The Impact of Patenting on New Product Introductions in the Pharmaceutical Industry

Graham Stuart and Matthew Higgins

Georgia Institute of Technology

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Stuart J.H. Graham[a], Matthew J. Higgins[b*]

[a] *College of Management, Georgia Institute of Technology, Atlanta, GA, 30308, USA*

[b] *College of Management, Georgia Institute of Technology, Atlanta, GA, 30308, USA*

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Abstract

Since Comanor and Scherer (1969), researchers have been using patents as a proxy for new product development. In this paper, we reevaluate this relationship by using novel new data. We demonstrate that the relationship between patenting and new FDA-approved product introductions has diminished considerably since the 1950s, and in fact no longer holds. Moreover, we also find that the relationship between R&D expenditures and new product introductions is considerably smaller than previously reported. While measures of patenting remain important in predicting the arrival of product introductions, the most important predictor is the *loss of exclusivity protection* on a current product. Our evidence suggests that pharmaceutical firms are acting strategically with respect to new product introductions. Finally, we find no relationship between firm size and new product introductions.

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*Corresponding author contact information: E-mail address: matt.higgins@mgt.gatech.edu

1.0 Introduction

The role that patenting plays in the firm value equation has long been a question of considerable interest in the literature (Schmookler, 1962; Comanor and Scherer, 1969; Pakes, 1985; Jaffe, 1986; Cockburn and Griliches, 1988; Griliches, 1990; Shan, *et al*., 1994; Henderson and Cockburn, 1994; Bloom and Van Reenen, 2002; Hagedoorn and Cloodt, 2003; Hall, *et al*., 2003). This role is particularly relevant in the pharmaceutical industry given the high likelihood that firms will patent inventions (Cohen *et al*., 2003). However, it remains a theoretical and empirical question: How adequately do patent counts, or various other patent-derived measures, proxy for the innovative success of the firm? In this paper we explore this question with fresh data, using for the first time we are aware the combination of actual new product introductions by pharmaceutical firms, their associated product sales data, and these firms' patents, both those explicitly linked to the new products, and all other pharmaceutical research patents issued to these firms.

We make multiple contributions to the literature. First, we demonstrate that the relationship between patenting (and citation-weighted patenting) and new Food and Drug Administration (FDA) approved product introductions has diminished considerably since results offered in the seminal work by Comanor and Scherer (1969) and later efforts by Hagedoorn and Cloodt (2003). We also demonstrate that the relationship between research and development (R&D) expenditures and new FDA approved product introductions is considerably smaller than previously reported. Based upon superior data, our results provide evidence that calls into question the efficacy of using patents, citation-weighted patents and R&D expenditures as proxies for new product development.

Second, we demonstrate that while measures of patenting and citation-weighted patenting remain important in predicting the arrival and the number of product introductions, the most important predictor is the *loss of exclusivity protection* on a current product. Our evidence suggests that pharmaceutical firms are acting strategically, targeting the three-year window around the loss of exclusivity to introduce new products. The apparent ability of pharmaceutical firms, in general, to smooth firm revenues by targeting introductions appears to us impressive given the long development periods they face.

Third, some researchers have moved away from raw patent counts and instead focus on citation-weighted counts in order to determine "strength" or "importance" of a patent, or as a proxy for "value" (Bloom and Van Reenen, 2002; Hall, *et al*., 2003). Using a large sample of pharmaceutical-related patents for our firms, we are able to demonstrate that more highly-cited patents are more likely to be associated with an FDA-approved product. This finding is economically meaningful since these patents protect the revenue streams of approved products. In 2001, for example, average FDA approved products had revenues of $243 million.

Fourth, we explore the implications of relying upon the *original filing date* of United States patents, instead of relying upon the artificial "application date" listed on the front page of the patent document. Consistent with Graham (2004), we use the first in what may be a string of patent application *continuations*, as an indicator of the date on which the granted patent originally entered the patent system. This correction is particularly important in the pharmaceutical industry, since a large share of granted patents in this sector have had at least one continuation in their application lineage. In our analysis, we find significant differences in the amount of pre-grant application lag that this correction offers. Moreover, we find that continuation counts are a positive and significant predictor of new product introductions, suggesting to us that this variable contains information about the strategic use of the patenting process by firms.

Fifth, unlike the extant empirical literature, we explicitly control for each pharmaceutical firm's underlying research portfolio. Across all specifications tested we find a positive and significant impact on new product introductions. This finding confirms prior research that shows the importance for firms to maintain healthy research pipelines (Higgins and Rodriguez, 2006).

Finally, we find no relationship between firm size and new product introductions. Other work that uses patenting as a proxy for new product development has found a relationship between these two variables, either positive or negative (Rothaermel and Hess, 2007; Nohria and Gulati, 1996; Shan *et al*., 1994; Acs and Audretsch, 1989; and, Bound *et al*, 1984). In contrast, our findings are consistent with prior work that uses *actual* new product introductions as a dependent variable and introduces firm size as an

independent variable, and finds a size effect not significantly different from zero (Jensen, 1987).

The remainder of the paper follows this structure: Section 2 briefly discusses patenting, new product development and research productivity trends in the pharmaceutical industry; Section 3 discusses the data used in our analysis; Section 4 presents and discusses our empirical finding; and Section 5 summarizes the analysis and discusses the implications of our results.

2.0 Patenting, new product development, and research productivity trends in the pharmaceutical industry

2.1 Research productivity trends

Our analysis demonstrates that research productivity in the pharmaceutical industry (as measured by the overall industry drug-exclusivity and patent horizon) declined in the late 1990s—precisely when pharmaceutical patenting was exploding (Hall, et al., 2001). A substantial factor contributing to these declines was that current-market drugs were losing exclusivity protection at a much higher rate than they were being replaced by new FDA-approved products with exclusivity protection.[1] The term "exclusivity" refers to exclusive regulatory marketing rights granted by the FDA under 21 C.F.R. 314.108, which prevent generic products from entering the market.

The pharmaceutical industry had a combined total of approximately 1,100 years of aggregate exclusivity protection in 1998. By 2001, the exclusivity horizon had fallen to just over eight hundred years and showed a rapid rate of decline. Figure 1 plots the total aggregate count of exclusive years for unique products approved by the FDA in the focal year. The aging of the overall industry product profile is a critical factor explaining the observed rapid decline.

[1] One explanation put forth by industry representatives for this decline is that the easy drugs have already been developed and that the drugs currently under development are much more sophisticated and target more difficult diseases. A second explanation, described in the Wall Street Journal (2004), suggests that the heavy reliance on combinatorial chemistry and high-throughput screening did not produce the hits that were initially hoped for when this technology was adopted in the 1990s.

Figure 2 plots the numbers of drug candidates at various stages of clinical testing. Overall the number of candidates in some stage of testing has dramatically increased. Nevertheless, the number of products actually approved by the FDA has remained relatively constant. This discrepancy suggests that a comparatively large number of drug candidates fail or are withdrawn during the testing process. For example, the ratio of candidates that mature to an NDA filing compared to the number of candidates in Phase III testing declined from 29 percent to 17 percent through the 1990s.[2]

Further compounding the problem for the industry, new products take an average of ten to fifteen years to develop from initial discovery to final FDA approval (DiMasi, 2001). From 1988 to 2001, the average time required for the FDA to approve a new drug was approximately 20 months (Federal Trade Commission, 2002). Over the same time period, the real cost of developing a new drug product increased, from $231 million in 1987 to $802 million in 2000 (DiMasi, 2001). Domestic research and development expenditures have followed the same trend. In 1990, R&D expenditures for U.S. pharmaceutical companies totaled $6.8 billion, growing by 2000 to over $21.3 billion (constant dollars). However, as a percentage of sales, R&D expenditures have remained fairly stable at around 15 percent from 1990 to 2001 (See Figure 3).

2.2 Patenting and new product development

Explorations of the relationship between patenting and new product introduction in the context of pharmaceutical innovation has a long lineage in the literature. Comanor and Scherer (1969) produced one of the first comprehensive empirical studies to analyze the link. Primarily interested in exploring the relationship between patents and technological change, their paper investigates how drug firms' patent counts during 1952 to 1957 correlate with an input measure, the number of research personnel, and with an output measure, new drug product introductions from 1955 to 1960. Measuring the latter as the number of "new chemical entities" (weighted by their sales in the two years following introduction), the authors demonstrate that, when scale effects are controlled for, patents appear to be a predictor of new product introductions.

[2] Author's calculations based on data from Pharmaprojects and NDA Pipeline.

Their paper, along with Schmookler (1962), has been a fountainhead for much of the literature published on this topic thereafter. Patent counts have become a generally accepted indicator of innovative performance in terms of new technologies, new processes and new products (e.g., Acs and Audretsch, 1989; Aspden, 1983; Bresman et al, 1999; Cantwell and Hodson, 1991; Freeman and Soete, 1997; Griliches, 1998; Napolitano and Sirilli, 1990; Patel and Pavitt, 1995; Pavitt, 1988; Ahuja, 2000; Hagedoorn and Schakenraad, 1994; Henderson and Cockburn, 1994, Owen-Smith and Powell, 2004; Shan et al., 1994; Stuart, 2000). The paper's implications are reasonably straightforward, although the authors did voice one important caveat that is too often given short shrift by subsequent authors who use patents as proxies for "research output." Discussing their results, Comanor and Scherer (1969) state:

> [o]ur empirical findings also suggest that patents may be a better index of research input than output. [] The number of patents applied for may represent the effort expended by the firm in inventing, rather than the magnitude of the inventions which result from this effort. While this finding is highly tentative, it is supported by the likelihood that the significance of a patent in terms of input is less variable than its significance in terms of output (p. 398).

As such, these authors admonish researchers to take care in interpreting their correlations too broadly.

Subsequent studies of the patent-performance relationship have attempted to reduce the variability found by Comanor and Scherer (1969), principally by using different, or adding additional, measures. Cockburn and Griliches (1988), for instance, examined whether changes in market value (Tobin's Q) are related to a firms' development of knowledge capital over time (measured as depreciated stocks of R&D expenditures and patent grants), and whether information on the importance of patents as an appropriability mechanism (Levin, *et al*., 1987) adds meaningful information and improves predictive power. While they find that patent measures on their own appear to capture some relevant aspects of intangible capital, they note that when R&D measures are included the patent estimate either disappears or is heavily attenuated. As such, the authors declare that there is "interesting information in patent counts, but it is subject to much error. Data on R&D expenditures, where available, are stronger measures of input to the process by which firms produce technical innovation than patents are of its

'output.'" (p. 422). Hall, Jaffe, and Trajtenberg (2003) add patent citations, finding that the inclusion of this "importance" metric significantly improves a model in which patenting is related to firm value, finding that patenting alone is a less meaningful predictor.

