment. Our first hypothesis is that greater product market competition induces the firm to reduce investments in assets in place and increase investments in R&D. The intuition provided by the model is similar to the “escape the competition” effect in neck-and-neck industries (e.g., Aghion, Bloom, Blundell, and Griffith (2005)), where increased competition erodes margins on existing products, making them less attractive relative to new R&D products that are under patent protection.⁵

Our second hypothesis is that firms will carry more cash in response to greater competition. The intuition for this in our model is that firms may want to avoid reliance on external financing in future states of the world in which it may be needed but unavailable or very costly. This intuition is similar to the notion of “financing risk” for innovation, as in Nanda and Rhodes-Kropf (2013, 2016).⁶ Other reasons may hold as well. For example, carrying cash has strategic implications in a more competitive environment, even when external financing is available. Based on the Bolton and Scharfstein (1990) model, Neff (2003) points out that, as competition increases, self-financed firms are in a stronger position to engage in predation relative to debt-financed firms, thus increasing the attractiveness of carrying more cash. Moreover, carrying additional cash to avoid reliance on external financing minimizes the inadvertent disclosure of valuable project information to competitors through the act of raising capital (e.g., Kamien and Schwartz (1978)). The relatively large cash balances

⁵It is also consistent with Chernyshev’s (2017) general equilibrium model in which R&D investments may increase with competition even when the “depletion effect” of Acemoglu (2009) is taken into account. The notion of competition we have in mind throughout our empirical tests is that of product market competition. A different type of competition would be R&D competition—where firms compete *only* in the market for (early-stage) ideas—which may generate different effects. For expositional simplicity, we will be referring to product market competition whenever we use the term “competition”.

⁶Along similar lines, to the extent that greater competition encourages more R&D, it would also increase the firm’s future hedging needs due to the higher probability of future low cash flow states arising from the risky nature of R&D. As Acharya, Almeida and Campello (2007) note, this creates an incentive for firms to increase cash holdings.

of R&D-intensive companies and their reliance on internal funds are consistent with these implications (see Hall and Lerner (2010)).

Our third hypothesis is that net debt will decline in response to greater competition. One reason in our model is related to the first hypothesis, that greater competition leads to lower investments in assets in place, reducing the collateral base that generates debt capacity. Moreover, higher debt may cause an inefficient interim liquidation of R&D. Beyond our model, however, there are other reasons debt may decline in response to competition. For example, even if new investments in assets in place are unchanged, greater competition may adversely affect pledgeable assets (where pledgeability is constrained by moral hazard, as in Holmstrom and Tirole (1997)), which reduces the firm's ability to finance with debt (e.g., Petropoulos (2015)). Additionally, higher R&D investment goes hand-in-hand with greater investments in (illiquid) firm-specific human capital by employees, which also makes debt less attractive (see Berk, Stanton, and Zechner (2010) and Jaggia and Thakor (1994)).

Using data on publicly-traded biopharma companies, we provide empirical support for these predictions. We note that biopharma firms face competition with both endogenous and exogenous elements. Endogenous competition is affected by how much the firm spends on R&D; greater R&D spending provides a stronger shield against competition. Exogenous competition is affected by changes in market structure, regulation, and the nature of patent protection, developments that are plausibly exogenous at least at the level of individual firms.

To deal with these endogeneity concerns, and to provide causal evidence of the impact of competition on the variables we study, we exploit a quasi-natural experiment. This was a legislative change that induced an exogenous increase in competition in the biopharma industry: the Hatch-Waxman Act of 1984. This legislation made it significantly easier for generic drugs to compete with patented drugs, and has been widely regarded as an act that increased competition in the industry (e.g. Grabowski and Vernon (1986, 1992)).

Using a differences-in-differences strategy, we examine the effect of this legislative change

on the biopharma industry. We do so by first exploiting between-industry variation and comparing the reaction of financial characteristics of biopharma firms to a control group of R&D-intensive firms in other industries matched by propensity score that were not affected by the legislation. We find strong supporting evidence for the main hypotheses, which survive a number of robustness checks.

One concern with our approach is that, by using a control group of firms in other industries, we may not be able to fully account for unobservable characteristics or structural changes that may drive differences between the treatment group and the control group. We therefore focus our analysis on exploiting variation *within* the biopharma industry with respect to the degree of exposure of firms to the Hatch-Waxman Act. First, we compare the reaction of generic drug manufacturers in the pharma sector, firms for which our hypotheses are less applicable, to other pharma firms in a differences-in-differences approach following the enactment of the Hatch-Waxman Act. Second, we compare the responses of firms with relatively more approved drugs in high competition therapeutic classes (and therefore more affected by the Hatch-Waxman Act) to those of firms with fewer drugs in such therapeutic classes. Finally, we explore whether the effects for firms that operate in higher competition classes are more concentrated among firms with lower profit margins. In all of these tests, we again find strong supporting evidence for the main hypotheses.

As a final set of analyses, we delve deeper into the effects of competition on innovation, exploring whether the increased R&D investment and other effects that we have documented lead to higher innovative *output*, as measured by the number of patents. We find that, despite the increase in R&D investment stemming from an exogenous shock to competition, firms produce relatively *fewer* patents. However, we also find that the market value of these patents *increases* following the increase in competition, using the firm-level innovation value measure of Kogan, Papanikolaou, Seru, and Stoffman (2017). This suggests that, faced with greater competition, firms specialize and focus on producing “targeted” or “impactful” innovations in order to differentiate themselves, rather than on simply increasing the number of total

innovations.⁷ This is novel evidence that the effect of competition on innovative output is nuanced, that increased spending on R&D in response to increased competition leads to fewer, but more valuable, innovations.

Our paper is related to the theoretical industrial organization literature on the effects of competition on innovation. Some theoretical papers have validated Arrow’s (1962) original insight that competitive firms will innovate more than a monopolist. For example, Tirole (1988) shows this through via the so-called “replacement effect”, while Aghion, Harris, Howitt, and Vickers (2001) show that innovation generates an “escape the competition” effect. Other papers have shown that the level of competition may affect how competition affects innovation (e.g., Aghion, Bloom, Blundell, Griffith, and Howitt (2005), Aghion, Dewatripont and Rey (1999), and Chernyshev (2017)).⁸ There are also theories which imply that more profitable firms will innovate less when faced with greater competition (e.g., Christensen, Raynor and McDonald (2015), and Holmes, Levine and Schmitz (2012)). The hypothesis emerging from our model that an increase in competition will increase innovation through increased R&D investment is consistent with this literature. However, we go beyond this literature to focus on the impact of competition on the firm’s choice of funding for innovation. We also provide novel causal evidence on the differential effect of competition on R&D, innovation, and its economic value.

Our paper is also related to the literature on the financing of R&D.⁹ Bergemann and Hege

⁷Put together, these results are broadly consistent with the documented decrease in R&D efficiency (e.g., Kortum (1993) and Scannell, Blanckley, Boldon, and Warrington (2012)), which some have argued is caused by increased competition. However, these results also suggest that firms are offsetting the reduction in total output with an increase in the value of each incremental output, which is consistent with one of the explanations of Kortum (1993) for the reduced ratio of patents to R&D over time.

⁸Garfinkel and Hammoudeh (2020) provide recent evidence. Lin (2017) shows theoretically that an increase in competition on existing assets will lead to an increase in innovation. Other authors have also made the point that patentable innovation is one way for firms to protect against profit erosion induced by competition. For example, Langinier and Moschini (2002) note that the duration of a patent can affect the length of time the holder can exert monopoly power; see also Grant and Jordan (2015). Lie and Yang (2017) empirically show that the increase in import penetration by Chinese firms boosted innovation by U.S. firms and also prompted them to reduce their capital expenditures, although Hombert and Matray (2018) show that the reduction in capital expenditures is attenuated for R&D-intensive firms.

⁹Our work is related to the vast literature on capital structure, e.g., Jensen and Meckling (1976), Myers and Majluf (1984), Stulz (1990), Zwiebel (1996), and Abel (2014); see Graham and Leary (2011) and Myers (2001) for comprehensive reviews.

(2005) develop a theoretical model of the choice of relationship in arms-length financing by borrowers in their R&D funding. Brown, Fazzari, and Petersen (2009) empirically document a positive relationship between financing supply and R&D. Hall and Lerner (2010) show that large firms prefer internal funds to finance R&D, while small firms experience high external financing costs that are only partially mitigated by venture capital. These papers do not consider how R&D financing is affected by product market competition. More recently, a few papers have explored how competition affects the firm's innovation incentives and cash holdings. Morellec, Nikolov, and Zucchi (2014) develop a dynamic model and provide empirical support that competition increases cash holdings and equity issues. Lyandres and Palazzo (2016) show theoretically and empirically that the firms use cash as a commitment device for implementing innovations. Mann (2018) documents that R&D-intensive firms use patents as collateral for debt financing.

Additionally, our paper is related to the empirical literature that examines R&D costs, returns, and risks in the pharmaceutical industry. For example, Grabowski and Vernon (1990) and DiMasi, Grabowski, and Vernon (1995) examine a selection of drugs introduced in the U.S. and document both a substantial increase in competition and a skewed distribution of sales from the drugs. DiMasi, Hansen, and Grabowski (2003) examine the cost of new drug development. Ellison, Cockburn, Griliches, and Hausman (1997) model the demand for pharmaceutical products and compute price elasticities. Myers and Howe (1997) build a Monte Carlo life-cycle model of drug R&D development for the pharmaceutical industry, and examine the model's estimates of risk, return, net present value, and the cost of capital. Gans, Hsu, and Stern (2002) and Gans and Stern (2003) examine how the innovation strategies of R&D-intensive firms are affected by competition and cooperation. Our paper complements these studies, but we differ from them in our focus on the interaction between competition, R&D spending, and the capital structure decisions of biopharma companies, which have not been previously examined.

In Section 2 of this paper, we discuss the testable hypotheses emerging from the exist-

ing theories. We describe our data and time-series statistics in Section 3. In Section 4, we describe our main empirical methodology, and give the results using between-industry variation between the biopharma industry and other R&D-intensive industries. Section 5 provides additional tests of our main predictions by exploiting a heterogeneity within the biopharma industry. Section 6 examines the effect of competition on the quantity and value of innovation output. We conclude in Section 7. The Appendix contains additional results.

2 Theoretical Model and Hypotheses

In this section, we describe a model of R&D investment and financing to develop our hypotheses. The main intended purpose of the model is as an expositional tool to provide a theoretical foundation for our empirical analyses.

2.1 The Model

We consider a large biopharmaceutical firm in a three-date model in which final payoffs occur at $t = 2$. The firm decides at date $t = 0$ how much to invest in R&D, how much to invest in assets in place, and its capital structure.

If the firm invests in R&D, the R&D will consist of two stages. The initial R&D investment at $t = 0$ will be for first-stage research. At $t = 1$, it will be known whether the first-stage research failed, was modestly successful, or was very successful. At this stage, R&D produces no cash flows, but allows the possibility of further investment. If the first-stage research was successful, the firm must decide whether to invest in second-stage R&D. Such a setup captures the staged R&D investment in biopharma firms in which a drug is considered a “success” if it passes phases 1–3 of clinical trials, where each phase requires an additional investment. At $t = 2$, if the firm invested in both first-stage and second-stage research, the R&D produces a stochastic cash flow. The R&D produces benefits that can be contracted upon with outside financiers, such as commercializable products, as well as ben-

efits for insiders that cannot be contracted upon, such as knowledge generation. If the firm invests in assets in place, they produce a positive cash flow at $t = 2$ that varies depending on the competition (described below) and the state of the economy.

At $t = 0$, the firm makes its capital structure decision, which involves determining the mix of debt and equity with which to finance the firm, and how much excess cash to carry to date $t = 1$. At $t = 1$, the firm can again choose to raise capital. We assume that external financing for the second-stage R&D cannot be raised at $t = 1$ if the first-stage research failed or was only modestly successful.¹⁰ However, insiders would still like to fund the second-stage R&D even if the first-stage research has been only modestly successful, because of the non-contractable benefits to insiders.

The firm's cash flows are taxable, debt repayments are tax-deductible, and the firm operates in an adverse selection environment in that there are observationally identical "lemons" that also raise financing at $t = 0$. These lemon firms, while appearing identical to viable good firms, do not have the ability to produce cash flows from their R&D. At $t = 1$, the firm's bondholders receive a noisy and informative signal that enables them to update their priors on whether the firm is good or a lemon. If a firm is suspected of being a lemon based on the signal, bondholders will demand to be repaid at $t = 1$. This leads to liquidation, since the firm has no cash flows at the interim date.¹¹ Thus, debt has a monitoring role in reducing the misappropriation of resources, in line with theories of debt discipline extensively discussed in the literature (e.g., Hart and Moore (1995, 1998), Jensen (1986), and Calomiris and Kahn (1991)). Since the signal is noisy, the probability of a good firm being liquidated is positive.

Competition is modeled as a probability that a competing firm will arrive. If it does

¹⁰This assumption is consistent with the empirical evidence of Grabowski and Vernon (1990), who document a skewed distribution of returns for drugs in the marketplace, with "blockbuster" drugs achieving much higher returns than other drugs. Given the large investment costs of drug development (e.g., DiMasi and Grabowski (2007)), a very successful commercial result is often needed in order for the project to be perceived as positive NPV.

¹¹The debt need not be viewed as short-term debt, but could be interpreted as long-term debt where bondholders detect a covenant violation at the interim date and demand repayment then, or an interest payment that bondholders have the option of forgiving until a later date.

arrive, the firm engages in competition with the incumbent firm, driving down the cash flows on its assets in place, due to a decline in the maximum markups firms can charge as competition increases.¹² R&D, when successful, is patent-protected and thus unaffected by competitive entry. For example, one reason why firms in the biopharma industry engage in R&D is to replace old drugs, many of which may be off-patent and thus face competitive pressure, with new drugs, which are patent-protected and insulated from competition.¹³

The formal model is analyzed in the Appendix. Here we provide the intuition for our main results.

2.2 Intuition and Predictions

Using this model, we are able to characterize the firm’s optimal investments in R&D and assets in place, and examine how these respond to competition.

Result 1: *Higher competition causes investments in assets in place to decline, and investments in R&D to increase; therefore, R&D grows relative to assets in place.*

The intuition behind this result lies in the patent-protected rents that successful R&D offers the firm. An increase in competition erodes the payoffs of assets in place, since existing products are no longer under patent protection, which makes the payoffs from investment in R&D relatively more attractive. The firm then has an incentive to shift investment away

¹²The effect of competition here is the same as in Bertrand competition, where two firms will reduce their prices down to their marginal costs. In our model, competition can be interpreted as structural changes in the industry, or other changes in competition that are exogenous to the individual firm. Important drivers of competition in industries such as biopharma are exogenous technology or regulatory shocks that lower entry costs. For example, the Human Genome Project represented a technology shock that was plausibly exogenous to any individual firm’s decision, and it led to the entry of numerous small biotech firms into the industry (see Thakor et. al. (2017)). Another example is the Hatch-Waxman Act, which was a source of exogenous variation in competition for the biopharma industry, which we will use for identification purposes later in our analysis. However, since R&D by incumbents can also affect the degree of competition, some portion of the degree of competition is endogenous (e.g., Gans and Stern (2000)). Our empirical tests are designed to tackle this potential endogeneity.

¹³This is consistent with the earlier cited literature, e.g., Tirole (1988), Langinier and Moschini (2002), and Grant and Jordan (2015). The specific way we have described competition is not critical to our prediction. All that is needed is that the firm’s profit margins on patentable drugs emerging from R&D are higher than those from existing products that do not enjoy patent protection.

from assets in place and towards R&D.¹⁴

The decision about firm’s capital structure makes a trade-off between tax benefits against the possible loss of R&D rents if the (good) firm is erroneously liquidated at $t = 1$. The presence of lemons makes such early repayment/liquidation optimal for the bondholders in the second-period subgame, even though it is costly for them. This leads to our second result.

Result 2: *As competition increases, debt financing declines.*

The intuition behind this result is twofold. First, since the firm reduces its investment in assets in place, it reduces its collateral base, which makes it unable to support as much debt. Assets in place here include both the fixed assets needed to produce existing drugs, such as manufacturing facilities, as well as existing patents.¹⁵ In terms of the latter, Mann (2018) provides evidence that patents serve as collateral for debt financing.¹⁶ Hochberg, Serrano, and Ziedonis (2018) also provide evidence that patents are used for loans in the context of venture lending in tech start-ups. Second, given the firm’s larger investment in R&D in response to increased competition, the possible loss of R&D rents due to erroneous liquidation at $t = 1$ is greater.

We also show that the potential lack of access to external second-stage R&D funding at $t = 1$ when the firm’s insiders want to invest causes the firm to carry excess cash from $t = 0$ to $t = 1$. This is because there is a future state of the world (when the first-stage R&D is

¹⁴In the terminology of Aghion et. al. (2005), we are modeling “neck-and-neck” firms competing in the product market.

¹⁵For pharma firms, which are generally involved in both development and production, assets in place consist of patents, facilities for research, and plants for production. Indeed, a firm such as Pfizer maintains R&D labs but also manufacturing sites for the production and distribution of drugs. These can be used as collateral in the same way as firms in other industries use analogous facilities, and contribute to assets in place. However, smaller biotech firms may not be involved in drug production, and thus would rely more on patents for collateral.

¹⁶Specifically examining drugs as patent collateral, Mann (2018) shows in Panel A of Figure 1 that drugs and medicine as a category represent thousands of patents that are pledged as collateral. In a sample of loan agreements collateralized by patents, Fischer and Ringler (2014) show that pharmaceutical and biotechnology companies account for a comparable number of agreements measured against other industries. Focusing on the biotechnology sector, Deshpande and Nagendra (2017) find that both small and large biotech companies use drug patents as collateral, with 523 companies using their patents as collateral from 2010 to 2015.

modestly successful) in which outside investors will be unwilling to fund second-stage R&D, even though the firm’s insiders consider it valuable to do so due to non-contractible R&D rents.¹⁷ Since the amount of second-stage funding is positively related to the investment in first-stage R&D, the higher relative investment in R&D in response to higher competition also means that the firm carries more excess cash as competition increases. This result is similar to a precautionary demand for liquidity in anticipation of future states in which there may be a shortfall (see, for example, Bolton, Chen, and Wang (2014)). This result leads to our final result:

***Result 3:** The excess cash held by the firm, combined with the earlier result about lower debt financing, means that the firm’s net debt will fall as it faces higher competition.*

3 Test Using Between-Industry Variation

In this section, we begin the empirical analysis of our earlier hypotheses using data from the biopharma industry. We first provide summary statistics for the biopharma industry that are consistent with the predictions in the previous section, given the past trends in competition for the industry. We then undertake an empirical analysis, exploring the effect of the Hatch-Waxman Act on the biopharma industry compared to other R&D-intensive industries in a differences-in-differences analysis.

3.1 Data and Summary Statistics

Our main data come from Compustat. The focus of our empirical analysis is the biopharma industry, which we take to be all firms under Global Industry Classification Standard (GICS) codes 352020 (pharmaceuticals) and 352010 (biotechnology).¹⁸ We use GICS codes to iden-

¹⁷An alternative interpretation of this result is that the firm’s insiders have information about the quality of the R&D that they cannot credibly communicate to investors, and therefore investors are unwilling to provide additional funding.

¹⁸We include all firms denominated in U.S. dollars, although our results are equivalent if we restrict the sample to firms incorporated in the U.S.

tify biopharma firms because GICS is a newer and more accurate classification system, one widely used by analysts, and less exposed to the shortcomings of other classification systems (such as SIC and NAICS) in identifying biopharma firms that have been noted by others (e.g., Carlson (2016) and Thakor et al. (2017)).¹⁹ However, our results are also robust to identifying biopharma firms using other systems, such as SIC codes. Our identification procedure provides us with an initial sample of 1,489 biopharma firms from 1950 to 2016, which we compare to other firms in Compustat.

We construct the following variables at the firm-year level. R&D investment is measured by $R\&D/TA$, which is R&D expenditure scaled by total assets. Assets in place are measured by PPE/TA , which is property, plant, and equipment scaled by total assets. Cash is represented by $Cash/TA$, which is measured by cash and short-term investments scaled by total assets. Debt is represented by $Debt/TA$, which is the sum of total long-term debt and short-term debt (debt in current liabilities). Net debt is represented by $Net\ Debt/TA$, where $Net\ Debt = Debt - Cash$.²⁰

Summary statistics for these variables for the biopharma sector are given in *Table 1*. The entries in *Table 1* show that R&D spending is substantial for the industry, averaging roughly 37% of total assets over the sample period. In addition, cash holdings are also substantial, averaging 51% of total assets. While the mean level of debt is somewhat high, at 28.5% of total assets, the much lower median and 25th percentile values (as well as the high standard deviation) indicate that the distribution is skewed, that is, there are a few firms with substantial amounts of debt on their balance sheet that drive the mean up. However, after accounting for cash holdings and computing net debt, the mean firm and the median firm in the industry hold substantially negative net debt as a result of their cash holdings.

¹⁹As an example, the standard way to identify biopharma firms via SIC codes is to use: Drugs (2830), Biological Products (2831), Medicinal Chemical and Botanical Products (2833), Pharmaceutical Preparations (2834), In Vitro and In Vivo Diagnostic Substances (2835), and Biological Products except diagnostics (2836). These are the same SIC codes that comprise the Fama and French (1993) “Drugs” industry. However, because SIC is an older classification system, and the nature of the biopharma industry has evolved over time, there are newer biotech firms which do not cleanly fit into SIC categories in a way that makes it difficult to distinguish them from non-drug firms.

²⁰Variables are winsorized at the 1% level across all firms in order to reduce the impact of extreme outliers.

[Table 1 Here]

To provide preliminary evidence documenting the change in the competitive environment in the biopharma industry over time, we take a simple approach, and focus on two measures. The first measure is the increase in the number of firms operating in the industry. The second is the average number of new drugs per category of therapeutic indication, a measure of the number of drugs competing in the same space, motivated by papers that have documented the importance of examining competition at the therapeutic class-level (e.g., Ellison, Cockburn, Griliches, and Hausman (1997), Azoulay (2002), and Ellison and Ellison (2011)).²¹

Panel A of *Figure 1* shows that the number of competitors in the industry has increased steadily until the mid-1990s. This suggests a substantial increase in competition over time from the 1950s, with the largest increase starting in the 1980s and continuing until the late 1990s, when it began to taper off, and became relatively flat until increasing again after 2010.²² Panel B of *Figure 1* shows a similar increasing trend over time when examining the mean number of new drug approvals per category of drug therapeutic indication, which suggests that each drug has faced increasing competition.²³

²¹We focus on these measures because the typical measures of industry competition, such as the Herfindahl-Hirschman Index or concentration ratio, present a distorted view of competition due to the fact that they are based on sales. For the biopharma industry in particular, many small biotech firms compete with larger firms through their R&D efforts, even though they may not have products that are commercialized, and therefore have little or no sales. In addition, since the FDA approval process for drugs is lengthy, new competitors may not have an effect on industry sales until several years after they enter. Thus, sales-based metrics and other traditional measures of competition are unlikely to accurately capture changes in competition for the biopharma industry.

²²The flattening of the number of firms beginning in the late 1990s may be the result of a number of trends, such as towards types of vertical industrial organization in which biotech firms have become suppliers of molecules to larger pharma firms through being acquired or licensing deals. Other significant structural changes have occurred in the industry which may contribute to such trends, such as the introduction of the Human Genome Project. In order to mitigate concerns related to these potential effects, in the subsequent sections of the paper, we examine a natural experiment surrounding a legislatively-induced change in competition.

²³The data on new drug approvals over time are taken from the Informa BioMedTracker database. A notable spike in the number of new approvals can be seen in the graph in the mid-1990s. Given that the average development time from Phase 1 to FDA approval for a drug is approximately 8 years, (e.g., DiMasi and Grabowski (2007)), this jump would align with an increase in new project initiations following the introduction of the Hatch-Waxman Act, as explored in Sections 4 to 6. These trends are consistent with existing papers (e.g., Caves, Whinston, and Hurwitz (1991), Grabowski and Vernon (1990, 1992), Grabowski and Kyle (2007), and others) that have shown that the industry has become more competitive over time.

