

## **How Do Firms “Use” Users?: Collaborative innovation in the medical device industry<sup>1</sup>**

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Abstract:

Prior research on corporate innovation has highlighted the importance of accessing external knowledge from other firms and universities. However, survey evidence indicates that product users are perhaps the most important source of external knowledge. Interestingly, previous studies on corporate knowledge sourcing have not theoretically considered the distinct nature of user-based knowledge and we have scant empirical evidence as to whether accessing user knowledge enhances firm innovation. We focus on the potential innovative benefits of engaging users in the innovation process by studying collaborations between medical device companies and physicians. We propose that firms benefit from these collaborations by accessing unique user knowledge that enables the firm to both generate higher quality inventions and develop more (FDA approved) product innovations. Our analysis of a panel of medical device firms yields evidence that supports our propositions.

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## INTRODUCTION

Firms continuously struggle to generate new sources of competitive advantage, often by developing new products and targeting new markets. A considerable amount of academic research has examined how firms manage innovation, focusing on both internal and external sources of new ideas. This work has found that internal development of substantial new inventions may be constrained by internal bureaucracy, competency traps, or existing customer preferences. Thus, the importance of extramural knowledge, or knowledge generated outside of the firm, is paramount (Cohen and Levinthal 1994). A survey by Cohen et al. (2002) identifies customers as the most important source of information for suggesting new projects, more useful than the firm's own operations, joint ventures, competitors, and universities, and the third most important source of information contributing to project completion (only after the firm's own manufacturing operations and independent suppliers).

This finding is closely linked to a literature that considers the importance of "user" innovation (von Hippel 1976; von Hippel 1988; von Hippel 1998; Baldwin et al. 2006; Lettl et al. 2006). This work generally views users as a potentially important source of novel inventions due to their unique knowledge base accumulated through use of the product. For example, users have specific knowledge about market needs and potential solutions that manufacturers of the products do not. This knowledge is difficult to transfer (i.e. "sticky") because it is rooted in the accumulated experiences of the user, and provides users with an advantage in developing novel inventions that match anticipated market needs (Dahlin et al. 2004; Chatterji and Fabrizio 2008). Accessing user knowledge can provide both valuable technical insights to spur new inventions and profitable marketing information regarding the needs of customers.

Our paper builds on these two theoretical foundations. First, prior work has argued that knowledge outside of the firm's own boundaries is often critical to developing new inventions (Arrow 1974; Cohen and Levinthal 1990). Second, other scholars have proposed that product users possess valuable technical (i.e. knowledge useful in developing important new inventions) and market (i.e. knowledge useful in generating new product market innovations) knowledge that is distinct from knowledge developed within firms and is difficult to transfer to firms without interpersonal interactions (von Hippel 1986; von Hippel 1988; von Hippel 1994; Powell et al. 1996; Luthje et al. 2005). Taken together, these theories predict that collaborations with users may provide firms with enhanced access to knowledge useful in the innovation process. Importantly, we suggest that user knowledge is valuable both in generating substantial new inventions and in developing commercializable new products, and that these contributions are distinct.

Our empirical investigation utilizes a new dataset covering an unbalanced panel of 126 public medical device firms over the 1985-1997 time period. Of these firms, 84 have at least one patented invention that was co-invented with a U.S. physician. We examine the effect of prior doctor collaborations, in the form of co-invented patented inventions, on changes in two performance outcomes of the firm: Citation weighted patents, a proxy for inventive outcomes, and FDA approved new product introductions, a proxy for product market innovations.

Based on results from a poisson quasi-maximum likelihood conditional fixed effects estimation, we find that both citation weighted patent outcomes and product market introductions increase following firm-doctor co-inventions. Further analysis by quartiles of firm R&D intensity suggests that it is primarily low-R&D intensity firms that experience superior inventive outcomes following doctor co-inventions. In addition, analysis of the results of a random

coefficient model suggest that firms with lower R&D productivity benefit more from doctor co-inventions in terms of both inventive and innovative outcomes. Interestingly, these results do not support predictions based on the absorptive capacity benefits of internal R&D. Instead, they suggest that firms are specializing in terms of internal or external knowledge generation.

This paper contributes to the growing literature on firm strategies for accessing knowledge outside the firm boundaries and also extends the user innovation literature by focusing on the unique benefits of user knowledge for incumbent firm innovation. Users hold potential knowledge that is not available from other sources because their knowledge is developed through experience using of the product. This knowledge, both in relation to the technical aspect of inventive solutions and the potential for new market opportunities, can impact a firm's future inventions and product innovations. Furthermore, we demonstrate that the impact of collaborations with users varies across firms in a pattern inconsistent with the prior literature on absorptive capacity.

In the next section, we review the relevant literature on why and how firms access knowledge beyond their boundaries, explain why user knowledge may be particularly useful for firms, and present testable hypotheses motivated by this prior work. We then describe our empirical setting and methods and present our results. We conclude with a discussion of the contributions of this study and open questions meriting further investigation.

