


Competition and R&D Financing: Evidence From the Biopharmaceutical Industry

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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. We hypothesize that as competition increases, R&D-intensive firms will: i) increase R&D investment relative to existing assets in place; ii) carry more cash; and iii) maintain less net debt. Using the Hatch–Waxman Act as an exogenous shock to competition, we provide causal evidence supporting 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.

I. 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 to be deleterious. This effect has also depended on

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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 (2015), and 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 that firms make to fund innovative activities?

The primary goal of this article 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 that overcomes concerns about endogeneity.⁴ The interaction effects and concerns about endogeneity are especially important because theory suggests not only that competition affects incentives to innovate, but also that innovation can affect competition (see, e.g., Thakor (2012), Aghion, Bechtold, Cassar, and Herz (2014)), generating an endogenous effect in addition to the exogenous drivers of changes in competition.

In our analysis, we begin by developing a model 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 3 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,

¹See Cohen and Levin (1989), Ahn (2002), and Aghion, Akcigit, and Howitt (2014) for reviews. Also see, e.g., 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.

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 and 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.

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 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 vs. 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, Griffith, and Howitt (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), (2017).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 (2012) 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 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

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.

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 Jaggia and Thakor (1994), Berk, Stanton, and Zechner (2010)).

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 the 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 was 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 are 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, when 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 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, Dewatripont, and Rey (1999), Aghion, Bloom, Blundell, Griffith, and Howitt (2005), and Chernyshev (2017)).⁸ There are also theories that imply that more profitable firms will innovate less when faced with greater competition (e.g., Holmes, Levine, and Schmitz (2012), Christensen, Raynor, and McDonald (2015)). 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 (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)

⁷Put together, these results are broadly consistent with the documented decrease in R&D efficiency (e.g., Kortum (1993), 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 Myers (2001) and Graham and Leary (2011) for comprehensive reviews.

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 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 has not been previously examined.

In Section II of this article, we describe a theoretical model and discuss the testable hypotheses that emerge from the model. In Section III, 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 IV provides additional tests of our main predictions by exploiting a heterogeneity within the biopharma industry. Section V examines the effect of competition on the quantity and value of innovation output. We conclude in Section VI. The Appendix contains additional results.

II. 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.

A. 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 2 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 benefits 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 noncontractible 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 as 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., Jensen (1986), Calomiris and Kahn (1991), and Hart and Moore (1995), (1998)). 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 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

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.

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 Supplementary Material. Here we provide the intuition for our main results.

B. 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 from assets in place and toward R&D.¹⁴

The decision about the firm's capital structure makes a trade-off between tax benefits and 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

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.

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

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 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 noncontractible 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, e.g., 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.

III. 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.

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 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 his 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.

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.

A. 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 identify 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), 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 expenditures 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 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 scaled by total assets). 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. 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 up the mean. 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.

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 2 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

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.

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 Diagnostic Substances (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 that do not cleanly fit into SIC categories in a way that makes it difficult to distinguish them from nondrug firms.

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

TABLE 1
Summary Statistics of Biopharma Firms Over Time

Table 1 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 $\text{NET_DEBT/TA} = \text{DEBT} - \text{CASH}$. All variables run from 1950 to 2012. All variables are at the firm-year level, and are winsorized at the 1% level. Obs. is number of observations, p25 is 25th percentile, p75 is 75th percentile, and SD is standard deviation.

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

examining competition at the therapeutic class level (e.g., Ellison, Cockburn, Griliches, and Hausman (1997), Azoulay (2002), and Ellison and Ellison (2011)).²¹

Graph A of Figure 1 shows that the number of competitors in the industry 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 Graph 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

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

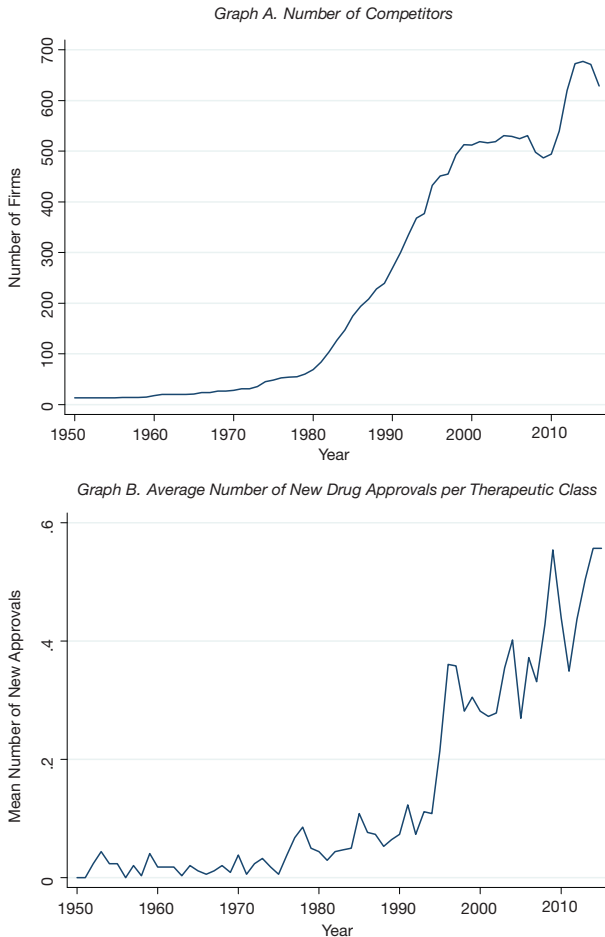
²¹We focus on these measures because the typical measures of industry competition, such as the Herfindahl–Hirschman Index or concentration ratio, present a distorted view of competition due to the fact that they are based on sales. For the biopharma industry in particular, many small biotech firms compete 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 toward 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 Section IV. These trends are consistent with existing papers (e.g., Grabowski and Vernon (1990), (1992), Caves, Whinston, and Hurwitz (1991), Grabowski and Kyle (2007), and others) that have shown that the industry has become more competitive over time.