[Figure 1 Here]

With this increase in competition over time as a backdrop, we now examine the financial characteristics of firms in the biopharma industry. *Figure 2* shows how the financial characteristics of the biopharma industry have evolved. The mean and median values of $R\&D/TA$, PPE/TA , $Cash/TA$, $Debt/TA$, and $Net\ Debt/TA$ are calculated for each year. In order to distinguish these trends from larger trends in other industries, the mean values of these variables are also included for all other industries apart from the biopharma industry.

[Figure 2 Here]

The graphs presented in *Figure 2* are consistent with the predictions from Section 2. In particular, as competition has increased over time, both mean and median R&D expenditures have increased, while assets in place (measured by PPE) have decreased sharply.²⁴ Moreover, cash holdings have increased substantially.²⁵ Finally, while the mean level of debt has increased over time (mostly in the 1970s and the 2000s), the median level of debt has declined consistently from the mid-1970s. As the summary statistics also indicate, the debt levels are cross-sectionally skewed across firms, with some firms holding very large amounts of debt, which pushes up the mean. But the median debt levels indicate that the *majority* of firms have decreased their debt. Net debt shows a similar trend, although the decline in both mean and median values is more pronounced until the late 1990s. The changes in these variables are the largest in the 1980s and 1990s, which mirror the trend in the number of firms over the sample period. For all of the variables, the trends for the biopharma industry are more striking than those for other industries, suggesting that the biopharma trends are not simply driven by aggregate trends affecting all industries.

²⁴The secular increase in mean R&D expenditures understates an interesting cyclicity. One explanation for this cyclicity is a change in profitability each year, which partly determines how much firms are able to spend on R&D, which in turn is partly dependent on the overall state of the economy. A graph of R&D expenditures scaled by earnings reveals a smoother trend over time. We examine PPE in order to capture investment as well as divestment of the stock of assets in place; however, examining capex or the ratio of capex to R&D shows a similar decline over time.

²⁵The cash trends for biopharma compared to other industries are also in line with the findings of Begenu and Palazzo (2016), who show evidence that the overall increase in firm cash holdings is driven by the entry of more R&D-intensive firms.

3.2 Institutional Setting: The Hatch-Waxman Act

While the previous stylized facts are generally consistent with the predictions of the model, they do not account for possible endogeneity, when R&D is affected by competition, but competition is also affected by R&D. The ideal test for endogeneity is to find two groups of firms with similar characteristics, exogenously change the degree of competition for one group, and then examine if the resulting difference conforms to the predictions. We do this by exploiting the exogenous variation in competition introduced by the passage of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act.

The Hatch-Waxman Act was introduced for the expressed purpose of increasing competition in the drug marketplace, by facilitating the entry of generic drugs after the expiration of a patent. The rationale for this legislation was that greater generic competition would benefit consumers by allowing them more drug choices at a lower cost. Prior to the act, onerous Food and Drug Administration (FDA) requirements made it necessary for generic drugs to replicate many of the original drug's tests in order to gain market approval. However, after the act was passed, generic drugs only needed to prove bioequivalence to the original drug, thus substantially decreasing the barriers to competitive entry.

A number of papers have provided evidence that the Hatch-Waxman Act did indeed facilitate the entry of generic drugs, leading to increased price competition and an erosion in the market shares of existing drugs.²⁶ For example, Grabowski (2007) notes that the time lag between patent expiration and generic entry shortened dramatically from 3-4 years to 1-3 months following the passage of the law. While this change in competition clearly reduces

²⁶See the analysis and evidence by Grabowski and Vernon (1986, 1992), who look at entry, market share, and price data for a sample of drugs after the enactment of the law, and Grabowski (2007) for an overview. Media accounts following the passage of the law are also consistent with this. For example, an article in *The New York Times* in early 1985 notes "Late last year, Congress passed the Drug Price Competition and Patent Restoration Act. Some applications for approval of generic drugs had languished at the Food and Drug Administration for several years [...] The new law greatly shortens the generic approval process, however, and more than 200 generic applications have flooded into Washington since the law was signed in October. Industry executives are groping desperately for ways to deal with generics" (Williams (1985)).

the current margins of off-patent drugs, it also similarly affects firms with on-patent drugs in a number of ways. First, it reduces the *future* margins of on-patent drugs, changing ex ante investment and finance incentives. Second, the Hatch-Waxman Act introduced a provision where generic manufacturers can more easily challenge the validity of product patents of brand drugs, which led to a rise in patent litigation for many drugs early in their product life-cycle (see Grabowski (2004) for details).²⁷

While evidence of the effect of the Hatch-Waxman Act on competition in the biopharma industry has been established in the studies mentioned above, it can also be seen empirically. As shown in *Figure 1* Panel A, the number of new entrants increases substantially after 1984, although there is an increasing trend in the years prior. Furthermore, as can be seen in *Figure 1* Panel B, the dramatic spike in new drug approvals beginning in the early-to-mid 1990s is consistent with firms beginning research on new drugs in the mid-to-late 1980s following the Hatch-Waxman Act, coupled with a mean duration to approval of 8 years (e.g., DiMasi and Grabowski (2007)).

Statements by industry practitioners after the enactment of the Hatch-Waxman Act are also consistent with the notion that the act increased competition and led to firms increasing their R&D in response. For example, the CEO of generic drug firm Henry Schein noted that, in response to increased competition from generic drugs, “the speed with which the large drug companies accelerate their R&D programs and come up with new and exciting products’ [...] could undercut the older generics” (see Lewis (1992)). Statements made in company annual reports in the years following the Hatch-Waxman Act also support this and the other hypothesized effects. In its 1985 annual report, Merck notes that, “Generic competition

²⁷Another provision of the Hatch-Waxman Act was to enhance marketing exclusivity periods for *new* drug approvals subsequent to the act’s passage. As this increases a firm’s rents from successfully innovating after the act, it also serves to increase R&D competition immediately following the act in order for firms to capture those rents (Lewis (1992)). While in the longer term, this provision has the potential to reduce competition once firms have successfully innovated and are able to enjoy the enhanced exclusivity protections, previous analyses have shown that any such effect is outweighed by the increased generic competition facilitated by the act (Grabowski (2007) and U.S. Congressional Budget Office (1998)). Put differently, the economic effect of increased competition due to generic entry *via drug sales* is the first-order effect of the Hatch-Waxman Act.

grew stronger in 1985, stimulated in the United States by 1984 legislation that simplified approval requirements for marketing such duplicative products. Generic copies cut deeply into sales of Merck drug discoveries whose patents have recently expired [...] This illustrates the importance Merck’s growth of continued significant investment in research.”²⁸

3.3 Empirical Methodology

We first use the Hatch-Waxman Act as a source of exogenous between-industry variation to conduct a differences-in-differences analysis in order to provide clearer empirical support for the predictions identified in Section 2. Because the Hatch-Waxman Act specifically impacted the biopharma industry, the treatment group consists of all biopharma firms in our sample. Since the predictions are applicable for firms in R&D-intensive industries in general, we choose firms from the five top R&D-intensive industries other than biopharma as our control group.²⁹

A concern with this approach is that the control group has different enough characteristics to be insufficiently comparable to the biopharma industry. To deal with this concern, we construct the control group by using propensity-score matching to choose firms from the other R&D-intensive industries that are comparable to biopharma firms based on observable characteristics in the sample period before the law was passed. Specifically, we choose firms in the other R&D-intensive industries that match biopharma firms based on their mean observable characteristics in the years between 1977 and 1983. The matching characteristics are: size ($\log(\text{Net Assets})$), profitability ($EBIT/TA$), capital structure ($Net Debt/TA$),

²⁸Merck notes in its 1986 annual report that “[...] a low ratio of debt to total capital and adequate credit availability, provides a high degree of flexibility in obtaining funds on competitive terms. The ability to finance operations primarily from internally-generated funds is desirable because of the risks inherent in research and development required to develop and market innovative new products and the highly competitive nature of the pharmaceutical industry.” It also notes that “[c]apital outlays declined to \$211 million in 1986, 35% lower than the 1981 high [...]”, and that this scaling back was due to a reduction in inventory and consolidation of manufacturing processes.

²⁹These industries are identified by the NSF (National Science Foundation (1999)) as being the top R&D-intensive industries, and include: Industrial and other chemicals (2-digit SIC code 28, excluding 3-digit code 283), industrial and commercial machinery and computers (2-digit SIC code 35), electrical equipment (2-digit SIC code 36), transportation equipment including aircraft and missiles (2-digit SIC code 37), and measuring and analyzing equipment (2-digit SIC code 38).

cash holdings ($Cash/TA$), R&D ($R\&D/TA$), assets in place (PPE/TA) and investment opportunities as proxied by market-to-book (ME/BE).³⁰ This results in a total of 435 firms and 3,083 firm-year observations in our sample. Of these, the treatment group contains 336 firms, and the control group contains 99 firms.³¹

Using these treatment and control groups, we estimate the following regression:

$$Y_{i,t} = \gamma_0 + \gamma_1 HW_t \times Biopharma_i + \eta X_{i,t} + \mu_i + \lambda_t + \varepsilon_{i,t}. \quad (1)$$

In (1), $Y_{i,t}$ represents the dependent variable of interest for firm i in year t , predicted to vary as a function of competition by the theoretical model. HW_t is an indicator variable which takes a value of 1 if the year is 1984 or later, the period after the Hatch-Waxman Act was enacted into law. $Biopharma_i$ is an indicator variable which takes a value of 1 if firm i is in the biopharma industry, and 0 if it is in the control group. It follows that the regression estimate of γ_1 is the differences-in-differences estimator, the effect of the increase in competition stemming from the Hatch-Waxman Act on $Y_{i,t}$. For the financial characteristics of the firms, we specifically examine $R\&D/TA$, PPE/TA , $Cash/TA$, $Debt/TA$, and $Net\ Debt/TA$ as choices for $Y_{i,t}$. In subsequent tests presented in Section 6, we also explore patent-related outcomes as choices for $Y_{i,t}$. To control for the possibility of differential trends between the control and treatment groups that are not accounted for by the matching procedure, $X_{i,t}$ is a vector of contemporaneous and lagged control variables that may also co-vary with the dependent variable. Control variables that comprise $X_{i,t}$ for the financial characteristic vari-

³⁰{To choose these control firms, we implement the propensity-score matching using one-to-one logit matching without replacement, and restrict control observations to a common support.

³¹ *Tables B1 and B2* in the Appendix provides summary statistics for the firms over our sample period, as well as summary statistics separately for the treatment and control groups for the pre-period. As noted above, for the sample we use in our primary tests, we use all biopharma firms in Compustat that operate at any time in the period from 1977 to 1991 as our treatment group. This allows newly listed biopharma firms to appear in the treatment group during our sample period. We note that our predictions are applicable for these new entrants as well, not only for incumbent firms. For example, a private or venture capital-backed firm should still respond to a change in competition in the way hypothesized in Section 2, and this would be (correctly) reflected in our sample when that firm goes public. We show that our results hold when focusing only on incumbent firms and thus a balanced number of treatment and control firms.

ables include: $\log(NA)$ (where $NA = TA - Cash$), a proxy for net profitability or cash flow measured by $EBITDA/TA$ (earnings before interest, taxes, depreciation, and amortization as a fraction of total assets), ME/BE (market value of equity to book value of equity), and Div/TA (the amount of common/ordinary dividends paid). Since the dependent variables are also simultaneously determined, we include the following lagged endogenous variables: $R\&D/TA$, PPE/TA , $Cash/TA$, $Debt/TA$.³² Finally, μ_i represents firm fixed effects, to control for time-invariant firm characteristics, and λ_t represents year fixed effects, to control for time trends.

Equation (1) is estimated for the period from 1977 to 1991, which includes the seven years prior to and seven years subsequent to the passage of the law. We choose a relatively long estimation window to capture any delayed effects of competition on the variables of interest, given the well-documented long gestation periods in the biopharma industry (DiMasi and Grabowski (2007)), which may drive a slower response in many of the financial characteristics that we examine.³³

3.4 Results

A critical assumption of the differences-in-differences framework is that the treatment and control groups exhibit parallel trends in terms of the outcome variables prior to the event in question. *Figure 3* provides graphical evidence of parallel trends for the years surrounding the passage of the Hatch-Waxman Act. In the left graphs, the solid blue lines represent average values for the biopharma industry, while the dashed red lines represent average values for other R&D-intensive firms. A vertical red line is included at 1983, the final year of the pre-period, and thus all years to the right of the line are when the Hatch-Waxman Act is in effect. The right graphs depict the differences between the treatment and control

³²Including firm fixed effects and the lagged dependent variables allows us to control for the past or pre-reform levels of these variables.

³³However, as noted by Bertrand, Duflo, and Mullainathan (2004), a concern with differences-in-differences estimators with long estimation windows is that they are potentially biased due to autocorrelation. We examine this concern and other robustness issues in the next section.

groups for all the variables.

[Figure 3 Here]

The levels of R&D expenditures, cash holdings, debt, net debt, and assets in place are all similar for both biopharma and the control group in the pre-period, showing that these two industries are indeed similar in terms of these financial characteristics. After the act is implemented, the values for the two groups diverge in a way consistent with our predictions. Specifically, in the period following the enactment of the law, R&D expenditures and cash holdings for biopharma firms increase sharply relative to the control group, while debt, net debt, and assets in place decrease within a few years after the act was passed relative to the trend for the control group.³⁴ Moreover, R&D, cash, net debt, and assets in place exhibit strong parallel trends before the Hatch-Waxman Act was implemented, although these are noisier for debt. Overall, the graphs provide evidence supporting the appropriateness of the differences-in-differences analysis in this setting, and also for the effect of the Hatch-Waxman Act on the financial characteristics of the biopharma industry.

The estimation results for regression (1) are included in *Table 2*. Results both with and without control variables and fixed effects are included.

[Table 2 Here]

Overall, the results from the differences-in-differences analysis are consistent with the predictions in Section 2. The difference-in-difference estimator for $R\&D$ is positive and significant without or with control variables and fixed effects (columns (1) and (2)). This indicates that, as the Hatch-Waxman Act increased competition in the biopharma industry, firms in that industry increased their R&D relative to the control group. Based on the coefficient from column (2), biopharma firms increased their R&D expenditures as a percentage

³⁴In particular, these results demonstrate that other R&D-intensive firms also exhibited similar trends (for example, increasing R&D) prior to 1984. The differences-in-differences analysis shows that the changes in the outcome variables occurred in biopharma *relative* to the changes in other R&D-intensive industries. The differences for assets in place exhibit a negative trend after the law was passed, but this is less striking than for the other variables. However, we provide stronger evidence of the effect for this variable in Section 5 using within-industry variation.

of total assets relative to the control group by about 2.4 percentage points after the act was passed. This effect is economically significant as well. Consider a biopharma firm with \$500 million in total assets. The estimated coefficient implies that such a firm will increase its R&D expenditures by roughly \$12 million compared to control firms after the act was passed. Assuming a level of R&D of \$61.74 million before the act, based on the pre-period mean level of $R\&D/TA$ for biopharma firms, this implies a relative increase in R&D expenditures of 19%.³⁵

The difference-in-difference estimator for *PPE* is negative in both columns (3) and (4), but the effects are insignificant. This indicates that firms are (weakly) reducing their stock of assets in place in response to increased competition.³⁶ The difference-in-difference estimator for *Cash* is positive and significant whether controls are included or not, indicating that firms in the biopharma industry increased their cash holdings relative to the control group as a result of the Hatch-Waxman Act, by roughly 7.6%. The difference-in-difference estimator for *Debt* is negative and significant in both columns (7) and (8), providing evidence that firms in the biopharma industry decreased their debt as a result of the increase in competition.

³⁵The relative increase in R&D expenditures that we find for biopharma firms following the Hatch-Waxman Act is central to interpreting how such firms respond to changes in competition. In *Table B3*, we explore the robustness of this result to alternative specifications and the inclusion of additional controls, including the coefficient estimates for all variables in order to increase clarity. First, we re-estimate our regression for R&D, but show that it is robust to controlling for a more general time trend (the time to or from the Hatch-Waxman Act) instead of using year fixed effects. Second, we exclude the lagged dependent variables, to demonstrate how controlling or not controlling for lagged levels R&D affects our results, given the documented persistence of R&D over time. Third, we add firm age (defined as the number of years that a given firm has appeared in Compustat) and external equity issuance as additional control variables, motivated by previous studies that have documented that external equity issues are an important source of funding for R&D (e.g., Brown, Fazzari, and Petersen (2009), and Brown, Martinsson, and Petersen (2012, 2013)). In all cases, the result for the difference-in-difference estimator is essentially unchanged, both in terms of significance and magnitude of the coefficient. Finally, we also examine the logarithm of total R&D rather than scaling by total assets, to account for the possibility that our results are driven by changes in the amount of total assets rather than the variables of interest. We again find very similar results when running the variables in logs, which suggests that firms are actively changing their investment and financing decisions rather than simply experiencing a change in size. Similar results (untabulated for brevity) obtain for our other outcome variables as well.

³⁶The insignificant coefficient for assets in place may be due to some firms choosing to acquiring later-stage projects from other firms, which soon require manufacturing capability after they are commercialized. This would offset some of the reduction in assets in place that other firms undertake. However, if we alternatively examine the *relative* investment into PPE compared to R&D as a dependent variable, the ratio of R&D expenditures to capex, we find that the difference-in-difference coefficient is positive and significant. This provides further evidence that these firms are shifting their investment away from assets in place and towards R&D.

However, this result should be interpreted with some caution, due to the noisy pre-trends shown earlier. Finally, the estimator for *Net Debt* is negative and significant in both columns (9) and (10), indicating that net debt also declined compared to the control group as a result of increased competition in the biopharma industry, by roughly 11.6%.³⁷

In the Appendix, we provide a number of robustness checks. First, we conduct falsification tests, and show that our results are likely not driven by time trends, by examining whether the effect holds in alternate sample periods when we falsely specify a year for the implementation of the Act. We find insignificant results for these tests.³⁸ Second, we show that our results are not driven by serial correlation due to the length of the sample window that we use (e.g., Bertrand, Duflo, and Mullainathan (2004)).³⁹ Finally, we demonstrate that our main results hold by restricting our sample only to incumbents that were operating

³⁷As noted previously, an additional implication of the predictions is that biopharma firms should be relatively more likely to use venture capital (VC) funding in response to an increase in competition. In *Figure B1* of the Appendix, we explore whether this is the case using aggregated data from the Thomson Reuters VentureXpert database for VC deals for biopharma firms and other R&D-intensive firms from 1977 to 1990. In the figure, we graph the differences between biopharma firms and other R&D-intensive firms over time in terms of the number of firms receiving funding, the number of VC deals, the average amount of equity invested by a VC firm, and the total aggregated amount of equity invested by VC firms. Across all of these outcomes, investments by VC firms were steadily increasing for the other R&D-intensive industries relative to biopharma prior to 1984. This increase is consistent with the strong increase in general of VC funding during this period, as documented by Kortum and Lerner (2000), and suggests that the increase flowed relatively more to non-biopharma R&D-intensive firms. However, beginning in 1984, this trend reversed itself sharply for all outcomes, as biopharma firms began to receive increasingly more VC funding than other R&D-intensive firms, in line with our predictions. This also provides a view into how private biopharma firms, which do not have access to public equity markets and may be more reliant on VC funding, respond to increased competition.

³⁸In *Table B4*, we conduct two falsification tests in which we re-estimate regression (1) for different sample periods. The first is in the immediate pre-Act sample period from 1969 to 1983, falsely specifying that the Hatch-Waxman Act was implemented in 1976. The second is in the period after our main tests take place, from 1992 to 2005, falsely specifying that the Act was implemented in 1999. The disadvantage of the first falsification test is that there are few biopharma firms operating in the period from 1969 to 1983, and so a null result may be simply due to a lack of power; the later period in our second falsification test allows a larger number of biopharma firms. As before, biopharma firms are our treatment group, and we choose propensity-score matched R&D-intensive firms as our control group, based on observable characteristics in the respective placebo pre-periods.

³⁹We show this in two ways in *Table B5*. We first re-estimate our results using Newey and West (1987) standard errors (Panel A), and show that our results remain unchanged. We next follow Bertrand, Duflo, and Mullainathan (2004), and collapse the sample into two data points, one for the pre-period and one for the post-period, for each cross-sectional unit by taking means across time (Panel B). The authors note that this procedure performs well in terms of correcting for autocorrelation, but has the disadvantage of low power. With the exception of debt, which may be due to the low power of the procedure, the sign and significance of the earlier results remain.

before the law was enacted, to ensure that our results are not driven by systematic differences between the characteristics of newly-listed biopharma firms entering our sample and those of existing firms.⁴⁰

4 Tests Using Variation within Biopharma

A potential concern with the previous methodology is that, even after performing matching and controlling for fixed effects and other observables, the control group may be different in unobservable ways from the treatment group. A related concern is that any results may be due to contemporaneous structural changes occurring in either the treatment or control group industries that are unrelated to the Hatch-Waxman Act.⁴¹ This can make it difficult to attribute changes in biopharma relative to other R&D-intensive firms as being solely due to the change in competition introduced by Hatch-Waxman.

Therefore, in this section, we conduct additional tests by exploiting variation *within* the biopharma industry, with respect to biopharma firms that were more and less exposed to competition following the Hatch-Waxman Act. The basic idea behind these tests is that the impact of competition is likely to differ across firms within the biopharma industry based on the type of product (e.g., its drug therapeutic class) that a firm focuses on (e.g., Grabowski (2004)). We conduct two additional tests along these lines. Our first test relies on differences between generic drug manufacturers and other pharma firms. Our second test exploits differences between the approved drug portfolios of biopharma firms and the therapeutic classes in which they operate.⁴²

⁴⁰*Table B6* estimates regression (1) for the restricted sample of incumbents. The results in terms of significance, sign, and magnitude are all very similar to those for the full sample presented in *Table 2*. This provides evidence that our main results are not due to a sample composition effect.

⁴¹For example, the 1980s saw such broader trends as merger waves, the increasing legal recognition of intellectual property culminating in agreements such as TRIPS in the 1990s (see Kyle and McGahan (2012)), and a weakening of patent standards starting in the early 1980s that led to a general increase in patents granted (Jaffe and Lerner (2004)). The biopharma industry in particular also saw a number of trends starting in the 1980s, such as the rise of the biotech industry and the introduction of a number of new classes of drugs (see Grabowski (2004)).

⁴²The disadvantage of these tests is that, by focusing solely on biopharma firms, we potentially suffer from

4.1 Test using Generic Manufacturers and Other Pharma Firms

4.1.1 Empirical Approach

In our first within-industry test, we compare the reaction to the Hatch-Waxman Act by pharma firms that are focused on generic drug manufacturing to that of other pharma firms. The logic is that, since the new law increased competition by facilitating the entry of generic drugs into the marketplace, the hypotheses in Section 2 should apply *less* to the firms that were already primarily generic manufacturers prior to the passage of the law. In other words, generic pharma firms should *reduce* their R&D and cash, and *increase* their debt, net debt, and assets in place relative to other pharma firms after the act was passed.

To identify generic drug manufacturers, we use data from the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the Orange Book), which contains historical information on every drug approved by the FDA and its applicant. Using this data, we identify all applications for the approval of generic drugs, and construct a measure for each firm of the proportion of total drug applications prior to 1984 that consists of generic drugs.⁴³ We construct our treatment group in this setting as firms for which at least 15% of their (pre-act) drug portfolios are composed of generic drugs.⁴⁴ One disadvantage of this approach is that there are relatively few generic drug manufacturers in our sample. Only 21 firms operated in the treatment group prior to the enactment of the new law. This potentially reduces the power of our analysis, but also makes it critical to select appropriate firms for the control group.⁴⁵ We therefore construct our control group of pharma firms using propensity-score matching in the same way as described in Section 4.2. Using these treatment and control groups, we estimate the same difference-in-difference specification as (1) from 1977 to 1991, replacing *Biopharma* with *Generic* as the indicator for our treatment

low power. Nonetheless, between these results, our findings are consistent with our previous results and hypotheses.