Despite these findings, other studies continue to rely upon patent counts alone as a reasonably good predictor of firm research productivity. Henderson and Cockburn (1994) posit that, in the pharmaceutical context, patents are a meaningful measure of drug discovery because of the critical role that patents play in securing competitive advantage, suggesting that in science-intensive industries patents are highly correlated with profitability and market value. Ahuja (2002) also relies upon this relationship in his study of organizational networks in the chemical industry, employing a count of issued patents as a measure of innovation output in this science-intensive sector. Bloom and Van Reenen (2002) present evidence from a panel of British firms that patent and patent citation measures are strong predictors of firm market value, and suggest that these patent measures are potentially powerful indicators of technological innovation.

Hagadoorn and Clodt (2003) examine the relationship between R&D expenditures, patent counts, and patent forward citations to new product announcements. They thus appear to update the Comanor and Scherer analysis, employing data not from the 1950s but from the 1990s, and across four sectors (aerospace, computers, drugs, and electronics). The authors "present a set of clear-cut conclusions" about their four indicators of innovative performance: patent counts, patent forward citations, R&D expenditures, and new product announcements (culled from news stories). Analyzing their data with correlation and factor analysis, the authors assert that "in high-tech sectors any of these [] indicators could be taken as a measure of innovative performance in the broad sense." This statement explicitly includes the drug sector, about which they state that "the results of our statistical analysis certainly do not dictate that a single indicator approach is invalid for the pharmaceutical industry …." Thus, Hagadoorn and Cloodt claim that their evidence supports the use by researchers of only patent citations, or only simple patent counts, as an adequate proxy for innovative performance in the pharmaceutical sector. The authors suggest an improvement, stating that a composite

measure would likely be a better indicator, however they maintain that any single indicator is a meaningful proxy for firm innovative performance.

In sum, this body of work suggests to us that the academy's understanding of the relationship between patenting and firm performance is unsettled. Indeed early work by Comanor and Scherer (1969) and Cockburn and Griliches (1988) each included caveats concerning the usefulness of employing patent data as a proxy for innovative performance. Accordingly, statements in the subsequent literature declaring that any single patent indicator is an adequately proxy deserve scholarly attention. Below we examine that hypothesis, as well as to test the nuances of these relationships, using what we believe are the best data available—actual new product introductions by pharmaceutical firms, their associated product sales data, and these firms' patents, both those explicitly linked to the new products, and all other pharmaceutical research patents issued to these firms. We find that, in the drugs industry, the patent-new product relationship does not hold.

3.0 Data and sample

Table 1 presents descriptions and definitions for the variables we employ in this analysis, while Table 2 presents descriptive statistics and correlations for these variables. We collected financial data from Compustat, stock market data from CRSP, pharmaceutical sales data from IMS Health, and research pipeline data from Pharmaprojects and NDA Pipeline. All financial variables are presented in constant 2000 dollars. When the original source is in a foreign currency, we convert into U.S. dollars using the average of the 12 monthly foreign/U.S. exchange rates over the relevant year.

The average aggregate market capitalization (represented in *Log market cap*) of our sample firms is approximately $28.2 billion. These firms spend per year, on average, approximately $1.3 billion on R&D (*Log R&D*) and generate approximately $4.35 billion in prescription drug revenues (*Log sales*). They maintain per year on average 28 products in some stage of clinical phase testing (*Pipeline Count*) and file an average of six patents per year (*Patent filings*).

3.1 Pharmaceutical firm sample selection

Our sample is limited to those pharmaceutical firms that have had at least one FDA-approved product during the time period 1985 to 2001. Unique firms are identified from the FDA Orange Book. Subsidiaries are identified using the LexisNexis Corporate Affiliations database. Overall, we have identified 308 unique domestic and foreign firms with at least one FDA-approved product 1985-2001.

We limited our sample to firms having at least one approval so as to make the overall sample more homogenous and to concentrate our analysis on firms that have demonstrated commercial success. Firm size tends to vary widely in the pharmaceutical industry, ranging from the smallest start-up to the largest multi-national firm, and thus parallels the large variability in patenting and commercial activity. Our sample selection criteria map onto the questions we explore in this paper, which are for the most part appropriate for more established firms. Furthermore, we are fairly confident that our selection captures a reasonably complete picture of the industry: For example, in 2001 our sample firms' sales totaled 79 percent of the entire industry.[3]

3.2 Research pipeline profiles

We believe that determining product-pipeline characteristics for our firms is a useful analytical innovation, and particularly meaningful given our research questions. In an effort to determine which products are in development at our sample firms, we use data from Pharmaprojects and NDA Pipeline during 1990 to 2001. These data contain information relating to the various stages of product development. For purposes of this study we focus on the following phases: Phase I, Phase II, and Phase III. In the FDA-drug approval process, Phase I involves safety testing, Phase II is concerned with small-scale human efficacy trials, and Phase III focuses on large-scale human efficacy trials (See Figure 2). We also identify the broad therapeutic categories, through the Uniform Standard of Classification, in which each stream of research is focused.

[3] Author's calculations based on sales data from IMS Health.

We consider two measures of a firm's research pipeline. Our primary measure, *Pipeline count*, is a count variable, in a given year, of the number of projects that a sample firm has in either Phase I, Phase II or Phase III clinical testing. The average firm in our sample has 28 products in some stage of clinical testing in any year.

As a robustness check to this measure we follow Higgins and Rodriguez (2006) and assign clinical probabilities to each of the phases of research. These assigned clinical probabilities reflect the likelihood that a potential treatment has of receiving FDA approval. We subsequently employ these values to construct a weighted value of each company's pipeline products, which we refer to as the *Pipeline score*.

The overall industry *Pipeline count* shows a marked increase in the mid-1990s and reflects an underlying increase in the number of products in firms' research pipelines (See Figure 2). The number of early-stage pipeline products dramatically increased in the late 1990s as did, to a lesser extent, the number of late-stage products. FDA approvals throughout this time period, however, remained fairly flat. Comparing this trend to those presented in Figure 1, the increase in pipeline products appears to have not produced sufficient numbers of new unique products to stem the decline in the industry-wide firm exclusivity horizon.

3.3 Patent profiles

In this paper, we use patents issued in the U.S. by the United States Patent and Trademark Office (USPTO). The patents assigned to pharmaceutical firms may be characterized into two different types. First, firms are issued patents that are directly attached to an FDA-approved drug (as identified in the FDA Orange Book.) Second, firms are assigned a stock of non-attached patents. These stocks of non-attached patents contain patents that are related to pharmaceutical research and patents that are related to other types of activities (e.g., medical devices, consumer products, management software, etc.) In order to obtain a more meaningful picture of firm-level "pharmaceutical" patenting, we employ a mechanism to select patents from among this stock, so as to isolate patents germane to our pharmaceutical R&D study.

Following an approach used in Graham and Mowery (2003) for identifying software patents, we distinguish relevant pharmaceutical-related patents by reference to their international patent classification (IPC). We identified the twenty-five largest pharmaceutical firms by market capitalization (year 2000) and matched these firms to twenty-nine USPTO unique firm codes based upon an analysis of major subsidiaries using the LexisNexis Corporate Affiliations database. We are thus able to identify 11,090 U.S. patents granted to these organizations between 1975 and 2002. Analysis of the primary international patent classes into which these patents fall demonstrates that 36.4 percent were classed in "A61K" and 26.4 percent are classed in "C07D." The next most frequent class includes only 5.3 percent of patents. These two classes (A61K and C07D)[4] thus account for a cumulative 62.8 percent of these firms' patents, and we use these classes as our filter to identify "pharmaceutical patents."

In order to test the robustness of this definition, we generate the population of 1,951 products identified in the FDA Orange Book from 1982 to June 2006 (these include all reformulations) and isolate the relevant applicant and patent information. For the associated 1,267 unique patents attached to NDAs through 2002, we found that 73.1 percent and 7.0 percent of these patents are classed into A61K and C07D, respectively. Thus, over 83 percent of patents actually attached to NDAs are assigned to these classes. Moreover, there is substantial overlap when using USPTO (as opposed to IPC) classifications. Using the 36 NBER patent database "technological subcategories" derived from 418 USPTO classifications (Hall *et al*., 2003), we find that 75.6 percent of our 11,090 sample patents fall into two aggregated categories (numbered 14 and 31). This share compares with the 93.7 percent of the 1,267 NDA-associated patents that fall into these same two categories. Since these two technology subcategories (built on USPTO patent classifications) are closely associated with approved FDA products, we can be reasonably confident that the underlying research related to patents in classes A61K and C07D is pharmaceutical related.

We make use of these international patent classifications to build a sample of pharmaceutical research patents assigned to commercially active pharmaceutical firms. Employing our population of 1,951 products identified in the FDA Orange Book from

[4] We exclude subclass A61K 07 which primarily comprises cosmetics (Harhoff and Hall, 2003).

1982 to June 2006, we create a sample of all firms to which at least one FDA-approved product was assigned. These firms match to 325 unique USPTO organization codes, and we find that these organizations were issued a total of 154,775 patents during 1975 to 2001, and that 50,466 (32.6 percent) of these patents are assigned into the primary "pharmaceutical" classes A61K and C067.[5] Excluding the patents associated with FDA-approved products, we are left with 49,563 patents, 96.5 percent of which are assigned into the NBER technology subcategories 14 and 31 described above. For each major commercial drug firm in our sample, therefore, we produce a patent profile that includes both (1) all firm patents attached directly to FDA-approved products (n=903) and (2) the firm's underlying non-attached pharmaceutical-related patents (n=49,563).

We make one more correction to the patent data. It is common for researchers to use the "application date" disclosed on the front page of the U.S. patent document to represent the approximate date on which an invention was reduced to practice, or more conservatively entered into the formal patent system. As described in Graham (2006), this assumption is mistaken because it fails to account for the string of "continuation" events in the application history of the patents. This assumption is particularly problematic when working with pharmaceutical patent data because the continuation rates in these patents may be as high as 60 percent of all issued patents (Graham, 2006). The continuation is a procedure available in the U.S. patent law that permits an applicant to re-start the application process, at will. There is no limit to the number of times that an application may be continued,[6] and the "application date" specified on the face of the patent document is merely the last of what may be a string of continued applications (Graham and Mowery, 2004).