FIGURE 1
Competition in the Biopharma Industry

Figure 1 presents basic measures of competition in the biopharma industry over time. Graph A shows the number of firm-level competitors operating in the biopharma industry over time. Graph B shows the average number of newly approved drugs each year per therapeutic class.



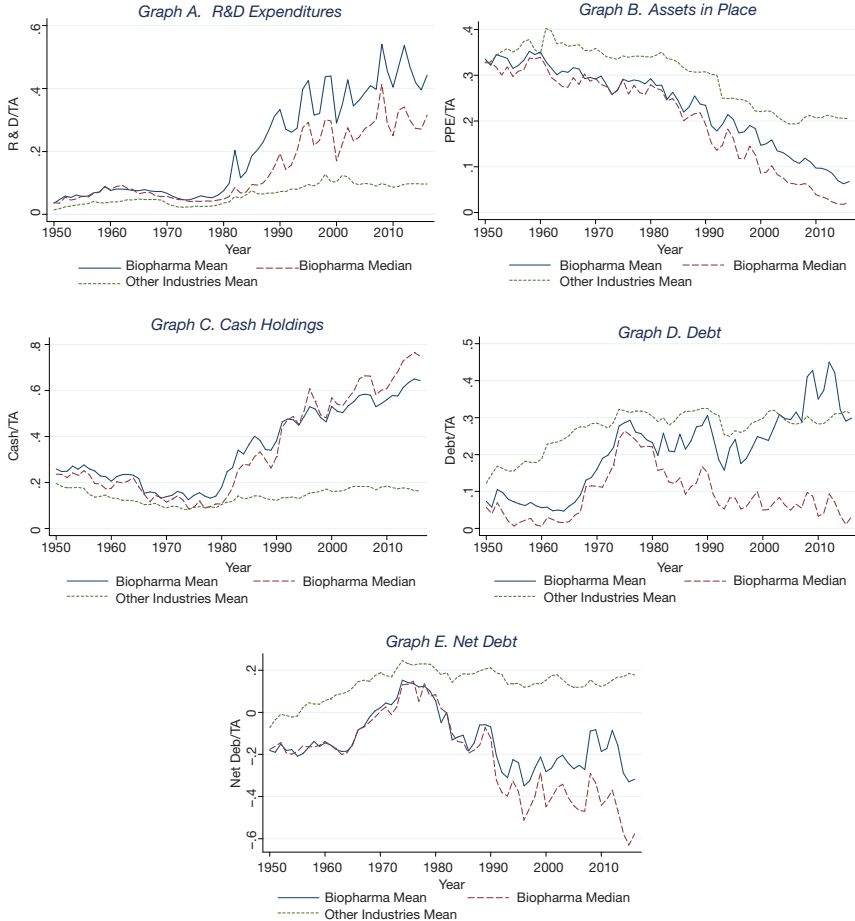
evolved. The mean and median values of R&D/TA, PPE/TA, CASH/TA, DEBT/TA, and NET_DEBT/TA are calculated for each year. In order to distinguish these trends from larger trends in other industries, the mean values of these variables are also included for all other industries apart from the biopharma industry.

The findings presented in Figure 2 are consistent with the predictions from Section II. 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

²⁴The increase in mean R&D expenditures also highlights an interesting cyclicity. One explanation for this cyclicity is a change in profitability each year, which partly determines how much firms are able

FIGURE 2
Financial Characteristics Over Time

The graphs in Figure 2 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.



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

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 Begenau and Palazzo (2021), who show evidence that the overall increase in firm cash holdings is driven by the entry of more R&D-intensive firms.

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.

B. 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 2 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 express 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 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

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)).

brand-name 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 Graph A of Figure 1, 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 Graph 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 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

C. 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 II. 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

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.

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.

applicable for firms in R&D-intensive industries in general, we choose firms from the 5 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 (EBITDA/TA), capital structure (NET_DEBT/TA), 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:

$$(1) \quad Y_{i,t} = \gamma_0 + \gamma_1 \text{HW}_t \times \text{BIOPHARMA}_i + \eta X_{i,t} + \mu_i + \lambda_t + \varepsilon_{i,t}.$$

In regression (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 that 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 that 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 V, 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

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).

³⁰To 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.

³¹Tables A1 and A2 provide 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 II, 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.

also co-vary with the dependent variable. Control variables that comprise $X_{i,t}$ for the financial characteristic variables include: $\log(\text{NA})$ (where $\text{NA} = \text{TA} - \text{CASH}$), 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: $\text{R\&D}/\text{TA}$, PPE/TA , CASH/TA , and 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.

Regression (1) is estimated for the period from 1977 to 1991, which includes the 7 years prior to and 7 years after 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

D. 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 groups for all the variables.

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 2 groupings are indeed similar in terms of these financial characteristics. After the Act is implemented, the values for the 2 groups diverge in ways 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

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.