⁴³A generic drug application is classified as an Abbreviated New Drug Application (ANDA).

⁴⁴Among firms in the sample, this corresponds to the top quartile in terms of the proportion of drugs which are generics.

⁴⁵These reasons also make it infeasible to run our treatment as a continuous variable.

group.⁴⁶

4.1.2 Results

The regression results are included in *Table 3*. These results are broadly consistent with the hypotheses developed in Section 2. The difference-in-difference estimator for *R&D* is negative and significant without control variables and fixed effects (columns (1)), but is marginally insignificant (p-value of 0.16) when controls and fixed effects are included. This indicates that, as the Hatch-Waxman Act increased competition in the industry, generic manufacturers did not increase their R&D as much as other pharma firms. The difference-in-difference estimator for *PPE* is positive and significant in column (3), which is consistent with our hypotheses that generic firms increased their assets in place relative to other pharma firms in response to the Hatch-Waxman Act. The difference-in-difference estimator for *Cash* is negative and significant in both columns (5) and (6), indicating that generic pharma firms decreased their cash holdings relative to the control group as a result of the Hatch-Waxman Act. The difference-in-difference estimator for *Debt* is positive but insignificant in both columns (7) and (8)), while *Net Debt* is positive in columns (9) and (10), but is significant only without controls and fixed effects. This provides some evidence that generic firms increased their net debt as a result of the increase in competition. Nevertheless, the findings should be interpreted with caution due to the noisy pre-trends and the potentially low power owing to the small sample size.⁴⁷

⁴⁶*Figure B2* depicts the parallel trends for the treatment and control groups. For R&D and cash, the levels of the treatment and control groups are very similar prior to the enactment of the Hatch-Waxman Act, and exhibit parallel trends in the pre-period. Subsequently, the control group increases relative to the treatment group, consistent with the predictions. In contrast, debt and net debt appear to only move in parallel in the two or three years before the passage of the law; prior to that, they appear to move in opposite directions. While the trends for net debt then diverge in ways consistent with the predictions, the trends for debt are noisy throughout. Thus, the parallel trends assumption for these variables is less likely to hold, and their results should be interpreted with caution. Finally, the trends for assets in place are also noisy, though to a lesser extent. Here, the treatment and control group move roughly in parallel for the first four years of the sample, but then begin to diverge in the years prior to the law change. However, the divergence then widens in a manner consistent with the predictions.

⁴⁷An implication of the analysis of Acharya, Almeida, and Campello (2007) is that debt will not decline and cash will increase when the hedging needs of firms go up. This channel may contribute to the relatively weaker effect of debt compared to the net debt (the total debt net of cash) in our setting.

[Table 3 Here]

4.2 Test using Heterogeneity in Approved Drug Portfolios

4.2.1 Empirical Approach

In our second within-industry test, we exploit the variation across the approved drug portfolios of biopharma firms. The reasoning behind this test comes from recognizing that competition within the biopharma industry occurs at the therapeutic class level (e.g., Henderson and Cockburn (1994, 1996), Cockburn and Henderson (1994, 1998), Cockburn, Henderson, and Stern (2000)). For example, a firm that makes only cancer drugs will likely not be in direct competition with a firm that makes only cardiovascular drugs. As a result, we test whether firms that operated in therapeutic classes that were more exposed to the Hatch-Waxman Act responded more to the increase in competition than other firms.⁴⁸

In particular, for each biopharma firm in our sample, we identify all of that firm’s approved drugs as of 1983 using the FDA’s Orange Book. We then manually match each firm’s drugs to a therapeutic class using the Drugs.com and IBM Micromedex databases.⁴⁹ We proxy for whether a therapeutic class was more affected by the Hatch-Waxman Act by identifying whether it was more competitive prior to the enactment of the law. The basic idea is that classes with more approved drugs represented areas that were ripe for entry prior to the law, and therefore were also attractive for new generic entry following the law’s passage.

With the idea that competition between drugs is based on their therapeutic class in mind, we construct a continuous measure that reflects the degree of competition faced by each firm, based on the firm’s overall approved drug portfolio as of 1983. The measure, denoted by $HighCompetition_i$, is the proportion of a firm’s approved drugs that are in

⁴⁸Our empirical strategy is similar in spirit to papers such as Krieger, Li, and Papanikolaou (2018), who exploit variation in exposures of firms to Medicare Part D in order to examine how shocks to cash flow affect firms’ development decisions.

⁴⁹This provides us with 202 therapeutic classes for drugs that were approved prior to 1984. Examples of therapeutic classes include “antidiarrheals”, “antihistamines”, and “muscle relaxants”. As of 1983, firms in our sample operated in 5 therapeutic classes on average, with a standard deviation of 12.25.

highly competitive therapeutic classes, defined as therapeutic classes that are in the top quartile in terms of number of drugs prior to 1984. We estimate the previous difference-in-difference specification (1) from 1977 to 1991, replacing *Biopharma* with the continuous variable *High Competition_i* as our treatment intensity. For robustness, we construct an alternate measure (denoted by *Low Concentration_i*), defined as the proportion of a firm’s approved drugs that are in less concentrated therapeutic classes, i.e., therapeutic classes that are below the median in terms of concentration of drugs prior to 1984, as measured through a Herfindahl Index of approved drugs in each therapeutic class.⁵⁰ With both of these measures, a higher value indicates that a firm’s drug portfolio should be more exposed to the effect of the Hatch-Waxman Act.

As a further test, we also condition on a firm’s profitability of existing assets. More specifically, we examine whether the effects based on the degree of therapeutic area competition are centered on the firms with relatively lower profitability. The theoretical motivation for this comes from Arrow’s (1962) original insight that monopolists will innovate less than competitive firms, and the recent contributions of Christensen, Raynor and McDonald (2015) and Holmes, Levine and Schmitz (2012). Christensen et al. (2015) argue that incumbents, when faced with new entrants who may be engaging in disruptive innovation as a strategy for entry into a competitive market, may choose not to respond with their own attempts at innovation if they can focus on improving existing products and services for their most profitable customers. Holmes et al. (2012) present a variant of this argument in a new theory in which firms often face major problems in integrating new technologies, including temporarily reducing output, i.e., they face “switchover disruptions”. A cost of adoption, then, is the forgone rents on the sales of lost or delayed production, and these opportunity

⁵⁰These different measures are designed to provide views of the results using different definitions of competition, and different cutoffs for what is considered a “competitive” therapeutic area. The results are qualitatively robust to alternate cutoffs with each definition. Firms in our sample had a mean of 8.6 approved drugs (i.e. drug-indication pairs), with a standard deviation of 22.7 due to the influence of large pharma producers, underscoring the reason why we measure our treatment proportionally rather than in terms of raw numbers of drugs. These firms had 7 unique drugs on average (given that a drug may affect more than one indication), with a standard deviation of 18.7.

costs will be larger when the profitability of those lost units is higher.

In order to conduct this empirical examination, we run our difference-in-difference specification with *High Competition_i* as a treatment variable separately for firms with above- and below-median levels of pre-act profitability.⁵¹ The logic behind this test is that not all firms operating in more competitive areas will necessarily respond in the same way to an increase in competition. In particular, firms that already enjoy high profit margins will likely have successful drugs on the market, and under patent protection, and thus will be able to rely on their monopoly profits since their drugs are less subject to erosion via competition. As a result, they are less likely to move away from their existing profitable assets when faced with increased competition. In contrast, firms with lower ex ante profits do not enjoy this same position and are thus predicted to respond to increased competition, with their incentives being stronger the more competitive the area they are operating in (e.g., Aghion et al. (2005)).

Using these measures, we examine the effect of the Hatch-Waxman Act on biopharma firms with differing exposures to competition. We run our specifications (1) from 1977 to 1991 using all biopharma firms in Compustat, and replacing *Biopharma* with each of the above treatment variables. The prediction is that the hypothesized effects of the Hatch-Waxman Act should be stronger for firms operating in more competitive therapeutic areas, and that the effect is centered on less profitable firms operating in more competitive areas.

4.2.2 Results

The regression results split first by therapeutic area competition are given in *Table 4*. Panel A provides results using *High Competition_i* as the treatment variable, while Panel B provides results using *Low Concentration_i* as the treatment variable. These results are broadly in line with the hypotheses in Section 2. In both specifications, while R&D is insignificant, the

⁵¹Profitability is defined as EBITDA scaled by total assets, and firms are classified as high or low profitability based on their profitability the year before the Hatch-Waxman Act (1983).

PPE is negative and significant, while the cash is positive and significant.⁵² Like previous results, the sign on debt is negative and thus consistent with the hypotheses in Section 2, but is insignificant. However, the net debt is negative and significant in Panel A, and is negative but marginally insignificant in Panel B (a p-value of 0.136).

[Table 4 Here]

Table 5 shows the results when splitting the sample by ex ante lower and higher profitability firms. The tables shows that the results center around the firms with relatively *lower* ex ante profitability. In particular, for the below median profitability firms, the R&D is now positive and significant. The PPE is negative, although insignificant, with a p-value of 0.16. The cash is positive and significant. While the debt is insignificant for both sets of firms, the net debt is negative and significant for the firms with relatively lower profitability.

[Table 5 Here]

Overall, these results in combination with the within-industry results in Section 4.1 provide additional supporting evidence for each of the hypotheses laid out in Section 2, suggesting that the earlier results are not due simply to broader industry changes that are distinct from the effects of competition.

5 Effect on Innovation Output

In the final part of our analysis, we explore the how the effects of competition translate into innovation output by exploring the number of patents granted to each firm, as well as the market value of those patents.

⁵²In untabulated results, we find that the logarithm of the level of R&D is positive and marginally insignificant when using *High Competition_i* as the treatment variable, but is positive and significant when using *Low Concentration_i* as the treatment variable.

5.1 Data and Parallel Trends

In order to address this part of our analysis, we obtain data on patents granted and the market value of those patents from Kogan, Papanikolaou, Seru, and Stoffman (2017).⁵³ This dataset contains the number of patents granted to each firm in each year, the number of patents weighted by forward citation, and an estimate of the economic value of those granted patents. The economic value of patents is calculated using the stock price reaction of a firm following a patent’s grant or application publication (controlling for the market return as well as other sources of measurement error). A single measure of innovation at the firm-year level is obtained by summing the stock price reaction across all patents granted (or applications published) for each firm in each year. This is scaled by the end-of-year market capitalization of the firm in order to calculate the final measure of innovation value.⁵⁴ We refer to this variable as *Innovation Value*.

With this data in hand, we follow the methodology from the previous sections and explore the effect of the Hatch-Waxman Act as a positive shock to competition for biopharma firms. Specifically, we estimate equation (1) using the patent counts and innovation value measure as choices for $Y_{i,t}$. We begin by examining biopharma firms compared to other R&D-intensive firms, as in Section 3, and then verify that the results are consistent for the within-industry tests.⁵⁵

Figure 4 below provides graphs showing the trends for both the biopharma and the R&D-intensive control group of the average number of patents at the firm level, the citation-

⁵³The data are obtained from Noah Stoffman’s website.

⁵⁴See Kogan et al. (2017) for details.

⁵⁵We include the lagged outcome variable as a control in each specification to control for time persistence. For the sample of biopharma firms compared to other R&D-intensive control firms, we match by propensity score as before, but additionally match on the log of citation-weighted patents, the number of patents scaled by total assets, and *Innovation Value*. We additionally implement one-to-one matching only including the incumbent firms that are matched for both the treatment and control groups, restricting both groups to a common support. Because a number of firms do not have significant patenting activity in the pre-period, this restricts how many firms can be included in our regressions, thus reducing our power. We do this to ensure parallel trends hold between our treatment and control groups, given the documented pre-trends related to innovative output for the biopharma industry (e.g., Scannell et al. (2012)). However, our regression results are robust to not imposing this restriction, as well as to a variety of other matching assumptions.

weighted number of patents, and the innovation value measure.⁵⁶ For the number of patents and the citation-weighted patents, the trends between the treatment and control groups are roughly parallel, with only a slight downward trend before the passage of the law, but after its enactment, there is a decrease in the number of new patents for biopharma firms relative to the control group. For the innovation value measure, the treatment and control groups move very closely together prior to its enactment, after which the market value of the patents increases sharply for the treatment group relative to the control group.⁵⁷ Overall, the graphs suggest that the assumption of parallel trends holds for these measures of innovation.

[Figure 4 Here]

5.2 Innovation Output Results

The results of the regression are provided in *Table 6* below.⁵⁸ Following the increase in competition after the passage of the Hatch-Waxman Act, biopharma firms have significantly fewer patents granted (or patent applications published) than other R&D-intensive firms, in terms of both the raw number of patents and log patents. The results are similar when examining citation-weighted patents, which are typically used as an estimate for the scientific value of a patent. These results suggest that, despite the increased R&D spending by biopharma firms, the total innovation output of these firms fell compared to the control group. However, the total market value of the innovations for biopharma firms (column (5)) *rises* relative to the control group.

[Table 6 Here]

⁵⁶ *Table B7* of the Appendix provides the summary statistics for the innovation outcomes over the sample.

⁵⁷ As *Figure 4* indicates, the overall number of patent grants increase over this period, consistent with the evidence related by Jaffe and Lerner (2004) to patenting incentives put in place by the government. Our results show that biopharma firms patented *relatively* less than other R&D-intensive firms, which we attribute to the effect of competition.

⁵⁸ *Table B8* of the Appendix provides results which allow for the entry of new biopharma firms into the sample, thus allowing a larger number of firms in the regression results to address the previously noted concern regarding the power of the test. Our results are essentially unchanged after removing the restriction to incumbent firms.

We next examine the results for the specifications within the biopharma industry. We first explore firms focused on producing generic drugs compared to other pharma firms. We note that this test has the disadvantage of low power, given that this sample has a small number of firms that are both focused on generic drugs and have data on patents and innovation value. In addition, the intuition developed earlier about innovation does not cleanly translate to generic-focused manufacturers, as they would also have an incentive to focus on generic drugs and thus innovate less. These issues notwithstanding, we generally find consistent results with this test, in that other pharma firms appear to significantly reduce their innovation even more than firms with a greater focus on generic drugs, and the value of those innovations are higher than those from the generic-focused firms, although without statistical significance. These results are provided in *Table 7*.⁵⁹

[Table 7 Here]

Table 8 follows up the approach in *Table 5* of Section 4.2, examining the effects on innovation outcomes based on the degree of competition by therapeutic area split by firms with relatively higher and lower median levels of pre-act profitability. As with the previous results, the effects are centered on firms with relatively lower ex-ante profitability. For these firms, we again find consistent results, in that firms operating in more competitive therapeutic classes, and thus more exposed to the Hatch-Waxman Act, experienced significant decreases in patent counts (both regular and weighted by citation). Furthermore, there is a significant increase in innovation value for these firms.⁶⁰

[Table 8 Here]

⁵⁹The insignificance of the innovation value measure may be due to the relatively low power of these tests. The graph of parallel trends for this test is given in *Figure B3* of the Appendix.

⁶⁰We split firms by profitability based on their average profitability in the pre-period for firms with patent data for these tests, since some firms may not report patent data in a particular year. The results for firms with profitability above the median is insignificant for patent counts, but it is positive and significant at the 10% level for citation-weighted patents and innovation value. However, these results are driven specifically by outlier firm-year observations; winsorizing or censoring the sample tails eliminates the significance for the above-median firms.

Put together, these results suggest that firms may focus more on producing commercially valuable innovations in order to separate themselves from competitors, rather than producing a greater number of total innovations. That is, faced with greater competition, firms concentrate their efforts on trying to find niches in which they can specialize, potentially producing valuable “hits” in those areas, while narrowing the total number of areas in which they research. Our results provide evidence that the effect of competition on R&D and innovation is more nuanced than has been previously noted. While competition spurs additional R&D investment (consistent with the “escape-the-competition” effect), these investments do not generate more innovations (seemingly consistent with a Schumpeterian effect). However, the relatively fewer innovations they do generate are more valuable, a result that, to the best of our knowledge, has not been predicted by existing theories or documented previously.

6 Conclusion

In this paper, we explore the interaction between competition, R&D investment, and financing choices. We motivate our empirical hypotheses with the insights of existing theories which, viewed collectively, predict that as competition increases, firms will increase their R&D investment, reduce investment in assets in place, carry more cash, and have lower levels of net debt. We provide time series evidence on firms in the biopharma industry that are consistent with these hypotheses. To overcome endogeneity concerns, we use the Hatch-Waxman Act of 1984 as a source of exogenous variation that increased competition in the biopharma industry, and conduct differences-in-differences tests that exploit differences both between the biopharma industry and other R&D-intensive industries as well as within-industry differences between biopharma firms. We find strong supporting evidence for our hypotheses, which survive various robustness tests. We also examine the effect of competition on the innovative output of these firms, and find that, while firms reduce the number of their patents following an increase in competition, the economic value of those patents

increase. Although we have focused on the biopharma industry, we believe our results are also applicable to other R&D-intensive firms.

At a broad level, innovative industries like biopharma have been subject to increased competitive pressures over time, through both regulation and technological breakthroughs that have facilitated easier entry, such as the Human Genome Project and increasingly faster and cheaper sequencing technologies. We highlight how these changes in competition may affect important financial characteristics, which may in turn affect the amount of funding that R&D-intensive firms are able to raise. For example, while increased competition may spur innovation through increased R&D investment, it may also increase the reliance of these firms on funding through equity markets. This in turn could slow innovation down during “cold” markets, or alter the types of investments these firms make due to adverse selection in the capital markets.

Our analysis of the nuanced nature of R&D output also carries with it other important implications. For example, innovation in the biopharma industry leads to valuable drugs, and a reduction in the number of new drugs may lead to fewer diseases being treated. If the goal of R&D from a societal perspective is to have more innovation, then policies besides increased competition may be needed. In addition, given the increase in R&D spending associated with increased competitive pressures over time, another implication of our results may be that more money may be needed in order to spur additional innovation. For example, a recent financial innovation that has been proposed in the biopharma industry is a portfolio of R&D projects, through the “megafund” idea of Fernandez, Stein and Lo (2012), Fagnan, Fernandez, Lo, and Stein (2013), and Hull, Lo, and Stein (2017).⁶¹ These financial innovations may change the effects of competition on innovation in important ways, and increase the total volume of innovation.

⁶¹Other financial innovations to spur biopharma innovation include insurance contracts called “FDA Hedges”; see Philipson (2015) and Jørring et al. (2017).

References

1. Abel, Andrew B. "Optimal Debt and Profitability in the Tradeoff Theory." Working Paper, 2014.
2. Acemoglu, Daron. *Introduction to Modern Economic Growth*. Princeton University Press, Princeton, NJ, 2009.
3. Acharya, Viral V., Heitor Almeida, and Murillo Campello. "Is cash negative debt? A hedging perspective on corporate financial policies." *Journal of financial intermediation* 16, no. 4 (2007): 515-554.
4. Aghion, Philippe, Ufuk Akcigit, and Peter Howitt. "What do we learn from Schumpeterian growth theory?." In *Handbook of Economic Growth*, vol. 2, pp. 515-563. Elsevier, 2014.
5. Aghion, Philippe, Stefan Bechtold, Lea Cassar, and Holger Herz. The causal effects of competition on innovation: Experimental Evidence. No. w19987. National Bureau of Economic Research, 2014.
6. Aghion, Philippe, Nick Bloom, Richard Blundell, Rachel Griffith, and Peter Howitt. "Competition and Innovation: an Inverted-U Relationship." *The Quarterly Journal of Economics* 120, no. 2 (2005): 701-728.
7. Aghion, Phillippe, Mathias Dewatripont, and Patrick Rey. "Competition, Financial Discipline and Growth." *The Review of Economic Studies* 66, no. 4 (1999): 825-852.
8. Aghion, Philippe, Christopher Harris, Peter Howitt, and John Vickers. "Competition, imitation and growth with step-by-step innovation." *The Review of Economic Studies* 68, no. 3 (2001): 467-492.
9. Ahn, Sanghoon. *Competition, Innovation and Productivity Growth: A Review of Theory and Evidence*. No. 317. OECD Publishing, 2002.
10. Arrow, Kenneth J. "Economic welfare and the allocation of resources." In *The Rate and Direction of Inventive Activity: Economic and Social Factors* (1962), edited by the Universities-National Bureau Committee for Economic Research and the Committee on Economic Growth of the Social Science Research Councils, 609-26. Princeton, NJ: Princeton University Press.
11. Azoulay, Pierre. "Do pharmaceutical sales respond to scientific evidence?." *Journal of Economics & Management Strategy* 11, no. 4 (2002): 551-594.
12. Begenau, Juliane, and Berardino Palazzo. "Firm selection and corporate cash holdings." *Journal of Financial Economics* (2020).
13. Bergemann, Dirk, and Ulrich Hege. "The Financing of Innovation: Learning and Stopping." *RAND Journal of Economics* 36, no. 4 (2005): 719-752.

14. Berk, Jonathan B., Richard Stanton, and Josef Zechner. "Human capital, bankruptcy, and capital structure." *The Journal of Finance* 65, no. 3 (2010): 891-926.
15. Bertrand, Marianne, Esther Duflo, and Sendhil Mullainathan. "How Much Should We Trust Differences-in-Differences Estimates?." *Quarterly Journal of Economics* 119, no. 1 (2004).
16. Bolton, Patrick, Hui Chen, and Neng Wang. Debt, Taxes, and Liquidity. No. w20009. National Bureau of Economic Research, 2014.
17. Bolton, Patrick, and David S. Scharfstein. "A theory of predation based on agency problems in financial contracting." *The American Economic Review* (1990): 93-106.
18. Brown, James R., Steven M. Fazzari, and Bruce C. Petersen. "Financing Innovation and Growth: Cash Flow, External Equity, and the 1990s R&D Boom." *The Journal of Finance* 64, no. 1 (2009): 151-185.
19. Brown, James R., Gustav Martinsson, and Bruce C. Petersen. "Do financing constraints matter for R&D?." *European Economic Review* 56, no. 8 (2012): 1512-1529.
20. Brown, James R., Gustav Martinsson, and Bruce C. Petersen. "Law, stock markets, and innovation." *The Journal of Finance* 68, no. 4 (2013): 1517-1549.
21. Calomiris, Charles W., and Charles M. Kahn. "The role of demandable debt in structuring optimal banking arrangements." *The American Economic Review* (1991): 497-513.
22. Carlson, Robert. "Estimating the biotech sector's contribution to the US economy." *Nature Biotechnology* 34, no. 3 (2016): 247-255.
23. Caves, Richard E., Whinston, Michael D., and Mark A. Hurwitz, 1991, "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry". *Brookings Papers on Economic Activity: Microeconomics* Vol. 1991, 1-66.
24. Chernyshev, Nikolay. "Inverted-U Relationship between R&D and Competition: Reconciling Theory and Evidence." Working paper, 2017.
25. Christensen, Clayton M., Michael E. Raynor, and Rory McDonald. "What is disruptive innovation." *Harvard business review* 93, no. 12 (2015): 44-53.
26. Cockburn, Iain, and Rebecca Henderson. "Racing to invest? The dynamics of competition in ethical drug discovery." *Journal of Economics & Management Strategy* 3, no. 3 (1994): 481-519.
27. Cockburn, Iain M., and Rebecca M. Henderson. "Absorptive capacity, coauthoring behavior, and the organization of research in drug discovery." *The Journal of Industrial Economics* 46, no. 2 (1998): 157-182.

