

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

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Abstract

What is the interaction between competition, R&D investments, and the financing choices of R&D-intensive firms? Motivated by existing theories, we hypothesize that as competition increases, R&D-intensive firms will: (1) increase R&D investment relative to assets-in-place that support existing products; (2) carry more cash; and (3) maintain less net debt. We provide causal evidence supporting these hypotheses by exploiting differences between the biopharma industry and other industries, as well as heterogeneity within the biopharma industry, in response to an exogenous change in competition. We also explore how these changes affect innovative output, and provide novel evidence that in response to greater competition, companies increasingly “focus” their efforts—there is a relative decline in the total number of innovations, but an increase in the economic value of these innovations.

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

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

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1 Introduction

The idea that innovation is a key to economic growth has a long tradition, dating back at least to Adam Smith, who explicitly recognized the role of technological progress in the production function of the firm. Competition also grows with the economy, and it is well known that competition affects innovation (e.g. Aghion, Bloom, Blundell, Griffith, and Howitt (2005)). Innovation often requires large investments in R&D, investments that must be externally financed, so financing frictions affect innovation as well (e.g. Hall and Lerner (2010), and Cornaggia, Mao, Tian, and Wolfe (2013)). Since firms seek financing through the lowest-cost means, competition, innovation, and the financing choices of firms are inextricably linked. The research question this raises is: how does product-market competition affect innovation and the financing mix choices firms make to fund innovative activities?

The primary goal of this paper is to provide an empirical answer to this question. 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 endogeneity concerns.¹ The interactive effects and endogeneity concerns are especially important because theory suggests that competition affects innovation incentives but innovation can affect competition as well (see, e.g., Aghion, Bechtold, Lassar, and Herz (2010) and Thakor (2012)), generating an endogenous effect in addition to the exogenous drivers of changes in competition. For our analysis, we begin by using existing theories 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, and provide additional novel evidence of their ultimate effects on innovation.

Our choice of the biopharma industry is motivated by two considerations. First, it is

¹Moreover, decisions related to capital budgeting and financing for R&D that these firms make depart sharply from those made for other capital projects, due to the high-risk, staged nature of R&D investment and the absence of observable post-investment cash flows for many years. This makes it difficult to simply extrapolate the insights on investment and financing choices for other kinds of firms to R&D-intensive firms—see Myers and Howe (1997), who lay out these issues for the pharmaceutical industry.

an economically significant industry—it is intimately tied to health care, a sector that is now one-fifth of the U.S. economy—for which R&D is the lifeblood, with spending on R&D that often dwarfs spending on property, plant, and equipment. Second, this industry has become increasingly competitive over time for a variety of reasons, including regulation, lower costs of entry due to improvements in technology, and the expiration of patents combined with high development costs of new therapeutics (e.g. Caves, Whinston, and Hurwitz (1991), Grabowski and Vernon (1992), and others). These factors have squeezed margins from existing products associated with assets-in-place, with marked implications for R&D investments in new products as well as the capital structure choices of these firms. These factors make the biopharma industry well-suited for the study of the question posed above.

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

Our second hypothesis is that firms will carry more cash in response to greater competition. One reason is to avoid reliance on external financing in future states of the world in which it may be needed but unavailable. This intuition is similar to the notion of “financing risk” for innovation, as in Nanda and Rhodes-Kropf (2013, 2016). Another reason for carrying additional cash to avoid reliance on external financing is to minimize the inadvertent revelation 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 are consistent with these implications.

Our third hypothesis is that net debt will decline in response to greater competition. One

reason, related to the first hypothesis, is that greater competition leads to lower investments in assets-in-place, reducing the collateral base that generates debt capacity. A second reason is that the higher R&D investment goes hand-in-hand with greater investments in (illiquid) firm-specific human capital by employees, which also makes debt less attractive (see Berk, Stanton, and Zechner (2010) and Jaggia and Thakor (1994)).

Using data on publicly-traded biopharma companies, we provide empirical support for these predictions. In order to uncover some relevant empirical regularities, we first provide time series evidence, taking as a given the increase in competition over time noted in previous research. We document that R&D and cash holdings of the firms in the sample are substantial, and have increased over time in response to increasing competition. In addition, assets-in-place and net debt as a percentage of total assets declined for the average biopharma firm as competition increased.

While these stylized facts are consistent with our hypotheses, they do not address endogeneity concerns. In particular, biopharma firms face competition that has both endogenous and exogenous elements. Endogenous competition is affected by how much the firm spends on R&D; greater R&D spending provides a stronger shield against competition. Exogenous competition is affected by changes in market structure, regulation, and the nature of patent protection—developments that are plausibly exogenous at least at the individual firm level. To deal with these endogeneity concerns and 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 approach, we examine the effect of this legislative change on the biopharma industry. Specifically, we compare the reaction of financial characteristics of biopharma firms to a propensity-score-matched control group of R&D-intensive firms in

other industries that were not affected by the legislation. We find strong supporting evidence for the main hypotheses. The results survive a number of robustness checks, including a falsification test for the year of passage of the Act, tests that correct for the potential effect of serial correlation, and restricting our sample to account for changes in sample composition.

A potential 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 and control groups. We therefore conduct a final test by exploiting variation *within* the biopharma industry. Specifically, we use the Hatch-Waxman Act in order to compare the reaction of generic drug manufacturers in the pharma sector—firms for which the hypotheses are less applicable—to other pharma firms in a differences-in-differences approach. We again find supporting evidence for the main hypotheses.

Finally, we delve deeper into the effect of competition on innovation, to explore whether the increased R&D investment and other effects that we document lead to higher innovative *output* (measured by patents). We find that, despite the increase in R&D investment stemming from an exogenous shock to competition, firms produce relatively *fewer* patents. However, we also find that the market value of these patents *increases* following the increase in competition, using the firm-level innovation value measure of Kogan, Papanikolaou, Seru, and Stoffman (2017). This suggests that, faced with greater competition, firms specialize and focus on producing “targeted” or “impactful” innovations in order to differentiate themselves, rather than on simply increasing the number of total innovations.² This is novel evidence that the effect of competition on innovative output is nuanced—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 how competi-

²Put together, these results are broadly consistent with the documented decrease in R&D efficiency (e.g. Kortum (1993) and Scannell, Blanckley, Boldon, and Warrington (2012)), for which some have argued increased competition is a cause of. However, the 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.

tion affects innovation. A number of papers have shown that competitive firms will innovate more than a monopolist via the so-called “replacement effect” (Tirole (1988)), and that innovation generates an “escape-the-competition” effect (e.g. Aghion, Harris, Howitt, and Vickers (2001)). Aghion, Bloom, Blundell, Griffith, and Howitt (2005) build a model where firms facing large competitive pressures may innovate in order to regain lost profit margins, but this effect may be reversed in industries where competition is intense and laggard firms face large costs to catch up to industry leaders; see also Aghion, Dewatripont and Rey (1999). More recently, Aghion, Bechtold, Cassar and Herz (2014) have provided evidence based on lab experiments.³ We rely on this literature for our hypothesis that an increase in competition will increase innovation (through increased R&D investment). However, we also go beyond this literature and focus on the impact of competition on the firm’s choice of funding for innovation. We also provide novel evidence related to the differential effect of competition on R&D, innovation, and the economic value of the innovation.

Our paper is also related to the literature on the financing of R&D.⁴ Bergemann and Hege (2005) develop a theoretical model in which they examine how the choice of relationship versus arms-length financing by borrowers affects their R&D funding. Brown, Fazzari, and Petersen (2009) empirically document a positive relationship between financing supply and R&D. Hall and Lerner (2010) show that large firms prefer internal funds to finance R&D, whereas small firms experience high external financing costs that are only partially mitigated by venture capital. While these papers focus on issues related to R&D financing, they do not consider how it is affected by product market competition. More recently, a few papers have explored how competition affects firms’ innovation incentives and cash holdings. Morellec,

³Lin (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). And Lie and Yang (2017) empirically shows that the increase in import penetration by Chinese firms boosted innovation by US firms, and also prompted them to reduce their capital expenditures.

⁴Our work is also related to the vast capital structure literature, e.g. Jensen and Meckling (1976), Myers and Majluf (1984), Stulz (1990), Zwiebel (1996), Abel (2014); see Graham and Leary (2011) and Myers (2001) for comprehensive reviews.

Nikolov, and Zucchi (2014) develop a dynamic model and provide empirical support that competition increases corporate cash holdings and equity issues. Lyandres and Palazzo (2016) show theoretically and empirically that the firms that successfully innovate use cash as a commitment device for implementing innovations.

Also related is the empirical literature that examines R&D costs, returns, and risks in the pharmaceutical industry. For example, Grabowski and Vernon (1990) and DiMasi, Grabowski, and Vernon (1995) examine a selection of drugs introduced in the U.S. and document both a substantial increase in competition and a skewed distribution of sales from the drugs. DiMasi, Hansen, and Grabowski (2003) examine the cost of new drug development. Ellison, Cockburn, Griliches, and Hausman (1997) model the demand for pharmaceutical products and compute price elasticities. Myers and Howe (1997) build a Monte Carlo life-cycle model of drug R&D development for the pharmaceutical industry, and examine the model's estimates of risk, return, NPV, and 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 also provide additional empirical evidence focused on financial characteristics. Moreover, we focus explicitly on the interaction between competition, R&D spending, and capital structure decisions of biopharma companies which has not been examined previously.