In our sample of pharmaceutical research patents, we correct for continuing applications, testing the implications of using the "application date" versus the "original filing date". We define “original filing date” as the date associated with the first continuing application in the granted patent's application lineage. We find significant differences. By way of description, 46.2 percent of our sample of 50,466

[5] We used a year 2001 truncation because elements of our product level sales data are available only to that year. Our 50,466 sample excludes A61K 07 "cosmetics" patents.

[6] Although, since 1995, the applicant is limited to a total window of 20 years in which to both apply-for and enjoy protection upon a patent.

"pharmaceutical research" patents assigned to major commercial firms had at least one continuation in their patent application lineage. We also empirically test the lag between the original filing date and grant date for this sample. We find a mean lag between original application filing and patent grant of 35 months, while the median lag is 32 months. These measures compare with a mean of 24 months and a median of 22 months when one uses the "application date" on the face of the U.S. patent document.

Figure 4 shows the time trend in patenting for our sample firms within the defined technology classes. The dotted line plots patent applications while the solid line accounts for new patent grants within our defined technology classes. The trend in patent issues for our sample firms has gradually been increasing from approximately 1,700 in 1990 to nearly 2,500 patents issued per year in 2001.

Finally, we explore the propensity to patent. Consistent with Hicks *et al*., (2001) we define ”propensity to patent” as the ratio of patents to R&D expenditures (constant dollars, in millions). Our numerator in this measure equals the total number of (defined) pharmaceutical patents issued to our sample firms. Using a similarly-constructed measure, Hicks *et al*., (2001) find a constant propensity to patent of 0.38 from 1991 to 1998 in the chemical sector, which includes pharmaceuticals in their study.[7] We plot our patent intensity measure in Figure 3. For our sample firms, the measure declines from 1987 to 2001 with a sharp decline in the post-1995 period. For emphasis, Figure 3 compares this decline in “propensity to patent” against the ratio of real R&D expenditures to real sales. This latter ratio has remained reasonably constant at around 15 percent throughout the same time period. Accordingly, it appears that increases in R&D expenditures have kept pace with increases in sales. At the same time, however, overall patenting within our defined technology classes has also increased (see Figure 4). Taken together this suggests that the rate of R&D expenditures is increasing at a faster pace than is patenting, thereby depressing the overall “propensity to patent” measure in the later years depicted in Figure 3. Our interpretation is consistent with the overall decline in

[7] The time frame was broken into two patent year samples. The first period consisted of patent years 1991 to 1994 with R&D expenditure years 1989 to 1992. The second period consisted of patent years 1995 to 1998 with R&D expenditure years 1993 to 1996. It should be noted that the Hicks *et al*. sample was limited to firms that received 50 or more patents per year.

research productivity in the pharmaceutical industry described by Higgins and Rodriguez (2006).

3.4 Patent lags

While we find that the mean lag between patent filing and grant is 35 months for our sample of 50,466 patents, we note that this lag is not the key measure for our purposes. Because we seek to replicate Comanor and Scherer (1969), we are interested in the relationship between patenting and new FDA-approved product introductions. Consistent with that earlier study, we determine the lag between original filing and FDA approval for those patents associated with new products.

The lag between patent filing and FDA approval has diminished considerably from 1985 to 2001. In 1985, the mean lag between patent filing and FDA approval was 180.6 months (median is 167 months). This lag declined to a mean of 117 months (median is 107 months) in 1990, declining yet further to a mean of 77.6 months in 1995 (median is 71 months). By 2001, the mean lag between patent filing and FDA approval fell to 35.3 months (median is 47 months). Over the entire sample period, the mean lag is 59.6 months while the median lag is 61 months.

Since we find an average lag from 1990 to 2001 of 71 months, an average lag from 1995 to 2001 of 60 months, and an overall sample mean lag from 1985 to 2001 of 60 months, we use as our benchmark a lag of five years, or 60 months. We employ this figure to examine the relationship between patent filings from 1985 to 1996 (and citation-weighted filings) on new FDA product introductions from 1990 to 2001. Because our lag is longer than the three-year lag originally reported and used by Comanor and Scherer (1969) in their analysis, and also longer than that used in several other studies (e.g., Rothaermel and Hess, 2007; Hagedoorn and Cloodt, 2003; Ernst, 2001; Henderson and Cockburn, 1994; and Hagedoorn and Schakenraad, 1994), we discuss below results derived from using both a three- and five-year lag for robustness.

3.5 Size of the firm

Studies that have considered firm-size in the context of patenting and firm performance have come to inconsistent conclusions about the role that *firm size* plays. On one hand, Jensen (1987) employs actual new products as a dependent variable and reports that firm size has no effect when introduced as an independent variable. On the other hand, studies that have proxied for new products have shown firm effects to be significant (Rothaermel and Hess, 2007; Nohria and Gulati, 1996; Shan *et al*., 1994; Acs and Audretsch, 1989; and, Bound *et al*, 1984).

We are able, like Comanor and Scherer (1969) and Jensen (1987), to use superior data in that we use actual new product introductions, and not proxies, as our dependent variable. As a result, we introduce four different measures of firm size in order to ensure that we are adequately controlling for any possible size effects. The four variables we use are: the natural log of firm market capitalization (*Log market cap*), number of employees (*Employees*), natural log of firm total assets (*Log total assets*) and natural log of pharmaceutical sales (*Log sales*).

4.0 Empirical findings

4.1 Patenting as a proxy for new product development

Since Comanor and Scherer (1969), researchers have been using patents as a proxy for new product development. The relationship between patents and new products has been backed by empirical analysis reported in Hagedoorn and Cloodt (2003). Given the extreme importance that this hypothesized relationship plays as a foundation for the findings reported in subsequent research, we examine the methodology employed in each of these studies in greater detail.

Comanor and Scherer (1969) focus on the correlation between new chemical entities (NCEs) introduced in the pharmaceutical industry from 1955 to 1960. They weight NCEs by the sum of sales in the first two years of introduction. In order to determine the appropriate time periods for their patent variable, they empirically determine the lag between patent application and product introduction. They find the median lag to be three years. As a consequence, they examine the relationship between

patent filings from 1952 to 1957 (i.e., lagged three years) and report a simple correlation of 0.713 between lagged patent applications and sales-weighted new product introductions. Holding firm size constant, they report a partial correlation coefficient of 0.373 between these two same variables.

Hagedoorn and Cloodt (2003) search out news articles for announcements of new products in the pharmaceutical industry and correlate these with patenting activity. Their patent period covers 1992 to 1999 while their window for new product announcements ranges from 1997 to 2000. Hagedoorn and Cloodt report a simple correlation of 0.589 between lagged patent applications and new product announcements (from news stories) for the pharmaceutical industry. They do not sales-weigh their new product measure, so a direct comparison with Comanor and Scherer (1969) is not appropriate.

We discuss these two works because they have important implications for the use of patenting as a proxy for new product development in the pharmaceutical industry. Our analysis produces *dramatically* different results. Simply stated, our results do not comport with the findings reported in the above works, thereby drawing into question the efficacy of using patents as a proxy for new product development – at least in the pharmaceutical sector.

In order to determine the origins of the differences, we duplicate the methodology employed by Comanor and Scherer (1969) with our data. Our empirically-derived lag between patent application and new product introduction is five years. As a robustness check and in order to compare directly with Comanor and Scherer, we also report results for a three-year lag. We match products approved from the FDA Orange book from 1990 to 2001 and sales-weight these with sales data provided by IMS Health. We are thus able to produce a measure that duplicates Comanor and Scherer's (1969) methodology. Next, we correlate this sales-weighted NCE measure with patent filings from 1985 to 1996 (five year lag). Summary statistics show a firm-year mean of 5.91 filings, with a maximum of 9.0 in 1994.

Our analysis produces a simple correlation of 0.1911. When we instead use a three-year lag (patent filings from 1987 to 1998) we find a simple correlation of 0.2350. Holding firm size constant, we find partial correlations of 0.1785 and 0.2215,

respectively. As stated above, these results are dramatically smaller than those reported in Comanor and Scherer (1969).

Next, we duplicate to the extent possible the methodology employed by Hagedoorn and Cloodt (2003). We mimic their approach and limit patent applications and product introductions to the same time periods they employ, and find a simple correlation of 0.2775 between patent applications and new product introductions. Over our larger sample time period, we find an overall simple correlation of 0.2314 between patent applications (three year lag) and new product introductions. When we consider a five-year lag on patent applications, we find a slightly lower simple correlation of 0.2263. Regardless of the sample period or lag, our results are considerably lower than the 0.589 simple correlation reported by Hagedoorn and Cloodt (2003).

As discussed above in Section 2.0, Comanor and Scherer (1969) conclude their paper by suggesting that "…patents may be a better index of research input than output." (p.398) Our simple and partial correlation results lend support to this statement. Given the relatively low correlations we find between patenting and new products in the pharmaceutical industry, we suggest that patents are not an effective proxy for new product introductions in this industry.

In an effort to explore this issue in more depth, we analyze the simple correlations between *Lagged patent filings* and *New drug indicator* yearly from 1985 to 2001. Results are reported in Table 3(i). Correlations range from 0.0984 in 1986 to 0.3919 in 1991. All but three years are significant at the 1 percent level.[8] The overall sample correlation is significant at the 1 percent level. There appears to be no discernable pattern over this time period as regards changes or trends in the correlations. We do note, however, that the first year in our sample, 1985, follows the start of the so-called "strong patent period" reported by others and said to be ushered in by the creation of the U.S. Court of Appeals for the Federal Circuit, a unitary patent appeals court (Kortum and Lerner, 1999). The year 1985 also follows the structural break (1983-84) in U.S. patenting identified by Hall (2004). Whether a discernable pattern in the change of

[8] Of the remaining three years, our correlations for two of the years are significant at the 90% confidence interval. One year is insignificant.

correlations over time occurred between 1960 (the end of Commor and Scherer's panel) and 1985 is, however, beyond the scope of our paper.