28. Cockburn, Iain M., Rebecca M. Henderson, and Scott Stern. "Untangling the origins of competitive advantage." *Strategic Management Journal* 21, no. 10-11 (2000): 1123-1145.
29. Cohen, Wesley M., and Richard C. Levin. "Empirical studies of innovation and market structure." *Handbook of Industrial Organization* 2 (1989): 1059-1107.
30. Cornaggia, Jess, Yifei Mao, Xuan Tian, and Brian Wolfe. "Does banking competition affect innovation?" *Journal of Financial Economics* 115, no. 1 (2015): 189-209.
31. Deshpande, Nishad, and Asha Nagendra. "Patents as collateral for securitization." *Nature Biotechnology* 35, no. 6 (2017): 514-516.
32. DiMasi, Joseph A., and Henry G. Grabowski. "The cost of biopharmaceutical R&D: is biotech different?" *Managerial and Decision Economics* 28, no. 4-5 (2007): 469-479.
33. DiMasi, Joseph A., Henry G. Grabowski, and Ronald W. Hansen. "Innovation in the pharmaceutical industry: new estimates of R&D costs." *Journal of Health Economics* 47 (2016): 20-33.
34. DiMasi, Joseph A., Henry G. Grabowski, and John Vernon. "R&D Costs, Innovative Output and Firm Size in the Pharmaceutical Industry." *International Journal of the Economics of Business* 2, no. 2 (1995): 201-219.
35. DiMasi, Joseph A., Ronald W. Hansen, and Henry G. Grabowski. "The Price of Innovation: New Estimates of Drug Development Costs." *Journal of Health Economics* 22, no. 2 (2003): 151-185.
36. Ellison, Sara Fisher, Iain M. Cockburn, Zvi Griliches, and Jerry A. Hausman. "Characteristics of Demand for Pharmaceutical Products: An Examination of Four Cephalosporins." *RAND Journal of Economics* 28, no. 3 (1997): 426-446.
37. Ellison, Glenn, and Sara Fisher Ellison. "Strategic entry deterrence and the behavior of pharmaceutical incumbents prior to patent expiration." *American Economic Journal: Microeconomics* 3, no. 1 (2011): 1-36.
38. Fagnan, David E., Jose Maria Fernandez, Andrew W. Lo, and Roger M. Stein. "Can Financial Engineering Cure Cancer?" *The American Economic Review* 103, no. 3 (2013): 406-411.
39. Fama, Eugene F., and Kenneth R. French. "Common Risk Factors in the Returns on Stocks and Bonds." *Journal of Financial Economics* 33, no. 1 (1993): 3-56.
40. Fernandez, Jose-Maria, Roger M. Stein, and Andrew W. Lo. "Commercializing biomedical research through securitization techniques." *Nature Biotechnology* 30, no. 10 (2012): 964-975.
41. Fischer, Timo, and Philipp Ringler. "What patents are used as collateral?—an empirical analysis of patent reassignment data." *Journal of Business Venturing* 29, no. 5 (2014): 633-650.

42. Gans, Joshua S., and Scott Stern. "Incumbency and R&D incentives: Licensing the Gale of Creative Destruction." *Journal of Economics & Management Strategy* 9, no. 4 (2000): 485-511.
43. Gans, Joshua S., and Scott Stern. "The Product Market and the Market for "Ideas": Commercialization Strategies for Technology Entrepreneurs." *Research Policy* 32, no. 2 (2003): 333-350.
44. Gans, Joshua S., David H. Hsu, and Scott Stern. "When Does Start-up Innovation Spur the Gale of Creative Destruction?" *RAND Journal of Economics* 33, no. 4 (2002): 571-586.
45. Garfinkel, Jon A., and Mosab Hammoudeh. "Competition Threats and Rival Innovation Responses: Evidence from Breakthrough Therapies." Available at SSRN 3684095 (2020).
46. Grabowski, Henry. "Are the economics of pharmaceutical research and development changing?." *Pharmacoeconomics* 22, no. 2 (2004): 15-24.
47. Grabowski, Henry G. "Competition between generic and branded drugs." *Pharmaceutical innovation: incentives, competition, and cost-benefit analysis in international perspective* (2007).
48. Grabowski, Henry G., and Margaret Kyle. "Generic competition and market exclusivity periods in pharmaceuticals." *Managerial and Decision Economics* 28, no. 4-5 (2007): 491-502.
49. Grabowski, Henry, and John Vernon. "Longer Patents for Lower Imitation Barriers: The 1984 Drug Act." *American Economic Review* 76, no. 2 (1986): 195-98.
50. Grabowski, Henry, and John Vernon. "A New Look at the Returns and Risks to Pharmaceutical R&D." *Management Science* 36, no. 7 (1990): 804-821.
51. Grabowski, Henry G., and John M. Vernon. "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act." *Journal of Law and Economics* 35, no. 2 (1992): 331-50.
52. Graham, John R., and Mark T. Leary. "A Review of Empirical Capital Structure Research and Directions for the Future." *Annual Review of Financial Economics* 3, no. 1 (2011): 309-345.
53. Grant, Robert M., and Judith J. Jordan. *Foundations of Strategy*. John Wiley & Sons, 2015.
54. Hall, Bronwyn H., and Josh Lerner. "The Financing of R&D and Innovation." *Handbook of the Economics of Innovation* 1 (2010): 609-639.
55. Hart, Oliver, and John Moore. "Debt and Seniority: An Analysis of the Role of Hard Claims in Constraining Management." *The American Economic Review* 85, no. 3 (1995): 567.

56. Hart, Oliver, and John Moore. "Default and renegotiation: A dynamic model of debt." *The Quarterly Journal of Economics* 113, no. 1 (1998): 1-41.
57. Henderson, Rebecca, and Iain Cockburn. "Measuring competence? Exploring firm effects in pharmaceutical research." *Strategic Management Journal* 15, no. S1 (1994): 63-84.
58. Henderson, R., and I. Cockburn. "Scale, scope, and spillovers: the determinants of research productivity in drug discovery." *The Rand Journal of Economics* 27, no. 1 (1996): 32.
59. Hochberg, Yael V., Carlos J. Serrano, and Rosemarie H. Ziedonis. "Patent collateral, investor commitment, and the market for venture lending." *Journal of Financial Economics* 130, no. 1 (2018): 74-94.
60. Holmes, Thomas J., David K. Levine, and James A. Schmitz. "Monopoly and the incentive to innovate when adoption involves switchover disruptions." *American Economic Journal: Microeconomics* 4, no. 3 (2012): 1-33.
61. Holmstrom, Bengt, and Jean Tirole. "Financial intermediation, loanable funds, and the real sector." *The Quarterly Journal of Economics* 112, no. 3 (1997): 663-691.
62. Hombert, Johan, and Adrien Matray. "Can innovation help US manufacturing firms escape import competition from China?." *The Journal of Finance* 73, no. 5 (2018): 2003-2039.
63. Hull, John C. and Lo, Andrew W. and Stein, Roger M., Funding Long Shots (October 25, 2017). Available at SSRN: <https://ssrn.com/abstract=3058472>.
64. Jaffe, Adam B., and Joshua Lerner. *Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and what to Do about it*. Princeton University Press, 2004.
65. Jaggia, Priscilla Butt, and Anjan V. Thakor. "Firm-specific human capital and optimal capital structure." *International Economic Review* (1994): 283-308.
66. Jensen, Michael C. "Agency costs of free cash flow, corporate finance, and takeovers." *The American Economic Review* 76, no. 2 (1986): 323-329.
67. Jensen, Michael C., and William H. Meckling. "Theory of the Firm: Managerial Behavior, Agency Costs and Ownership Structure." *Journal of Financial Economics* 3, no. 4 (1976): 305-360.
68. Jørring, Adam, Andrew W. Lo, Tomas J. Philipson, Manita Singh, and Richard T. Thakor. Sharing R&D Risk in Healthcare via FDA Hedges. No. w23344. National Bureau of Economic Research, 2017.
69. Kamien, Morton I., and Nancy L. Schwartz. "Self-Financing of an R and D Project." *The American Economic Review* 68, no. 3 (1978): 252-261

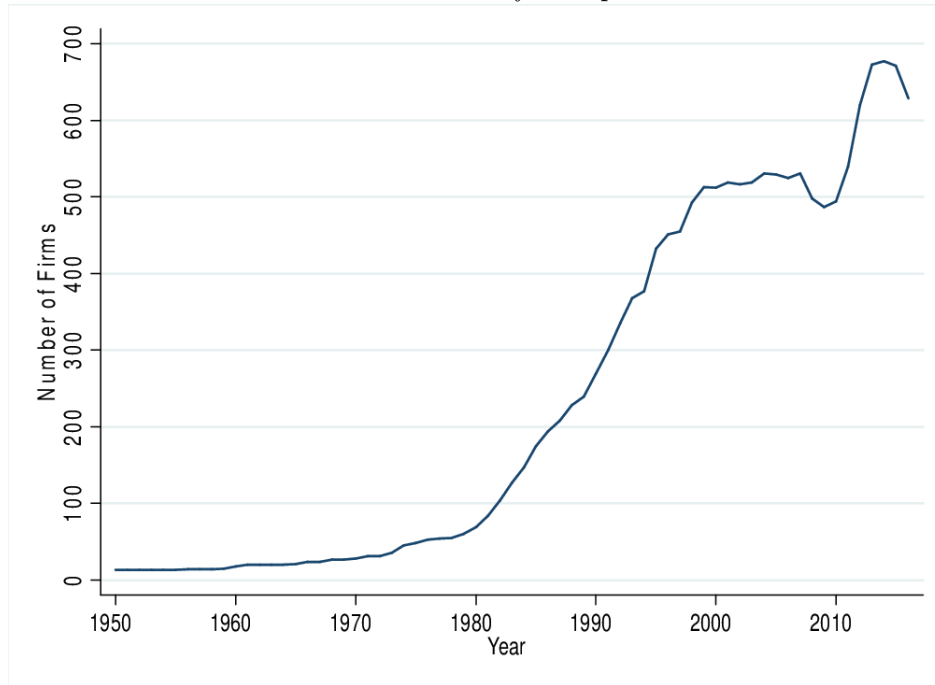
70. Kogan, Leonid, Dimitris Papanikolaou, Amit Seru, and Noah Stoffman. "Technological innovation, resource allocation, and growth." *The Quarterly Journal of Economics* 132, no. 2 (2017): 665-712.
71. Kortum, Samuel. "Equilibrium r&d and the patent--r&d ratio: Us evidence." *The American Economic Review* 83, no. 2 (1993): 450-457.
72. Kortum, Samuel, and Josh Lerner. "Assessing the contribution of venture capital to innovation." *RAND Journal of Economics* 31, no. 4 (2000): 674-692.
73. Krieger, Joshua L., Danielle Li, and Dimitris Papanikolaou. Developing novel drugs. No. w24595. National Bureau of Economic Research, 2018.
74. Kyle, Margaret K., and Anita M. McGahan. "Investments in pharmaceuticals before and after TRIPS." *Review of Economics and Statistics* 94, no. 4 (2012): 1157-1172.
75. Langinier, Corinne, and GianCarlo Moschini. "The Economics of Patents: An Overview." (2002).
76. Lewis, Ralph A. "The Emerging Effects of the Drug Price Competition and Patent Term Restoration Act of 1984." *Journal of Contemporary Health Law & Policy* (1985-2015) 8, no. 1 (1992): 361-378.
77. Lie, Erik, and Keyang Daniel Yang. "Enter the Dragon: Import Penetration and Innovation." (2017).
78. Lin, Danmo. "Swallow Poison to Innovate: R&D Investment Under Financial Constraints and Competition." (2017).
79. Lyandres, Evgeny, and Berardino Palazzo. "Cash holdings, competition, and innovation." *Journal of Financial and Quantitative Analysis* 51, no. 6 (2016): 1823-1861.
80. Mann, William. "Creditor rights and innovation: Evidence from patent collateral." *Journal of Financial Economics* 130, no. 1 (2018): 25-47.
81. Morellec, Erwan, Boris Nikolov, and Francesca Zucchi. "Competition, cash holdings, and financing decisions." Swiss Finance Institute Research Paper 13-72 (2014).
82. Myers, Stewart C. "Capital Structure." *Journal of Economic Perspectives* 15, no. 2 (2001): 81-102.
83. Myers, Stewart C., and Christopher D. Howe, 1997, *A Life-Cycle Financial Model of Pharmaceutical R&D*. Program on the Pharmaceutical Industry, Sloan School of Management, Massachusetts Institute of Technology.
84. Myers, Stewart C., and Nicholas S. Majluf. "Corporate Financing and Investment Decisions When Firms have Information that Investors do not Have." *Journal of Financial Economics* 13, no. 2 (1984): 187-221.

85. Nanda, Ramana, and Matthew Rhodes-Kropf. "Investment cycles and startup innovation." *Journal of Financial Economics* 110, no. 2 (2013): 403-418.
86. Nanda, Ramana, and Matthew Rhodes-Kropf. "Financing risk and innovation." *Management Science* 63, no. 4 (2017): 901-918.
87. National Science Foundation, *National Patterns of R&D Resources: 1998*, by Steven Payson, NSF 99-335 (Arlington, VA, 1999).
88. Neff, Cornelia. *Corporate Finance, Innovation, and Strategic Competition*. Vol. 522. Springer Science & Business Media, 2012.
89. Newey, Whitney K., and Kenneth D. West. "A Simple, Positive Semi-definite, Heteroskedasticity and Autocorrelation Consistent Covariance Matrix." *Econometrica* 55, no. 3 (1987): 703-08.
90. Petropoulos, Georgios. "The Relationship Between Competition and Innovation: How Important are Firms' Financial Constraints?." (2015).
91. Philipson, Tomas J. "Hedging Pipeline Risk in Pharma." *Milken Institute* (March 2015).
92. Scannell, Jack W., Alex Blanckley, Helen Boldon, and Brian Warrington. "Diagnosing the decline in pharmaceutical R&D efficiency." *Nature reviews Drug discovery* 11, no. 3 (2012): 191.
93. Schumpeter, Joseph Alois. *Capitalism, socialism, and democracy*. (1942).
94. Stulz, Rene M. "Managerial Discretion and Optimal Financing Policies." *Journal of Financial Economics* 26, no. 1 (1990): 3-27.
95. Thakor, Anjan V. "Incentives to innovate and financial crises." *Journal of Financial Economics* 103, no. 1 (2012): 130-148.
96. Thakor, Richard T., Nicholas Anaya, Yuwei Zhang, Christian Vilanilam, Kien Wei Siah, Chi Heem Wong, and Andrew W. Lo. "Just how good an investment is the biopharmaceutical sector?." *Nature Biotechnology* 35, no. 12 (2017): 1149.
97. Tirole, Jean. *The Theory of Industrial Organization*. MIT press, 1988.
98. United States. Congressional Budget Office. *How increased competition from generic drugs has affected prices and returns in the pharmaceutical industry*. US Government Printing Office, 1998.
99. Williams, Winston. "Glory Days End for Pharmaceuticals." *The New York Times* 24 Feb. 1985.
100. Zwiebel, Jeffrey. "Dynamic Capital Structure under Managerial Entrenchment." *The American Economic Review* 86, no. 5 (1996): 1197-1215.

Figure 1: Competition in the Biopharma Industry

This figure presents basic measures of competition in the biopharma industry over time. Panel A shows the number of firm-level competitors operating in the biopharma industry over time. Panel B shows the average number of newly approved drugs each year across all therapeutic classes.

Panel A: Number of Competitors



Panel B: Average Number of New Drug Approvals per Therapeutic Class

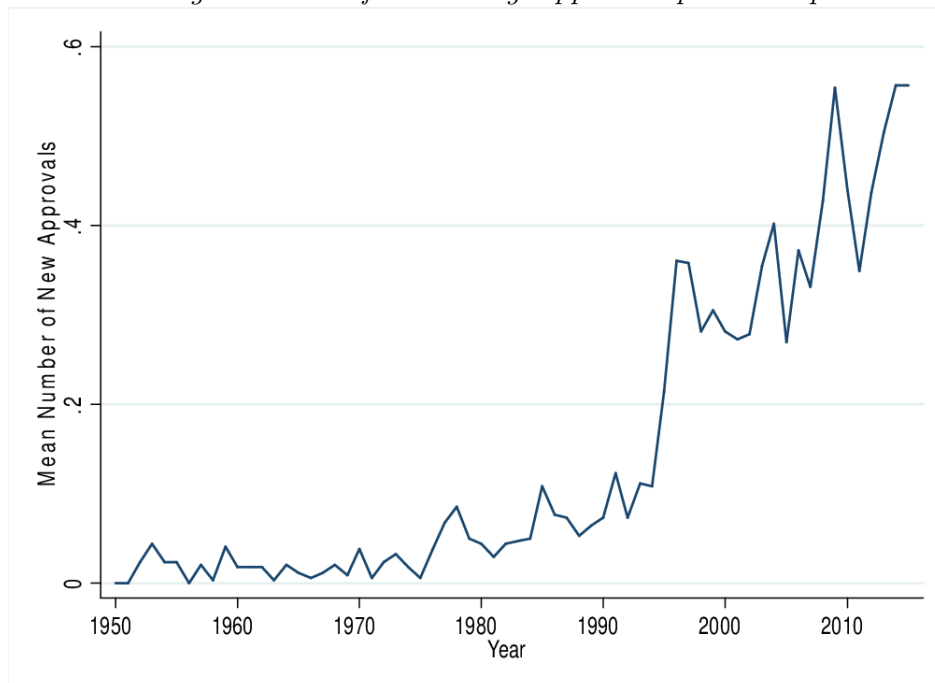


Figure 2: Financial Characteristics over Time

These graphs show the mean (solid blue line) and median (dashed red line) values of financial characteristics for the biopharma industry in each year. The green dotted lines represent the mean values of financial characteristics for all other industries.

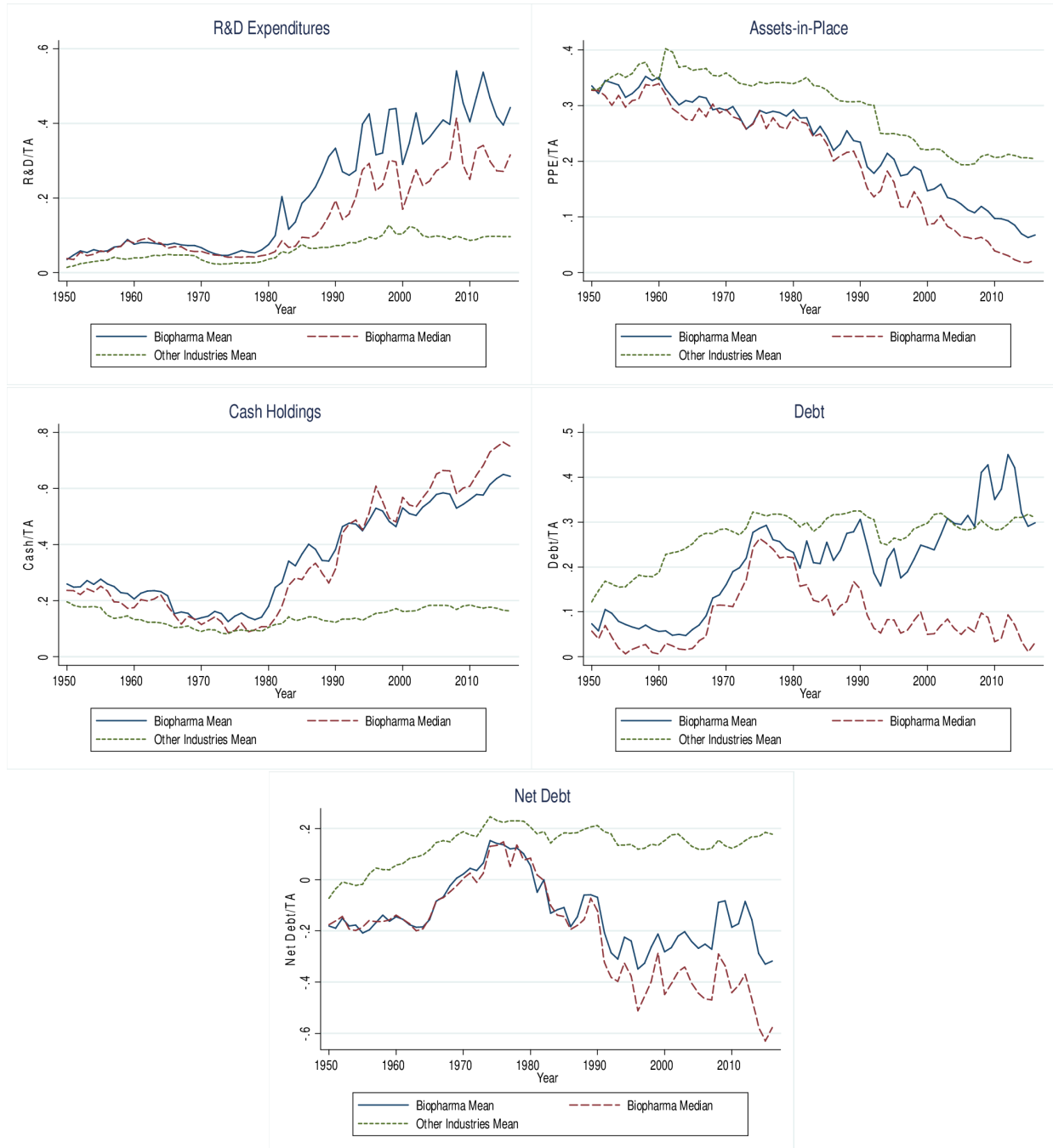


Figure 3: Main Results: Trends for Treatment and Control Groups

Inter-industry trends for R&D expenditures, cash holdings, debt, net debt, and assets in place, all scaled by total assets. The graphs on the left represent averages for each group. The solid blue lines give averages for the biopharma industry, while the red dashed lines give averages for the sample of R&D-intensive firms matched by propensity score. A vertical red line is included, representing the year that the Hatch-Waxman Act was implemented. The graphs on the right depict the differences between the treatment and control groups (treatment minus control), with pre- and post-period trend lines added.