In Section 2 we discuss the testable hypotheses emerging from the existing theories. We describe our data and time-series statistics in Section 3. In Section 4, we describe our main empirical methodology. Section 5 provides our main results and robustness tests, as well as an additional test of our main predictions by exploiting heterogeneity within the biopharma industry. Section 6 examines the effect of competition on the quantity and value of innovation output. We conclude in Section 7. The Appendix contains additional results.

2 Formulating Testable Hypotheses

In this section, we motivate the testable hypotheses we consider in our empirical analysis. Since there is not a single theoretical model that considers all of the interactions we study, we extrapolate based on several theories.⁵

Imagine an R&D-intensive firm, say a biopharma company, that has assets-in-place as well as an opportunity to invest in R&D. The firm must decide: (i) how much to invest in assets-in-place and how much to invest in R&D; and (ii) the capital structure with which to finance the firm, including how much cash to carry.

The firm faces competition on the products related to its assets-in-place, and an increase in this competition erodes the firm’s profit margins and cash flows from asset-in-place.⁶ R&D, when successful, is patent-protected and thus insulated from competitive entry. So a biopharma firm may engage in R&D to replace old drugs (many of which may be off-patent and thus face competitive pressures) with new (patent-protected) drugs that have higher margins.⁷ An implication is that an increase in product-market competition induces the firm to invest more in R&D and less in assets-in-place. This is similar to the “escape-the-competition” effect (e.g. Aghion, Harris, Howitt, and Vickers (2001), and Aghion, Bloom, Blundell, Griffith, and Howitt (2005)).⁸ This is our first testable hypothesis:

⁵An integrated theoretical model that captures all these interactions in reduced form, and generates the predictions we test, is available upon request.

⁶The notion of competition here is Bertrand competition, where the 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. Another example is the Hatch-Waxman Act, which was a source of exogenous variation in competition for the biopharma industry, and something we use for identification purposes later in our analysis. However, since 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.

⁷This 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.

⁸In their terminology, we are describing “neck-and-neck” firms competing in the product market. Aghion et al. (2005) also note that at high levels of competition, an increase in competition may decrease innovation.

1) *As product-market competition increases, firms will increase R&D investment and reduce assets-in-place that support existing products.*

The firm also has to determine how to fund its R&D investments. Some R&D payoffs can be contracted upon with outside financiers, such as commercializable products, but other payoffs like knowledge generation and associated spillover effects for insiders cannot be contracted upon at reasonable costs. Thus, there may be future states of the world in which insiders wish to raise additional financing, but outsiders are unwilling to provide it. This may constrain the firm's ability to pursue certain innovations, and the anticipation of such future constraints may induce the firm to carry cash balances as insurance. This desire for cash can be viewed as precautionary demand for liquidity (see, for example, Bolton, Chen, and Wang (2014)) or a hedge against "financing risk" for innovation (Nanda and Rhodes-Kropf (2013, 2016)). See the theory proposed by Lyandres and Palazzo (2016) for similar intuition.

Furthermore, R&D-intensive firms possess proprietary knowledge about their R&D, and it may be damaging to reveal it to its competitors. Because the firm knows more relative to the market, the very act of raising financing in the capital market may (inadvertently) reveal information to competitors (see Kamien and Schwartz (1978) and Thakor and Lo (2018)). As a result, an R&D-intensive firm has more of an incentive to carry cash and fund R&D internally as competitive pressures increase. Putting these arguments together leads to our second hypothesis:

2) *As competition increases, firms will carry more cash.*

Finally, the firm has to determine its capital structure beyond its cash holdings. The firm's income is taxable and debt interest payments are tax deductible. This makes debt attractive,

As we will show in Section 3, the level of competition in the biopharma sector continued to increase even after our period of focus, indicating that it was not especially high during our period of focus. We thus note that our empirical setting matches more closely the former "escape-the-competition" effect. However, we also show later that there may be a disconnect between R&D expenditures, innovative output, and the value of that innovation in terms of their responses to competition. We thus provide new evidence of the relationship between these effects that is not fully captured by existing theories.

all else equal. However, there are three reasons why debt is less attractive to R&D-intensive firms than others. First, borrowing at a reasonable cost requires collateralizable assets.⁹ As the firm shifts its investment from assets-in-place to R&D, it has less collateralizable assets. Second, since R&D investments can be expensed for tax purposes, they generate tax shields that diminish the marginal value of the debt tax shield (Thakor and Lo (2018)).

Third, R&D often requires employees to make *firm-specific* human capital investments that may not be completely portable to other firms. Incentivizing employees to make these investments requires long-term contracts that provide insurance against adverse ability-perception shocks, but the effectiveness of these contracts is diminished by the prospect of bankruptcy that can allow these contracts to be renegotiated or unwound. Employees will thus respond *ex ante* to higher firm leverage by reducing their firm-specific human capital investments in R&D. This is the essence of the human-capital-based capital structure theories developed by Berk, Stanton, and Zechner (2010) and Jaggia and Thakor (1994). These arguments lead to our final prediction:

3) *As competition increases, debt and net debt will decline.*

3 Data and Stylized Facts

In this section, we describe the data and present stylized facts about the intertemporal evolution of the characteristics of the biopharma industry.

3.1 Data and Summary Statistics

Our main data come from Compustat. The focus of our empirical analysis is the biopharma industry, which we take to be all firms that are comprised of Global Industry Classification Standard (GICS) codes 352020 (pharmaceuticals) and 352010 (biotechnology).¹⁰ We use

⁹The positive correlation between tangible collateralizable assets and debt financing is well-established both theoretically and empirically, e.g., Rampini and Viswanathan (2013).

¹⁰We include all firms denominated in USD, although our results are equivalent if we restrict the sample to firms incorporated in the US.

GICS codes to identify biopharma firms because it is a newer and more accurate classification system widely used by analysts, and is thus less exposed to the shortcomings of other classifications (such as SIC and NAICS) in identifying biopharma firms that have been noted by others (e.g. Carlson (2016) and Thakor et al. (2017)).¹¹ However, our results are also robust to identifying biopharma firms using classifications such as SIC codes. This 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 measured by cash and short-term investments scaled by total assets. Debt is represented by $Debt/TA$, which is the sum of total long-term debt and short-term debt (debt in current liabilities). Net debt is represented by $Net\ Debt/TA$, where $Net\ Debt = Debt - Cash$.¹²

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

¹¹As an example, the standard way to identify biopharma firms via SIC codes is to use: Drugs (2830), Biological Products (2831), Medicinal Chemical and Botanical Products (2833), Pharmaceutical Preparations (2834), In Vitro and In Vivo Diagnostic Substances (2835), and Biological Products except diagnostics (2836). These are the same SIC codes that comprise the Fama and French (1993) “Drugs” industry. However, given that SIC is an older classification system and the nature of the biopharma industry has evolved over time, there are newer biotech firms which do not cleanly fit into SIC industries in a way that makes it difficult to distinguish them from non-drug firms.

¹²Variables are winsorized at the 1% level across all firms in order to reduce the impact of extreme outliers.

[Table 1 Here]

3.2 Time-Series Stylized Facts

To document how the competitive environment in the biopharma industry has changed over time, we take a simple approach and focus on the increase in the number of firms operating in the industry. We do so because typical measures of industry competition, such as the Herfindahl-Hirschman Index or concentration ratio, present a distorted view of competition because they are sales-based measures. 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.

Figure 1 shows that the number of competitors in the industry has increased steadily until the mid-1990s, after which it has remained relatively flat. 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. This is consistent with existing papers (e.g. Caves, Whinston, and Hurwitz (1991), Grabowski and Vernon (1990, 1992), and others) that have shown that the industry has become more competitive over time.

[Figure 1 Here]

Taking this increase in competition over time as a given, we now examine the financial characteristics of firms in the biopharma industry. *Figure 2* shows how the financial characteristics of the biopharma industry have evolved. The mean and median values of $R\&D/TA$, PPE/TA , $Cash/TA$, $Debt/TA$, and $Net\ Debt/TA$ are calculated for each year. In order

to distinguish these trends from larger trends in other industries, the mean values of these variables are also included for all other industries apart from the biopharma industry.

[Figure 2 Here]

The graphs presented in *Figure 2* are consistent with the predictions from Section 2. In particular, as competition has increased over time, both mean and median R&D expenditures have increased, while assets-in-place (measured by PPE) have decreased sharply.¹³ Moreover, cash holdings have increased substantially.¹⁴ 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 indicated, the debt levels are cross-sectionally skewed across firms, with some firms holding very large amounts of debt—this 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 are more pronounced until the late-1990s. The changes in these variables are the largest in the 1980s and 1990s, which mirrors 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.

4 Empirical Methodology

While the previous stylized facts are generally consistent with the predictions of the model, they do not account for endogeneity—that R&D is affected by competition, but competition

¹³The secular increase in mean R&D expenditures understates an interesting cyclicity. One explanation for this cyclicity is a change in profitability each year, which partly determines how much firms are able to spend on R&D—and 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.

¹⁴The cash trends for biopharma compared to other industries are also in line with the findings of Begenau and Palazzo (2016), who show evidence that the overall increase in firm cash holdings is driven by the entry of more R&D-intensive firms.

is also affected by R&D. The ideal test is to find two groups of firms with similar characteristics, exogenously change the degree of competition for one group, and then examine if the resulting difference conforms to the predictions. We do this by exploiting the exogenous variation in competition introduced by the passage of the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act).