As a robustness check, we consider two additional simple correlations which are reported in Table 3(ii) and Table 3(iii). First, in Table 3(ii) we present the simple correlation between *Citation weighted filings* and *New drug indicator* where *Citation weighted filings* is defined as a combination of *Lagged patent filings* and *Total citations III*. These correlations are marginally larger than those reported in Table 3(i), with an overall sample correlation of 0.2375 (significant at the 1 percent level). In Table 3(iii), we present simple correlations between *All lagged patent filings* and *New drug indicator*. *All lagged patent filings* combines *Lagged patent filings* with all other (non-pharmaceutical) patents for each firm. Predictably, the correlations decrease considerably, showing a total simple correlation of 0.1395 (significant at the 1 percent level).

One possible explanation for these results is that there has been a fundamental paradigm shift with respect to overall patenting activity within the pharmaceutical industry. Clearly, the amount of patenting in the industry has dramatically increased over time (see Figure 4). This increase in patenting over time, when coupled with the relatively stagnant number of new FDA-approved products, may be putting substantial downward pressure on these correlations. So, while we remain agnostic as to whether patenting may serve as an adequate measure of "invention activity," our findings suggest that patenting is not an appropriate proxy for innovation, or firm innovative performance, as defined by new FDA-approved products marketed by the pharmaceutical industry.

4.2 New FDA approved product introductions

Patent counts have become a increasingly-used indicator of innovative performance, especially in studies of new technologies, new processes and new products (e.g., Acs and Audretsch, 1989; Aspden, 1983; Bresman et al, 1999; Cantwell and Hodson, 1991; Freeman and Soete, 1997; Griliches, 1998; Napolitano and Sirilli, 1990; Patel and Pavitt, 1995; Pavitt, 1988; Ahuja, 2000; Hagedoorn and Schakenraad, 1994; Henderson and Cockburn, 1994, Owen-Smith and Powell, 2004; Shan et al., 1994; Stuart,

2000). However, because our findings suggest that pharmaceutical patenting is no longer an adequate proxy for new products, we must ask: What purpose does it serve? We now move beyond simple correlations and begin to focus on more the nuanced relationship between patenting and new FDA-approved product introductions.

Table 4 presents probit estimates for our data regressing *New drug indicator* on a series of independent variables expected to affect the probability that a firm introduces a new FDA approved product.[9] In following sections we explore whether certain variables are related to *the number* (count) of drugs introduced. The dependent variable used in the regressions reported in Table 4 is an indicator variable $y_{it,}$ that assumes a value of one for a given firm *i* in a specific year *t* if that firm introduces an FDA-approved product in a given year, and is zero otherwise. For independent variables we use five-year lagged counts of firm patent applications (*Lagged patent filings*), the number of patent forward citations (*Total citations II*), the number of patent continuations (*Total continuations*), an indicator of a firm losing exclusivity protection on an existing product in years ranging from (t-1) to (t+2) (*Drug loss*), a measure of each firm's research pipeline (*Pipeline count*), the natural log of R&D expenses (*Log R&D*), the number of employees (*Employees*) and the natural log of firm market capitalization (*Log market cap*). Firm and year dummies are included in all models. As a robustness check, we include an alternate measure of each firm's research pipeline (as *Pipeline score*) and alternate lags for *Lagged patent filings*. See Table 1 for variable definitions and Table 2 for descriptive statistics and variable correlations.

Across all four models (Model 1 to Model 4), we find a positive and significant impact of *Lagged patent filings* on the probability that a FDA-approved product is introduced in a given year. Marginal effects range from 0.27 percent to 0.37 percent and are all significant at the 1 percent level. With mean lagged filings of 5.50 and a standard deviation of 14.19, this suggests that for a one standard deviation change in *Lagged patent filings* there is between a 3.83 percent and 5.25 percent increase in the probability a new product is introduced.

The largest effects we report relate to the loss of exclusivity protection, represented as *Drug loss* and its various lags, both forward (*Drug loss (t+1)* and *Drug*

[9] Results remain robust when a logit model is considered.

loss (t+2)) and backward (*Drug loss (t-1)*). We find a positive and significant impact of *Drug loss* on the probability a product is introduced in a given year. In Model 3 and Model 4, we report the three other variants of *Drug loss*. We focus on whether there is a drug loss in the year prior to introduction (*Drug loss (t-1)*), a drug loss in the year of introduction (*Drug loss*), a drug loss in the year following introduction (*Drug loss (t+1)*) and a drug loss in the two years following an introduction (*Drug loss (t+2)*). Provocatively, we find the largest effect associated with *Drug loss*, implying that firms are more likely to introduce new products in the same year that older products lose exclusivity protection. One obvious interpretation of this result is that firms are simply attempting to smooth earnings by ensuring that threatened revenues are replaced by new ones.

In Model 3, marginal effects for *Drug loss (t-1)*, *Drug loss*, and *Drug loss (t+1)* are 5.10 percent, 6.41 percent and 2.15 percent, respectively. Marginal effects are similar in Model 4, showing 5.09 percent, 6.48 percent and 2.16 percent, respectively, for the same variables. The marginal effects associated with *Drug loss* and its various lags are individually consistent with those associated with *Lagged patent filings*. However, viewed cumulatively, the loss of exclusivity in the three-year window surrounding the introduction of a drug is significantly larger than *Lagged patent filings.* The cumulative coefficients for the *Drug loss* variables range from 13.66 percent to 13.73 percent. Our results suggest that the loss of exclusivity on a current drug is a far more important predictor of a new product introduction than is a firm's lagged patent applications.

It should be no surprise that pharmaceutical firms attempt to manage product introductions so as to smooth revenues. What is more surprising that firms appear to be successful in managing that process, especially given the long lags involved in new product development. The loss of exclusivity on an existing drug is an important and economically meaningful event to the firm. As such, we take it that firms are aware of which revenue streams they have that are threatened, and have strong incentives to act strategically. In an effort to illustrate this point, we combine sales data from IMS Health for FDA-approved drugs from 1990 to 2001. Consistent with Higgins and Rodriguez (2006), we find that 74.19 percent of sales occur during this five-year exclusivity

protection period after FDA approval, while 15 percent of sales are realized in the three years following the loss of exclusivity.

Interested as we are in the role that these product introductions are playing, we add an empirical innovation and, in contrast to existing research, we explicitly control for the underlying research pipelines of the sample pharmaceutical firms. We consider two different measures: *Pipeline count* and *Pipeline score*. Both measures involve counts of the underlying number of research projects a firm has active in a given year. *Pipeline score* is a more complex measure in that it attaches probability weightings to the various-stage projects to generate an overall value in each time period (Higgins and Rodriguez, 2006). Even though it is more complex in its construction, unreported regressions show the effects remain similar to *Pipeline count*. Overall, we find positive and significant effects across all four models on the probability of new product introduction, with marginal effects ranging from 0.06 percent to 0.12 percent. With a mean value of 27.87 and a standard deviation of 41.56, this suggest that for a one standard deviation change in *Pipeline count* there is between a 2.49 percent and 4.98 percent increase in the probability a new product is introduced. Our pipeline findings are approximately the same in magnitude to those on *Lagged patent filings*.

In all four models, our variable *Log R&D* is positive and significant, with marginal effects ranging from 1.04 percent to 1.11 percent. For a one standard deviation increase in R&D expenditures we can expect approximately a 2.0 percent increase in the probability a new drug is introduced. The literature is replete with findings that relate R&D expenditures to patenting (e.g., Pakes, 1985; Jaffe, 1986; Cockburn and Griliches, 1988; Acs and Audretsch, 1989; Griliches, 1990; Trajtenberg, 1990; Ernst, 2001; Hagedoorn and Cloodt, 2003). However, there are fewer studies focusing on the relationship between R&D spending and new product development, especially in the pharmaceutical industry. An exception is Jensen (1987) in which a Poisson model was used to study the effects of R&D on new chemical entities (NCEs), producing a finding that increases in R&D expenditures increase the probability that a new drug is discovered.

Hagedoorn and Cloodt (2003) find a simple correlation of 0.817 between R&D and new products in the pharmaceutical industry (defined by SIC code). For our sample,

the overall simple correlation between *New drug indicator* and *Log R&D* is 0.1046. If we limit our sample to the same time period considered by Hagedoorn and Cloodt, then the correlation falls to 0.0626. We have no explanation for this difference.

The interpretation between R&D and patent applications is much clearer than the relationship between R&D and new product introductions, especially in the pharmaceutical industry. The average development time for a new pharmaceutical product is ten to fifteen years from initial discovery to final FDA approval (DiMasi, 2001). The development process requires significant R&D expenditures throughout the entire time period. As a result, finding a positive and significant relationship between R&D expenditures and patenting may reflect some common unobserved factor in the firms' overall underlying research programs.

Finally, we directly measure firm size by *Log market cap* and *Log total assets* and indirectly by *Employees* and *Log sales*. Contrary to other work that has found some effect, either positive or negative, between firm size and innovative performance (e.g., Rothaermel and Hess, 2007; Nohria and Gulati, 1996), we find no effect between firm size, either direct or indirect, and new product introductions. Our finding is, however, consistent with Jensen (1987).

4.3 Patenting and new product introductions

Table 5(a) presents negative binomial estimates for our data, regressing *New drugs* on a series of independent variables expected to affect the number of new FDA-approved products a firm introduces in a given year. Our results remain robust to both ordered logit and OLS specifications. We apply a Hausman (1978) specification test, revealing that a random-effects estimation is appropriate.

Across all six models reported in the table (Model 1 to Model 6), we find a positive and significant relationship between patenting (*Lagged patent filings*) and the expected number of new product introductions (*New drugs*). Coefficients range from 0.0289 to 0.0513 with corresponding marginal effects ranging between 0.32 percent and 0.94 percent. (Marginal effects for all significant values in Table 5(a) are reported in Table 5(b).) These marginal effects imply that for a one standard deviation change in

Lagged patent filings that there is between a 4.54 percent and 12.06 percent increase in the expected number of new product introductions.

Brouwer and Kleinknecht (1999) contend that simple patent counts may be a problematic indicator for innovation due to varying patenting intensities of firms. In order to address this issue we replace *Lagged patent filings* with *Patent intensity* where *Patent intensity* is defined by *Lagged patent filings* divided by *Log R&D*. In regressions replicating those presented in Table 4(a) we find coefficients ranging from 0.1613 to 0.1730, with marginal effects ranging from 4.17 percent to 4.48 percent. These marginal effects imply that for a one standard deviation change in *Patent intensity* that there is between a 1.72 percent and 1.85 percent increase in the expected number of new product introductions.