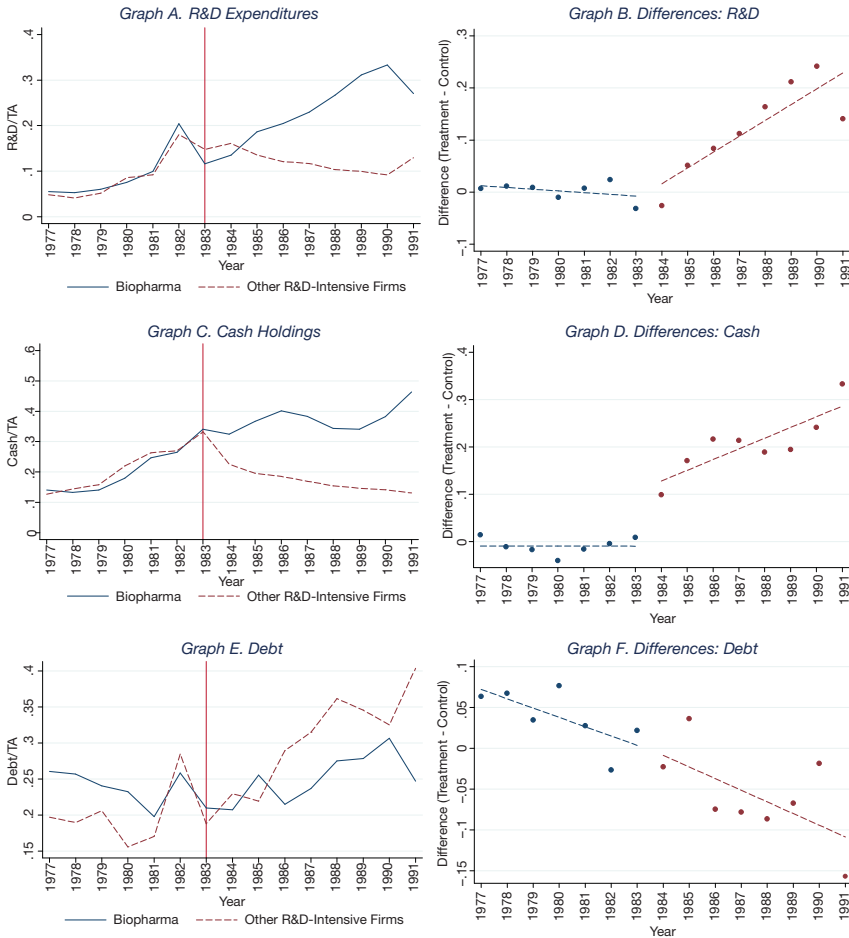
³⁴In particular, these results demonstrate that other R&D-intensive firms also exhibited similar trends (e.g., increasing R&D) prior to 1984. The differences-in-differences analysis shows that the changes in the outcome variables occurred in biopharma *relative* to the changes in other R&D-intensive 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 IV using within-industry variation.

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.

FIGURE 3
Main Results: Trends for Treatment and Control Groups

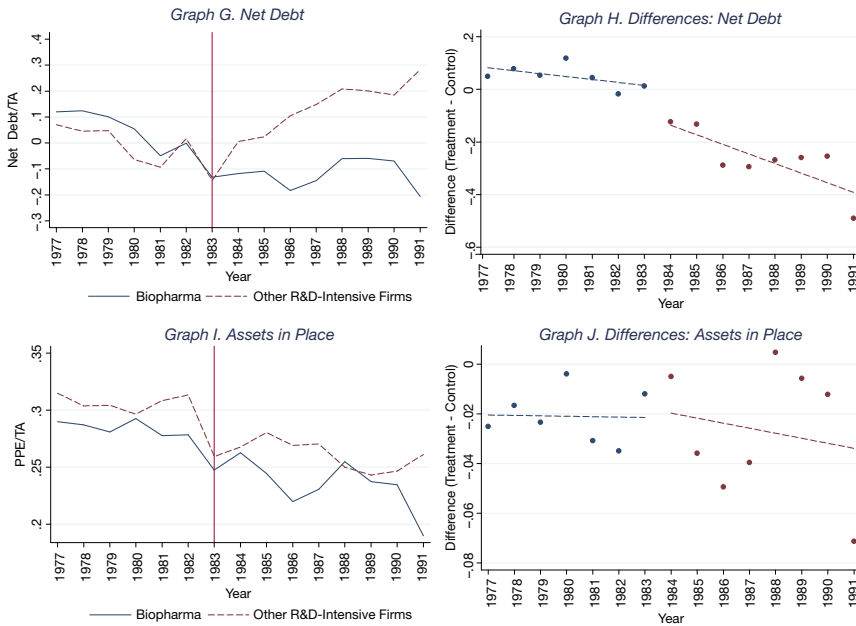
Figure 3 presents inter-industry trends for R&D expenditures, cash holdings, debt, net debt, and assets in place, all scaled by total assets. Graphs A, C, E, G, and I represent averages for each group. The solid blue lines give averages for the biopharma industry, while the red dashed lines give averages for the sample of R&D-intensive firms matched by propensity score. A vertical red line is included, representing the final year of the pre-period, before the Hatch–Waxman Act was implemented. Graphs B, D, F, H, and J depict the differences between the treatment and control groups (treatment minus control), with pre- and post-period trend lines added.



(continued on next page)

FIGURE 3 (continued)

Main Results: Trends for Treatment and Control Groups



Overall, the results from the differences-in-differences analysis are consistent with the predictions in Section II. The difference-in-difference estimator for R&D is positive and significant without or with control variables and fixed effects (columns 1 and 2, respectively). 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 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

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 A3, 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 of 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

TABLE 2

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

Table 2 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_i is a dummy variable that takes a value of 1 if the year is 1984 or later, and a value of 0 otherwise. $BIOPHARMA_i$ is a dummy variable that 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 $\log(\text{NA})$, EBITDA/TA , ME/BE , DIV/TA , and lagged values of PPE/TA , CASH/TA , DEBT/TA , and $\text{R\&D}/\text{TA}$. 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% levels, respectively.