4.1 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. 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.¹⁵ 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 law introduced a provision where generic manufacturers can more easily challenge the validity of product patents of brand drugs, which lead to a rise in patent litigation for many drugs early in their product life-cycle (see Grabowski (2004) for details).

While evidence of the effect of the law on competition in the biopharma industry has

¹⁵See 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, as well as Grabowski (2007) for an overview.

been established in the studies mentioned above, it can also be seen empirically. As shown in *Figure 1*, the number of new entrants increases substantially after 1984, although there is an increasing trend in the years prior.

4.2 Empirical Methodology: Inter-Industry Variation

We first use the Hatch-Waxman Act as a source of exogenous inter-industry variation to conduct a differences-in-differences analysis in order to provide clearer empirical support for the predictions identified in Section 2. Because the Hatch-Waxman Act specifically impacted the biopharma industry, the treatment group consists of biopharma firms. Since the predictions are applicable for firms in R&D-intensive industries in general, we choose firms from the five top R&D-intensive industries other than biopharma as our control group.¹⁶

A concern with such an approach is that the control group has different characteristics and is thus not sufficiently comparable to the biopharma industry. To deal with this, we construct the control group by using propensity-score matching to choose firms from the other R&D-intensive industries that are comparable to biopharma firms based on observable characteristics in the sample period before the law was passed. Specifically, we choose firms in the other R&D-intensive industries that match biopharma firms based on their mean observable characteristics in the years between 1977 and 1983. The matching characteristics are: size ($\log(\text{Net Assets})$), profitability ($EBIT/TA$), capital structure ($Net\ Debt/TA$), 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).¹⁷ We show in Section 5.1 that the parallel trends assumption holds for the treatment and control groups.

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

¹⁶These 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).

¹⁷To choose these control firms, we implement the propensity score matching using one-to-one logit matching without replacement, and restrict observations to a common support.

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

In (1), $Y_{i,t}$ represents the dependent variable of interest for firm i in year t , predicted to vary as a function of competition by the theoretical model. HW_t is an indicator variable which takes a value of 1 if the year is 1984 or later, which is the period after the Act was enacted into law. $Biopharma_i$ is an indicator variable which takes a value of 1 if firm i is in the biopharma industry, and 0 if it is in the control group. It follows that the regression estimate of γ_1 is the differences-in-differences (diff-in-diff) estimator—the effect of the increase in competition stemming from the Hatch-Waxman Act on $Y_{i,t}$. Specifically, for the financial characteristics we examine $R\&D/TA$, PPE/TA , $Cash/TA$, $Debt/TA$, and $Net\ Debt/TA$ as choices for $Y_{i,t}$. To control for the possibility of differential trends between the control and treatment groups that are not accounted for by the matching procedure, $X_{i,t}$ is a vector of contemporaneous and lagged control variables that may also covary with the dependent variable.¹⁸ Finally, μ_i represents firm fixed effects, to control for time-invariant firm characteristics, and λ_t represents year fixed effects, to control for time-trends.

Equation (1) is estimated for the period from 1977 to 1991, which includes the seven years prior to and seven years subsequent to the passage of the law. We choose a relatively long estimation window to capture any delayed effects of competition on the variables of interest, given the well-documented long gestation periods in the biopharma industry, which will likely drive a slower response in many of the financial characteristics that we examine.¹⁹ However, 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 Section 5.

¹⁸Control variables included in $X_{i,t}$ for the financial characteristic variables include: $\log(NA)$ (where $NA = TA - Cash$), $EBIT/TA$ (earnings as a fraction of total assets to control for profitability), 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 also include the following lagged endogenous variables: $R\&D/TA$, PPE/TA , $Cash/TA$, $Debt/TA$.

¹⁹DiMasi & Grabowski (2007) document that the mean project length across the pharma and biotech sectors is approximately 8 years.

5 Results and Robustness

In this section, we present our main results, followed by various robustness checks.

5.1 Parallel Trends

A critical assumption of the diff-in-diff 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. Vertical red lines are include in 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.

[Figure 3 Here]

The levels of R&D expenditures, cash holdings, debt, net debt, and assets-in-place are all similar for both biopharma and the control group in the pre-period, showing that these two industries are indeed similar in terms of these financial characteristics. After the Act was implemented, the values for the two groups diverge in a way consistent with the 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.²⁰ Moreover, R&D, cash, net debt, and assets-in-place exhibit strong parallel trends before the Hatch-Waxman Act was implemented, although these are noisier for debt. Overall, the graphs provide evidence supporting the appropriateness of the

²⁰The differences for assets-in-place exhibits 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 7 using intra-industry variation.

differences-in-differences analysis in this setting, and also provide evidence for the effect of the Hatch-Waxman Act on the financial characteristics of the biopharma industry.

5.2 Regression Results

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

[Table 2 Here]

Overall, the results from the differences-in-differences analysis are consistent with the predictions in Section 2. The diff-in-diff estimator for *R&D* is positive and significant with or without control variables and fixed effects (columns (1) and (2)). This indicates that, as the Hatch-Waxman Act increased competition in the biopharma industry, firms in that industry increased their R&D relative to the control group. Based on the coefficient from column (2), biopharma firms increased their R&D expenditures as a percentage of total assets relative to the control group by about 2.4%. The diff-in-diff 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.²¹ The diff-in-diff 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 diff-in-diff 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

²¹The insignificant coefficient for assets-in-place may be due to some firms choosing to acquiring later-stage projects from other firms, which soon require manufacturing capability after they are commercialized. This would offset some of the reduction in assets-in-place that other firms undertake. However, if we alternatively examine the *relative* investment into PPE compared to R&D as a dependent variable—the ratio of capex to R&D expenditures—we find that the diff-in-diff coefficient has a negative and significant coefficient. This provides further evidence that these firms are shifting their investment away from assets-in-place and towards R&D.

pre-trends shown earlier.²² Finally, the estimator for *Net Debt* is negative and significant in both columns (9) and (10), indicating that net debt also declined compared to the control group (by roughly 11.6%) as a result of increased competition in the biopharma industry.

5.3 Robustness: Falsification Test

As a robustness check to account for the possibility that our results are being driven by trends that started before our sample period, we conduct a falsification test, in which we estimate regression (1) for the pre-Act sample period from 1969 to 1983, but falsely specify that the Act was implemented in 1976. As before, biopharma firms are our treatment group, and we choose propensity-score matched (based on observable characteristics in the period from 1969 to 1975) R&D-intensive firms as our control group.

The results of this falsification test are included in *Table 3*. When run over this time period, all of the variables are insignificant. This indicates that the results from the previous sections are not caused by any long-term trends between the treatment and control groups.

[Table 3 Here]

5.4 Robustness: Serial Correlation

A potential concern with our results is that they are biased due to serial correlation, driven by the relatively long sample window that we use (e.g. Bertrand, Duflo, and Mullainathan (2004)). We choose such a sample window because of the long R&D gestation periods in biopharma. However, we examine the robustness of our results to accounting for serial correlation to address these concerns.

One direct way to correct for the potential influence of serial correlation is to perform an adjustment of the standard errors. We therefore re-estimate our results using Newey and

²²Since we scale our outcomes by total assets, it is possible that our results are driven by changes in the amount of total assets rather than the variables of interest. In untabulated results, we find very similar results when running the variables in logs rather than scaling by total assets, which suggests that firms are actively changing their investment and financing decisions rather than simply experiencing a change in size.

West (1987) standard errors. The results are given in *Table 4* below.

[Table 4 Here]

The results using Newey-West standard errors are very similar to the previous results. As before, in comparing biopharma to other R&D-intensive firms, R&D is positive and significant, PPE is negative though insignificant, cash is positive and significant, and debt in addition to net debt are both negative and significant. Thus, our results are robust to explicitly correcting for serial correlation.

A potentially improved way to account for autocorrelation is suggested by Bertrand, Duflo, and Mullainathan (2004), and it involves collapsing the sample into two datapoints—one for the pre-period and one for the post-period—for each cross-sectional unit by taking means across time. They note that this procedure performs well in terms of correcting for autocorrelation, but has the disadvantage of low power. We perform this analysis in *Table 5*.²³

[Table 5 Here]

The results are similar to those in *Table 2*. The diff-in-diff estimator for R&D is again positive and significant, the estimator for cash is again positive and significant, and the estimator for net debt is again negative and significant. The estimators for debt and assets-in-place in this case are negative but insignificant. While this result for assets-in-place is similar to earlier results, the insignificance of debt is in contrast to the prior results; however, this may be due to the low power of the procedure, as noted above.

Put together, these results suggests that our main results are not driven by serial correlation induced by our longer estimation window.

5.5 Robustness: Incumbent Firms

Another concern is that our results could be driven by changes in the sample composition over time. In particular, if the characteristics of newly-listed biopharma firms entering our

²³The regression specifications include year and treatment group fixed effects.

sample are systematically different from those of existing firms, our results may be driven by these differences. We note that our predictions are applicable for these new entrants as well, and not just for incumbent firms—for example, a private or venture capital-backed firm should still respond to a change in competition in the way hypothesized in Section 2, and then this would be (correctly) reflected in our sample when that firm goes public. Nevertheless, we examine whether our main results hold by restricting our sample to just incumbents that were operating before the law was enacted.

Table 6 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*. Relative to the control group, incumbent biopharma firms increase their R&D and cash significantly in response to the Hatch-Waxman Act. They also decrease their net debt significantly, and decrease their assets-in-place and debt (although the effect is not significant for assets-in-place, as before, the effect for debt is marginally insignificant with a p-value of 0.105). This provides evidence that our main results are not due to a sample composition effect.