In Model 3 to Model 6 we report our findings for *Drug loss* and its various lags. In contrast to the results in Table 4 in which we find the coefficients peaking with *Drug loss*, these negative binomial specifications show that the coefficients are largest on *Drug loss (t-1)* and decline in magnitude to *Drug loss (t+1)*. The variable is not significant by year *(t+2)*. This result may be interpreted as suggesting that firms focus new product introductions on the three year period surrounding the loss of exclusivity protection of a current drug, with the largest emphasis on (*t-1*). Coefficients range from 0.4524 to 0.5348 for *Drug loss (t-1)*; 0.3986 to 0.4442 for *Drug loss*; and, 0.2955 to 0.3831 for *Drug loss (t+1)*. Corresponding marginal effects range from 14.21 percent to 17.10 percent for *Drug loss (t-1)*; 12.11 percent to 13.48 percent for *Drug loss*; and, 8.39 percent to 11.56 percent for *Drug loss (t+1)*. Once again, while there is a positive and significant relationship between patenting and new product introduction, the cumulative effects surrounding the loss of exclusivity are large (approaching 40 percent), and far outweigh the influence of patenting.

In contrast to the models employing probit estimations (Table 4), we find no effect between *Log R&D* and the number of expected new product introductions. Across all specifications, both reported and unreported, the coefficients are not significant (tested to a 90 percent confidence interval). For robustness, we replicate Jensen's (1987) use of a Poisson model, finding no significance on the coefficient for this variable. As a further robustness check we perform Levine and Renelt's (1992) implementation of Leamer's

(1978, 1983, 1985, and 1988) extreme bound analysis (EBA) on *Log R&D*. We find that *Log R&D* is not significant in any of the iterations. Interpreting the divergent results produced in the probit and negative binomial regressions, our findings may suggest that the size of R&D expenditures has an effect on the probability that a new drug is introduced by a firm in any year, but not on the number of expected drug introductions.

Finally, consistent with our findings in Section 4.2, we find no effect between our measures of firm size (*Log market cap* or *Employees*) and new product introductions. In unreported regressions, we produce similar results for *Log total assets* and *Log sales*. In addition to controlling for firm size, we again control for the underlying research pipelines of the sample pharmaceutical firms. Results are consistent with our previous findings. We find positive and significant (1 percent level) effects between a firm's research pipeline and new product introductions. Overall results in this specification are consistent with our probit analysis. In sum, these results bolster our findings that the largest marginal effects we demonstrate involve the loss of exclusivity protection on a current drug.

4.4 Patent citations and new product introductions

Some researchers have moved away from raw patent counts and instead focus on citation-weighted counts in order to determine the "strength" or "importance" of a patent, or as a proxy for its "value" (e.g., Aspden, 1983; Narin and Olivastro, 1988b; Trajtenberg, 1990; Stuart, 2000; Bloom and Van Reenen, 2002; Hagedoorn and Cloodt, 2003; Fabrizio, 2004). We address the issue of citation-weighted patents in two ways. First, we explore whether citation-weighted patents are a more meaningful proxy for new products than are simple patent counts. Second, we address whether citation-weighted patents and the notion that they signal "strength" or "importance".[10]

Hagedoorn and Cloodt (2003) report a correlation coefficient of 0.382 between patent citations and new products in the pharmaceutical industry. This figure compares to the 0.589 correlation they find between patenting and new products, suggesting that,

[10] The relationship between patents, citation-weighted patents and market value is explored directly in Graham, Higgins and McKenzie (2006).

contrary to other empirical findings (Harhoff *et al*., 2003, Hall *et al*., 2003), citations contain less information about value than do simple patent counts. Over the same time period considered by Hagedoorn and Cloodt, our analysis instead produces a correlation coefficient of 0.2379 between *Citation weighted filings* and *New drug indicator*, significant at the 1 percent level. For our overall sample, which comprises a longer time period, we find a correlation coefficient 0.2593 between *Citation weighted filings* and *New drug indicator,* again significant at the 1 percent level. While our results are again lower than those reported by Hagedoorn and Cloodt (2003), they are consistent with the correlation coefficients we report in Table 3 between raw patenting and new products. Our citation measure therefore, unlike Hagedoorn and Cloodt, shows a higher correlation coefficient than do simple patent counts, thereby lending support to the findings in Harhoff *et al*. (2003) and Hall *et al*. (2003) that patent citations contain more information than simple patent counts.

As a robustness check, we generate the trend in correlations over our entire time period. We present yearly correlation coefficients between *Citation weighted filing* and *New drug indicator* in column (ii) of Table 3. Similar to the figures reported in column (i), no obvious pattern is discernable in the correlation coefficients over time. Our correlations thus cast doubt on the appropriateness of using citation-weighted patent measures as a proxy for new products in the pharmaceutical industry. While patent citations appear to have more information content than do simple patent counts, that added information does not reduce the variability sufficiently to adequately proxy for new product introductions in this sector.

If, as our correlations suggest, citation-weighted counts are not an adequate proxy for new products, we remain curious about what information citation-weighted counts provide, and what relationships other researchers may be observing. To shed light on this question, we replicate the analysis from Section 4.3, replacing *Lagged patent filings* with *Citation weighted filings* in order to test whether citation-weighted counts affect the expected number of FDA approved product introductions. Negative binomial estimates regressing *New drugs* on a series of independent variables that we expect to influence the number of expected new FDA-approved products are reported in Table 6(a). Marginal effects are reported in Table 6(b).

Consistent with our previous findings with respect to *Lagged patent filings*, we find a positive and significant relationship between *Citation weighted filings* and *New drugs* across all six models. Coefficients range from 0.0039 to 0.0091 with marginal effects ranging from 0.05 percent to 0.14 percent. All are significant at the 1 percent level. These marginal effects imply that for a one standard deviation change in *Citation weighted filings* there is between a 1.06 percent and 2.97 percent increase in the expected number of new product introductions.

In Model 3 through Model 6 we report our findings for *Drug loss* and its various lags. Similar to the results we report in Table 5(a), the coefficients peak with *Drug loss (t-1)* and decline in magnitude to *Drug loss (t+1)*. The variable is not significantly different than zero by year *(t+2)*. These results again suggest to us that firms focus new product introductions in the three-year period surrounding the loss of exclusivity protection of a current drug, with the greatest emphasis at (*t-1*). Coefficients in this specification are slightly greater in magnitude than those we report in Table 5(a), ranging from 0.5791 to 0.6663 for *Drug loss (t-1)*; 0.5457 to 0.7019 for *Drug loss*; and, 0.3913 to 0.4995 for *Drug loss (t+1)*. Corresponding marginal effects range from 17.10 percent to 22.97 percent for *Drug loss (t-1)*; 17.55 percent to 22.20 percent for *Drug loss*; and, 11.73 percent to 14.89 percent for *Drug loss (t+1)*. Once again, the cumulative effect of the loss of exclusivity in the three-year window is large (approaching 50 percent) and far exceeds the impact associated with the other independent variables.

The extent to which firms are reaching across international borders to tap into research expertise may also improve research productivity, and lead to commercializable products (Thursby and Thursby, 2006). To shed light upon the effect that firms' international research presence has upon new products, we introduce a variable *Non-U.S. inventor* constructed as a count variable, equaling the number of patent filings in any firm-year for which the first inventor listed on the U.S. patent is a foreign resident. Results reported in Tables 5(a) (Model 6) and Table 6(a) (Models 4 and 6) demonstrate that, whether using probit or negative binomial estimations, the coefficients associated with *Non-U.S. inventor* are positive and significant predictors of *New drugs.* The marginal effects in Tables 5(b) and 6(b) imply that for a one standard deviation increase

in *Non-U.S. inventor*, there is between 2.50 percent and 4.18 percent increase in the expected number of new product introductions.

Finally, our control for the underlying research pipeline of our sample firms, *Pipeline count*, remains positive and significant, and the overall effects remain consistent with those reported in Table 5(a) and Table 5(b). Once again, we find no significant effect associated with any of our firm size measures.

4.5 Patent citations and value

Griliches (1990) and his progeny have suggested that patents attracting a greater number of forward citations are more valuable, or important, or have a higher quality than are more rarely-cited patents. Because we can directly relate actual sales data to specific patents, we can test this hypothesis. Again, we identify the exact patent(s) linked (by the FDA Orange Book) to FDA-approved products and collect the relevant sales data for these same products. If we find that a firm's non-FDA-Orange-Book-linked patents are more highly-cited than patents linked to products in the Orange Book, the connotation from the existing literature would be that patents unattached to a product are more "important" or "valuable" than the product-attached patents. The implication of such a result would be profound, at least within the context of the pharmaceutical industry, because it would turn practical experience on its head. If the more highly-cited patents are legally challenged (say, in the courts) and protection is subsequently lost, the firm would lose the ability to enforce a patent. However, if a patent associated with a FDA-approved product were challenged and the protection lost, the revenues associated with that underlying patent would be put at substantial risk from competition.

We address this issue directly in Table 7. We compile all pharmaceutical-related patents for our sample firms from 1985 to 2001 and generate three separate citation measures: *Total citations I*, *Total citations II*, and *Total citations III*. We also generate a dummy variable, *NDA*, which equals 1 if a patent is associated with a FDA approved product. Logit regression estimates for this data regressing *NDA* on these separate measures of citations are reported in Table 7(a). Across all three models there is a positive and significant probability that a more highly-cited patent is associated with a

FDA-approved product. Therefore, within the pharmaceutical industry, we add support to the notion that more highly cited patents are more "valuable."

We are also interested in determining whether this "value" relationship has changed over time. Table 7(b) reports average FDA-approved product sales from 1990 to 2001. Values are in constant 2000 dollars. The average FDA-approved product had sales of only $42 million in 1990. This figure had grown substantially, to over $243 million by 2001. The trend in sales has been increasing across the entire decade. Combined with our discussion in the Section 4.4, our results suggest that even though citation-weighted patents do not serve as an adequate proxy for new FDA product introductions, we nevertheless find that approved products are more likely to be linked in the FDA Orange Book to more highly-cited patents.[11]

4.6 Timing of new product introductions and patent continuations

"Continuation" application practices permitted in the U.S. patent system allow firms to manage the timing of patent grants. Because patent applicants may trigger a "continuation" application at will, even in the face of a positive grant decision by the patent examiner, the patentee is able to control the ultimate grant-date of the issued patent.[12] Discussions with patent attorneys, and empirical evidence in Graham (2006), support the notion that pharmaceutical firms use continuation applications to map the grant-date of important patents to the approval of drugs in the FDA-endorsement process. Consequently, we expect that the use by the firms in our sample of "continuations" in their patenting practice will be positively related to new drug approvals.