Dependent Variable	R&D 1	R&D 2	PPE 3	PPE 4	CASH 5	CASH 6	DEBT 7	DEBT 8	NET_DEBT 9	NET_DEBT 10
$HW_i \times BIOPHARMA_i$	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_i	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
No. of obs.	2,768	2,156	3,083	2,174	3,083	2,174	3,075	2,172	3,075	2,172
No. 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

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. 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

that external equity issues are an important source of funding for R&D (e.g., Brown, Fazzari, and Petersen (2009), 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) are obtained for our other outcome variables as well.

³⁶The insignificant coefficient for assets in place may be due to some firms choosing to acquire 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 toward R&D.

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 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

IV. 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

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 A1, 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 nonbiopharma R&D-intensive firms. However, beginning in 1984, this trend reversed 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 A4, 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 A5. 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.

⁴⁰Table A6 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.

group may be different from the treatment group in unobservable ways. 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 or 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 2 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

A. Test Using Generic Manufacturers and Other Pharma Firms

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 II 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 of the proportion of total drug applications prior to 1984 that consists of generic drugs for each firm.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

⁴¹For example, the 1980s saw broader trends such 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 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 that are generics.

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 not only 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 III.C. Using these treatment and control groups, we estimate the same difference-in-difference specification as (1) from 1977 to 1991, replacing BIOPHARMA_i with GENERIC_i as the indicator for our treatment group.⁴⁶

2. Results

The regression results are included in Table 3. These results are broadly consistent with the hypotheses developed in Section II. The difference-in-difference estimator for R&D is negative and significant without control variables and fixed effects (column 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

TABLE 3
The Effect of the Hatch–Waxman Act on Generic-Focused and Other Pharma Firms

Table 3 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 that takes a value of 1 if the year is 1984 or later, and a value of 0 otherwise. GENERIC_{*i*} is a dummy variable that 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, ME/BE, 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% levels, respectively.

Dependent Variable	R&D 1	R&D 2	PPE 3	PPE 4	CASH 5	CASH 6	DEBT 7	DEBT 8	NET_DEBT 9	NET_DEBT 10
HW _{<i>t</i>} × GENERIC _{<i>i</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>i</i>}	0.004 (0.010)		0.007 (0.036)		0.001 (0.047)		-0.048 (0.042)		-0.046 (0.078)	
HW _{<i>t</i>}	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
No. of obs.	487	417	494	419	494	419	487	418	487	418
No. 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

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

⁴⁶Figure A2 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 2 or 3 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 groups move roughly in parallel for the first 4 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.

R&D as much as other pharma firms. The difference-in-difference estimator for PPE is positive and significant in column 4, 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

B. Test Using Heterogeneity in Approved Drug Portfolios

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., Cockburn and Henderson (1994), (1998), Henderson and Cockburn (1994), (1996), and 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

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.

⁴⁸Our empirical strategy is similar in spirit to that of 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.

as of 1983. The measure, denoted by $HIGH_COMPETITION_i$, is the proportion of a firm's approved drugs that are in highly competitive therapeutic classes, defined as therapeutic classes that are in the top quartile in terms of number of approved drugs prior to 1984. We estimate the previous difference-in-difference specification (1) from 1977 to 1991, replacing $BIOPHARMA_i$ 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 Holmes, Levine, and Schmitz (2012) and Christensen, Raynor, and McDonald (2015). Christensen et al. 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. 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 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

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 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.

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).

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 $BIOPHARMA_i$ 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.

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

TABLE 4
The Effect of the Hatch–Waxman Act on Biopharma Firms, Exposure to Competition

Table 4 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_i is a dummy variable that takes a value of 1 if the year is 1984 or later, and a value of 0 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 $\log(NA)$, $EBITDA/TA$, ME/BE , 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% levels, respectively.

Dependent Variable	R&D	PPE	CASH	DEBT	NET_DEBT
	1	2	3	4	5
<i>Panel A. Biopharma Firms With Drugs in Competitive Therapeutic Classes</i>					
$HW_i \times HIGH_COMPETITION_i$	-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
No. of obs.	1,459	1,468	1,468	1,466	1,466
No. of firms	261	262	262	262	262
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>					
$HW_i \times LOW_CONCENTRATION_i$	-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
No. of obs.	1,459	1,468	1,468	1,466	1,466
No. 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

Table 5 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 NET_DEBT, each scaled by total assets. HW_{*i*} is a dummy variable that takes a value of 1 if the year is 1984 or later, and a value of 0 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 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, ME/BE, 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% levels, respectively.

Dependent Variable	Below-Median Profitability					Above-Median Profitability				
	R&D 1	PPE 2	CASH 3	DEBT 4	NET_DEBT 5	R&D 6	PPE 7	CASH 8	DEBT 9	NET_DEBT 10
HW _{<i>i</i>} × HIGH_COMPETITION _{<i>i</i>}	0.059* (0.032)	-0.082 (0.058)	0.274*** (0.069)	0.030 (0.081)	-0.245* (0.139)	-0.016 (0.010)	-0.015 (0.015)	0.037 (0.036)	-0.018 (0.039)	-0.056 (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
No. of obs.	438	441	441	441	441	534	537	537	535	535
No. 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

Section II. In both specifications, while R&D is insignificant, PPE is negative and significant, while CASH is positive and significant.⁵² Like previous results, the sign on debt is negative and thus consistent with the hypotheses in Section II, but is insignificant. However, 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 5 shows the results when splitting the sample by ex ante lower and higher profitability firms. The table shows that the results center around the firms with relatively *lower* ex ante profitability. In particular, for the below-median profitability firms, the coefficient for R&D is now positive and significant. The coefficient for PPE is negative, although insignificant, with a *p*-value of 0.16. The coefficient for cash is positive and significant. While the coefficient for debt is insignificant for both sets of firms, the coefficient for net debt is negative and significant for the firms with relatively lower profitability.