[Table 6 Here]

5.6 An Additional Test Using Intra-industry Variation

A potential concern with the previous methodology is that, even after performing matching and controlling for fixed effects and other observables, the control group may be different in unobservable ways from the treatment group. A related concern is that any results may be due to contemporaneous structural changes occurring in the control group industries that are unrelated to the Hatch-Waxman Act. Therefore, in this section, we conduct an additional test by exploiting variation *within* the biopharma industry.

We compare the reaction to the law by pharma firms that are focused on generic drug manufacturing to that of other pharma firms. The logic is that, since the Hatch-Waxman Act increased competition by facilitating the entry of generic drugs into the market place,

the hypotheses in Section 2 should apply *less* to the firms that were already primarily generic manufacturers prior to the passage of the law. In other words, generic pharma firms should *reduce* their R&D and cash, and *increase* their debt, net debt, and assets-in-place relative to other pharma firms after the Act was passed.

To identify generic drug manufacturers, we use data from the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the Orange Book), which contains historical information on every drug approved by the FDA and who the applicant is. Using this data, we identify all applications for the approval of generic drugs, and construct a measure for each firm of the proportion of total drug applications prior to 1984 that consists of generic drugs.²⁴ We construct our treatment group in this setting as firms for which at least 15% of their (pre-Act) drug portfolios are comprised of generic drugs.²⁵ One disadvantage of this approach is that there are relatively few generic drug manufacturers in our sample—21 firms operated in the treatment group prior to the enactment of the law. This has the potential to reduce the power of our analysis, but also makes it critical to select appropriate firms for the control group.²⁶ We therefore construct our control group of pharma firms using propensity-score matching in the same way as described in Section 4.2. Using these treatment and control groups, we estimate the same diff-in-diff specification as (1), replacing *Biopharma* with *Generic* as the indicator for our treatment group.²⁷

The regression results are included in *Table 7*. These results are broadly consistent with

²⁴A generic drug application is classified as an Abbreviated New Drug Application (ANDA).

²⁵Among firms in the sample, this corresponds to the top quartile in terms of the proportion of drugs which are generics.

²⁶These reasons also make it infeasible to run our treatment as a continuous variable.

²⁷*Figure A1* depicts the parallel trends for the treatment and control groups. For R&D and cash, the levels of the treatment and control groups are very similar prior to the enactment of the Hatch-Waxman Act, and exhibit parallel trends in the pre-period. Subsequently, the control group increases relative to the treatment group, consistent with the predictions. In contrast, debt and net debt appear to only move in parallel in the two or three years before to 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 assets-in-place are also noisy, though to a lesser extent—the treatment and control group move roughly in parallel for the first four years of the sample, but then begin to diverge in the years prior to the law change. However, the divergence then widens in a manner consistent with the predictions.

the hypotheses developed in Section 2. The diff-in-diff estimator for *R&D* is negative and significant without control variables and fixed effects (columns (1)), but is marginally insignificant (p-value of 0.16) when controls and fixed effects are included. This indicates that, as the Hatch-Waxman Act increased competition for the industry, generic manufacturers did not increase their R&D by as much as other pharma firms. The diff-in-diff estimator for *PPE* is positive and significant in column (3), which is consistent with our hypotheses—generic firms increased their assets-in-place relative to other pharma firms in response to the Hatch-Waxman Act. The diff-in-diff 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 diff-in-diff estimator for *Debt* is positive but insignificant in both columns (7) and (8)), and *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, but the findings should be interpreted with caution due to the noisy pre-trends and potentially low power owing to the small sample size.

[Table 7 Here]

Overall, these results, in combination with the previous inter-industry results, provide strong evidence for the hypotheses laid out in Section 2.

6 Effect on Innovation Output

We now explore the how these effects translate into actual innovation output by exploring the patents granted to each firm, as well as the value the market places on those patents.

6.1 Data and Parallel Trends

In order to explore this question, we obtain data on patents granted and the market value of those patents from Kogan, Papanikolaou, Seru, and Stoffman (2017).²⁸ The dataset contains the number of patents granted to each firm in each year, the forward citation-weighted number of patents, as well as 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, and this is scaled by the end-of-year market capitalization of the firm in order to calculate the final innovation value measure.²⁹ 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 compared to other R&D-intensive firms. Specifically, we estimate equation (1) using the patent counts and innovation value measure as choices for $Y_{i,t}$.³⁰ *Figure 4* below provides graphs showing trends for biopharma and control firms of the average number of patents (at the firm-level), citation-weighted patents, and the innovation value measure. For the number of patents and 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 Act 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

²⁸The data are obtained from Noah Stoffman’s website.

²⁹See Kogan et al. (2017) for details.

³⁰We propensity-score match 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 incumbent firms that are matched in both the treatment and control groups. While our regression results are robust to not imposing this restriction as well as a variety of other matching assumptions, we do this to ensure parallel trends hold between the treatment and control groups, given the documented pre-trends related to patents for the biopharma industry (e.g. Scannell et al. (2012)).

control groups move very closely together prior to the enactment of the Act, after which the market value of the patents increases sharply for the treatment group relative to the control group. Overall, the graphs suggest that the parallel trends assumption holds for these measures of innovation.

[Figure 4 Here]

The regression results are provided in *Table 8* below. Following the increase in competition following the Act, biopharma firms have significantly fewer patents granted (or patent applications published) than other R&D-intensive firms, in terms of both the raw number of patents and log patents. The results are similar when examining citation-weighted patents, which are typically used as an estimate to account 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.³¹

[Table 8 Here]

Put together, these results suggest that firms may be more focused on producing commercially valuable innovations in order to separate from competitors, rather than on producing a greater number of total innovations. That is, faced with greater competition, they are concentrating their efforts on trying to find niches that they can specialize in, potentially producing valuable “hits” in those areas, while narrowing the total number of areas that they research in. 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

³¹We focus on biopharma compared to other R&D-intensive firms, rather than generic-focused compared to other biopharma firms, because the latter sample has a small number of firms that are both generic-focused and have data on patents and innovation value. In addition, the intuition related to innovation does not cleanly translate to generic-focused manufacturers, as they would also have an incentive to focus on their generic drugs and thus innovate less. These issues notwithstanding, we generally find consistent results with this subsample—other pharma firms appear to reduce their innovation even more than firms that are more generic-focused, and the value of those innovations are higher than those from the generic-focused firms. These results are provided in *Figure A2* and *Table A1* of the Appendix.

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 fewer innovations are more valuable, a result that we are not aware is either predicted by existing theories or documented previously.

7 Conclusion

In this paper, we explore the interaction between competition, R&D investments, 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 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 a differences-in-differences test. We find strong supporting evidence for our hypotheses, which survive various robustness tests as well as an additional test which exploits within-industry variation. We also examine the effect of competition on the innovative output of these firms, and find that while firms reduce the number of patents they publish following an increase in competition, the economic value of those patents increase. Although we have focused on the biopharma industry, we believe our results are also applicable to other R&D-intensive firms.

At a broad level, innovative industries like biopharma have been subject to increased competitive pressures over time, through both regulation and technological breakthroughs that have facilitated easier entry (such as the Human Genome Project and increasingly faster and cheaper sequencing technologies). We highlight how these changes in competition may affect important financial characteristics, which may, in turn, affect the amount of funding that R&D-intensive firms are able to raise. For example, while increased competition may

spur innovation through increased R&D investment, it may also increase the reliance of these firms on funding through equity markets. This, in turn, could slow innovation down during “cold” markets, or alter the types of investments these firms make due to adverse selection in the capital markets.

Our analysis of the nuanced nature of R&D output also carries with it other important implications. For example, innovations in the biopharma industry lead to valuable drugs, and thus a reduction in the number of new drugs may lead to fewer diseases being treated. If the goal from a societal perspective is to have more innovations, then policies besides increasing competition may be needed. In addition, given the increase in R&D spending associated with increased competitive pressures over time, another implication of our results may be that more money may be needed in order to spur additional innovation. For example, a recent financial innovation that has been proposed in the biopharma industry is a portfolio of R&D projects, through the “megafund” idea of Fernandez, Stein and Lo (2012), Fagnan, Fernandez, Lo, and Stein (2013), and Hull, Lo, and Stein (2017).³² Such financial innovations may change the effects of competition on innovation in important ways, and increase the total volume of innovation.

³²Other financial innovations include insurance contracts called “FDA Hedges”; see Philipson (2015) and Jørring et al. (2017).

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Figure 1: Competition in the Biopharma Industry

This figure presents the number of competitors in the biopharma industry over time.