We explore this relationship by creating a variable *Total continuations* which measures the total number of continuing patent application filings associated with firm *i's*

[11] We express this finding with an important caveat, however: We have not tested in this paper whether this highly-cited characteristic is endogenous to the inclusion of the patent in the FDA Orange Book--indeed, it may be the case that the simple act of publication makes the future consumers of patent data more likely to become aware of the existence of the patent, and thus makes that patent's citing more likely *ex post*.

[12] This practice promised greater reward for the pharmaceutical firms prior to 1995 when the patent term was 17 years from date of issue. In the current regime, the patent term is 20 years from date of first application, and thus the firm suffers one day of lost patent term for each additional day of continuation application it chooses. See Graham (2004).

patents issued in year *t*.[13] Descriptive statistics of this variable show a firm-year mean of 5.8 continuations with a maximum in 1992 of 10.8 continuations and an overall standard deviation of 15.13. Reference to Tables 5(a) (Model 6) and Table 6(a) (Models 3-6) demonstrate that, whether using probit or negative binomial estimations, the coefficients associated with *Total continuations* are positive and significant predictors of *New drugs.* Consistent with our treatment of all patent data herein, our continuation measures enter these regressions lagged by five years, and our results remain robust to a three-year lag (unreported). Accordingly, there is predictive power in a firm's choice to use the continuation application process, possibly demonstrating the importance to these firms of employing patent-timing strategies. The marginal effects in Tables 5(b) and 6(b) imply that a one standard deviation increase in *Total continuations* leads to between a 4.50 percent to 6.05 percent increase in the expected number of new product introductions.

5.0 Conclusion

Since Schmookler (1962) and Comanor and Scherer (1969), researchers have been using patents (and citation-weighted patents) as a proxy for new product development. Within the context of the pharmaceutical industry, we demonstrate that this relationship no longer exists. Our results therefore draw into question the efficacy of using these measures as proxies. We also demonstrate that the relationship between R&D expenditures and new FDA-approved product introductions is considerably smaller than previously reported. We do not call into question the reliability of the results reported in Comanor and Scherer's work based on patents issued in the 1950s, but rather speculate that this change may be the result of a fundamental paradigm shift in pharmaceutical research, or in patenting (Kortum and Lerner, 1998), or in the use of patent strategies, all of which have been reported but largely ignored in this context.

We make other contributions to the literature. First, we demonstrate that while measures of patenting and citation-weighted patenting remain important in predicting both the introduction, and the number, of new products, by far the most important predictor is the loss of exclusivity on a current product. We consider the apparent ability

[13] Thus, a firm *i* with three issued patents in year *t* each with 3 associated continuation applications would have a *Total continuations* measure of 9.

of pharmaceutical firms to smooth firm revenues by targeting the timing of introductions as impressive given the long development period for drugs. Second, using a large sample of pharmaceutical-related patents for our firms, we are able to demonstrate that more highly cited patents are more likely to be associated with an FDA-approved product. This finding is economically meaningful since these patents protect the revenue streams of approved products. Third, we find that a correction for patent continuation applications leads to significant differences in the amount of pre-grant application lag, and also that continuation counts act as a significant and positive predictor of new product introduction, suggesting to us that the variable captures some information about firm patenting strategy. Fourth, we find a positive and significant impact of a firm's research pipeline on the probability and expected number of new product introductions. Finally, we find little relevance to firm effects.

We believe that considerable opportunities exist for further empirical research into these issues. It would be of interest, for instance, to determine if the results we find above generalize across other high-tech industries. Moreover, the data we use may be useful in exploring what effects alliance activity has upon FDA-approved product introductions. Most important, however, will be more research into the fundamental issue we highlight in this paper: If patents are not adequate to the task of representing innovative output of the firm, what measures are? We leave these issues to other research, and researchers.

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Fig. 1. Total number of exclusivity years remaining for all unique patented products identified in the Food and Drug Administration Orange Book for the period 1990 to 2001. Neither includes extensions to exclusivity stemming from litigation.

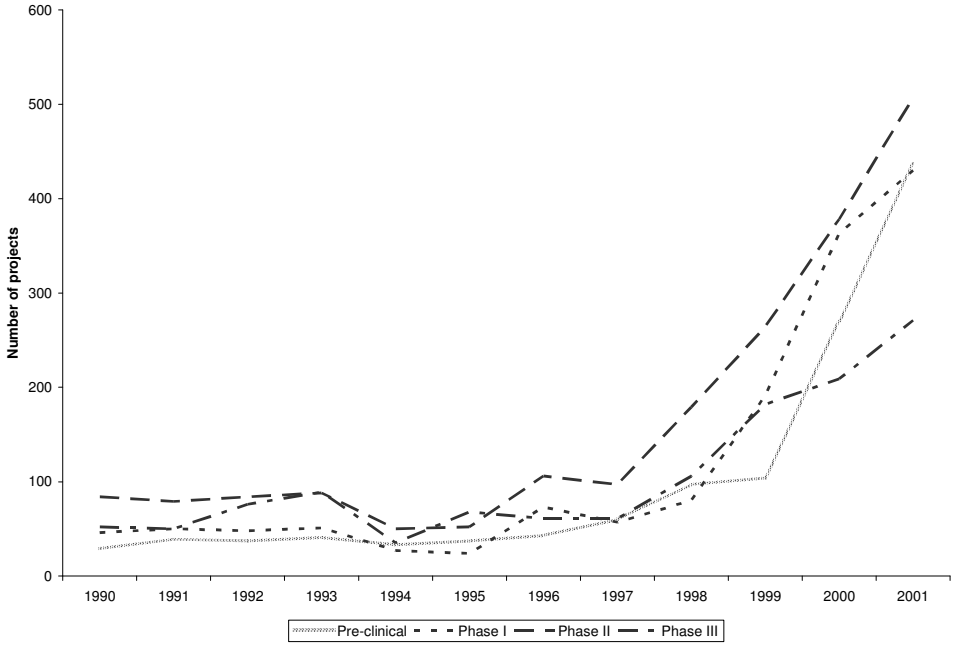

Fig. 2. Total number of drug candidates in the various stages of clinical research identified in the new drug approved (NDA) pipeline for the sample firms over the time period 1990 to 2001. Data comes from both Pharmaprojects and NDA Pipeline.

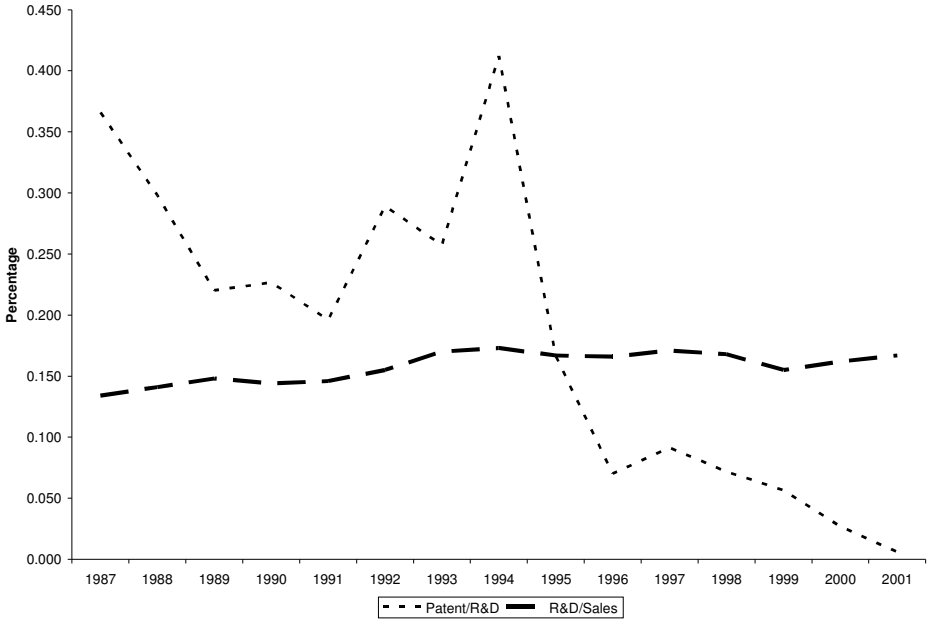

Fig. 3. The ratio of total firm pharmaceutical patenting to real R&D expenditures is plotted against the ratio of real R&D expenditures to real sales.

Fig. 4. The dotted line accounts for all patent applications filed on behalf of sample firms within defined technology classes (with right side truncation). The solid line accounts for new patents granted to our sample firms within defined technology classes. The mean time lag between an application and its subsequent grant in our sample is 35 months, while the median lag is 32 months.

Table 1: Definition and description of variables

Variable	Description
New drugs	Number of new FDA approved drugs introduced in a given year
New drug indicator	= 1 if a firm has a new FDA drug introduction in a given year
Patent filings	Total number of patents filed by a firm in a given year
Lagged patent filings	Variable *Patent filings* lagged five years
All lagged patent filings	*Lagged patent filings* plus all other firm patenting that was not included in *Patent filings* (primarily non-pharmaceutical related)
Non-US inventor	Number of patents that list a non-US individual as the first inventor
Total citations	Total patent citations, including self cites, thru 2004
Total citations II	Total patent citations, excluding self cites, thru 2004
Total citations III	Three year window of total patent citations, excluding self cites
Patent intensity	*Lagged patent filings* divided by *Log R&D*
Total continuations	Total number of continuations by filing year for each firm
Average claims	Average number of claims on issued patents
Citation weighted filings excluding	Three year window of citation weighted *Lagged patent filings* , self cites
Drug loss	= 1 if approved product loses exclusivity protection in a given year
Pipeline count	Total number of products in Phase I, Phase II and Phase clinical testing
Pipeline score	Weighted value (non monetary) of *Pipeline count*
NDA	= 1 if an underlying patent is linked with a FDA approved product
Log R&D	Natural log of sum of R&D expenses lagged three to five years
Employees	Number of firm employees
Log total assets	Natural log of firm total assets
Log sales	Natural log of firm level FDA approved pharmaceutical sales
Log market cap	Natural log of firm market capitalization

* All financials are in 2000 constant dollars.