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

V. Effect on Innovation Output

In the final part of our analysis, we explore 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.

A. 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 data set 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 regression (1) using the patent count and innovation value measures as choices for $Y_{i,t}$. We begin by examining biopharma firms compared to other R&D-intensive firms, as in Section III, and then verify that the results are consistent for the within-industry tests.⁵⁵

Figure 4 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-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 the law's 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 the law's 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.

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

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

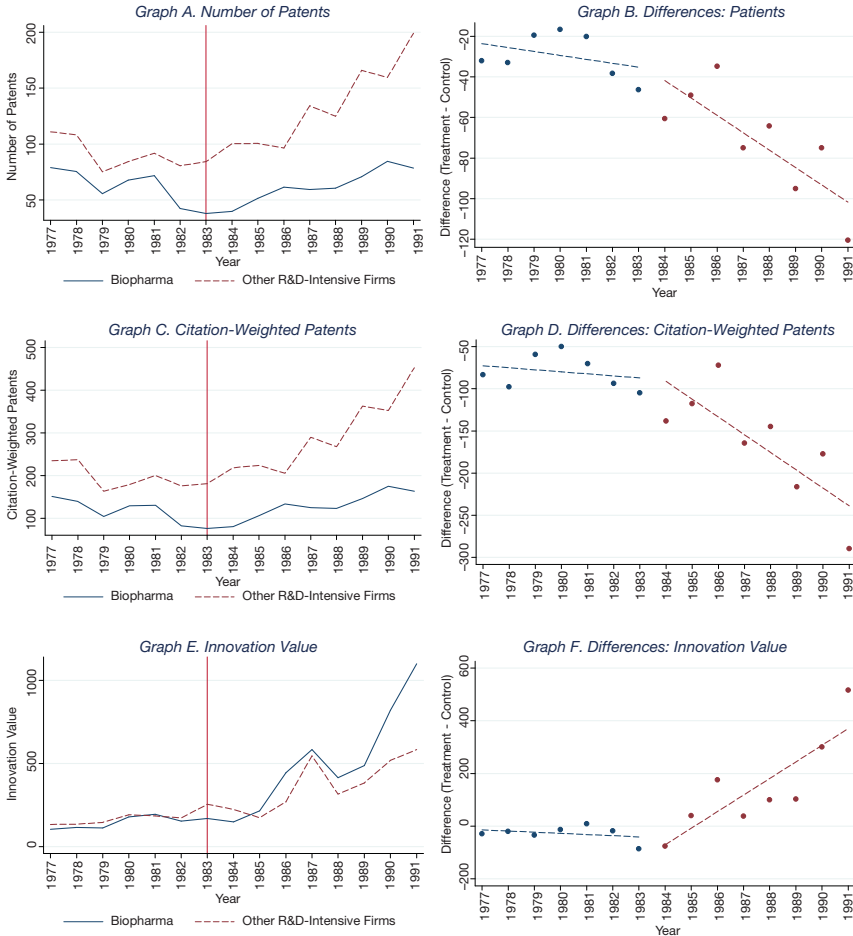
⁵⁵We include the lagged outcome variable as a control in each specification to control for time persistence. For the sample of biopharma firms compared to other R&D-intensive control firms, we match by propensity score as before, but additionally match on the log of citation-weighted patents, the number 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.

⁵⁶Table A7 provides the summary statistics for the innovation outcomes over the sample.

⁵⁷As 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.

FIGURE 4
Innovation Trends for Treatment and Control Groups

Figure 4 displays 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 final year of the pre-period, before 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.



B. Innovation Output Results

The results of the regression are provided in Table 6.⁵⁸ 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.

⁵⁸Table A8 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.

TABLE 6
Differences-in-Differences Regressions, Measures of Innovation

Table 6 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 that takes a value of 1 if the year is 1984 or later, and a value of 0 otherwise. BIOPHARMA_{*i*} is a dummy variable that 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, ME/BE, 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% levels, respectively.

Dependent Variable	PATENTS	log(1+PATENTS)	CW_PATENTS	log(1 + CW_PATENTS)	INNOVATION_VALUE
	1	2	3	4	5
HW _{<i>t</i>} × BIOPHARMA _{<i>i</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
No. of obs.	604	604	604	604	604
No. of firms	69	69	69	69	69
R ²	0.968	0.968	0.963	0.945	0.885

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.

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 is higher than those from the generic-focused firms, although without statistical significance. These results are provided in Table 7.⁵⁹

Table 8 follows up the approach in Table 5 of Section IV.B, 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

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 A3.

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

TABLE 7
Within-Industry Differences-in-Differences Regressions,
Generic-Focused and Other Pharma Firms

Table 7 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_i is a dummy variable that takes a value of 1 if the year is 1984 or later, and a value of 0 otherwise. $GENERIC_i$ is a dummy variable that 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 $\log(NA)$, $EBITDA/TA$, ME/BE , 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% levels, respectively.

Dependent Variable	PATENTS	$\log(1 + PATENTS)$	CW_PATENTS	$\log(1 + CW_PATENTS)$	INNOVATION_VALUE
	1	2	3	4	5
$HW_i \times GENERIC_i$	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
No. of obs.	215	215	215	215	215
No. 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

Table 8 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_i is a dummy variable that takes a value of 1 if the year is 1984 or later, and a value of 0 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 $\log(NA)$, $EBITDA/TA$, ME/BE , 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% levels, respectively.