## **THEORY & HYPOTHESES**

### **Importance of External Knowledge**

Incumbent firms face difficult challenges in managing their innovation activities to generate substantial new inventions and commercialize new product innovations (Henderson 1993). Since new ideas are often generated by bringing together diverse knowledge, established

firms may struggle to both generate and identify substantial new ideas within their organizational boundaries (Henderson 1993; Dushnitsky and Lenox 2005). Increasingly, scholars and practitioners are recognizing that valuable knowledge may reside outside of the firm (Cohen and Levinthal 1990), and that accessing and integrating this knowledge is key to firm innovative performance. How firms access external knowledge and combine knowledge across organizational boundaries, drawing from regional networks, other firms, and universities, has been the subject of substantial recent literature (Saxenian 1990; Mowery et al. 1996; Powell et al. 1996; Almeida and Kogut 1999; Stuart 2000; Ahuja and Katila 2001; Cohen et al. 2002; Grant and Baden-Fuller 2004).

Sourcing ideas from outside the firm poses significant challenges as it is often difficult to value unfamiliar ideas and integrate them into the firm's existing knowledge base. Research-related and experience-based knowledge often resides within the researcher herself and is "sticky" and difficult to transfer (von Hippel 1994). To overcome this difficulty, inter-organization knowledge transfer often relies upon interaction-facilitating institutions, such as joint ventures, alliances (Powell et al. 1996; Rosenkopf and Almeida 2003), research collaborations (Cockburn and Henderson 1998; Stuart 2000; Cohen et al. 2002), hiring employees away from competitors (Almeida and Rosenkopf 2003), consulting arrangements, corporate venture capital (CVC) investments and strategic acquisitions (Hayward 2002; Dushnitsky and Lenox 2005), or acquisitions (Mowery et al. 1996; Cockburn and Henderson 1998; Stuart 2000; Cohen et al. 2002; Rosenkopf and Almeida 2003; Dushnitsky and Lenox 2005). Enhanced economic and/or inventive performance depends on structuring interactions that promote the identification and transfer of valuable external knowledge.

## **User Knowledge**

This paper seeks to highlight and explore the potential of users as an additional knowledge source relevant to firm innovation. Prior studies of user innovation have demonstrated that the end users of products often possess valuable knowledge about evolving customer needs, market potential, and product improvements (von Hippel 2005). Moreover, survey evidence indicates that customers often provide important insights for new research and development (R&D) projects (Cohen et al. 2000). Below, we argue that user-based knowledge is distinct from the knowledge residing in other firms or in universities.<sup>2</sup> Users therefore hold the potential to contribute in a unique way to the innovative performance of established firms.

The user innovation literature has explored the motivations for users to innovate (Riggs and Von Hippel 1994; Shah 2006) and the particular type of knowledge they possess (von Hippel 1986; Luthje et al. 2005). Prior work has demonstrated that users innovators are often motivated by non-pecuniary factors, including by their own needs and desires, by career concerns or reputational benefits, by the urge to reinforce or create a social identity, or simply by their interest as a hobbyist (Shah 2006). These motivations result in substantial differences between the innovations generated by users and those generated by established firms. For example, users frequently innovate to solve their own particular needs, while manufacturers are more concerned with developing new products for large markets (von Hippel 2005). In addition, users are often focused on improving product functionality rather than selecting projects based on commercial viability.

Besides varying motivations, users also acquire knowledge that is fundamentally different than that of researchers within firms, namely the “local knowledge” that users gain from their own experience. While the accumulated knowledge base of a firm is the product of

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<sup>2</sup> It is important to note that in some of the prior literature, user innovators are actually downstream firms that modify a product of an upstream supplier.

previous research experience, users possess knowledge derived from their own use of a particular product that is tightly linked to their own needs. Users have an intimate knowledge of how a product performs in practice, when confronted with the challenges that arise in use. This may raise problems not envisioned by the manufacturers, and also suggest potential solutions or improvements. This distinct body of knowledge influences the inventions that users generate, creating important differences between the innovative outputs of users and manufacturers. The result is that there is the potential for firms to access substantial user knowledge that is valuable and distinct from the knowledge the firms holds already or is able to develop internally.

Despite the potential value of user-generated innovation, it can still be difficult for firms to access and integrate user-based knowledge. User based knowledge is often tacit, hard to write down, based on experience and thus difficult to transfer (von Hippel 1998). Truly free “spillovers” of such knowledge are therefore limited. As with other external sources of knowledge, collaborations allows for knowledge transfer that is more fine-grained, tacit, and cooperative than otherwise possible (Uzzi 1996; Uzzi 1997). Accordingly, benefits associated with user knowledge accrue to firms with active collaborations with users.