Table 2: Descriptive statistics and correlation matrix

	Mean	S.D.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
1. New Drugs	0.26	1.17	1.0000														
2. Patent filings	5.91	14.39	0.2533	1.0000													
3. Non-US inventor	2.59	8.36	0.1470	0.3282	1.0000												
4. Total citations I	31.39	91.15	0.0731	0.8201	0.1218	1.0000											
5. Total citations II	24.41	65.04	0.0444	0.7900	0.1446	0.9803	1.0000										
6. Total citations III	3.40	9.01	0.1526	0.8689	0.2166	0.8802	0.8762	1.0000									
7. Total continuations	5.83	15.73	0.1582	0.9133	0.1545	0.8496	0.8334	0.8299	1.0000								
8. Drug loss	0.10	0.67	0.3145	0.0063	0.0929	0.0079	-0.0054	0.0532	-0.0328	1.0000							
9. Pipeline count	27.87	41.56	-0.0052	0.1562	0.0272	0.1713	0.1558	0.1396	0.1557	0.0117	1.0000						
10. Log R&D ($M)	7.20	2.01	0.1046	0.2450	0.0839	-0.3016	-0.2286	-0.2508	-0.2329	0.0439	0.0234	1.0000					
11. Employees (000s)	47.46	53.33	-0.0947	-0.1931	0.0591	-0.2132	-0.1463	-0.1752	-0.1771	0.0713	0.0270	0.4765	1.0000				
12. Log total assets ($M)	7.87	2.17	-0.0923	-0.2245	0.0810	-0.2580	-0.1888	-0.2163	-0.2139	0.0533	0.0155	0.9160	0.8880	1.0000			
13. Log sales ($M)	8.35	2.49	0.3584	0.3123	0.2553	0.2146	0.1863	0.2204	0.2445	0.0520	0.3737	0.0437	0.1224	0.0092	1.0000		
14. Log market cap ($M)	10.25	2.53	0.0545	0.0193	0.0263	-0.0280	-0.0255	-0.0183	-0.0113	0.0385	0.2567	0.1861	0.2001	0.1791	0.2316	1.0000	
15. Average claims	6.55	7.98	0.1541	0.4202	0.3245	0.3360	0.3431	0.3882	0.3589	0.0420	-0.0399	-0.1675	-0.1669	-0.1406	0.1877	-0.0260	1.0000

*** All financial variables are in constant 2000 dollars. Statistics are based on firm-year figures.

Table 3: Correlation between patent applications and new product introduction

Column (i) presents simple correlations between *Lagged patent filings* and *New drug indicator* for the years 1985 to 2001. *Lagged patent filings* is lagged five years per our empirically derived lag between patent application and new product introduction. *New drug indicator* equals one if a new drug is introduced by firm *i* in year *t*. Column (ii) presents simple correlations between *Citation weighted patents* and *New drug indicator*. *Citation weighted patents* combines *Lagged patent filings* with *Total citations III*. Column (iii) presents simple correlations between *All lagged patent filings* and *New drug indicator*. *All lagged patent filings* combines *Lagged patent filings* with all other (non-pharmaceutical) patents for each firm. See Table 1 for variable descriptions. [a] denotes significance at the 1% level; [b] denotes significance at the 5% level; and [c] denotes significance at the 10% level.

	(i)	(ii)	(iii)
Product introduction year	Simple Correlation	Simple Correlation	Simple Correlation
1985	0.3242[a]	0.3317[a]	0.0822
1986	0.0984[c]	0.0774	0.2348[a]
1987	0.1505[a]	0.1434[b]	0.0462
1988	0.1412[a]	0.1187[b]	0.0003
1989	0.3453[a]	0.3438[a]	0.2297[a]
1990	0.2512[a]	0.2553[a]	0.2979[a]
1991	0.3919[a]	0.4227[a]	0.2070[a]
1992	0.2236[a]	0.2143[a]	0.0960
1993	0.3582[a]	0.3421[a]	0.2245[a]
1994	0.2419[a]	0.2741[a]	0.0412
1995	0.2847[a]	0.2881[a]	0.2669[c]
1996	0.2029[a]	0.2037[a]	0.1717[b]
1997	0.2905[a]	0.2874[a]	0.1063
1998	0.3126[a]	0.3151[a]	0.1979[a]
1999	0.3219[a]	0.2998[a]	0.1022
2000	0.0904	0.1043[c]	0.0664
2001	0.3517[a]	0.3480[a]	0.1224[b]
Total sample (1985 to 2001)	0.2263[a]	0.2379[a]	0.1395[a]
Total sample (1990 to 2001)	0.2664[a]	0.2643[a]	0.1459[a]

Table 4: New FDA approved product introductions

Probit estimates for our data regressing *New drug indicator* on a series of independent variables expected to impact a firm's probability of introducing new FDA approved products. The period for this analysis runs from 1985 to 2001. The universe of firms for this analysis includes all firms that have at least one FDA approved product from 1985 to 2001. Φ is the standard cumulative normal distribution. See Table 1 for independent variable definitions. Firm and year effects are included in all models. Robust standard errors are reported in parentheses. We test the model:

$$P(y_{i,t}\neq 0|x_{i,t}) = \Phi(x^1_{i,t} + x^2_{i,t} + x^3_{i,t} + x^4_{i,t} + x^5_{i,t} + x^6_{i,t} + x^7_{i,t} + x^8_{i,t} + x^9_{i,t} + x^{10}_{i,t} + x^{11}_{i,t} + FE + c),$$

$$\partial\Phi/\partial x_i = \phi(\mathbf{xb})b_i.$$

[a] denotes significance at the 1% level; [b] denotes significance at the 5% level; and [c] denotes significance at the 10% level.

	Model 1		Model 2		Model 3		Model 4	
Independent variable	Model 1	$\partial\Phi/\partial x$	Model 2	$\partial\Phi/\partial x$	Model 3	$\partial\Phi/\partial x$	Model 4	$\partial\Phi/\partial x$
x^1: *Lagged patent filings*	0.0175	0.0037	0.0153	0.0032	0.0132	0.0027	0.0133	0.0028
	(0.0024)[a]	(0.0005)[a]	(0.0026)[a]	(0.0005)[a]	(0.0027)[a]	(0.0005)[a]	(0.0027)[a]	(0.0005)[a]
x^2: *Total citations II*							-0.0002	
							(0.0009)	
x^3: *Total continuations*			0.0042	0.0008	0.0041	0.0008	0.0059	0.0012
			(0.0021)[b]	(0.0004)[b]	(0.0022)[c]	(0.0004)[b]	(0.0020)[a]	(0.0004)[a]
x^4: *Drug loss (t-1)*					0.2188	0.0510	0.2185	0.0509
					(0.1274)[c]	(0.0326)[c]	(0.1277)[c]	(0.0327)[c]
x^5: *Drug loss*					0.2703	0.0641	0.2728	0.0648
					(0.1109)[b]	(0.0293)[b]	(0.1109)[b]	(0.0293)[b]
x^6: *Drug loss (t+1)*					0.0979	0.0215	0.0984	0.0216
					(0.0325)[a]	(0.0022)[a]	(0.0319)[a]	(0.0064)[a]
x^7: *Drug loss (t+2)*					0.0480			
					(0.1244)			
x^8: *Pipeline count*	0.0055	0.0012	0.0054	0.0011	0.0051	0.0006	0.0051	0.0010
	(0.0008)[a]	(0.0001)[a]	(0.0008)[a]	(0.0042)[a]	(0.0008)[a]	(0.0001)[a]	(0.0008)[a]	(0.0042)[a]
x^9: *Log R&D*	0.0501	0.0106	0.0527	0.0111	0.0495	0.0104	0.0499	0.0105
	(0.0200)[b]	(0.0042)[b]	(0.0200)[a]	(0.0042)[a]	(0.0203)[b]	(0.0038)[b]	(0.0203)[b]	(0.0042)[b]
x^{10}: *Employees*			0.0008		0.0007			
			(0.0005)		(0.0005)			
x^{11}: *Log market cap*	-0.0077		-0.0074		-0.0081		-0.0080	
	(0.0095)		(0.0095)		(0.0095)		(0.0095)	
Constant	-1.612		-1.6310		-1.6520		-1.6563	
	(0.1968)[a]		(0.1976)[a]		(0.1986)[a]		(0.1982)[a]	
Firm dummies	Yes		Yes		Yes		Yes	
Year dummies	Yes		Yes		Yes		Yes	
N	3,196		3,196		3,196		3,196	
Pseudo R^2	0.1252		0.1274		0.1331		0.1330	
χ^2	192.50		200.73		218.39		218.14	

Table 5(a): Patenting and new FDA approved product introductions

Negative binomial estimates for our data regressing *New Drugs* on a series of independent variables expected to impact the number of introductions of new FDA approved products by a firm. We apply a Hausman specification test (1978), and its results reveal that a random-effects estimation is appropriate (results remain qualitatively robust to a fixed-effects estimation). The universe of firms for this analysis includes all firms that have at least one FDA approved product from 1985 to 2001. Firm and year effects are included in all models. See Table 1 for independent variable definitions. Robust standard errors are reported in parentheses. We test the model:

$$P(y_{i,t}|\varepsilon_{i,t}) = e^{-\lambda_{i,t}\exp(\varepsilon_{i,t})}\lambda^{y_{i,t}}/y_{i,t}!$$

where *y* is a non-negative count variable defined as the number of new products introduced by a firm in a given year. $P(y_{i,t}|\varepsilon_{i,t})$ is the probability that pharmaceutical firm *i* introduces *y* FDA approved products in year *t*.