Dependent Variable	PATENTS	$\log(1 + PATENTS)$	CW_PATENTS	$\log(1 + CW_PATENTS)$	INNOVATION_VALUE
	1	2	3	4	5
<i>Panel A. Below-Median Profitability Firms</i>					
$HW_i \times HIGH_COMPETITION_i$	-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
No. of obs.	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>					
$HW_i \times HIGH_COMPETITION_i$	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
No. of obs.	198	198	198	198	198
R^2	0.908	0.955	0.873	0.936	0.906

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.

VI. Conclusion

In this article, 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 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 increases. 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 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

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.

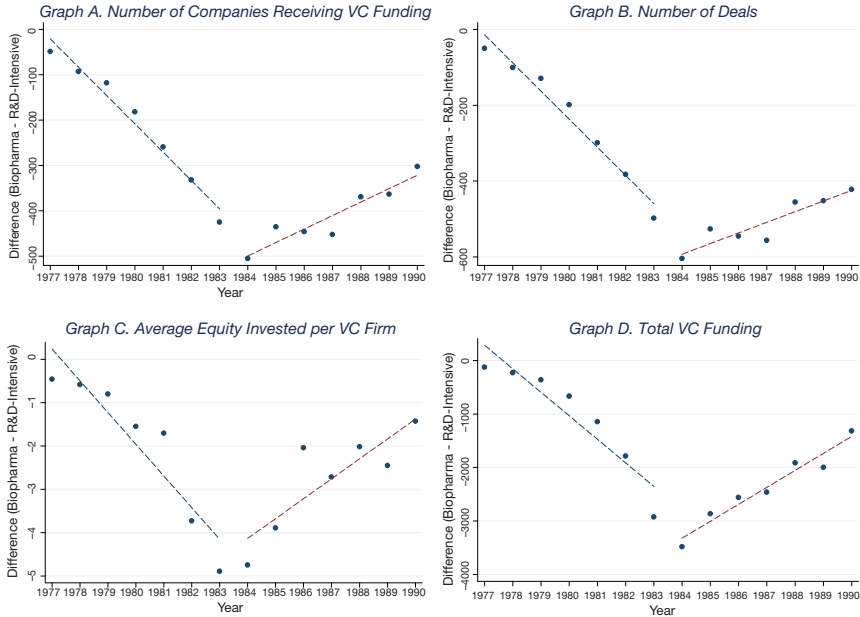
valuable drugs, and a reduction in the number of new drugs may lead to fewer diseases being treated. If the goal of R&D from a societal perspective is to have more innovation, then policies besides those intended to increase competition may be needed. In addition, given the increase in R&D spending associated with increased competitive pressures over time, another implication of our results is 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.

Appendix. Additional Results

FIGURE A1

Venture Capital (VC) Funding Around the Hatch–Waxman Act

Figure A1 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. All dollar amounts are in millions of real (2010) dollars.

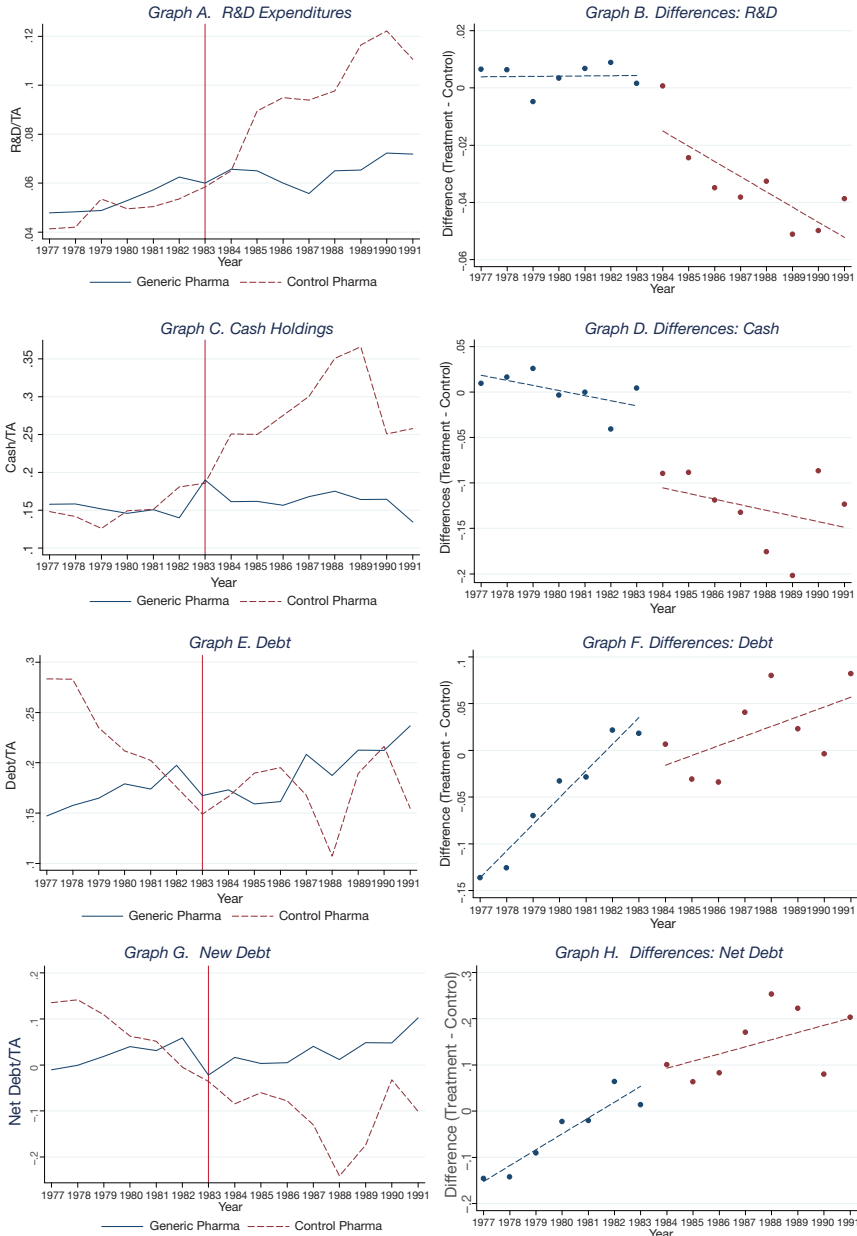


⁶¹Other financial innovations to spur biopharma innovation include insurance contracts called “FDA Hedges”; see Philipson (2015) and Jørring et al. (2017).