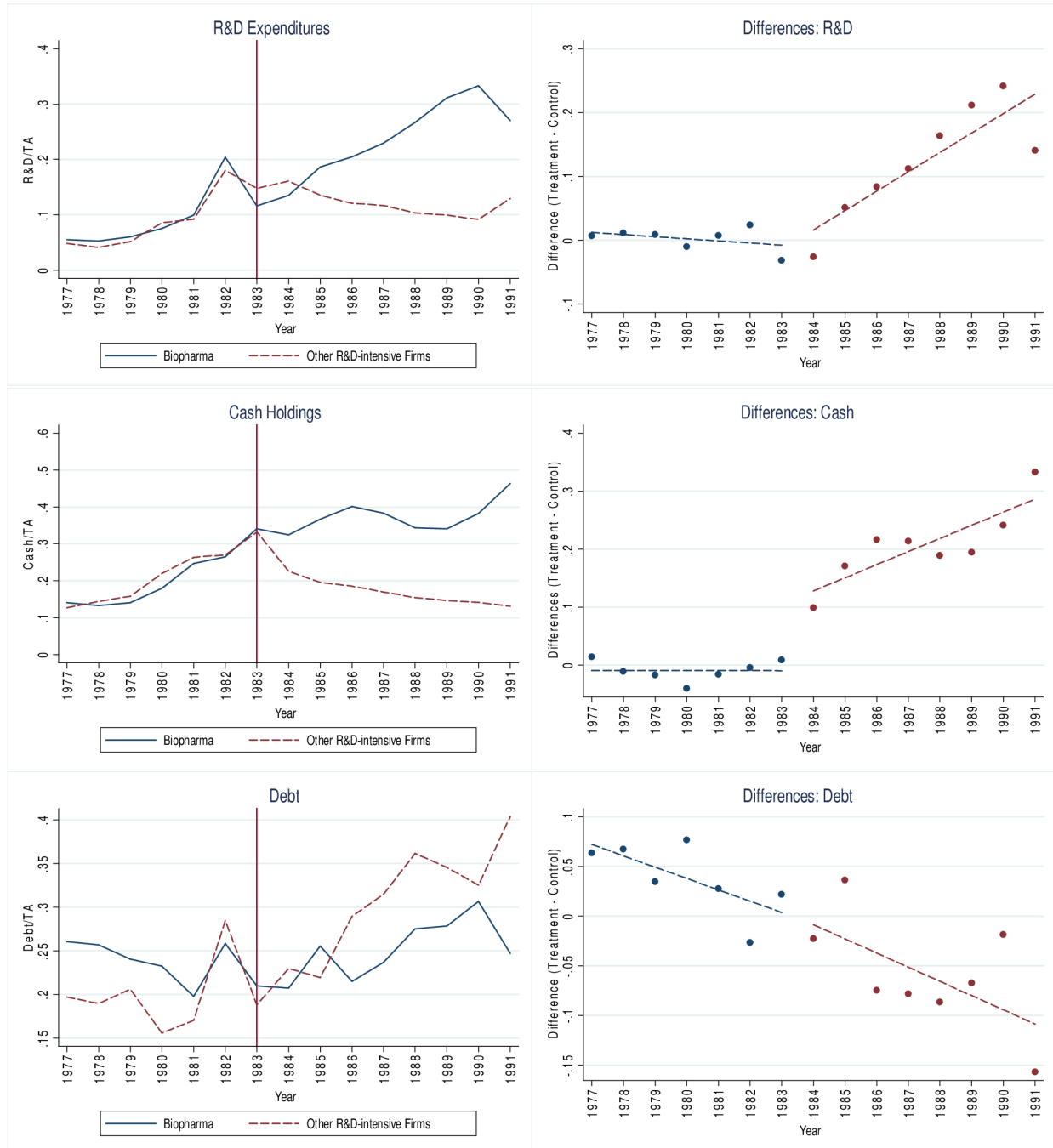


Figure 3 (continued): Main Results: Trends for Treatment and Control Groups

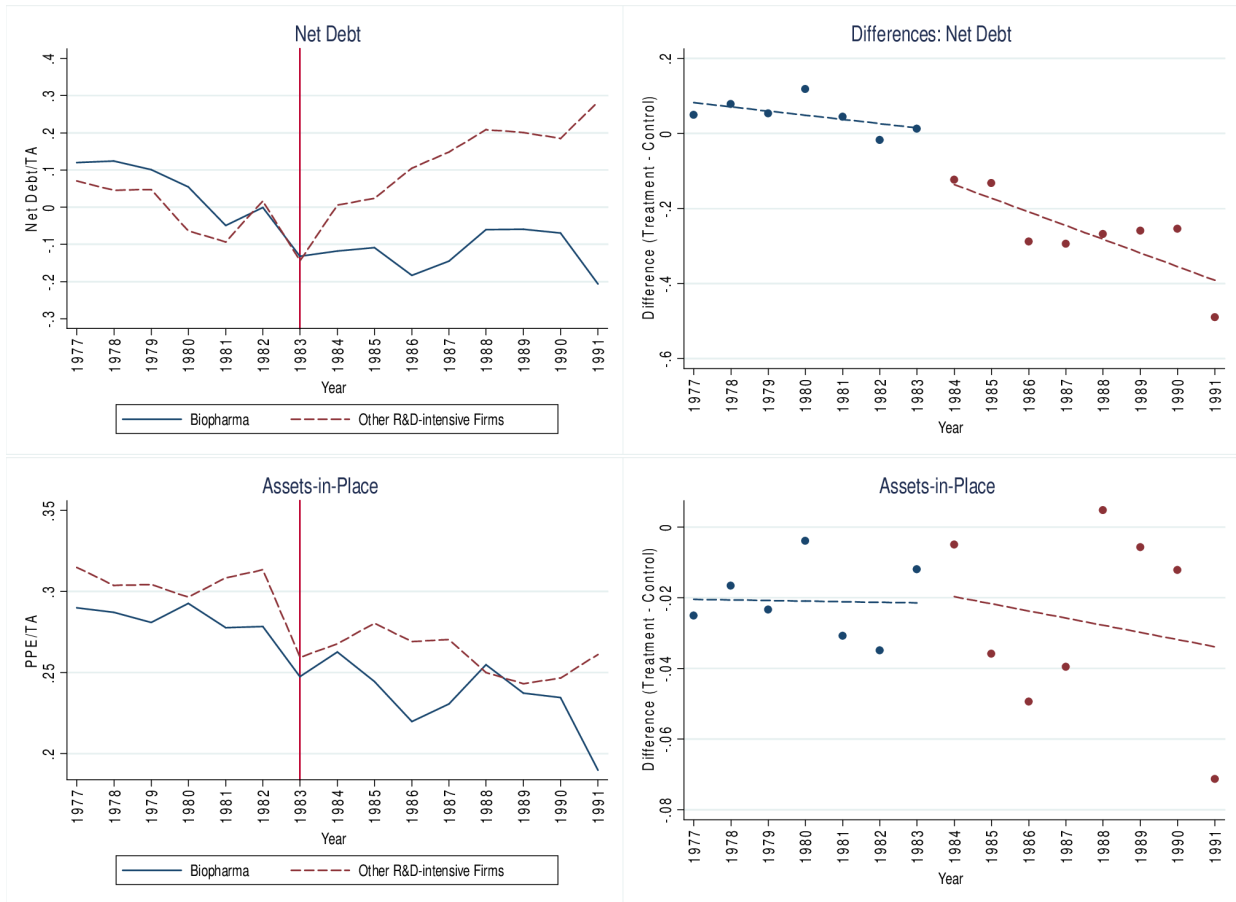


Figure 4: Innovation Trends for Treatment and Control Groups

Inter-industry trends for the number of total patents granted, citation-weighted patents, and the measure of economic value of patents granted (innovation value). The graphs on the left represent averages for each group. The solid blue lines give averages for the biopharma industry, while the red dashed lines give averages for the sample matched by propensity score of R&D-intensive firms. A vertical red line is included, representing the year that the Hatch-Waxman Act was implemented. The graphs on the right depict the differences between the treatment and control groups (treatment minus control), with pre- and post-period trend lines added.

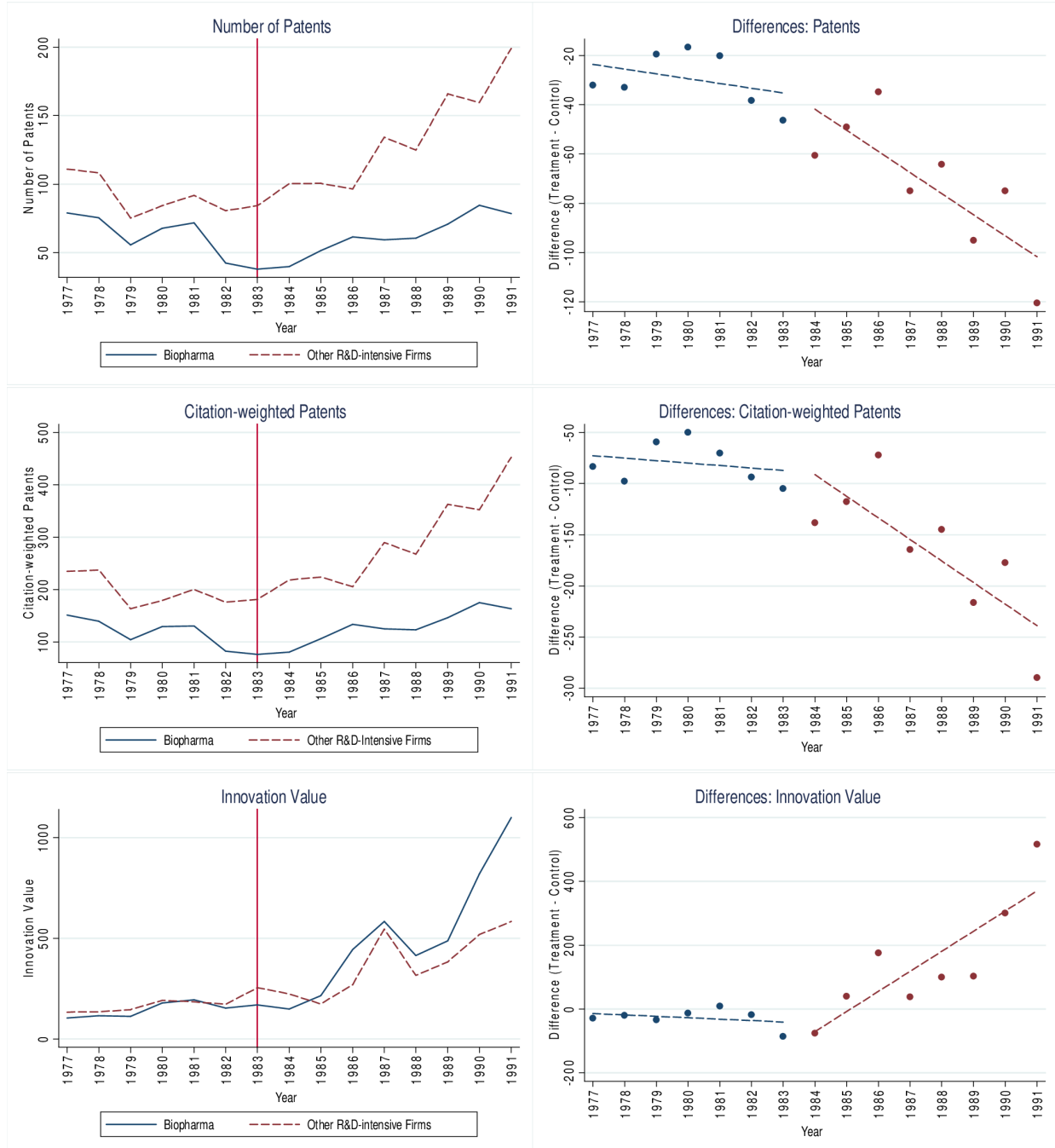


Table 1: Summary Statistics, Biopharma Firms over Time

This table provides summary statistics for biopharma firms from 1950 to 2016. $R\&D/TA$ is R&D expenditures scaled by total assets. PPE/TA is property, plant, and equipment scaled by total assets. $Cash/TA$ is cash and short-term investments scaled by total assets. $Debt/TA$ is debt, which is the sum of total long-term debt and short-term debt (debt in current liabilities), scaled by total assets. $Net\ Debt/TA$ is net debt scaled by total assets, where $Net\ Debt = Debt - Cash$. All variables run from 1950 to 2012. All variables are at the firm-year level, and are winsorized at the 1% level.

Variable	Obs	Mean	SD	p25	Median	p75
$R\&D/TA$	13,816	0.370	0.399	0.090	0.227	0.481
PPE/TA	14,821	0.152	0.165	0.022	0.094	0.238
$Cash/TA$	14,826	0.508	0.328	0.186	0.538	0.826
$Debt/TA$	14,745	0.285	0.544	0.000	0.078	0.292
$Net\ Debt/TA$	14,745	-0.207	0.740	-0.753	-0.338	0.061

Table 2: The Effect of the Hatch-Waxman Act on Biopharma and R&D-Intensive Firms

This table estimates the differences-in-differences regression (1) for financial characteristics. The sample consists of biopharma firms and a control group consisting of R&D-intensive firms matched by propensity score. The sample period spans from 1977 to 1991. The dependent variables consist of $R\&D$, PPE , $Cash$, $Debt$, and $Net\ Debt$, each scaled by total assets. HW_t is a dummy variable which takes a value of 1 if the year is 1984 or later, and a value of zero otherwise. $Biopharma_i$ is a dummy variable which takes a value of 1 if firm i is in the biopharma industry, and a value of 0 if it is in the control group. Control variables include $\log(NA)$, $EBITDA/TA$, M/B , Div/TA , and lagged values of PPE/TA , $Cash/TA$, $Debt/TA$, and $R\&D/TA$. Year and firm fixed effects are included where indicated, and a constant term is included in all regressions but not reported. Robust standard errors are given in parentheses, and standard errors are clustered at the firm level. *, **, and *** indicate significance at the 10%, 5%, and 1% level, respectively.

Dependent Variable:	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
	$R\&D$	$R\&D$	PPE	PPE	$Cash$	$Cash$	$Debt$	$Debt$	$Net\ Debt$	$Net\ Debt$
$HW_t \times Biopharma_i$	0.125*** (0.022)	0.024* (0.012)	-0.009 (0.019)	-0.004 (0.012)	0.212*** (0.027)	0.076*** (0.021)	-0.078* (0.043)	-0.040* (0.023)	-0.288*** (0.061)	-0.116*** (0.036)
$Biopharma_i$	0.004 (0.021)		-0.022 (0.023)		-0.003 (0.028)		0.031 (0.026)		0.035 (0.044)	
HW_t	0.019 (0.011)		-0.035** (0.014)		-0.061*** (0.019)		0.101*** (0.036)		0.163*** (0.049)	
Controls	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes
Firm Fixed Effects	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes
Year Fixed Effects	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes
Observations	2,768	2,156	3,083	2,174	3,083	2,174	3,075	2,172	3,075	2,172
Number of Firms	409	350	435	352	435	352	435	352	435	352
R^2	0.062	0.878	0.022	0.814	0.095	0.840	0.006	0.670	0.029	0.795

Table 3: The Effect of the Hatch-Waxman Act on Generic-focused and Other Pharma Firms

This table estimates a differences-in-differences regression for financial characteristics. The sample consists of pharma firms focused on generic drugs and a control group consisting of pharma firms matched by propensity score. The sample period spans from 1977 to 1991. The dependent variables consist of $R\&D$, PPE , $Cash$, $Debt$, and $Net\ Debt$, each scaled by total assets. HW_t is a dummy variable which takes a value of 1 if firm i takes a value of 1 if the year is 1984 or later, and a value of zero otherwise. $Generic_i$ is a dummy variable which takes a value of 1 if firm i is focused on generic drugs, and a value of 0 if it is in the control group. Control variables include $\log(NA)$, $EBITDA/TA$, M/B , Div/TA , and lagged values of PPE/TA , $Cash/TA$, $Debt/TA$, and $R\&D/TA$. Year and firm fixed effects are included where indicated, and a constant term is included in all regressions but not reported. Robust standard errors are given in parentheses, and standard errors are clustered at the firm level. *, **, and *** indicate significance at the 10%, 5%, and 1% level, respectively.

Dependent Variable:	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
	$R\&D$	$R\&D$	PPE	PPE	$Cash$	$Cash$	$Debt$	$Debt$	$Net\ Debt$	$Net\ Debt$
$HW_t \times Generic_i$	-0.035*** (0.012)	-0.008 (0.006)	0.024 (0.033)	0.018* (0.011)	-0.124** (0.054)	-0.057** (0.027)	0.066 (0.048)	0.008 (0.030)	0.187** (0.082)	0.064 (0.044)
$Generic_i$	0.004 (0.010)		0.007 (0.036)		0.001 (0.047)		-0.048 (0.042)		-0.046 (0.078)	
HW_t	0.045*** (0.010)		-0.027 (0.028)		0.128** (0.050)		-0.044 (0.040)		-0.171** (0.072)	
Controls	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes
Firm Fixed Effects	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes
Year Fixed Effects	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes
Observations	487	417	494	419	494	419	487	418	487	418
Number of Firms	42	41	42	41	42	41	42	41	42	41
R^2	0.119	0.823	0.012	0.879	0.079	0.733	0.013	0.733	0.044	0.796

Table 4: The Effect of the Hatch-Waxman Act on Biopharma Firms, Exposure to Competition

This table estimates a differences-in-differences regression for financial characteristics, examining the effect across biopharma firms based on their portfolios of approved drugs. The sample period spans from 1977 to 1991. The dependent variables consist of $R\&D$, PPE , $Cash$, $Debt$, and $Net\ Debt$, each scaled by total assets. HW_t is a dummy variable which takes a value of 1 if the year is 1984 or later, and a value of zero otherwise. $High\ Competition_i$ in Panel A is the proportion of firm i 's approved drugs that are in competitive therapeutic classes, defined as therapeutic classes that are in the top quartile in terms of number of approved drugs. $Low\ Concentration_i$ in Panel B is the proportion of firm i 's approved drugs that are in less-concentrated therapeutic classes, defined as therapeutic classes that are below-median in terms of concentration of drugs (measured through a Herfindahl Index of approved drugs in each class). Control variables include $\log(NA)$, $EBITDA/TA$, M/B , Div/TA , and lagged values of PPE/TA , $Cash/TA$, $Debt/TA$, and $R\&D/TA$. Year and firm fixed effects are included where indicated, and a constant term is included in all regressions but not reported. Robust standard errors are given in parentheses, and standard errors are clustered at the firm level. *, **, and *** indicate significance at the 10%, 5%, and 1% level, respectively.

<i>Panel A: Biopharma Firms with Drugs in Competitive Therapeutic Classes</i>					
Dependent Variable:	(1)	(2)	(3)	(4)	(5)
	$R\&D$	PPE	$Cash$	$Debt$	$Net\ Debt$
$HW_t \times High\ Competition_i$	-0.012 (0.033)	-0.042* (0.024)	0.126*** (0.044)	-0.067 (0.050)	-0.194** (0.082)
Controls	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes
Observations	1,459	1,468	1,468	1,466	1,466
Number of Firms	261	262	262	262	2362
R^2	0.877	0.773	0.839	0.645	0.793

<i>Panel B: Biopharma Firms with Drugs in Less-concentrated Therapeutic Classes</i>					
Dependent Variable:	(1)	(2)	(3)	(4)	(5)
	$R\&D$	PPE	$Cash$	$Debt$	$Net\ Debt$
$HW_t \times Low\ Concentration_i$	-0.009 (0.026)	-0.052** (0.022)	0.118*** (0.042)	-0.026 (0.048)	-0.145* (0.077)
Controls	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes
Observations	1,459	1,468	1,468	1,466	1,466
Number of Firms	261	262	262	262	262
R^2	0.877	0.774	0.839	0.644	0.792

Table 5: The Effect of the Hatch-Waxman Act on Biopharma Firms, Exposure to Competition Split by Profitability

This table estimates a differences-in-differences regression for financial characteristics, examining the effect across biopharma firms based on their approved drug portfolios, split by firms with profitability above or below the median. The sample period spans from 1977 to 1991. The dependent variables consist of $R\&D$, PPE , $Cash$, $Debt$, and $NetDebt$, each scaled by total assets. HW_t is a dummy variable which takes a value of 1 if the year is 1984 or later, and a value of zero otherwise. $HighCompetition_i$ is the proportion of firm i 's approved drugs that are in competitive therapeutic classes, defined as therapeutic classes that are in the top quartile in terms of number of approved drugs. Results are split by whether a firm is above or below the median in terms of their profitability ($EBITDA/TA$) in 1983. Control variables include $\log(NA)$, $EBITDA/TA$, M/B , Div/TA , and lagged values of PPE/TA , $Cash/TA$, $Debt/TA$, and $R\&D/TA$. Year and firm fixed effects are included where indicated, and a constant term is included in all regressions but not reported. Robust standard errors are given in parentheses, and standard errors are clustered at the firm level. *, **, and *** indicate significance at the 10%, 5%, and 1% level, respectively.

Dependent Variable:	Below-median Profitability					Above-median Profitability				
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
$HW_t \times HighCompetition_i$	$R\&D$	PPE	$Cash$	$Debt$	$NetDebt$	$R\&D$	PPE	$Cash$	$Debt$	$NetDebt$
	0.059*	-0.082	0.274***	0.030	-0.245*	-0.016	-0.015	0.037	-0.018	-0.056
	(0.032)	(0.058)	(0.069)	(0.081)	(0.139)	(0.010)	(0.015)	(0.036)	(0.039)	(0.056)
Controls	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Observations	438	441	441	441	441	534	537	537	535	535
Number of Firms	58	58	58	58	58	52	52	52	52	52
R^2	0.869	0.689	0.790	0.573	0.743	0.858	0.848	0.727	0.742	0.760

Table 6: Differences-in-Differences Regressions, Measures of Innovation

This table estimates the differences-in-differences regression (1) for measures of innovation. The sample consists of biopharma firms and a control group consisting of R&D-intensive firms matched by propensity score. The sample period spans from 1977 to 1991. The dependent variables consist of *patents* (the number of patents), *cw patents* (the number of citation-weighted patents), and *Innovation Value* (the market value of new patents). HW_t is a dummy variable which takes a value of 1 if the year is 1984 or later, and a value of zero otherwise. $Biopharma_i$ is a dummy variable which takes a value of 1 if firm i is in the biopharma industry, and a value of 0 if it is in the control group. Control variables include $\log(NA)$, $EBITDA/TA$, M/B , Div/TA , and lagged values of PPE/TA , $Cash/TA$, $Debt/TA$, $R\&D/TA$, and the respective dependent variables. Year and firm fixed effects are included where indicated, and a constant term is included in all regressions but not reported. Robust standard errors are given in parentheses, and standard errors are clustered at the firm level. *, **, and *** indicate significance at the 10%, 5%, and 1% level, respectively.

	(1)	(2)	(3)	(4)	(5)
Dependent Variable:	<i>patents</i>	$\log(1 + \textit{patents})$	<i>cw patents</i>	$\log(1 + \textit{cw patents})$	<i>Innovation Value</i>
$HW_t \times Biopharma_i$	-17.152** (7.157)	-0.210*** (0.077)	-35.796** (15.018)	-0.263** (0.120)	73.256** (35.520)
Controls	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes
Observations	604	604	604	604	604
Number of Firms	69	69	69	69	69
R^2	0.968	0.968	0.963	0.945	0.885

Table 7: Within-industry Differences-in-Differences Regressions, Generic-focused and Other Pharma Firms

This table estimates the differences-in-differences regression (1) for measures of innovation between firms within the biopharma industry. The sample includes pharma firms focused on generic drugs and a control group consisting of pharma firms matched by propensity score. The sample period spans from 1977 to 1991. The dependent variables consist of *patents* (the number of patents), *cw patents* (the number of citation-weighted patents), and *Innovation Value* (the market value of new patents). HW_t is a dummy variable which takes a value of 1 if the year is 1984 or later, and a value of zero otherwise. $Generic_i$ is a dummy variable which takes a value of 1 if firm i is focused on generic drugs, and a value of 0 if it is in the control group. Control variables include $\log(NA)$, $EBITDA/TA$, M/B , Div/TA , and lagged values of PPE/TA , $Cash/TA$, $Debt/TA$, $R\&D/TA$, and the respective dependent variable. Year and firm fixed effects are included where indicated, and a constant term is included in all regressions but not reported. Robust standard errors are given in parentheses, and standard errors are clustered at the firm level. *, **, and *** indicate significance at the 10%, 5%, and 1% level, respectively.

	(1)	(2)	(3)	(4)	(5)
Dependent Variable:	<i>patents</i>	$\log(1 + \textit{patents})$	<i>cw patents</i>	$\log(1 + \textit{cw patents})$	<i>Innovation Value</i>
$HW_t \times Generic_i$	9.809 (13.946)	0.226* (0.127)	41.740** (18.724)	0.382** (0.158)	-72.549 (66.639)
Controls	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes
Observations	215	215	215	215	215
Number of Firms	23	23	23	23	23
R^2	0.916	0.970	0.885	0.948	0.908

Table 8: Within-industry Differences-in-Differences Regressions, Exposure to Competition Split by Profitability

This table estimates the differences-in-differences regression (1) for measures of innovation between firms within the biopharma industry. The sample period spans from 1977 to 1991. The dependent variables consist of *patents* (the number of patents), *cw patents* (the number of citation-weighted patents), and *Innovation Value* (the market value of new patents). HW_t is a dummy variable which takes a value of 1 if the year is 1984 or later, and a value of zero otherwise. $High\ Competition_i$ is the proportion of firm i 's approved drugs that are in competitive therapeutic classes, defined as therapeutic classes that are in the top quartile in terms of number of approved drugs; results shown for firms that are below the median (Panel A) and above the median (Panel B) in terms of their average profitability ($EBITDA/TA$) prior to 1984. Control variables include $\log(NA)$, $EBITDA/TA$, M/B , Div/TA , and lagged values of PPE/TA , $Cash/TA$, $Debt/TA$, $R\&D/TA$, and the respective dependent variable. Year and firm fixed effects are included where indicated, and a constant term is included in all regressions but not reported. Robust standard errors are given in parentheses, and standard errors are clustered at the firm level. *, **, and *** indicate significance at the 10%, 5%, and 1% level, respectively.