[a] denotes significance at the 1% level; [b] denotes significance at the 5% level; and [c] denotes significance at the 10% level

	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6
Lagged patent filings	0.0513 (0.0045)[a]	0.0447 (0.0037)[a]	0.0337 (0.0044)[a]	0.0370 (0.0041)[a]	0.0308 (0.0049)[a]	0.0289 (0.0047)[a]
Total citations II			0.0021 (0.0013)			
Total citations III					0.0126 (0.0098)	
Total continuations						0.0105 (0.0048)[b]
Non-US Inventor						0.0141 (0.0083)[c]
Average claims					0.0132 (0.0112)	
Drug loss (t-1)			0.4871 (0.1960)[a]	0.4524 (0.1966)[b]	0.5108 (0.1979)[a]	0.5348 (0.1990)[a]
Drug loss			0.4278 (0.1755)[b]	0.3986 (0.1719)[b]	0.4219 (0.1740)[c]	0.4442 (0.1761)[a]
Drug loss (t+1)			0.3603 (0.2025)[c]	0.3831 (0.2054)[c]	0.3421 (0.1979)[c]	0.2955 (0.1651)[c]
Drug loss (t+2)			0.0073 (0.2323)			
Pipeline count		0.0053 (0.0011)[a]	0.0053 (0.0015)[a]	0.0054 (0.0015)[a]	0.0056 (0.0015)[a]	0.0052 (0.0016)[a]
Log R&D			0.0528 (0.0431)	0.0530 (0.0429)	0.0526 (0.0433)	0.0495 (0.0438)
Log market cap			0.0006 (0.0184)	0.0002 (0.0189)	0.0002 (0.0187)	0.0027 (0.0189)
Employees			-0.0003 (0.0015)			
Constant	-3.8142 (0.1302)[a]	-2.0567 (0.1421)[a]	-2.2887 (0.4159)[a]	-2.2852 (0.4134)[a]	-2.2861 (0.4192)[a]	-2.2534 (0.4183)[a]
Firm dummies	Yes	Yes	Yes	Yes	Yes	Yes
Year dummies	Yes	Yes	Yes	Yes	Yes	Yes
N	8,311	4,004	3,196	3,196	3,196	3,196
Log likelihood	-2529.25	-2214.85	-1501.37	-1502.45	-1500.15	-1498.71
χ^2	651.67	350.35	287.74	273.68	293.15	284.49

Table 6(a): Citation-weighted patenting and new FDA approved product introductions

Negative binomial estimates for our data regressing *New Drugs* on a series of independent variables expected to impact the number of new FDA approved drugs a firm generates. *Citations III* is used to weight patent filings. The results remain robust to the use of *Citations II* as an alternative. We apply a Hausman specification test (1978), and its results reveal that a random-effects estimation is appropriate (results remain qualitatively robust to a fixed-effects estimation). The universe of firms for this analysis includes all firms that have at least one FDA approved product from 1985 to 2001. Firm and year effects are included in all models. See Table 1 for independent variable definitions. Robust standard errors are reported in parentheses. We test the model:

$$P(y_{i,t}|\varepsilon_{i,t}) = e^{-\lambda_{i,t}\exp(\varepsilon_{i,t})}\lambda^{y_{i,t}}/y_{i,t}!$$

where y is a non-negative count variable defined as the number of new FDA approved products a firm has in a given year. $P(y_{i,t}|\varepsilon_{i,t})$ is the probability that pharmaceutical firm i introduces y FDA approved products in year t.

[a] denotes significance at the 1% level; [b] denotes significance at the 5% level; and [c] denotes significance at the 10% level

	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6
Citation weighted filings	0.0091 (0.0007)[a]	0.0078 (0.0006)[a]	0.0040 (0.0008)[a]	0.0039 (0.0007)[a]	0.0042 (0.0006)[a]	0.0039 (0.0006)[a]
Total continuations			0.0148 (0.0052)[a]	0.0124 (0.0051)[a]	0.0147 (0.0047)[a]	0.0133 (0.0046)[a]
Non-US Inventor				0.0199 (0.0078)[b]		0.0164 (0.0055)[a]
Average claims					0.0112 (0.0093)	
Drug loss (t-1)			0.6600 (0.2088)[a]	0.6663 (0.2062)[a]	0.5690 (0.1877)[a]	0.5791 (0.1880)[a]
Drug loss			0.5540 (0.1779)[a]	0.5457 (0.1749)[a]	0.7019 (0.1580)[a]	0.6955 (0.1576)[a]
Drug loss (t+1)			0.4738 (0.2019)[b]	0.3913 (0.1943)[b]	0.4995 (0.1684)[a]	0.4454 (0.1658)[a]
Drug loss (t+2)			0.0603 (0.2232)			
Pipeline count		0.0059 (0.0011)[a]	0.0055 (0.0016)[a]	0.0055 (0.0016)[a]	0.0031 (0.0012)[b]	0.0032 (0.0012)[a]
Log market cap			-0.0050 (0.0186)	-0.0007 (0.0188)	-0.0004 (0.0012)	-0.0002 (0.0012)
Log R&D			0.0653 (0.0424)	0.0518 (0.0429)	0.0508 (0.0349)	0.0507 (0.0351)
Constant	-3.5230 (0.1073)[a]	-1.9046 (0.1670)[a]	-2.1213 (0.4090)[a]	-2.0753 (0.4121)[a]	-2.4096 (0.3059)[a]	-2.3076 (0.3028)[a]
Firm dummies	Yes	Yes	Yes	Yes	Yes	Yes
Year dummies	Yes	Yes	Yes	Yes	Yes	Yes
N	8,311	4,004	3,196	3,196	3,196	3,196
Log likelihood	-2542.24	-2222.93	-1506.65	-1504.31	-2038.04	-2035.58
χ^2	684.74	358.87	285.53	294.54	392.20	388.32

Table 5(b): Marginal effects for patenting and new FDA approved product introductions

	Model 1 ∂y/∂x	Model 2 ∂y/∂x	Model 3 ∂y/∂x	Model 4 ∂y/∂x	Model 5 ∂y/∂x	Model 6 ∂y/∂x
Lagged patent filings	0.0032 (0.0003)[a]	0.0083 (0.0008)[a]	0.0085 (0.0012)[a]	0.0094 (0.0012)[a]	0.0077 (0.0013)[a]	0.0072 (0.0013)[a]
Total continuations						0.0026 (0.0012)[b]
Non-US Inventor						0.0035 (0.0020)[c]
Drug loss (t-1)			0.1541 (0.0766)[b]	0.1421 (0.0745)[c]	0.1627 (0.0784)[b]	0.1710 (0.0798)[b]
Drug loss			0.1305 (0.0639)[b]	0.1211 (0.0615)[b]	0.1278 (0.0629)[b]	0.1348 (0.0645)[b]
Drug loss (t+1)			0.1060 (0.0593)[b]	0.1156 (0.0700)[c]	0.1000 (0.0562)[b]	0.0839 (0.0424)[b]
Pipeline count		0.0009 (0.0021)[a]	0.0013 (0.0003)[a]	0.0013 (0.0039)[a]	0.0014 (0.0003)[a]	0.0013 (0.0003)[a]
Firm dummies	Yes	Yes	Yes	Yes	Yes	Yes
Year dummies	Yes	Yes	Yes	Yes	Yes	Yes
N	8,311	4,004	3,196	3,196	3,196	3,196

[a] denotes significance at the 1% level; [b] denotes significance at the 5% level; and [c] denotes significance at the 10% level

Table 6(b): Marginal effects for citation-weighted patenting and new FDA approved product introductions

	Model 1 ∂y/∂x	Model 2 ∂y/∂x	Model 3 ∂y/∂x	Model 4 ∂y/∂x	Model 5 ∂y/∂x	Model 6 ∂y/∂x
Citation weighted filings	0.0005 (0.0008)[a]	0.0014 (0.0001)[a]	0.0010 (0.0002)[a]	0.0010 (0.0002)[a]	0.0009 (0.0017)[a]	0.0009 (0.0001)[a]
Total continuations			0.0037 (0.0013)[a]	0.0031 (0.0013)[b]	0.0033 (0.0011)[a]	0.0030 (0.0010)[a]
Non-US Inventor				0.0050 (0.0019)[a]		0.0037 (0.0012)[a]
Drug loss (t-1)			0.2290 (0.0958)[b]	0.2297 (0.0944)[b]	0.1710 (0.0721)[b]	0.1734 (0.0723)[b]
Drug loss			0.1806 (0.0727)[b]	0.1755 (0.0706)[b]	0.2220 (0.0670)[a]	0.2175 (0.0659)[a]
Drug loss (t+1)			0.1489 (0.0768)[c]	0.1173 (0.0682)[c]	0.1436 (0.0595)[b]	0.1238 (0.0554)[b]
Pipeline count		0.0011 (0.0021)[a]	0.0014 (0.0004)[a]	0.0014 (0.0003)[a]	0.0007 (0.0003)[a]	0.0007 (0.0002)[a]
Firm dummies	Yes	Yes	Yes	Yes	Yes	Yes
Year dummies	Yes	Yes	Yes	Yes	Yes	Yes
N	8,311	4,004	3,196	3,196	3,196	3,196

[a] denotes significance at the 1% level; [b] denotes significance at the 5% level; and [c] denotes significance at the 10% level

Table 7(a): Relationship between citations and FDA approved products, 1985 to 2001

Logistic regression estimates for our data regressing an indicator, *NDA*, on three separate citations measures. *NDA* equals one if an underlying patent is linked with a FDA approved product. The population for this analysis includes all patents for sample firms from 1985 to 2001 within the same technology classifications as the population of FDA approved products. Year effects are included in all three models. Λ is the logistic distribution. See Table 1 for independent variable definitions. Robust standard errors are reported in parentheses. We test the model:

$$P(y_{i,t}\neq 0|x_{i,t}) = \Lambda(x) = e^{(x)}/[1 + e^{(x)}]$$

$$\partial\Lambda/\partial x_{i,t} = \lambda(\mathbf{x\beta})\beta_i$$

[a] denotes significance at the 1% level; [b] denotes significance at the 5% level; and [c] denotes significance at the 10% level

	Model 1 Odds Ratio	**Model 2 Odds Ratio**	**Model 3 Odds Ratio**
Total citations I	1.0292 (0.0016)[a]		
Total citations II		1.0355 (0.0021)[a]	
Total citations III			1.1628 (0.0162)[a]
Year dummies	Yes	Yes	Yes
N	39,601	39,601	39,601
Log likelihood	-3997.84	-4001.66	-4079.62
χ^2	550.10	542.48	386.56

Table 7(b): FDA approved product sales, 1990 to 2001

Year	Number of drugs	Mean (000s)	Min (000s)	Max (000s)	Total (000s)
1990	76	$42,139	$6	$702,503	$3,626,126
1991	95	$59,010	$12	$843,221	$5,605,981
1992	114	$75,684	$17	$985,047	$8,627,938
1993	135	$87,117	$2	$982,432	$11,760,843
1994	154	$101,103	$1	$997,535	$15,569,877
1995	175	$113,839	$2	$1,293,356	$19,919,868
1996	215	$122,112	$2	$1,856,558	$26,253,993
1997	263	$131,823	$1	$2,391,535	$34,669,550
1998	297	$170,925	$1	$3,580,407	$50,764,694
1999	326	$196,707	$2	$4,309,658	$64,126,433
2000	354	$219,397	$1	$4,717,466	$77,666,640
2001	377	$243,452	$1	$5,106,910	$91,781,516

* All financial variables are in constant 2000 dollars.