FIGURE A2

Generic-Focused and Other Pharma Firms: Trends for Treatment and Control Groups

Figure A2 reports intra-industry trends for financial characteristic variables 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 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 final year of the pre-period, before 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.



(continued on next page)

FIGURE A2 (continued)

Generic-Focused and Other Pharma Firms: Trends for Treatment and Control Groups

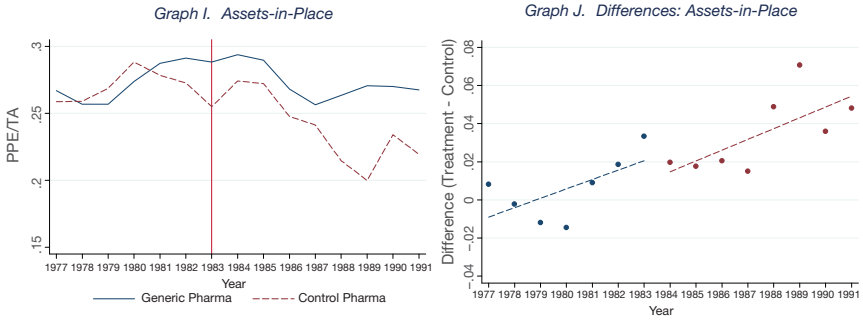


FIGURE A3

Innovation Trends for Generic-Focused and Other Pharma Firms

Figure A3 reports 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 final year of the pre-period, before 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.

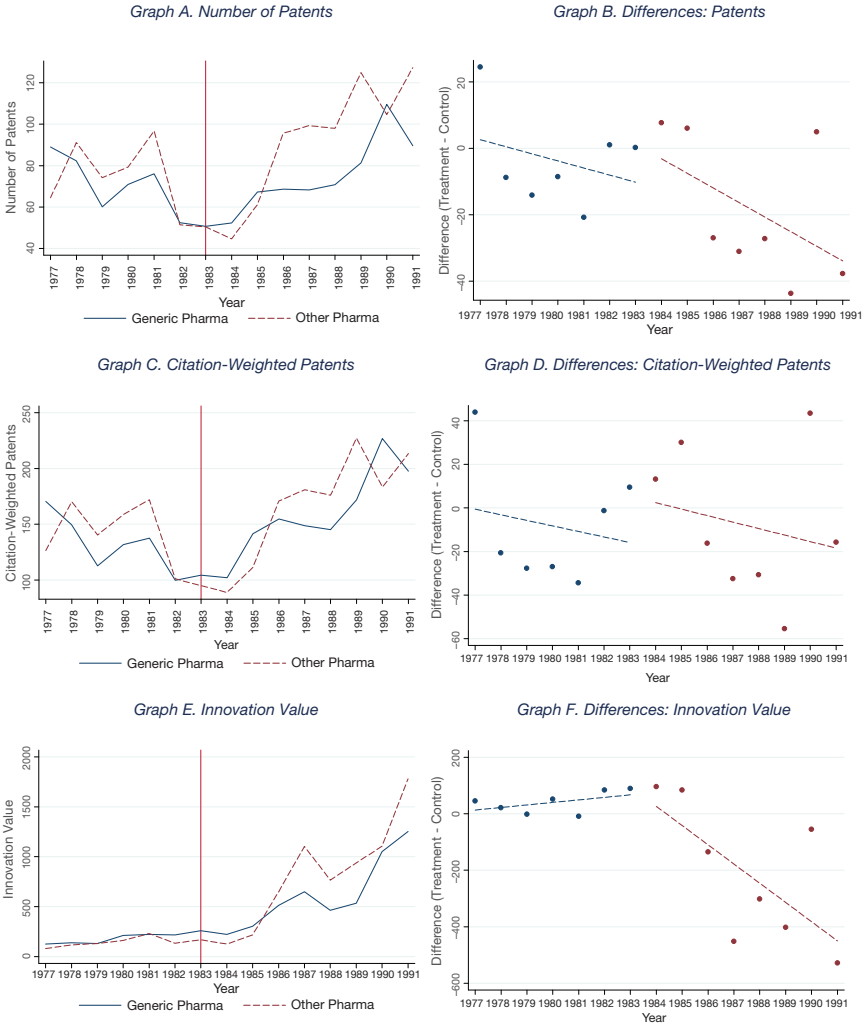


TABLE A1
Summary Statistics, Overall Sample for Hatch–Waxman Act Analysis

Table A1 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. p25 is 25th percentile, p75 is 75th percentile, and SD is standard deviation.

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 A2
Summary Statistics for Biopharma and Control Firms in the Pre-Period

Table A2 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. p25 is 25th percentile, p75 is 75th percentile, and SD is standard deviation.

Variable	Obs.	Mean	SD	p25	Median	p75
<i>Panel A. Biopharma Firms in the Pre-Period</i>						
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>						
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 A3
Robustness: The Hatch–Waxman Act and R&D

Table A3 estimates the differences-in-differences regression (1) for R&D. The dependent variables consist of R&D, scaled by total assets or in log levels. HW_t is a dummy variable that takes a value of 1 if the year is 1984 or later, and a value of 0 otherwise. $BIOPHARMA_i$ is a dummy variable that 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 $\log(\text{NA})$, EBITDA/TA , ME/BE , DIV/TA , AGE , $\text{EQUITY_ISSUANCE}/\text{TA}$, and lagged values of PPE/TA , CASH/TA , DEBT/TA , and $\text{R\&D}/\text{TA}$. 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% levels, respectively.