<i>Panel A: Below-median Profitability Firms</i>					
	(1)	(2)	(3)	(4)	(5)
Dependent Variable:	<i>patents</i>	$\log(1 + \textit{patents})$	<i>cw patents</i>	$\log(1 + \textit{cw patents})$	<i>Innovation Value</i>
$HW_t \times High\ Competition_i$	-34.973 (22.254)	-1.274*** (0.409)	-106.535** (41.280)	-2.336*** (0.720)	78.123** (33.531)
Controls	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes
Observations	148	148	148	148	148
R^2	0.967	0.931	0.854	0.866	0.922
<i>Panel B: Above-median Profitability Firms</i>					
	(1)	(2)	(3)	(4)	(5)
Dependent Variable:	<i>patents</i>	$\log(1 + \textit{patents})$	<i>cw patents</i>	$\log(1 + \textit{cw patents})$	<i>Innovation Value</i>
$HW_t \times High\ Competition_i$	17.380 (13.704)	0.277 (0.189)	55.096* (30.187)	0.455* (0.243)	138.862* (69.392)
Controls	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes
Observations	198	198	198	198	198
R^2	0.908	0.955	0.873	0.936	0.906

Appendix A: Analysis of the Formal Theoretical Model

A.1 Actors and Preferences

Consider a biopharmaceutical firm that faces a decision to undertake a staged R&D investment. There are two periods with three dates: $t = 0$, $t = 1$, and $t = 2$. At $t = 0$, the firm chooses an amount to invest in either assets in place (such as existing products) or in R&D (for new products). If it chooses to invest in an R&D project, the project has two stages. At $t = 0$, the first-stage investment is made. At $t = 1$, the second-stage investment is made.

At both of these dates, the firm may need to raise capital and can choose between issuing equity and debt. This external financing is raised in an environment of adverse selection. Specifically, there are two types of firms: good firms and lemons. The common prior is that the probability of a randomly chosen firm being good is $g \in (0.5, 1)$ and being a lemon is $1 - g$.⁶² The lemons are firms that lack the ability to produce R&D products, so their R&D investment produces no payoffs and their assets decline in value over time and also produce no cash flows.⁶³ The good firms are described below. The firm *privately* knows at $t = 0$ whether it is good or a lemon. Given this private information, we will model this as a game in which the informed firm moves first with its capital structure decision about how much financing to raise for R&D (and when to raise it). The uninformed capital market reacts to the firm's choice, and makes Bayesian rational inferences about the firm's payoffs, which then result in prices for the firm's securities.

At the final date, $t = 2$, all payoffs are realized, and shareholders and bondholders are paid off.

All agents are risk-neutral. The risk-free rate for a single period is $r > 0$ and is intertemporally constant.

⁶²The lower bound on g is to avoid a corner solution by ensuring that there are sufficiently many good firms to allow financing to be raised.

⁶³This could be due to mismanagement or outright fraud. The lemons are able to produce what appears to be successful first-stage R&D results, but the R&D is still worthless for these firms, since they are not able to produce any cash flows.

A.2 Investment Choices and the Effect of Competition

Let $A > 0$ denote the firm's investment in existing products and assets in place, and $R > 0$ its investment in R&D. Given managerial capacity constraints, we take the total investment size to be fixed at I . Thus, $A + R = I$, so the firm invests a certain proportion of its capital in assets in place and the remaining proportion in R&D. Our goal is to examine how A and R are determined. Since we are modeling an R&D-intensive firm, we can think of A as consisting mainly of existing patents and products on which patents have expired, but the products are still being produced and sold.

There are two states of the macroeconomy: an “up” state and a “down” state. The up state occurs with probability p , and the down state occurs with probability $1 - p$. When the up state occurs, the firm's existing products pay off $x_H(A)$, and when the down state occurs they pay off $x_L(A)$, with $x_H(A) > x_L(A) \forall A > 0$. That is, the payoff from existing products is perfectly correlated with the state of the economy. It is assumed that the NPV of investing in assets in place is non-negative, even if the down state occurs: $x_L(A)[1 + r]^{-2} \geq A \forall A$. We impose the standard assumptions on the production function $x(A)$:

$$\begin{aligned} \partial x_H / \partial A > \partial x_L / \partial A > 0, \quad \partial^2 x_H / \partial A^2 < 0, \\ \partial^2 x_L / \partial A^2 < 0, \quad |\partial^2 x_H / \partial A^2| > |\partial^2 x_L / \partial A^2|, \end{aligned} \tag{2}$$

We now model the effect of product market competition. If the degree of competition is $\theta \in [\underline{\theta}, \bar{\theta}]$, then a competitor arrives with probability θ . If this happens, the firm's profitability on existing products declines. Thus, a higher θ means greater product market competition.⁶⁴ For simplicity, we assume that when a competitor enters, the payoff of assets

⁶⁴In our model, changes in competition θ can be interpreted as structural changes in the industry or other changes in competition that are exogenous to the individual firm. Important drivers of competition to industries such as biopharma are exogenous technology or regulatory shocks that lower entry costs. For example, the Human Genome Project represented a technology shock that was plausibly exogenous to any individual firm's decision, and it led to the entry of numerous small biotech firms into the industry. Another example is the Hatch-Waxman Act, which was a source of exogenous variation in competition for the biopharma industry, and something we use for identification purposes later in our analysis. However, since

in place in the up state becomes $x_L(A)$, an effect analogous to Bertrand competition.⁶⁵ This can be interpreted as a decline in the maximum markup firms will charge when competition increases.

Investment in R&D involves two phases. At $t = 0$, the firm makes its first-stage R&D investment R . Then, if it observes at $t = 1$ that the successful state has occurred for R&D, it must invest a larger additional amount $\hat{\omega}R$, $\hat{\omega} > 1$, in order to realize the payoff conditional on success. This larger second investment reflects the escalating resource commitments for subsequent clinical R&D trials that biopharma firms face (see DiMasi, et al. (1991)). Absent this second-stage investment, the R&D payoff at $t = 2$ is zero.

If the firm invests R in R&D at $t = 0$, then at $t = 1$ it becomes publicly known whether the first-stage R&D was very successful, modestly successful, or failed. The probability of the first-stage R&D being very successful is $q_+ \in (0, 1)$, the probability of it being modestly successful is $q_- \in (0, 1)$, and the probability of failure is $1 - q_+ - q_-$. However, this observation does not resolve the uncertainty about whether the firm is good or a lemon, since the lemon firm can be in each of these three observable first-stage R&D outcome states as well, just like the good firm. If the firm is truly a lemon, however, then the second-stage R&D payoff is zero at $t = 2$, regardless of the first-stage R&D outcome at $t = 1$. If the firm is good, then the R&D payoff at $t = 2$ is a random variable \tilde{y} , where \tilde{y} is zero almost surely if the first-stage R&D fails at $t = 1$, has a probability density ξ_+ if the first-stage R&D is very successful at $t = 1$, and a probability density ξ_- if the first-stage R&D is modestly successful at $t = 1$. We assume that ξ_+ first-order stochastically dominates ξ_- . The expected payoffs are:

$$\int \tilde{y} \xi_+ d\tilde{y} = y_+(R) + B > 0, \quad (3)$$

R&D by incumbents can also affect the degree of competition, some portion of the degree of competition is endogenous (e.g., Gans and Stern (2000)). Our empirical tests are designed to tackle this potential endogeneity.

⁶⁵In other words, the incumbent firm and the competitor would each set their prices for existing products lower in order to undercut each other, thus reducing profitability. We model this directly through a reduction in profitability. Although not necessary for the analysis, we could assume that the present value of $x_L(A)$ is A , i.e., that competition reduces the NPV of existing assets to zero. This would correspond to the situation in Bertrand competition, where firms set their prices equal to their marginal costs.

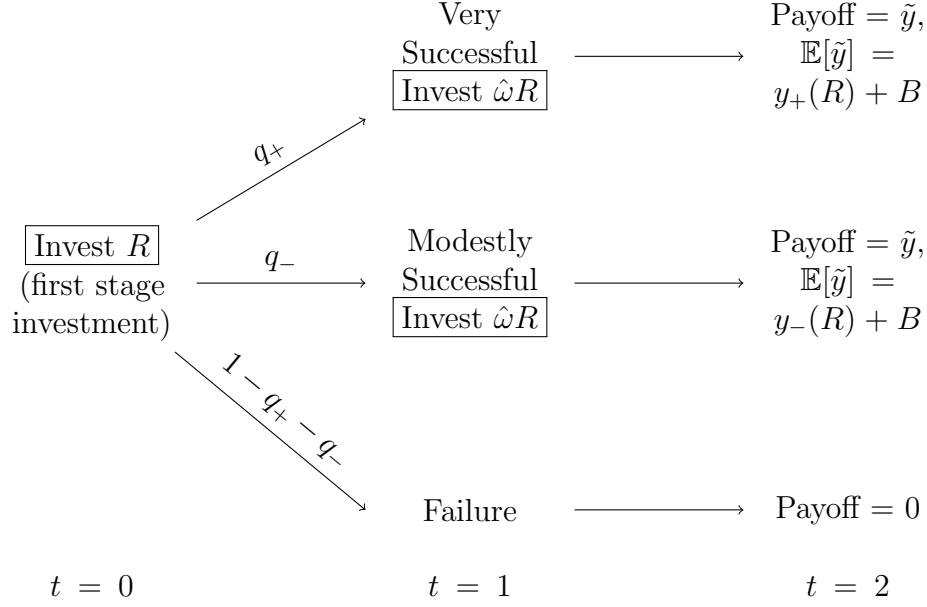


Figure A1: R&D Payoff Distribution Over Time

$$\int \tilde{y} \xi_- d\tilde{y} = y_-(R) + B > 0, \quad (4)$$

where $y_+(R) > y_-(R) \forall R > 0$, $y_+(0) = y_-(0) = 0$, and $B > 0$ is a non-contractible benefit of R&D to the insiders of the firm that cannot be verified and pledged to investors to make payments. We interpret B broadly to represent intangible knowledge payoffs that do not necessarily produce cash flows immediately, such as learning benefits for employees, generation of non-commercializable basic research knowledge, or potential future payoffs that may be expected to occur beyond the investment horizons of investors. We assume that the larger the investment in R&D, the larger the expected payoff:

$$\partial y_+ / \partial R > 0, \quad \partial y_- / \partial R > 0,$$

$$\partial^2 y_+ / \partial R^2 < 0, \quad \partial^2 y_- / \partial R^2 < 0. \quad (5)$$

The R&D payoff distribution is given in *Figure A1*.

We assume that R&D output is patent-protected, and hence immune to competitive

pressures. Thus, the arrival of the competitor has no impact on the firm's R&D payoff.⁶⁶ In other words, changes in θ affect the profitability of existing assets, which have largely exhausted their patent protection, and are thus vulnerable to competitive pressures, relative to new, patent-protected drugs that have greater immunity to competitive pressures. This assumption is consistent with the effect of the Hatch-Waxman Act on patent-possessing firms that exploit in our empirical analysis.

The payoffs of assets in place and R&D are taxable at a rate of $T \in (0, 1)$. We assume that the cash flows of the R&D investment of the good firm (i.e. the pledgeable portion of the payoff) create value, and thus there is positive NPV at $t = 0$ to the firm's insiders as well as investors, so:

$$[q_+y_+ + q_-y_-][1+r]^{-2}(1-T) > R + \hat{\omega}R[1+r]^{-1} \quad \forall R > 0. \quad (6)$$

We further assume that

$$\hat{g}y_-[1+r]^{-1}(1-T) < \hat{\omega}R, \quad (7)$$

$$y_-[1+r]^{-1}(1-T) + B > \hat{\omega}R + R, \quad (8)$$

$$B < \hat{\omega}R. \quad (9)$$

where \hat{g} is the posterior belief of investors that the firm is good, conditional on a good signal being received by bondholders; \hat{g} will be expressed explicitly later. Condition (7) implies that investors will be unwilling to provide financing at $t = 1$ if the R&D is discovered to have either failed or is only modestly successful, even if the bondholders' signal is good. Condition (8) implies that the firm's insiders will wish to invest $\hat{\omega}R$ at $t = 1$ even if the R&D is discovered to be modestly successful, and will also view this investment as beneficial at $t = 0$, taking into account the initial investment of R . Finally, condition (9) ensures that the value of the non-contractible benefits to insiders is not so large as to justify an investment

⁶⁶Of course, when the patent expires, these products become part of the firm's assets in place and are then subject to losses in profits due to competitive entry.

with no cash flow payoff.

A.3 Financing Choices

The firm has no internal funds available at $t = 0$. Therefore, in order to finance the existing product line and R&D, it raises all the necessary financing by issuing debt and equity at $t = 0$ and $t = 1$, which then determines its capital structure.

Shareholders will be paid off at $t = 2$. In order to raise equity, the firm's initial shareholders, who we treat as insiders, and who have no wealth of their own to invest, must give up ownership $\alpha \in (0, 1)$ in order to raise the necessary capital. At any date ($t = 0$ or $t = 1$), shareholder unanimity is needed to approve a decision to raise capital. Thus, at $t = 0$ this decision is made to maximize the wealth of the insiders (initial owners) plus the value of their non-contractible benefits, B . At $t = 1$, this decision will require those who became shareholders at $t = 0$ to also approve. Those new shareholders are pure investors who do not get any of the non-contractible benefits of R&D enjoyed by insiders, benefits that include knowledge generation, learning, etc.

If the firm issues debt, the face value of debt to be repaid at $t = 2$ is F . The initial debt financing raised is D . Although bondholders cannot distinguish between good firms and lemons at $t = 0$, they receive a noisy signal ϕ at $t = 1$ that indicates whether the firm is good or a lemon. The probability distribution of ϕ is:

$$\Pr(\phi = \text{good} \mid \text{firm is good}) = \Pr(\phi = \text{lemon} \mid \text{firm is a lemon}) = \delta \in (0.5, 1). \quad (10)$$

Upon receiving their signal, the bondholders can choose to wait until $t = 2$ to be paid, or to demand early repayment at $t = 1$ at a cost $c > 0$. If repayment occurs at $t = 1$ the bondholders are paid $F_1 \equiv F[1 + r]^{-1} < F$. In equilibrium, since the firm produces no cash flows at $t = 1$, the firm is liquidated to meet any repayment at $t = 1$ (if this is demanded) because it cannot meet the face value owed to bondholders. This modeling setup for debt

parallels that of Calomiris and Kahn (1991). If the firm is a good firm, but is erroneously liquidated at $t = 1$ and the R&D is stopped, then all that can be recovered is the present value of the smallest payoff from the assets in place, $x_L(A)[1 + r]^{-1}$, plus any cash on hand, where we discount at the riskless rate because liquidation is analogous to making the asset payoff the minimum in all states. If the firm is a lemon, then only the salvage value of assets in place can be recovered. Let this salvage value be $S \in (0, A)$. The value of the assets recovered in liquidation at $t = 1$ can only be determined after the liquidation is completed. We assume that:

$$\frac{[1 - g][1 - \delta]S}{g\delta + [1 - g][1 - \delta]} < c < \frac{[1 - g]\delta}{[1 - g]\delta + [1 - \delta]g}. \quad (11)$$

We will show that (11) is sufficient to ensure that bondholders will liquidate the firm when $\phi = \text{lemon}$, but not when $\phi = \text{good}$. We assume that all debt payments are tax deductible at the corporate tax rate T . For debt to be tax deductible, the face value of the debt issued at $t = 0$ cannot exceed the total amount of financing raised at $t = 0$.⁶⁷ The variables D , F , and α will all be endogenously determined.

We will assume henceforth that certain parametric restrictions hold:

$$\delta < \bar{\delta} \in (0.5, 1), \quad B > \bar{B}, \quad (12)$$

where $\bar{\delta}$ is an upper bound and \bar{B} is a lower bound. Thus, (12) implies that the non-contractible benefit of R&D to insiders is sufficiently high. The upper bound on δ means that there is sufficient noise in the bondholders' signal.

⁶⁷This is meant to capture the IRS limit on how much of a firm's financing can count as debt for tax purposes.

A.4 Analysis of the Model

We now present our analysis of the model. Throughout the analysis, we will focus on the good firms, since the lemons will always mimic the strategy of the good firm in equilibrium, and acting otherwise would unambiguously reveal them. Nonetheless, the presence of the lemons is needed for the liquidation strategy of the bondholders to be privately optimal for them in the continuation game.

We begin by presenting preliminary results in which we take as a given A^* and R^* , the investments by the firm in assets in place and R&D, as well as a conjectured face value of debt issued at $t = 0$. We subsequently verify these equilibrium values. Because taxes play no role in the first two results, we set $T = 0$ without loss of generality for now. The equilibrium for these choices and beliefs at $t = 0$ is a perfect Bayesian Nash equilibrium.⁶⁸

Lemma 1: *Fix the optimal values of investments A^* and R^* by the firm in assets in place and R&D, respectively. Suppose the firm issues debt with face value $F = x_L(A^*)$. Then it will be rational (privately optimal) for the bondholders to liquidate the firm at $t = 1$ if their signal is $\phi = \text{lemon}$, and allow it to continue if their signal is $\phi = \text{good}$.*

Proof: Suppose the bondholders' signal at $t = 1$ says $\phi = \text{lemon}$. Let

$$\hat{g}_l = \Pr(\text{firm is good} \mid \phi = \text{lemon}) = \frac{[1 - \delta]g}{[1 - \delta]g + [1 - g]\delta}. \quad (13)$$

For the bondholders to wish to liquidate the firm at $t = 1$, it must be true that:

$$[1 - \hat{g}_l]S + \hat{g}_l [x_L(A^*) [1 + r]^{-1}] - c > \hat{g}_l x_L(A^*) [1 + r]^{-1}, \quad (14)$$

where the left-hand side of (14) is the expected value of what the bondholders collect at $t = 1$ and the right-hand side is the expected present value of what the bondholders collect

⁶⁸The equilibrium of our focus also satisfies the conditions of sequential equilibrium (Kreps and Wilson (1982)) and the universal divinity refinement of Banks and Sobel (1987); details of the proofs of the characterized outcomes satisfying the universal divinity refinement are available upon request.

if they wait until $t = 2$. We see that (14) simplifies to

$$\left\{ \frac{[1-g]\delta}{[1-\delta]g + [1-g]\delta} \right\} S > c, \quad (15)$$

which we know holds by (11). Now suppose the bondholders' signal at $t = 1$ is $\phi = \text{good}$. Let \hat{g} be the posterior belief of the bondholders that the firm is good after having observed this signal. For the bondholders not to liquidate the firm, we need

$$[1 - \hat{g}] S + \hat{g} [x_L(A^*) [1 + r]^{-1}] - c < \hat{g} x_L(A^*) [1 + r]^{-1}, \quad (16)$$

where

$$\hat{g} = \frac{\delta g}{\delta g + [1 - \delta][1 - g]} < c. \quad (17)$$

Substituting (17) into (16), we see that we need

$$\frac{[1 - \delta][1 - g]S}{\delta g + [1 - \delta][1 - g]} < c, \quad (18)$$

which holds by (11). ■

Lemma 2: *Fix the optimal values of investments A^* and R^* by the firm in assets in place and R&D, respectively. Suppose the firm issues debt with face value $F = x_L(A^*)$. Then, for B large enough, it will prefer to raise at $t = 0$ the present value of the second-stage financing that will be needed at $t = 1$, and hold it as cash (invest it in the riskless asset) rather than wait until $t = 1$ to raise the financing.*

Proof: Given this F , it is clear that in the down state of the economy for the assets in place, (7) implies that the firm will be unable to raise second-stage financing for its R&D at $t = 1$ if the R&D is modestly successful and the expected R&D payoff at $t = 2$ is $y_-(R^*)$. We will compare the net benefit to the insiders from issuing equity at $t = 0$ to raise $\hat{\omega}R[1 + r]^{-1}$ in financing with the net benefit to them of issuing equity at $t = 1$ to raise the necessary

financing. Consider first the case of raising financing at $t = 0$, and let $\hat{\alpha} \in (0, 1)$ be the fraction of ownership given up in order to raise $\hat{\omega}R[1 + r]^{-1}$. Thus, the competitive pricing condition implies

$$\hat{\omega}R[1 + r]^{-1} = \hat{\alpha}gV_E, \quad (19)$$

where we define $V_E = [\delta\Omega_0 + [1 - \delta]\hat{\omega}R[1 + r]^{-1}]$ and (suppressing the arguments of functions):

$$\Omega_0 \equiv [1 + r]^{-1} [q_+y_+ + q_-y_-] + p[1 - \theta] [x_H - x_L] [1 + K]^{-2} + [1 - q_+ - q_-] \hat{\omega}R[1 + r]^{-1}. \quad (20)$$

So V_E is the true value of the good firm's equity at $t = 0$ as assessed by the insiders. Ω_0 can be understood as follows. The first term is the expected present value of the R&D payoff, the second term is present value of assets in place (where we recognize that $F = x_L$), and the third term is the additional R&D financing raised at $t = 0$ that remains idle at $t = 1$ because the R&D fails the first-stage. The market value of this equity is $g\delta V_E$ because the market assesses the probability of the firm being good as g , and δ is the probability that a good firm will be allowed to continue. Note that $1 - \delta$ is the probability that a good firm will be liquidated, in which case $x_L + \hat{\omega}R$ is recovered. Since $F = x_L$, the shareholders only collect $\hat{\omega}R$, with present value $\hat{\omega}R[1 + r]^{-1}$ at $t = 0$. This explains the $[1 - \delta]\hat{\omega}R[1 + r]^{-1}$ term in V_E in (19). Thus,

$$\hat{\alpha} = \frac{\hat{\omega}R[1 + r]^{-1}}{gV_E}. \quad (21)$$

The net wealth of the insiders plus the non-contractible benefits from raising extra financing at $t = 0$ is:

$$NW_0 = [1 - \hat{\alpha}] V_E + \delta [q_+ + q_-] B, \quad (22)$$

where $\delta [q_+ + q_-]$ is the probability that the extra R&D investment will be made at $t = 1$ and the R&D will be continued. Thus, substituting (21) into (22):

$$\begin{aligned} NW_0 &= V_E - \hat{\omega}R[1+r]^{-1}g^{-1} + \delta [q_+ + q_-] B \\ &= \delta\Omega_0 - \hat{\omega}R[1+r]^{-1} \{g^{-1} - [1-\delta]\} + \delta [q_+ + q_-] B. \end{aligned} \quad (23)$$

Now consider financing at $t = 1$. There are two possible states related to the assets in place: the up state and the down state. Moreover, financing will only be raised if: (i) the bondholders' signal $\phi = \text{good}$, and (ii) the R&D has been discovered to be very successful. Given (7) and the need for approval from those who became new shareholders at $t = 0$ by purchasing the equity issued by the firm then, it is clear that no financing can be raised at $t = 1$ if the R&D is only modestly successful. If $\phi = \text{good}$, the posterior belief of the bondholders about the firm's type becomes

$$\hat{g} = \Pr(\text{firm is good} \mid \phi = \text{good}) = \frac{\delta g}{\delta g + [1-\delta][1-g]}. \quad (24)$$

Let α_u be the ownership the firm must surrender at $t = 1$ in the up-state to raise $\hat{\omega}R$ then.