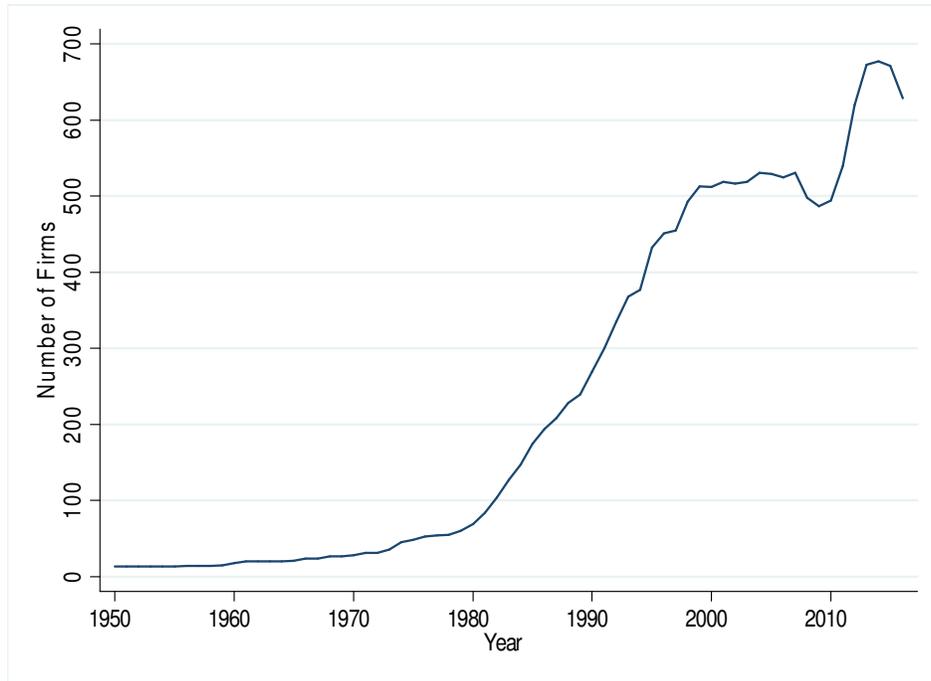


Figure 2: Financial Characteristics over Time

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

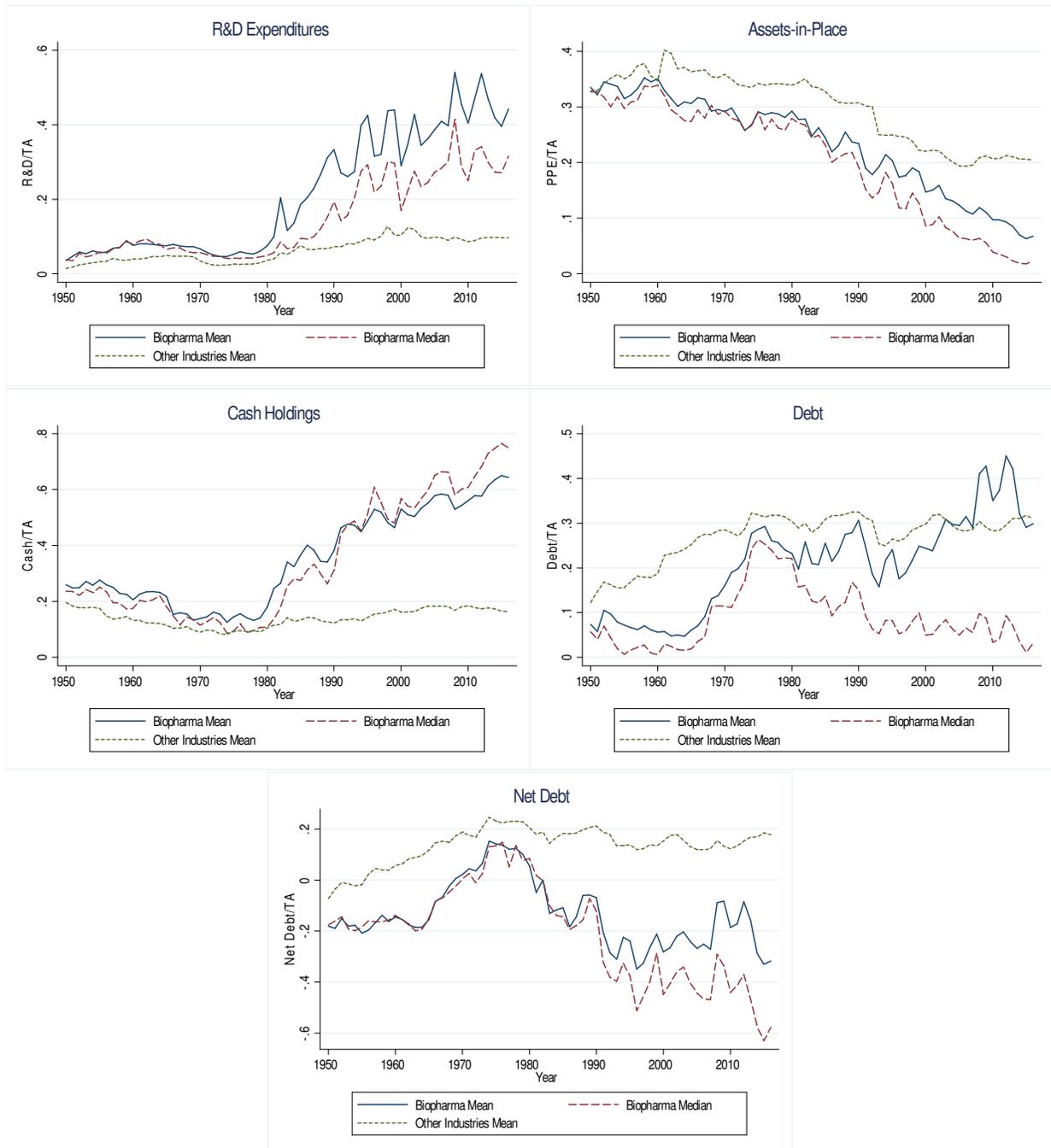


Figure 3: Main Results: Trends for Treatment and Control Groups

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

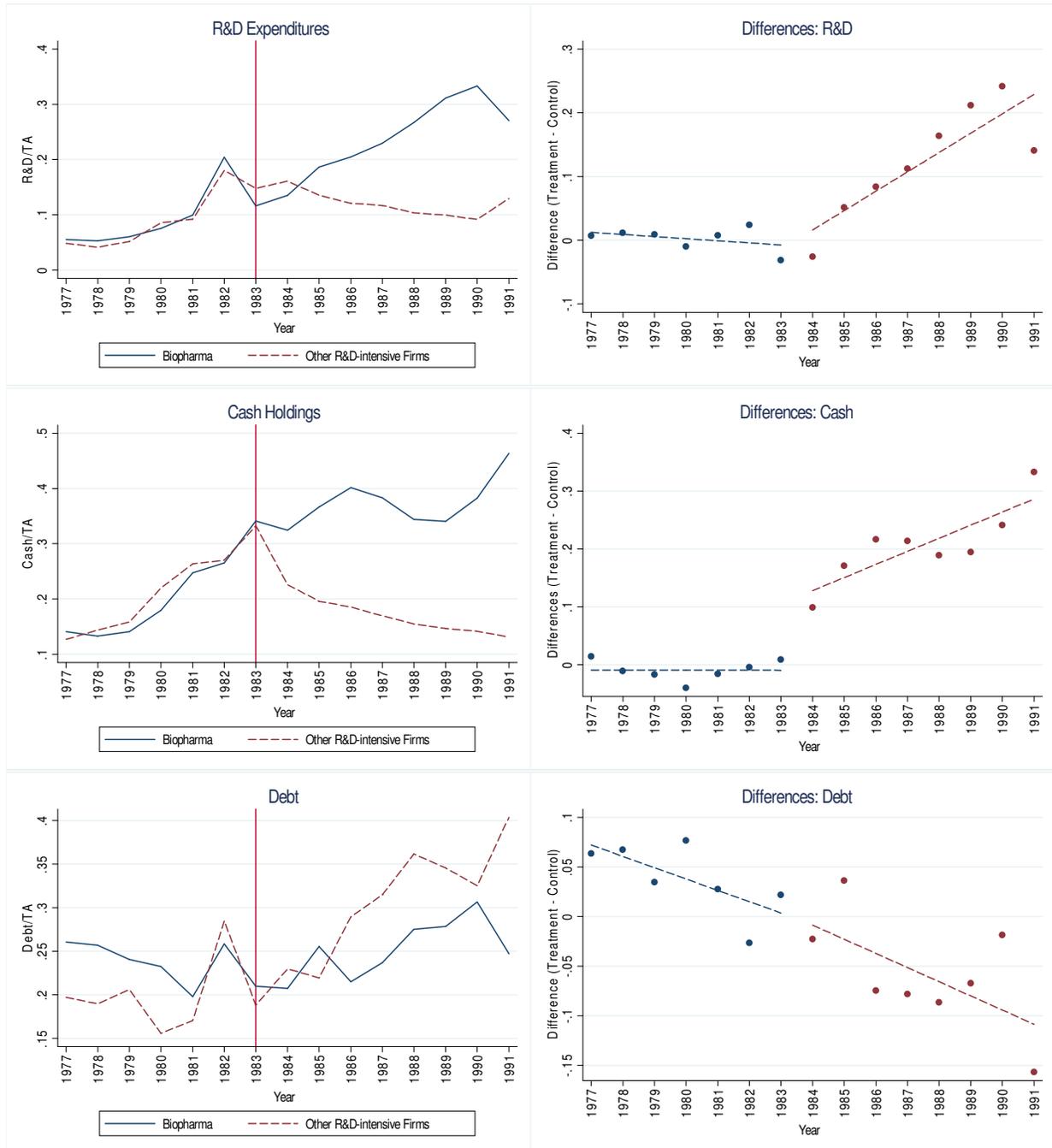


Figure 3 (continued): Main Results: Trends for Treatment and Control Groups

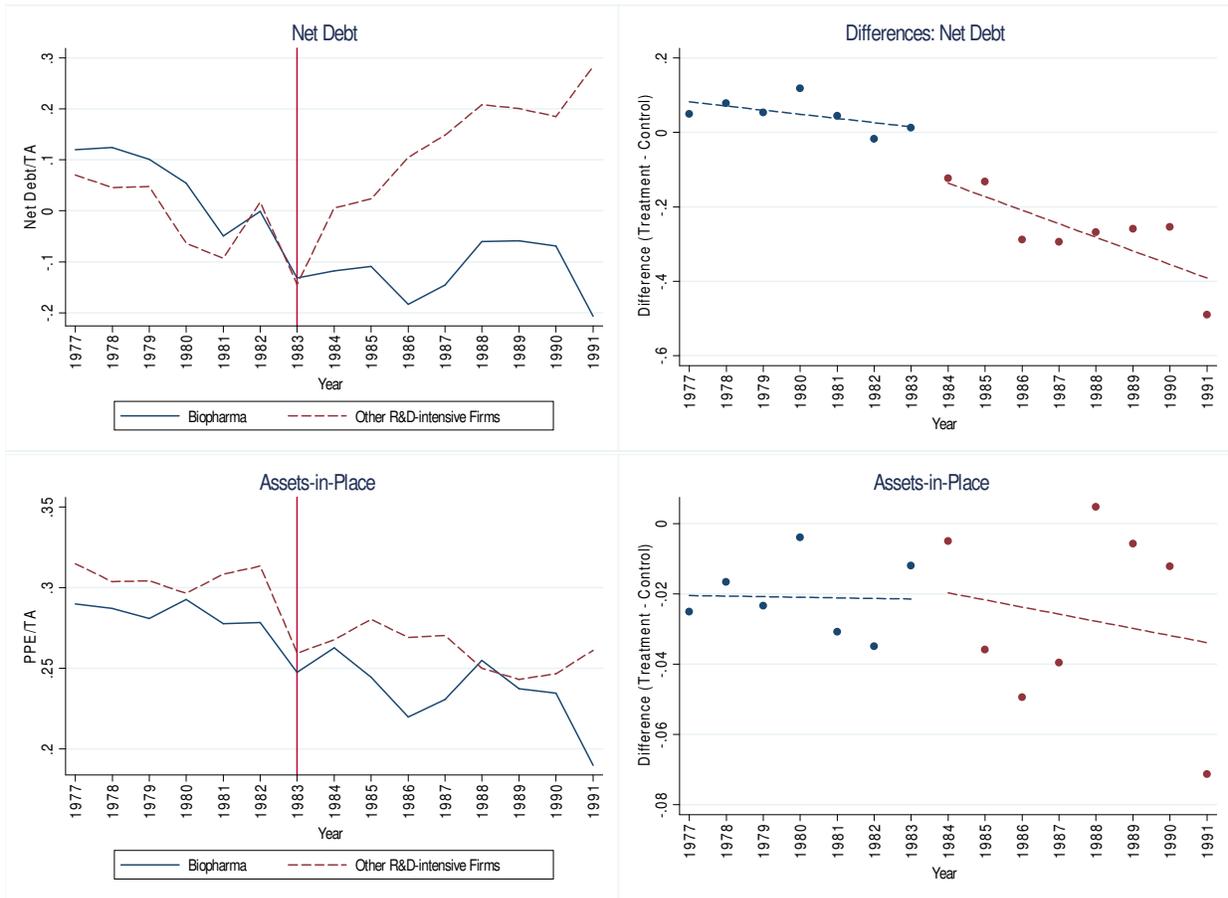


Figure 4: Innovation Trends for Treatment and Control Groups

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

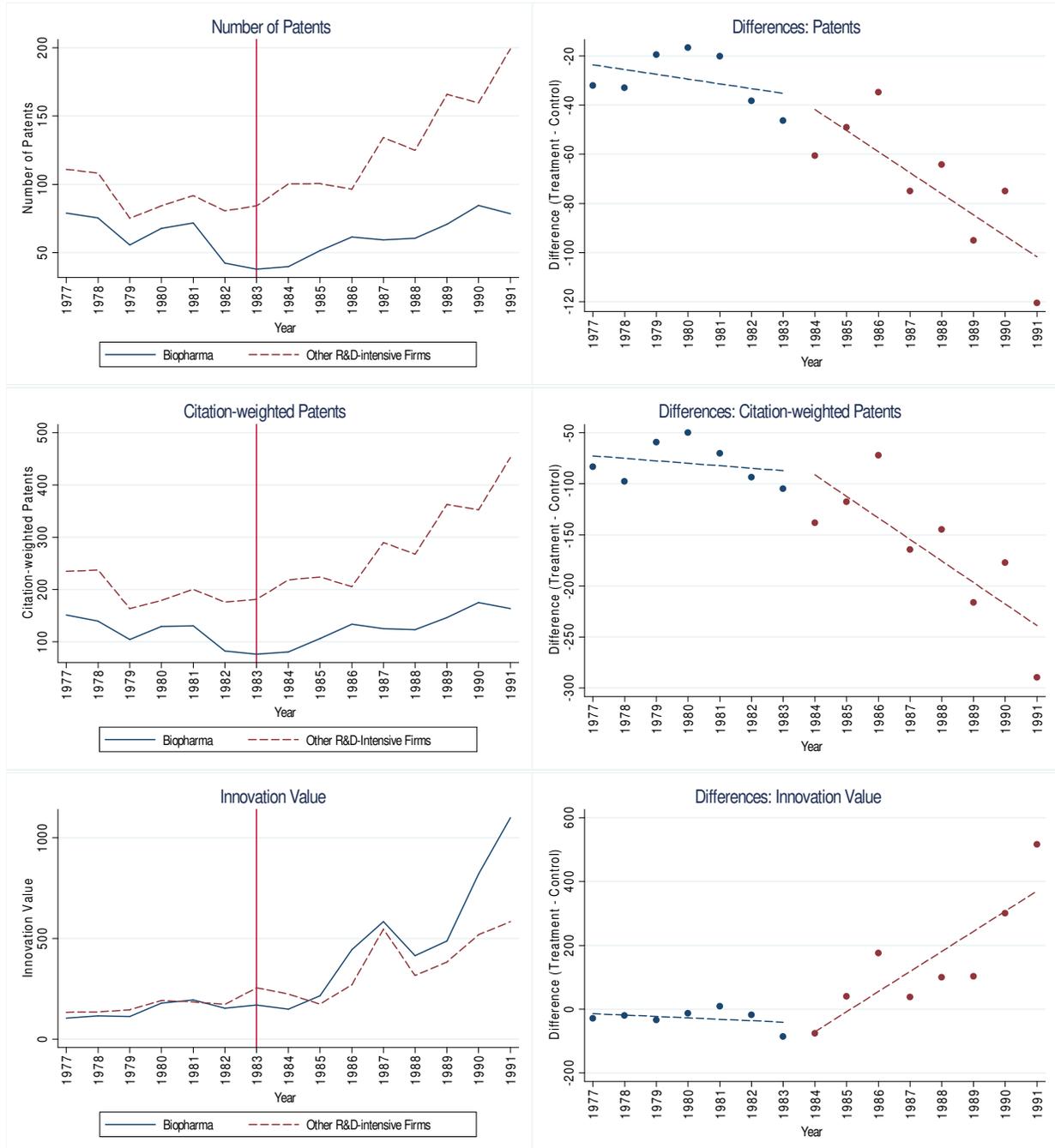


Table 1: Summary Statistics

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

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

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

This table estimates the differences-in-differences regression (1) for financial characteristics. The sample consists of biopharma firms and a control group consisting of propensity-score matched R&D-intensive firms. The sample period spans from 1977 to 1991. The dependent variables consist of $R\&D$, PPE , $Cash$, $Debt$, and $Net\ Debt$, each scaled by total assets. HW_t is a dummy variable which takes a value of 1 if the year is 1984 or later, and a value of zero otherwise. $Biopharma_i$ is a dummy variable which takes a value of 1 if firm i is in the biopharma industry, and