Dependent Variable	R&D/TA 1	R&D/TA 2	R&D/TA 3	R&D/TA 4	$\log(1 + \text{R\&D})$ 5
$HW_t \times \text{BIOPHARMA}_i$	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)				
$\log(\text{NA})_{i,t}$	-0.023*** (0.009)	-0.024*** (0.009)	-0.026*** (0.009)	-0.026*** (0.008)	0.448*** (0.041)
$\text{EBITDA}/\text{TA}_{i,t}$	-0.349*** (0.019)	-0.348*** (0.019)	-0.339*** (0.020)	-0.318*** (0.021)	-0.140*** (0.030)
$\text{DIV}/\text{TA}_{i,t}$	0.160 (0.131)	0.152 (0.135)	0.159 (0.126)	0.116 (0.107)	0.064 (0.664)
$\text{ME}/\text{BE}_{i,t}$	0.001 (0.001)	0.001* (0.001)	0.001** (0.001)	0.002*** (0.001)	0.003*** (0.001)
$\text{AGE}_{i,t}$			0.003** (0.001)	-0.012 (0.012)	0.014 (0.026)
$\text{EQUITY_ISSUANCE}/\text{TA}_{i,t}$			-0.033* (0.017)	-0.053** (0.024)	0.097** (0.041)
$\text{R\&D}/\text{TA}_{i,t-1}$				0.137*** (0.041)	0.201** (0.093)
$\text{CASH}/\text{TA}_{i,t-1}$				0.015 (0.030)	0.530*** (0.088)
$\text{DEBT}/\text{TA}_{i,t-1}$				-0.042** (0.020)	-0.071 (0.055)
$\text{PPE}/\text{TA}_{i,t-1}$				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
No. of obs.	2,356	2,356	2,252	2,057	2,057
No. of firms	365	365	363	348	348
R^2	0.859	0.860	0.863	0.878	0.979

TABLE A4
Falsification Robustness Tests for Biopharma and R&D-Intensive Firms

Table A4 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_i is a dummy variable that takes a value of 1 if the year is 1976 or later, and a value of 0 otherwise. ACT'_i is a dummy variable that takes a value of 1 if the year is 1999 or later, and a value of 0 otherwise. $BIOPHARMA_i$ is a dummy variable that 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 $\log(NA)$, $EBITDA/TA$, ME/BE , 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% levels, respectively.

Dependent Variable	R&D	PPE	CASH	DEBT	NET_DEBT
	1	2	3	4	5
<i>Panel A. Falsification Test From 1969 to 1983</i>					
$ACT_i \times BIOPHARMA_i$	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
No. of obs.	1,022	1,037	1,037	1,036	1,036
No. 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>					
$ACT'_i \times BIOPHARMA_i$	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
No. of obs.	7,455	7,497	7,499	7,490	7,490
No. 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 A5
Autocorrelation Robustness Tests for Biopharma and R&D-Intensive Firms

Table A5 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_i is a dummy variable that takes a value of 1 if the year is 1984 or later, and a value of 0 otherwise. $BIOPHARMA_i$ is a dummy variable that 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 $\log(NA)$, $EBITDA/TA$, ME/BE , 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 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% levels, respectively.

Dependent Variable	R&D	PPE	CASH	DEBT	NET_DEBT
	1	2	3	4	5
<i>Panel A. Newey–West Standard Errors</i>					
$HW_i \times BIOPHARMA_i$	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
No. of obs.	2,156	2,174	2,174	2,172	2,172
<i>Panel B. Collapsed Sample</i>					
$HW_i \times BIOPHARMA_i$	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
No. of obs.	597	639	639	639	639
R^2	0.100	0.018	0.090	0.009	0.027

TABLE A6

Restricted Incumbent Sample Robustness Test for Biopharma and R&D-Intensive Firms

Table A6 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 that takes a value of 1 if the year is 1984 or later, and a value of 0 otherwise. BIOPHARMA_{*i*} is a dummy variable that 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, ME/BE, 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% levels, respectively.

Dependent Variable	R&D	PPE	CASH	DEBT	NET_DEBT
	1	2	3	4	5
HW _{<i>t</i>} × BIOPHARMA _{<i>i</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
No. of obs.	1,624	1,638	1,638	1,636	1,636
No. of firms	193	194	194	194	194
R ²	0.851	0.811	0.798	0.680	0.780

TABLE A7

Summary Statistics for Innovation Outcomes

Table A7 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. p25 is 25th percentile, p75 is 75th percentile, and SD is standard deviation.

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 A8

Differences-in-Differences Regressions, Measures of Innovation Including Firm Entry

Table A8 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 that takes a value of 1 if the year is 1984 or later, and a value of 0 otherwise. BIOPHARMA_{*i*} is a dummy variable that 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, ME/BE, 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% levels, respectively.

Dependent Variable	PATENTS	log(1 + PATENTS)	CW_PATENTS	log(1 + CW PATENTS)	INNOVATION_VALUE
	1	2	3	4	5
HW _{<i>t</i>} × BIOPHARMA _{<i>i</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
No. of obs.	750	750	750	750	750
No. of firms	112	112	112	112	112
R ²	0.969	0.968	0.961	0.936	0.885

Supplementary Material

To view supplementary material for this article, please visit <http://doi.org/10.1017/S0022109021000284>.

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