This means

$$\alpha_u \hat{g} \{y_+ + [x_H - x_L]\} [1+r]^{-1} = \hat{\omega}R, \quad (25)$$

which implies that

$$\alpha_u = \frac{\hat{\omega}R}{\hat{g}V_u^1}, \quad (26)$$

where

$$V_u^1 \equiv \{y_+ + [x_H - x_L]\} [1+r]^{-1}. \quad (27)$$

If α_d is the ownership the firm must surrender at $t = 1$ in the down state to raise $\hat{\omega}R$, then

$\alpha_d \hat{g} y_+ [1+r]^{-1} = \hat{\omega} R$, which implies

$$\alpha_d = \frac{\hat{\omega} R}{\hat{g} V_d^1}, \quad (28)$$

where

$$V_d^1 \equiv y_+ [1+r]^{-1}. \quad (29)$$

For the firm's insiders at $t = 0$, their expected wealth from pursuing this strategy is

$$\begin{aligned} \mathbb{E}[NW_1] &= \delta \{q_+ p [1-\theta] [1-\alpha_u] V_u^1 + [1-q_+] [x_H - x_L] [1+r]^{-1}\} \\ &\quad + \delta \{q_+ [1-p[1-\theta]] [1-\alpha_d] V_d^1 + q_+ B\}, \end{aligned} \quad (30)$$

where we note that the non-contractible rent B is available to insiders only if the R&D is very successful. Expressing \hat{V}_u^1 and \hat{V}_d^1 as the date-0 present values of V_u^1 and V_d^1 respectively, we can write

$$\hat{V}_u^1 = \{y_+ + [x_H - x_L]\} [1+r]^{-2}, \quad (31)$$

$$\hat{V}_d^1 = y_+ [1+r]^{-2}. \quad (32)$$

Simplifying (30) by substituting (26) and (28), we get

$$\begin{aligned} \mathbb{E}[NW_1] &= \delta \{q_+ p [1-\theta] V_u^1 - q_+ p [1-\theta] \hat{\omega} R \hat{g}^{-1} + q_+ [1-p[1-\theta]] V_d^1\} \\ &\quad + \delta \{-q_+ [1-p[1-\theta]] \hat{\omega} R \hat{g}^{-1} + q_+ B + [1-q_+] [x_H - x_L] [1+r]^{-1}\}. \end{aligned} \quad (33)$$

Simplifying, we can write the present value (at $t = 0$) of $\mathbb{E}[NW_1]$ as:

$$\begin{aligned} \hat{\mathbb{E}}[NW_1] &= \delta \{q_+ p [1-\theta] \hat{V}_u^1 + q_+ [1-p[1-\theta]] \hat{V}_d^1\} \\ &\quad + \delta \{-q_+ [1+r]^{-1} \hat{\omega} R \hat{g}^{-1} + q_+ B + [1-q_+] [x_H - x_L] [1+r]^{-2}\}. \end{aligned} \quad (34)$$

The firm's insiders will prefer to raise the extra R&D financing at $t = 0$ rather than at

$t = 1$ if $NW_0 > \hat{\mathbb{E}}[NW_1]$, where NW_0 is defined in (23). Upon simplification, this condition becomes

$$q_- [B + y_- [1 + r]^{-2}] > \hat{\omega}R[1 + r]^{-1} \left\{ \frac{1}{g\delta + [1 - \delta][1 - g]} - \frac{1 - \delta}{\delta} - [1 - q_-] \right\}, \quad (35)$$

which holds for B large enough. ■

Let F be the face value of debt if the bondholders wait until $t = 2$ to be repaid, and let F_1 be the face value if they ask to be repaid at $t = 1$. We can now write down the firm's maximization problem, taking as a given that it will raise $R + \hat{\omega}R[1 + r]^{-1}$ for its R&D and A for its assets in place through a mix of debt and equity financing at $t = 0$. The value of equity as assessed by insiders at $t = 0$ is similar to the way it was expressed in the proof of Lemma 2:

$$\begin{aligned} V_E &= [1 - T]\delta\{[1 + r]^{-2} [q_+y_+(R) + q_-y_-(R)] + p[1 - \theta] [x_H(A) - F] [1 + r]^{-2} \\ &\quad + [1 - p[1 - \theta]] [x_L(A) - F] [1 + r]^{-2} + [1 - q_+ - q_-] \hat{\omega}R[1 + r]^{-1}\} \\ &\quad + [1 - T][1 + r]^{-1}[1 - \delta] \max\{0, \hat{\omega}R + x_L(A)[1 + r]^{-1} - F_1\}, \end{aligned} \quad (36)$$

where we recognize that a good firm will be liquidated at $t = 1$ with probability $1 - \delta$ by the bondholders, and the value of equity in this case will be equivalent to a call option on the liquidation value of the assets with a strike price equal to what bondholders are owed, F_1 .

If α is the fraction of equity surrendered in addition to F , the face value of debt to raise $A + R + \hat{\omega}R[1 + r]^{-1}$ at $t = 0$, then α satisfies:

$$\alpha V_E(A^*, R^*) = A^* + R^* + \hat{\omega}R^*[1 + r]^{-1} - D, \quad (37)$$

where D is the amount of debt financing raised at $t = 0$. So D satisfies:

$$D = \text{PV} \left\{ g \left[\delta \mathbb{E}_2[F] + [1 - \delta] \min \{ F_1, x_L(A^*) [1 + r]^{-1} + \hat{\omega} R^* \} \right] + [1 - g] \delta S [1 + r]^{-1} \right\}, \quad (38)$$

where PV is the present value operator, and (38) reflects the fact that if the firm is good (probability g), then bondholders allow it to continue with probability δ , yielding an expected payoff at $t = 2$ of $\mathbb{E}_2[F]$ to the bondholders. If the good firm is liquidated, the bondholders receive $\min \{ F_1, x_L(A^*) [1 + r]^{-1} + \hat{\omega} R^* \}$, while if the bad firm is liquidated, they receive S .

The insiders of the firm choose the investments A and R , and the mix of debt and equity to finance them, by solving the following problem:

$$\begin{aligned} \max_{(A,R) \in \mathbb{R}^2, \alpha \in [0,1], F \geq 0} \{ [1 - \alpha] V_E + \mathbb{E}[B] \} \\ \text{subject to (37) and (38)}. \end{aligned} \quad (39)$$

Here $\mathbb{E}[B]$ is the expected value of the insiders' non-contractible benefits, where the expectation depends on the firm's chosen capital structure.

We now establish a result about the firm's capital structure choice.

Proposition 1: *For any given A^* and R^* , the firm will set $F = x_L(A^*)$, $F_1 = F[1 + r]^{-1}$.*

Proof: Suppose counterfactually that $F > x_L(A^*)$. Then we will establish that the bondholders will find it subgame perfect to liquidate the firm at $t = 1$ regardless of ϕ . To see this, suppose $\phi = \text{good}$. Then the bondholders' expected payoff at $t = 1$ if they liquidate the firm is $\hat{g}F + [1 - \hat{g}]S$, since $x_L(A^*) [1 + r]^{-2} \geq A^*$, so $x_L(A^*) [1 + r]^{-1} + \hat{\omega} R^* > A^* + R^*$, given $\hat{\omega} > 1$ and $F < A^* + R^*$. If they allow the firm to continue, then their expected payoff is

$$\hat{g} \left\{ x_L(A^*) + \int_0^{F - x_L(A^*)} \tilde{y} \xi_+ dy \right\}, \quad (40)$$

if the R&D is very successful. Since $F > x_L(A^*)$, it is clear that

$$F > x_L(A^*) + \int_0^{F-x_L(A^*)} \tilde{y}\xi_+ dy, \quad (41)$$

so the bondholders will liquidate the firm. If $\phi = \text{lemon}$, the bondholders' payoff with liquidation is

$$g_l F + [1 - g_l] S, \quad (42)$$

and the continuation value of the bondholders' payoff is

$$g_l \left\{ x_L(A^*) + \int_0^{F-x_L(A^*)} \tilde{y}\xi_+ dy \right\}. \quad (43)$$

Clearly, the liquidation payoff is higher. Given this, it is not optimal for the insiders at $t = 0$ to set $F > x_L(A^*)$.

Suppose that $F < x_L(A^*)$. Then, given Lemma 1, we know that the firm will be liquidated if $\phi = \text{lemon}$ and allowed to continue if $\phi = \text{good}$. When $F < x_L(A^*)$, (36) can be written as:

$$\begin{aligned} \hat{V}_E &= [1 - T]\delta\{[1 + r]^{-2}[q_+y_+ + q_-y_-] + p[1 - \theta][x_H(A) - F][1 + r]^{-2} \\ &\quad + [1 - p[1 - \theta]][x_L(A) - F][1 + K]^{-2} + [1 - q_+ - q_-]\hat{\omega}R[1 + r]^{-1}\} \\ &\quad + [1 - T][1 + r]^{-1}[1 - \delta][\hat{\omega}R + x_L(A)[1 + r]^{-1} - F_1]. \end{aligned} \quad (44)$$

Thus, the total value of the insiders' claim plus non-contractible benefits is:

$$[1 - \alpha]\hat{V}_E + [q_+ + q_-]B, \quad (45)$$

where

$$\alpha = \frac{A + R[1 + \omega] - D}{g\hat{V}_E}, \quad (46)$$

$$\omega \equiv \hat{\omega}[1+r]^{-1}, \quad (47)$$

and using (38), we can write

$$D = gF[1+r]^{-2} + [1-g]\delta S[1+r]^{-1}, \quad (48)$$

where we recognize that if the firm is good, then the bondholders receive either $F_1 = F[1+r]^{-1}$ at $t = 1$, or F at $t = 2$, so this payoff is riskless and has present value $F[1+r]^{-2}$ at $t = 0$. If the firm is a lemon and the bondholders liquidate at $t = 1$ (joint probability $[1-g]\delta$), then their payoff is S , with present value $S[1+r]^{-1}$. Substituting (46) and (48) into (44) yields the insiders' objective function:

$$\begin{aligned} \Omega &= \hat{V}_E - \alpha\hat{V}_E + [q_+ + q_-] B \\ &= \hat{V}_E - \frac{\{A + R[1+\omega] - gF[1+r]^{-2} - [1-g]\delta S[1+r]^{-1}\}}{g} + [q_+ + q_-] B \\ &= \hat{V}_E - \frac{\{A + R[1+\omega] - [1-g]\delta S[1+r]^{-1}\}}{g} + F[1+r]^{-2} + [q_+ + q_-] B \end{aligned} \quad (49)$$

Thus,

$$\frac{\partial \Omega}{\partial F} = -[1-T]\delta[1+K]^{-2} + [1+r]^{-2} > 0. \quad (50)$$

Thus, the firm will wish to increase F when $F < x_L(A^*)$. Since $F > x_L(A^*)$ has been ruled out, it must be true that $F = x_L(A^*)$. ■

We next examine how the firm determines A^* and R^* , taking the capital structure choice just derived as given. That is, the firm solves:

$$(A, R) \in \arg \max_{\mathbb{R}^2} \Omega, \quad (51)$$

with $A + R = I$. The following result can now be proved.

Proposition 2: *At $t = 0$, There is a unique optimal level of investment in assets in place,*

A^* , and a unique optimal level of investment in R&D, R^* , with $\partial A^*/d\theta < 0$ and $\partial R^*/d\theta > 0$.

Proof: The first-order condition that A^* satisfies is $\partial\Omega/\partial A = 0$. Recognizing that $A + R = I$ and using (44) for \hat{V}_E , we can write the first-order condition as

$$\begin{aligned} & [1 - T]\delta \left\{ [1 + r]^{-2} \left[\left[\frac{\partial y_+}{\partial R} \right] \left[\frac{\partial R}{\partial A} \right] q_+ + \left[\frac{\partial y_-}{\partial R} \right] \left[\frac{\partial R}{\partial A} \right] q_- \right] + p[1 - \theta] \left[\frac{\partial x_H}{\partial A} - \frac{\partial x_L}{\partial A} \right] [1 + r]^{-2} \right. \\ & \left. + [1 - q_+ - q_-] \omega \left[\frac{\partial R}{\partial A} \right] \right\} + [1 - T][1 - \delta]\omega \left[\frac{\partial R}{\partial A} \right] - \frac{1 + \left[\frac{\partial R}{\partial A} \right] [1 + \omega]}{g} = 0 \end{aligned} \quad (52)$$

Since $\partial R/\partial A = -1$, we can write (52) as:

$$\begin{aligned} & [1 - T]\delta \left\{ -[1 + r]^{-2} \left[q_+ \left[\frac{\partial y_+}{\partial R} \right] + q_- \left[\frac{\partial y_-}{\partial R} \right] \right] + p[1 - \theta] \left[\frac{\partial x_H}{\partial A} - \frac{\partial x_L}{\partial A} \right] [1 + r]^{-2} - [1 - q_+ - q_-] \omega \right\} \\ & - [1 - T][1 - \delta]\omega - \omega g^{-1} = 0 \end{aligned} \quad (53)$$

The second-order condition for a unique maximum is $\partial^2\Omega/\partial A^2 < 0$, which translates to

$$[1 - T]\delta[1 + r]^{-2}p[1 - \theta] \left[\frac{\partial^2 x_H}{\partial A^2} - \frac{\partial^2 x_L}{\partial A^2} \right] < 0, \quad (54)$$

given (2). To show that $dA^*/d\theta < 0$, we totally differentiate the first-order condition (52):

$$[1 - T]\delta[1 + r]^{-2} \left\{ -p \left[\frac{\partial x_H}{\partial A} - \frac{\partial x_L}{\partial A} \right] + p[1 - \theta] \left[\frac{\partial^2 x_H}{\partial A^2} - \frac{\partial^2 x_L}{\partial A^2} \right] \left[\frac{dA^*}{d\theta} \right] \right\} = 0, \quad (55)$$

which yields

$$\frac{dA^*}{d\theta} = \frac{p \left[\frac{\partial x_H}{\partial A} - \frac{\partial x_L}{\partial A} \right]}{p[1 - \theta] \left[\frac{\partial^2 x_H}{\partial A^2} - \frac{\partial^2 x_L}{\partial A^2} \right]} < 0, \quad (56)$$

since by (2), $\partial x_H/\partial A > \partial x_L/\partial A$ and $\partial^2 x_H/\partial A^2 - \partial^2 x_L/\partial A^2 < 0$. The result that $dR^*/d\theta > 0$ follows from the fact that $\partial R/\partial A = -1$. Thus, since $dA^*/d\theta < 0$, it follows that $dR^*/d\theta > 0$.

■

This proposition shows that as competition increases, the firm invests more in R&D and

less in assets in place that are used to support and expand existing products. The economic intuition is that investing in coming up with proprietary new products/knowledge becomes more valuable *relative to* investing more in the existing business as competition compresses margins in existing products, but the output of R&D is patent-protected.

We now examine how competition affects the firm's debt and cash positions.

Proposition 3: *An increase in competition will reduce the debt issued by the firm and increase the cash carried.*

Proof: As shown in Proposition 2, $\partial A^*/\partial \theta < 0$, so an increase in competition θ reduces the amount invested in assets in place. Since $F = x_L(A^*)$ and $\partial x_L/\partial A > 0$ from (2), it follows that a smaller A^* means a lower F , and hence less debt. In terms of the response of cash reserves to competition, Lemma 2 shows that the firm will prefer to raise all of the financing that it anticipates in the future at $t = 0$, and hold it as cash. The amount that the firm holds as cash for the future R&D investment is ωR . Therefore, since $\partial R^*/\partial \theta > 0$ from Proposition 2, an increase in competition θ increases the amount invested in R&D and hence the amount of cash that the firm holds at $t = 0$. ■

The intuition behind this proposition is that an increase in competition will induce the firm to reduce its investment in assets in place, which in turn reduces the amount of debt that the firm can carry, since the face value is set to the lowest payout from the assets in place. Put differently, an increase in competition will reduce the collateral base of the firm that supports debt by reducing investment in assets in place. The firm holds additional cash in response to competition due to a precautionary demand for liquidity, since it may not be able to raise enough financing in some states in the future. As the relative attractiveness of R&D goes up due to higher competition, so does the excess cash the firm carries to meet future liquidity demand. These two results also imply that net debt (defined as debt minus cash) will decline as competition increases.

Appendix B: Additional Results

Figure B1: Venture Capital (VC) Funding around the Hatch-Waxman Act

This figure provides venture capital (VC) funding trends for biopharma firms compared to other R&D-intensive firms following the enactment of the Hatch-Waxman Act. The graphs depict the differences in the outcomes between the biopharma and other R&D-intensive firms (biopharma minus other), with pre- and post-period trend lines added. Number of companies is the aggregated number of companies receiving VC funding. Number of deals is the total number of VC deals. Average equity per VC firm is the average amount of equity invested by a VC firm. Total equity invested is the aggregate amount of equity invested by VC firms. A vertical red line is included, representing the year that the Hatch-Waxman Act was implemented. All dollar amounts are in millions of real (2010) dollars.

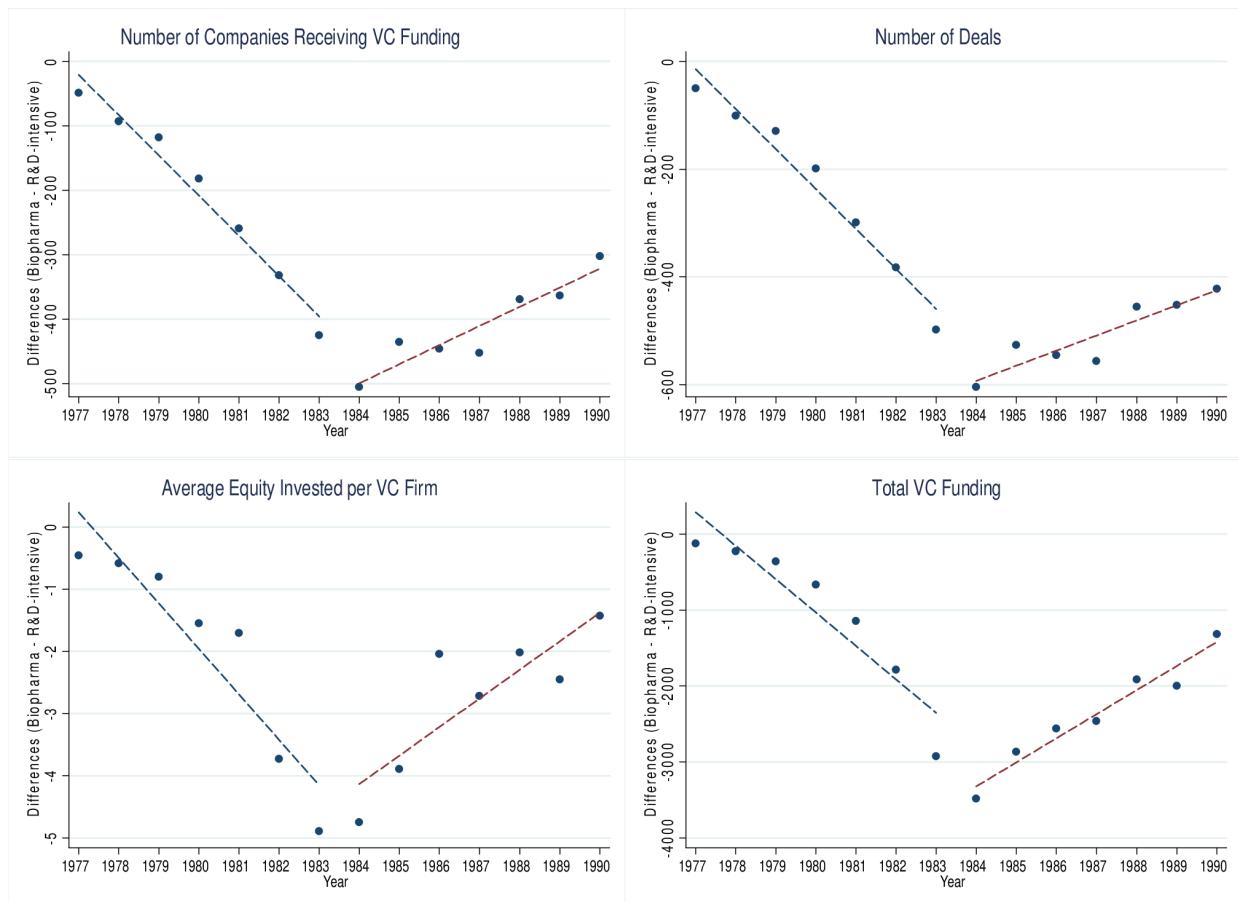


Figure B2: Generic-focused and Other Pharma Firms: Trends for Treatment and Control Groups

Intra-industry trends for financial characteristic variables for R&D expenditure, cash holdings, debt, net debt, and assets in place, all scaled by total assets. The graphs on the left represent averages for each group. The solid blue lines give averages for the treatment group of pharma firms focused on generic drugs, while the red dashed lines give averages for the control group of other matched pharma firms. A vertical red line is included, representing the year that the Hatch-Waxman Act was implemented. The graphs on the right depict the differences between the treatment and control groups (treatment minus control), with pre- and post-period trend lines added.

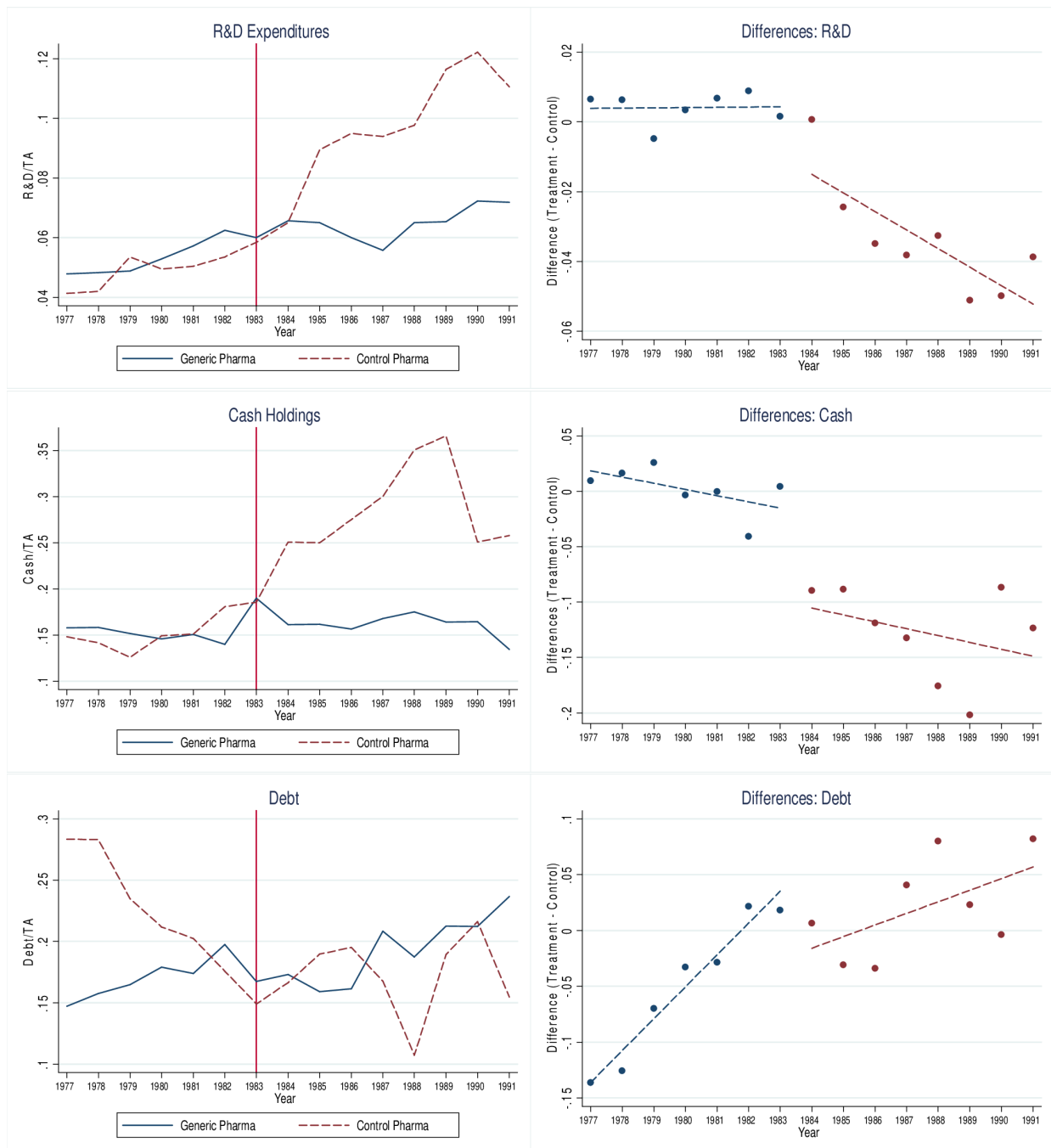


Figure B2 (continued): Generic-focused and Other Pharma Firms: Trends for Treatment and Control Groups