a value of 0 if it is in the control group. Control variables include $\log(NA)$, $EBIT/TA$, M/B , Div/TA , and lagged values of PPE/TA , $Cash/TA$, $Debt/TA$, and $R\&D/TA$. Year and firm fixed effects are included where indicated. Robust standard errors are given in parentheses, and standard errors are clustered at the firm level. *, **, and *** indicate significance at the 10%, 5%, and 1% level, respectively.

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

Table 3: Falsification Test

This table estimates the differences-in-differences regression (1), but over the sample period from 1969 to 1983. The dependent variables consist of $R\&D$, PPE , $Cash$, $Debt$, and $Net\ Debt$, each scaled by total assets. Act_t is a dummy variable which takes a value of 1 if the year is 1976 or later, and a value of zero otherwise. $Biopharma_i$ is a dummy variable which takes a value of 1 if firm i is in the biopharma industry, and a value of 0 if it is in the propensity-score matched control group of other R&D-intensive firms. Control variables include $\log(NA)$, $EBIT/TA$, M/B , Div/TA , and lagged values of PPE/TA , $Cash/TA$, $Debt/TA$, and $R\&D/TA$. Year and firm fixed effects are included, as indicated. Robust standard errors are given in parentheses, and standard errors are clustered at the firm level. *, **, and *** indicate significance at the 10%, 5%, and 1% level, respectively.

	(1)	(2)	(3)	(4)	(5)
Dependent Variable:	$R\&D$	PPE	$Cash$	$Debt$	$Net\ Debt$
$Act_t \times Biopharma_i$	0.005 (0.006)	0.0002 (0.009)	0.001 (0.015)	-0.019 (0.013)	-0.020 (0.023)
Controls	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes
Observations	1,022	1,037	1,037	1,036	1,036
Number of Firms	158	159	159	159	159
R^2	0.923	0.887	0.849	0.813	0.859

Table 4: Differences-in-Differences Regressions, Newey-West Standard Errors

This table estimates the differences-in-differences regression (1) for financial characteristics, correcting for autocorrelation using Newey-West standard errors. The dependent variables consist of $R\&D$, PPE , $Cash$, $Debt$, and $Net\ Debt$, each scaled by total assets. Act_t is a dummy variable which takes a value of 1 if the year is 1984 or later, and a value of zero otherwise. $Biopharma_i$ is a dummy variable which takes a value of 1 if firm i is in the biopharma industry, and a value of 0 if it is in the propensity-score matched control group of other R&D-intensive firms. Control variables include $\log(NA)$, $EBIT/TA$, M/B , Div/TA , and lagged values of PPE/TA , $Cash/TA$, $Debt/TA$, and $R\&D/TA$. Year and firm fixed effects are included. Newey-West standard errors are given in parentheses, with 10 lags. *, **, and *** indicate significance at the 10%, 5%, and 1% level, respectively.

	(1)	(2)	(3)	(4)	(5)
Dependent Variable:	$R\&D$	PPE	$Cash$	$Debt$	$Net\ Debt$
$Act_t \times Biopharma_i$	0.024** (0.011)	-0.004 (0.010)	0.076*** (0.018)	-0.040** (0.020)	-0.116*** (0.032)
Controls	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes
Observations	2,156	2,174	2,174	2,172	2,172

Table 5: Differences-in-Differences Regressions, Collapsed Sample

This table estimates the differences-in-differences regression (1) for financial characteristics, collapsing 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. Act_t is a dummy variable which takes a value of 1 if the year is 1974 or later, and a value of zero otherwise. $Biopharma_i$ is a dummy variable which takes a value of 1 if firm i is in the biopharma industry, and a value of 0 if it is in the propensity-score matched control group of R&D-intensive firms. Year and treatment group fixed effects are included. Robust standard errors are given in parentheses, and are clustered by firm. *, **, and *** indicate significance at the 10%, 5%, and 1% level, respectively.

	(1)	(2)	(3)	(4)	(5)
Dependent Variable:	$R\&D$	PPE	$Cash$	$Debt$	$Net\ Debt$
$Act_t \times Biopharma_i$	0.165*** (0.028)	-0.017 (0.018)	0.230*** (0.033)	-0.045 (0.045)	-0.270*** (0.066)
Fixed Effects	Yes	Yes	Yes	Yes	Yes
Observations	597	639	639	639	639
R^2	0.100	0.018	0.090	0.009	0.027

Table 6: Differences-in-Differences Regressions, Restricted Incumbent Sample

This table estimates the differences-in-differences regression (1) for financial characteristics using the restricted sample of incumbent firms. The sample consists of biopharma firms and a control group consisting of propensity-score matched R&D-intensive firms. The sample period spans from 1977 to 1991. The dependent variables consist of $R\&D$, PPE , $Cash$, $Debt$, and $Net\ Debt$, each scaled by total assets. HW_t is a dummy variable which takes a value of 1 if the year is 1984 or later, and a value of zero otherwise. $Biopharma_i$ is a dummy variable which takes a value of 1 if firm i is in the biopharma industry, and a value of 0 if it is in the control group. Control variables include $\log(NA)$, $EBIT/TA$, M/B , Div/TA , and lagged values of PPE/TA , $Cash/TA$, $Debt/TA$, and $R\&D/TA$. Year and firm fixed effects are included where indicated. Robust standard errors are given in parentheses, and standard errors are clustered at the firm level. *, **, and *** indicate significance at the 10%, 5%, and 1% level, respectively.

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

Table 7: The Effect of the Hatch-Waxman Act on Generic-focused and Other Pharma Firms

This table estimates the differences-in-differences regression (1) for financial characteristics. The sample consists of generic-focused pharma firms and a control group consisting of propensity-score matched pharma firms. The sample period spans from 1977 to 1991. The dependent variables consist of $R\&D$, PPE , $Cash$, $Debt$, and $Net\ Debt$, each scaled by total assets. HW_t is a dummy variable which takes a value of 1 if the year is 1984 or later, and a value of zero otherwise. $Generic_i$ is a dummy variable which takes a value of 1 if firm i is focused on generic drugs, and a value of 0 if it is in the control group. Control variables include $\log(NA)$, $EBIT/TA$, M/B , Div/TA , and lagged values of PPE/TA , $Cash/TA$, $Debt/TA$, and $R\&D/TA$. Year and firm fixed effects are included where indicated. Robust standard errors are given in parentheses, and standard errors are clustered at the firm level. *, **, and *** indicate significance at the 10%, 5%, and 1% level, respectively.

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

Table 8: Differences-in-Differences Regressions, Measures of Innovation

This table estimates the differences-in-differences regression (1) for the measures of innovation. The sample consists of biopharma firms and a control group consisting of propensity-score matched R&D-intensive firms. The sample period spans from 1977 to 1991. The dependent variables consist of *patents* (the number of patents), *cw patents* (the number of citation-weighted patents), and *Innovation Value* (the market value of new patents). HW_t is a dummy variable which takes a value of 1 if the year is 1984 or later, and a value of zero otherwise. $Biopharma_i$ is a dummy variable which takes a value of 1 if firm i is in the biopharma industry, and a value of 0 if it is in the control group. Control variables include $\log(NA)$, $EBIT/TA$, M/B , Div/TA , and lagged values of PPE/TA , $Cash/TA$, $Debt/TA$, $R\&D/TA$, and the respective dependent variable. Year and firm fixed effects are included where indicated. Robust standard errors are given in parentheses, and standard errors are clustered at the firm level. *, **, and *** indicate significance at the 10%, 5%, and 1% level, respectively.

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

Appendix: Additional Results

Figure A1: Generic-focused and Other Pharma Firms: Trends for Treatment and Control Groups

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 generic-focused pharma firms, while the red dashed lines give averages for the control group of other matched pharma firms. A vertical red line is included, representing the year that the Hatch-Waxman Act was implemented. The graphs on the right depict the differences between the treatment and control groups (treatment minus control), with pre- and post-period trend lines added.

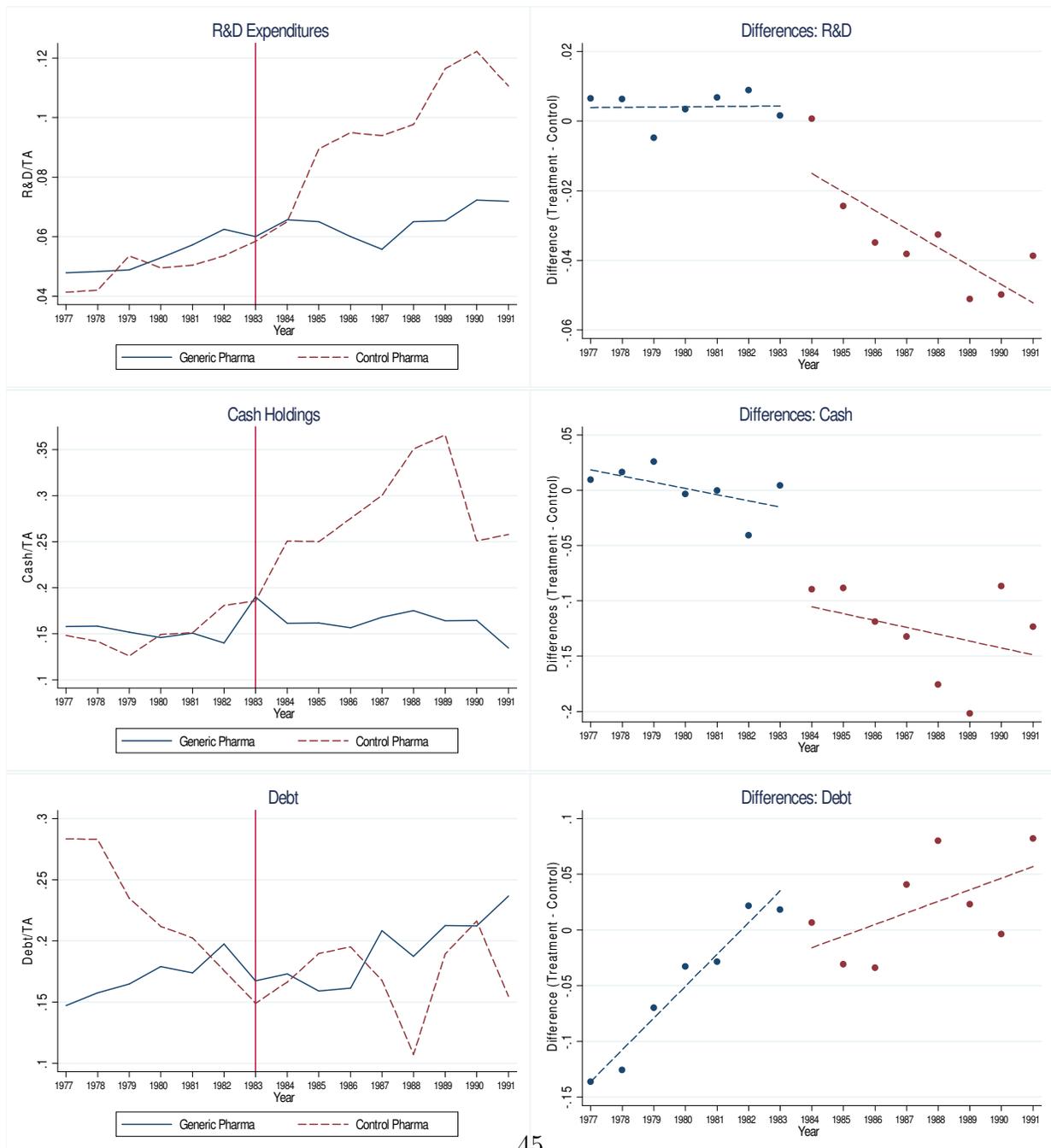


Figure A1 (continued): Generic-focused and Other Pharma Firms: Trends for Treatment and Control Groups