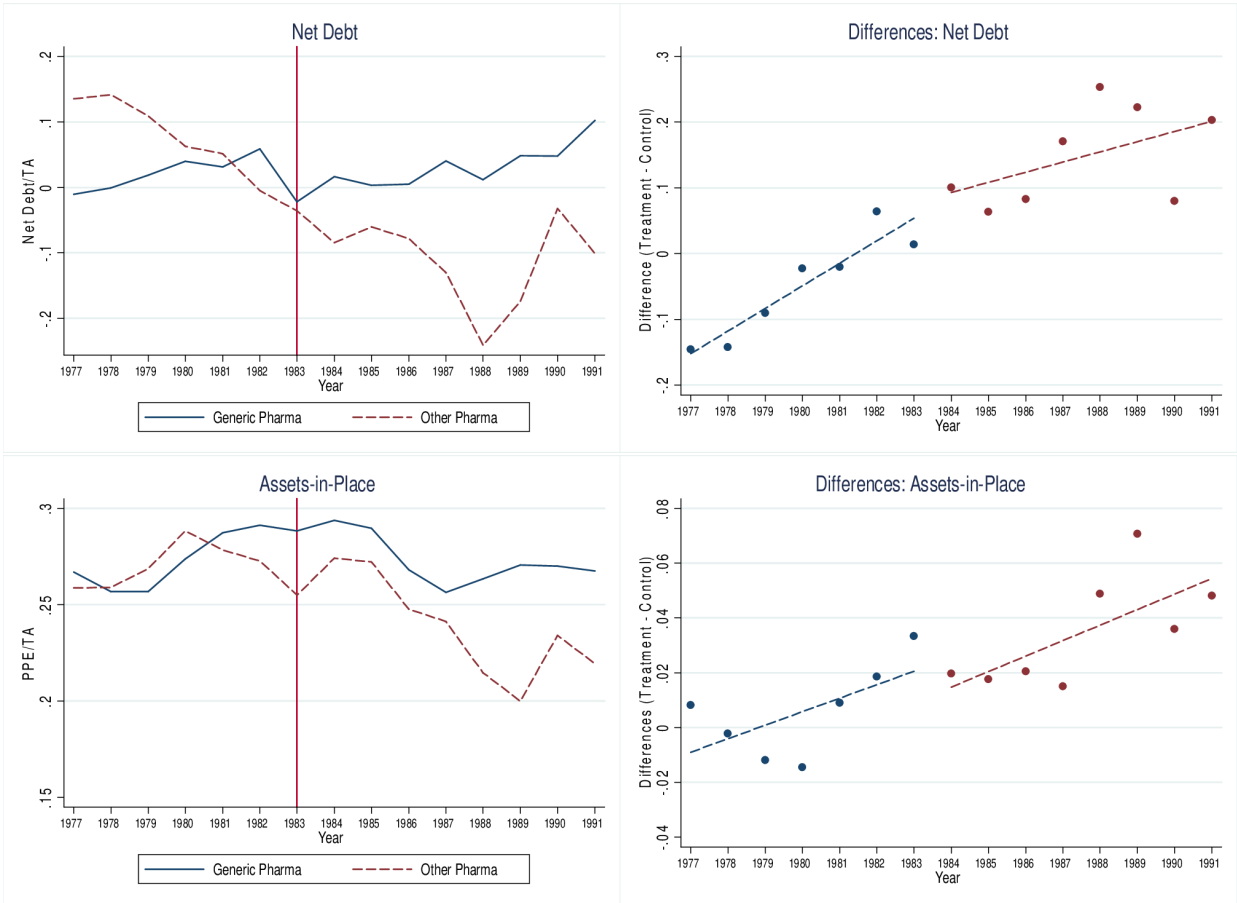


Figure B3: Innovation Trends for Generic-focused and Other Pharma Firms

Inter-industry trends for the number of total patents granted, citation-weighted patents, and the measure of economic value of patents granted (the innovation value). The graphs on the left represent averages for each group. The solid blue lines give averages for the pharma firms focused on generic drugs, while the red dashed lines give averages for the propensity-score-matched sample of other pharma firms. A vertical red line is included, representing the year that the Hatch-Waxman Act was implemented. The graphs on the right depict the differences between the treatment and control groups (treatment minus control), with pre- and post-period trend lines added.

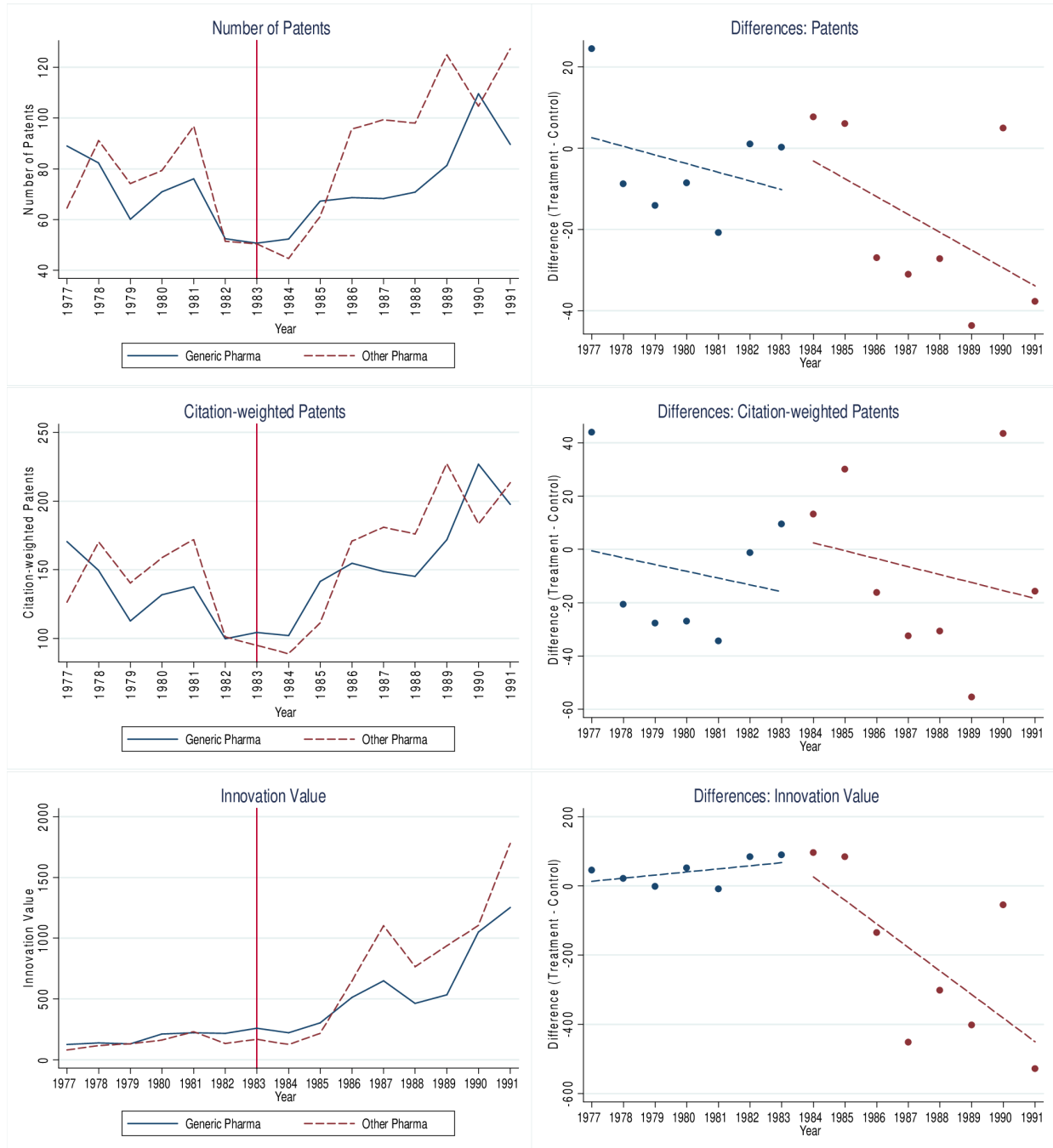


Table B1: Summary Statistics, Overall Sample for Hatch-Waxman Act Analysis

This table provides summary statistics for the outcome and control variables of the overall sample of firms, which run from 1977 to 1983. $R\&D/TA$ is R&D expenditures scaled by total assets. PPE/TA is property, plant, and equipment scaled by total assets. $Cash/TA$ is cash and short-term investments scaled by total assets. $Debt/TA$ is debt, which is the sum of total long-term debt and short-term debt (debt in current liabilities), scaled by total assets. $Net\ Debt/TA$ is net debt scaled by total assets, where $Net\ Debt = Debt - Cash$. All variables are at the firm-year level, and are winsorized at the 1% level. $\log(NA)$ is the natural logarithm of net assets, where $NA = TA - Cash$. $EBITDA/TA$ is earnings before interest, taxes, depreciation, and amortization as a fraction of total assets. ME/BE is market value of equity to book value of equity. Div/TA is the amount of common/ordinary dividends paid as a fraction of total assets. Age is the number of years that a firm has been included in Compustat. $Equity\ Issuance/TA$ is total equity issuance scaled by total assets.

Variable	Obs	Mean	SD	p25	Median	p75
$R\&D/TA$	2,768	0.184	0.280	0.039	0.081	0.193
PPE/TA	3,083	0.253	0.168	0.122	0.232	0.352
$Cash/TA$	3,083	0.299	0.285	0.052	0.199	0.495
$Debt/TA$	3,075	0.253	0.388	0.026	0.154	0.314
$Net\ Debt/TA$	3,075	-0.043	0.559	-0.388	-0.038	0.220
$\log(NA)$	3,085	3.113	2.541	1.031	2.372	4.577
$EBITDA/TA$	3,067	-0.187	0.678	-0.257	0.035	0.166
ME/BE	2,590	4.568	8.538	1.276	2.378	5.105
Div/TA	3,070	0.009	0.024	0.000	0.000	0.010
Age	3,314	10.497	10.647	3.000	6.000	14.000
$Equity\ Issuance/TA$	2,937	0.220	0.398	0.000	0.007	0.263

Table B2: Summary Statistics for Biopharma and Control Firms in the Pre-period

This table provides summary statistics for the main outcome variables for biopharma firms and control firms in the pre-period, from 1977 to 1983. Control firms consist of a propensity-score matched sample of R&D-intensive firms. $R\&D/TA$ is R&D expenditures scaled by total assets. PPE/TA is property, plant, and equipment scaled by total assets. $Cash/TA$ is cash and short-term investments scaled by total assets. $Debt/TA$ is debt, which is the sum of total long-term debt and short-term debt (debt in current liabilities), scaled by total assets. $Net\ Debt/TA$ is net debt scaled by total assets, where $Net\ Debt = Debt - Cash$. All variables are at the firm-year level, and are winsorized at the 1% level.

<i>Panel A: Biopharma Firms in the Pre-period</i>						
Variable	Obs	Mean	SD	p25	Median	p75
$R\&D/TA$	460	0.108	0.190	0.035	0.058	0.097
PPE/TA	522	0.275	0.157	0.164	0.267	0.362
$Cash/TA$	522	0.231	0.248	0.046	0.136	0.324
$Debt/TA$	517	0.233	0.289	0.072	0.165	0.310
$Net\ Debt/TA$	517	0.004	0.447	-0.225	0.026	0.232
<i>Panel B: Control Firms in the Pre-period</i>						
Variable	Obs	Mean	SD	p25	Median	p75
$R\&D/TA$	390	0.104	0.203	0.024	0.042	0.093
PPE/TA	424	0.297	0.174	0.162	0.270	0.416
$Cash/TA$	424	0.234	0.240	0.038	0.142	0.373
$Debt/TA$	424	0.202	0.248	0.042	0.166	0.265
$Net\ Debt/TA$	424	-0.031	0.389	-0.270	0.007	0.203

Table B3: Robustness: The Hatch-Waxman Act and R&D

This table estimates the differences-in-differences regression (1), but over the sample period from 1969 to 1983. The dependent variables consist of $R\&D$, scaled by total assets or in log levels. HW_t is a dummy variable which takes a value of 1 if the year is 1984 or later, and a value of zero otherwise. $Biopharma_i$ is a dummy variable which takes a value of 1 if firm i is in the biopharma industry, and a value of 0 if it is in the propensity-score matched control group of other R&D-intensive firms. Control variables include $\log(NA)$, $EBITDA/TA$, M/B , Div/TA , Age , $Equity\ Issuance/TA$, and lagged values of PPE/TA , $Cash/TA$, $Debt/TA$, and $R\&D/TA$. $Time\ HW_t$ is the number of years before or after the Hatch-Waxman Act. Year and firm fixed effects are included, as indicated. Robust standard errors are given in parentheses, and standard errors are clustered at the firm level. *, **, and *** indicate significance at the 10%, 5%, and 1% level, respectively.

	(1)	(2)	(3)	(4)	(5)
Dependent Variable:	$R\&D/TA$	$R\&D/TA$	$R\&D/TA$	$R\&D/TA$	$\log(1 + R\&D)$
$HW_t \times Biopharma_i$	0.027* (0.014)	0.027* (0.014)	0.024* (0.013)	0.024* (0.013)	0.160** (0.008)
HW_t	-0.036*** (0.013)				
$Time\ HW_t$	0.006*** (0.002)				
$\log(NA)_{i,t}$	-0.023*** (0.009)	-0.024*** (0.009)	-0.026*** (0.009)	-0.026*** (0.008)	0.448*** (0.041)
$EBITDA/TA_{i,t}$	-0.349*** (0.019)	-0.348*** (0.019)	-0.339*** (0.020)	-0.318*** (0.021)	-0.140*** (0.030)
$Div/TA_{i,t}$	0.160 (0.131)	0.152 (0.135)	0.159 (0.126)	0.116 (0.107)	0.064 (0.664)
$M/B_{i,t}$	0.001 (0.001)	0.001* (0.001)	0.001** (0.001)	0.002*** (0.001)	0.003*** (0.001)
$Age_{i,t}$			0.003** (0.001)	-0.012 (0.012)	0.014 (0.026)
$Equity\ Issuance/TA_{i,t}$			-0.033* (0.017)	-0.053** (0.024)	0.097** (0.041)
$R\&D/TA_{i,t-1}$				0.137*** (0.041)	0.201** (0.093)
$Cash/TA_{i,t-1}$				0.015 (0.030)	0.530*** (0.088)
$Debt/TA_{i,t-1}$				-0.042** (0.020)	-0.071 (0.055)
$PPE/TA_{i,t-1}$				0.059 (0.054)	0.524*** (0.157)
Constant	0.191*** (0.032)	0.158*** (0.023)	0.158*** (0.020)	0.393* (0.218)	-0.096 (0.463)
Firm Fixed Effects	Yes	Yes	Yes	Yes	Yes
Year Fixed Effects	No	Yes	Yes	Yes	Yes
Observations	2,356	2,356	2,252	2,057	2,057
Number of Firms	365	365	363	348	348
R^2	0.859	0.860	0.863	0.878	0.979

Table B4: Falsification Robustness Tests for Biopharma and R&D-intensive Firms

This table estimates the differences-in-differences regression (1), but over placebo periods immediately before and immediately after the sample period. Panel A runs regressions from 1969 to 1983, while panel B runs regressions from 1992 to 2005. The dependent variables consist of *R&D*, *PPE*, *Cash*, *Debt*, and *Net Debt*, each scaled by total assets. Act_t is a dummy variable which takes a value of 1 if the year is 1976 or later, and a value of zero otherwise. Act'_t is a dummy variable which takes a value of 1 if the year is 1999 or later, and a value of zero otherwise. $Biopharma_i$ is a dummy variable which takes a value of 1 if firm i is in the biopharma industry, and a value of 0 if it is in the propensity-score matched control group of other R&D-intensive firms. Control variables include $\log(NA)$, $EBITDA/TA$, M/B , Div/TA , and lagged values of PPE/TA , $Cash/TA$, $Debt/TA$, and $R\&D/TA$. Year and firm fixed effects are included, as indicated, and a constant term is included in all regressions but not reported. Robust standard errors are given in parentheses, and standard errors are clustered at the firm level. *, **, and *** indicate significance at the 10%, 5%, and 1% level, respectively.

<i>Panel A: Falsification Test from 1969 to 1983</i>					
Dependent Variable:	(1)	(2)	(3)	(4)	(5)
	<i>R&D</i>	<i>PPE</i>	<i>Cash</i>	<i>Debt</i>	<i>Net Debt</i>
$Act_t \times Biopharma_i$	0.005 (0.006)	0.0002 (0.009)	0.001 (0.015)	-0.019 (0.013)	-0.020 (0.023)
Controls	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes
Observations	1,022	1,037	1,037	1,036	1,036
Number of Firms	158	159	159	159	159
R^2	0.923	0.887	0.849	0.813	0.859
<i>Panel B: Falsification Test from 1992 to 2005</i>					
Dependent Variable:	(1)	(2)	(3)	(4)	(5)
	<i>R&D</i>	<i>PPE</i>	<i>Cash</i>	<i>Debt</i>	<i>Net Debt</i>
$Act'_t \times Biopharma_i$	0.008 (0.012)	0.008 (0.006)	0.008 (0.013)	0.008 (0.020)	-0.006 (0.027)
Controls	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes
Observations	7,455	7,497	7,499	7,490	7,490
Number of Firms	1,038	1,041	1,041	1,041	1,041
R^2	0.797	0.798	0.824	0.697	0.756

Table B5: Autocorrelation Robustness Tests for Biopharma and R&D-intensive Firms

This table estimates the differences-in-differences regression (1) for financial characteristics, correcting for autocorrelation. Panel A uses Newey-West standard errors, and Panel B collapses the samples into pre- and post-periods following the procedure of Bertrand, Duflo, and Mullainathan (2004). The dependent variables consist of $R\&D$, PPE , $Cash$, $Debt$, and $Net\ Debt$, each scaled by total assets. HW_t is a dummy variable which takes a value of 1 if the year is 1984 or later, and a value of zero otherwise.. $Biopharma_i$ is a dummy variable which takes a value of 1 if firm i is in the biopharma industry, and a value of 0 if it is in the propensity-score matched control group of other R&D-intensive firms. Control variables include $\log(NA)$, $EBITDA/TA$, M/B , Div/TA , and lagged values of PPE/TA , $Cash/TA$, $Debt/TA$, and $R\&D/TA$. Year and firm fixed effects are included in Panel A, and Year and treatment group fixed effects are included in Panel B. A constant term is included in all regressions but not reported. Newey-West standard errors are given in parentheses in with 10 lags in Panel A, and standard errors are clustered at the firm level in Panel B. *, **, and *** indicate significance at the 10%, 5%, and 1% level, respectively.

<i>Panel A: Newey-West Standard Errors</i>					
	(1)	(2)	(3)	(4)	(5)
Dependent Variable:	$R\&D$	PPE	$Cash$	$Debt$	$Net\ Debt$
$HW_t \times Biopharma_i$	0.024** (0.011)	-0.004 (0.010)	0.076*** (0.018)	-0.040** (0.020)	-0.116*** (0.032)
Controls	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes
Observations	2,156	2,174	2,174	2,172	2,172
<i>Panel B: Collapsed Sample</i>					
	(1)	(2)	(3)	(4)	(5)
Dependent Variable:	$R\&D$	PPE	$Cash$	$Debt$	$Net\ Debt$
$HW_t \times Biopharma_i$	0.165*** (0.028)	-0.017 (0.018)	0.230*** (0.033)	-0.045 (0.045)	-0.270*** (0.066)
Fixed Effects	Yes	Yes	Yes	Yes	Yes
Observations	597	639	639	639	639
R^2	0.100	0.018	0.090	0.009	0.027

Table B6: Restricted Incumbent Sample Robustness Test for Biopharma and R&D-intensive Firms

This table estimates the differences-in-differences regression (1) for financial characteristics using the restricted sample of incumbent firms. The sample consists of biopharma firms and a control group consisting of propensity-score matched R&D-intensive firms. The sample period spans from 1977 to 1991. The dependent variables consist of $R\&D$, PPE , $Cash$, $Debt$, and $Net\ Debt$, each scaled by total assets. HW_t is a dummy variable which takes a value of 1 if the year is 1984 or later, and a value of zero otherwise. $Biopharma_i$ is a dummy variable which takes a value of 1 if firm i is in the biopharma industry, and a value of 0 if it is in the control group. Control variables include $\log(NA)$, $EBITDA/TA$, M/B , Div/TA , and lagged values of PPE/TA , $Cash/TA$, $Debt/TA$, and $R\&D/TA$. Year and firm fixed effects are included where indicated, and a constant term is included in all regressions but not reported. Robust standard errors are given in parentheses, and standard errors are clustered at the firm level. *, **, and *** indicate significance at the 10%, 5%, and 1% level, respectively.

	(1)	(2)	(3)	(4)	(5)
Dependent Variable:	$R\&D$	PPE	$Cash$	$Debt$	$Net\ Debt$
$HW_t \times Biopharma_i$	0.021* (0.012)	-0.005 (0.011)	0.065*** (0.018)	-0.034 (0.021)	-0.099*** (0.032)
Controls	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes
Observations	1,624	1,638	1,638	1,636	1,636
Number of Firms	193	194	194	194	194
R^2	0.851	0.811	0.798	0.680	0.780

Table B7: Summary Statistics for Innovation Outcomes

This table provides summary statistics for the innovation outcomes for the sample of biopharma firms and control firms in the pre-period, from 1977 to 1983. Control firms consist of a propensity-score matched sample of R&D-intensive firms. $patents$ is the number of patents a firm has approved in a given year. $cw\ patents$ is the number of citation-weighted patents. $Innovation\ Value$ is the market value of new patents, from Kogan et al. (2017). All variables are at the firm-year level, and are winsorized at the 1% level.

Variable	Obs	Mean	SD	p25	Median	p75
$patents$	733	88.308	148.312	4.000	27.000	109.000
$cw\ patents$	733	187.068	316.747	9.111	57.922	237.154
$Innovation\ Value$	733	292.983	531.400	2.087	49.060	366.524

Table B8: Differences-in-Differences Regressions, Measures of Innovation including Firm Entry

This table estimates the differences-in-differences regression (1) for the measures of innovation, allowing for entry during the sample by biopharma firms. The sample consists of biopharma firms and a control group consisting of propensity-score matched R&D-intensive firms. The sample period spans from 1977 to 1991. The dependent variables consist of *patents* (the number of patents), *cw patents* (the number of citation-weighted patents), and *Innovation Value* (the market value of new patents). HW_t is a dummy variable which takes a value of 1 if the year is 1984 or later, and a value of zero otherwise. $Biopharma_i$ is a dummy variable which takes a value of 1 if firm i is in the biopharma industry, and a value of 0 if it is in the control group. Control variables include $\log(NA)$, $EBITDA/TA$, M/B , Div/TA , and lagged values of PPE/TA , $Cash/TA$, $Debt/TA$, $R\&D/TA$, and the respective dependent variable. Year and firm fixed effects are included where indicated, and a constant term is included in all regressions but not reported. Robust standard errors are given in parentheses, and standard errors are clustered at the firm level. *, **, and *** indicate significance at the 10%, 5%, and 1% level, respectively.

	(1)	(2)	(3)	(4)	(5)
Dependent Variable:	<i>patents</i>	$\log(1 + \textit{patents})$	<i>cw patents</i>	$\log(1 + \textit{cw patents})$	<i>Innovation Value</i>
$HW_t \times Biopharma_i$	-16.913** (7.216)	-0.198** (0.099)	-36.400** (15.246)	-0.203 (0.156)	81.833** (38.404)
Controls	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes
Observations	750	750	750	750	750
Number of Firms	112	112	112	112	112
R^2	0.969	0.968	0.961	0.936	0.885