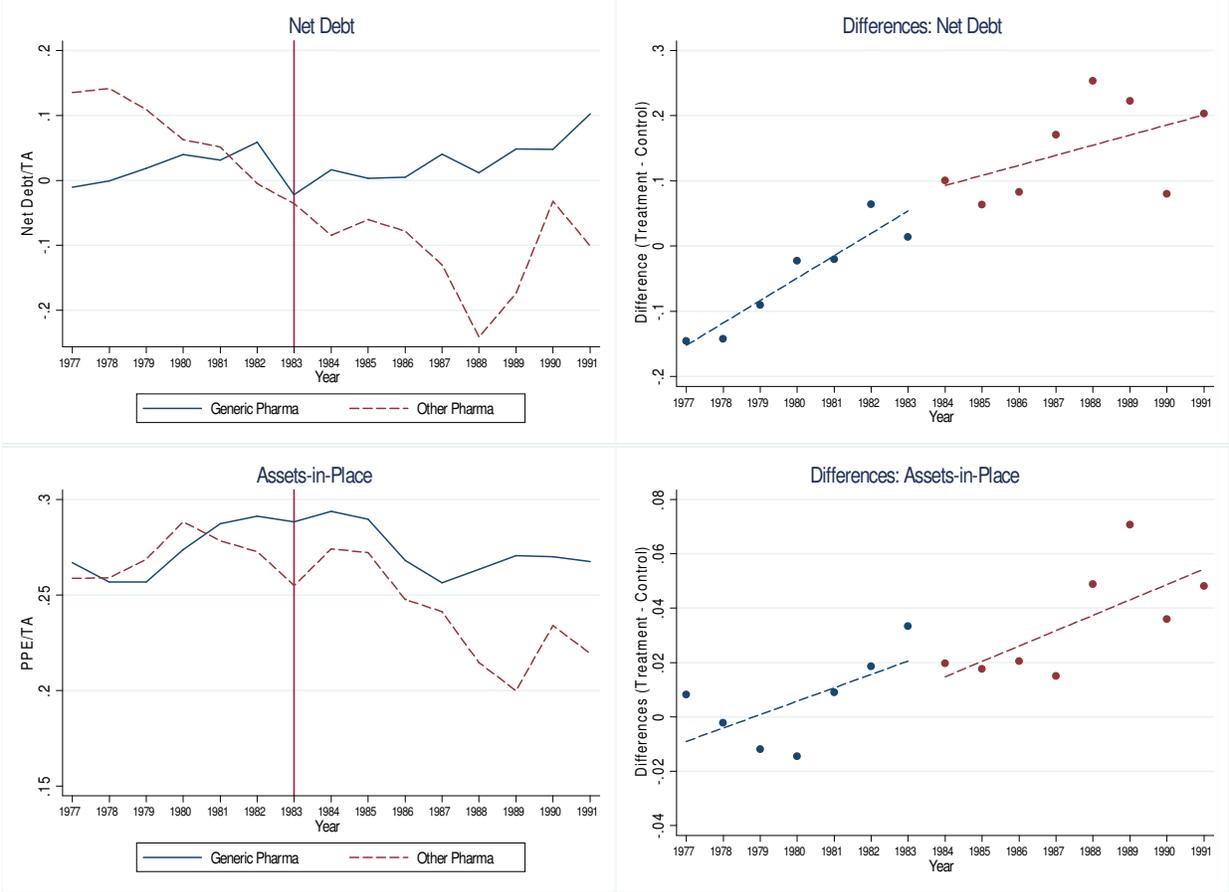


Figure A2: Innovation Trends for Generic-focused and Other Pharma Firms

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

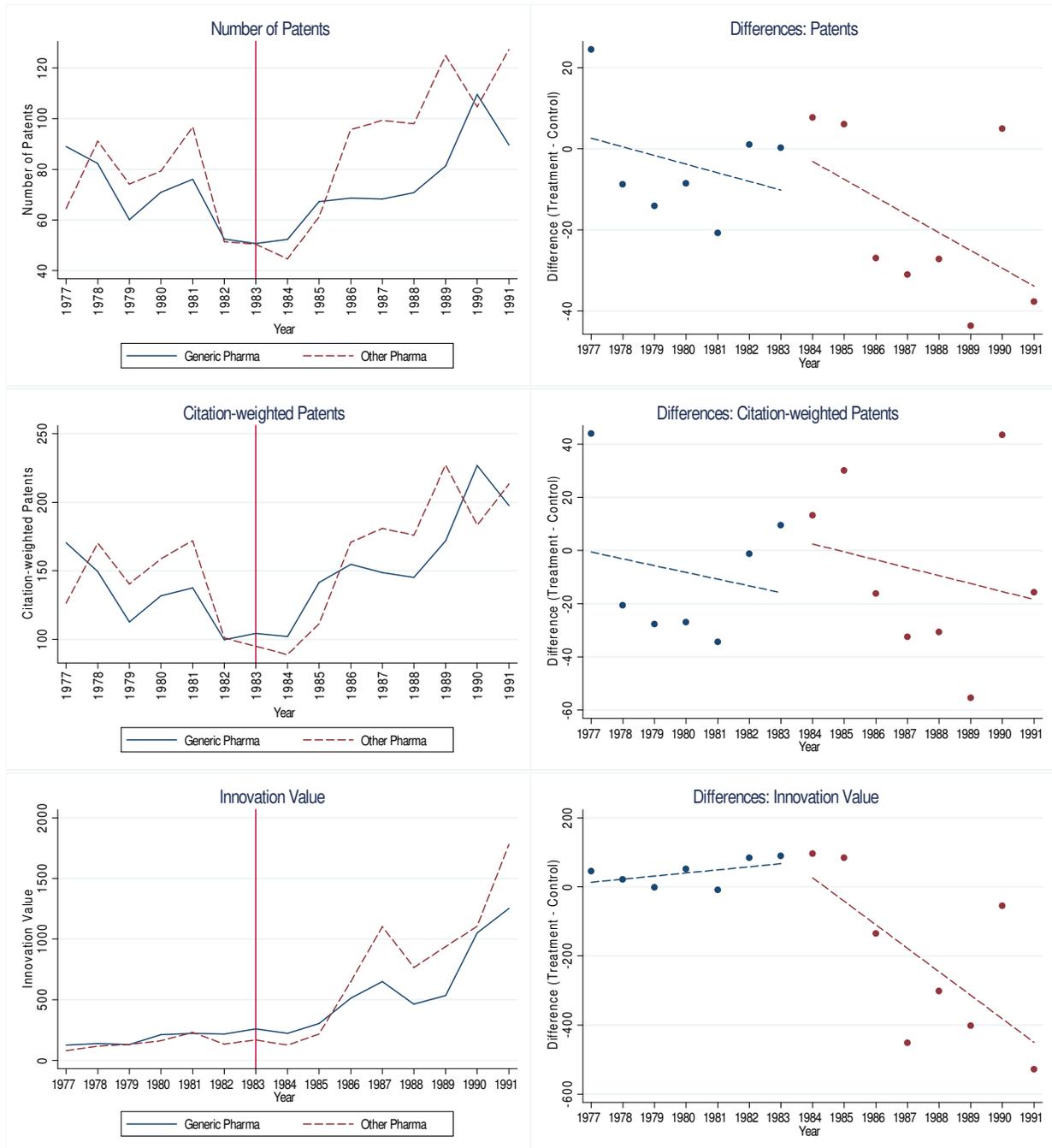


Table A1: Intra-industry Differences-in-Differences Regressions, Measures of Innovation

This table estimates the differences-in-differences regression (1) for the measures of innovation between generic and other pharma firms. The sample consists of generic-focused pharma firms and a control group consisting of propensity-score matched pharma firms. The sample period spans from 1977 to 1991. The dependent variables consist of *patents* (the number of patents), *cw patents* (the number of citation-weighted patents), and *Innovation Value* (the market value of new patents). HW_t is a dummy variable which takes a value of 1 if the year is 1984 or later, and a value of zero otherwise. $Generic_i$ is a dummy variable which takes a value of 1 if firm i is focused on generic drugs, and a value of 0 if it is in the control group. Control variables include $\log(NA)$, $EBIT/TA$, M/B , Div/TA , and lagged values of PPE/TA , $Cash/TA$, $Debt/TA$, $R\&D/TA$, and the respective dependent variable. Year and firm fixed effects are included where indicated. Robust standard errors are given in parentheses, and standard errors are clustered at the firm level. *, **, and *** indicate significance at the 10%, 5%, and 1% level, respectively.

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