### **The Duality of User Based Knowledge**

The unique character of user based knowledge leads to the potential to contribute to firm innovative performance in at least two ways. First, users can provide knowledge that enhances the firm’s future inventive performance – what we will refer to as “technical” knowledge. Second, users’ knowledge may be useful in translating accumulated knowledge and inventions into new product innovations that are likely to serve a future market need – “market” knowledge. This characterization is similar to the distinction proposed by Nerkar and Roberts (2004:779) to categorize the attributes of firms’ internal knowledge, where technical knowledge is required to

“assimilate a range of technological inputs into novel combinations” and market knowledge is required to “facilitate the manufacturing, sales, and distribution of” a particular product. Rather than the firm’s internally developed knowledge, we will focus on an external source of these two kinds of knowledge, namely product users.

Luthje (2004) makes a related point by dividing user expertise into “product related knowledge” and “use experience”. The first concept “consists of know-how about the product architecture and the used materials and technologies of the existing products in the market” (Luthje 2004:686). This knowledge will be beneficial to provide technical insights into how to improve future inventions. The second concept is a product of continued use which results in a deep familiarity with a product and its uses. This kind of knowledge may be helpful in the product development process.

### **Technical Knowledge**

Prior work has demonstrated that user innovations differ substantially from firm innovations, and have characteristics, including greater breadth and better anticipation of technological trajectories, that are considered valuable (Chatterji and Fabrizio 2008). In several previous industry studies, Eric von Hippel and his colleagues have found that between 20%-80% of important inventions have been generated by users (von Hippel 1988). Chatterji and Fabrizio (2008) find that 20% of innovations in the medical device industry come from practicing physicians. Through their continued use and experimentation with particular products and refinement and testing within their communities, we argue that users develop significant technical knowledge that can be useful to firms.

Through experience, users develop unique insight into the shortcomings of existing products. As a result, they are able to suggest to firms new problems to be solved. Indeed,

Cohen, Nelson, and Walsh (2002) find that customers are the most important source of information suggesting new projects, more so than the firm's own manufacturing operations. The insights of user experiences may also provide solutions to these problems that are different from those that would be developed by the firm. The solutions of users are likely to anticipate practicality, ease of use, and functionality with foresight that is based on experience and not available to firm researchers. Although knowledge accumulated through prior research gives firms an advantage in performing related research, the tendency toward local search also limits a firm's ability to identify new problems or solve old problems in a new way. Corporate research and development can utilize the contributions from user knowledge regarding new problems and potential new solutions to embark on novel streams of research that will result in new inventions. In addition, users may be able to rule out potential solutions early on, foreseeing problems that could occur in the use of a new invention. These insights will save a firm substantial time, effort, and cost associated with pursuing research agendas that would not result in successful inventions. All else being equal, we propose that accessing user's valuable technical knowledge will enhance the inventive outputs of a firm.

Thus we propose:

*H1: Greater firm collaborations with users lead to an increase in the firm's invention rate.*

### **Market Knowledge**

Logically, improvements in the firm's inventive output should increase the number of new product innovations generated by the firm. We suggest that the contribution of users has the potential to go beyond increasing inventive output by directly contributing "market" knowledge that is also valuable in product development.

Because product development is an inherently uncertain process (Luthje and Herstatt 2004), firms often seek outside knowledge to determine the best course of action. Herstatt and von Hippel (1992) argue that in many industries the most crucial information about new products and services resides in a few key lead users. Lead users are defined as those individuals who experience a need that the rest of the population will have later on and who experience significant benefits from finding a solution to their need (Herstatt and von Hippel 1992). Thus, lead users can provide valuable insight into potential new products for two related reasons. First, lead users are among the select few who can understand what the rest of the market will eventually want, simply by articulating what they need today. Second, since lead users expect to benefit significantly from a solution, they are motivated to collaborate with firms if collaboration will increase the likelihood of solving their problem. In addition, since users are often deeply embedded in the communities that will benefit most from a solution, they can often better anticipate and address future market opportunities (Riggs and Von Hippel 1994; von Hippel 2007).

Users' market knowledge is thus rooted in their own use, often through their status as lead users and their involvement in user communities. These conditions allow users to anticipate market needs and forecast the potential viability of various new products or product modifications. Users therefore are able to prioritize inventions based on their expectation of user response to the new or modified product. Without access to this market knowledge, firms may spend resources and time developing and testing products that are later discovered either to be non-optimal product solutions or for which the market potential is not sufficient. Firms able to access user knowledge can instead focus on developing and testing the product inventions with greatest potential to both successfully complete the testing process and meet significant demand

in the marketplace. As a result, these firms will generate more products that survive the development and testing process and emerge as commercialized innovations.

Thus, we argue that, all else being equal, valuable market knowledge provided by users during collaborations will lead to an increase in the numbers of products innovations generated by the firm.

*H2: Greater firm collaboration with users lead to an increase in the total number of product innovations generated by the firm*

It is entirely possible that any such increase in the number of product innovations associated with user collaborations could be attributable to the increase in inventions hypothesized in H1. In order to test our proposal that users contribute both technical knowledge, relevant to the invention process, and market knowledge, relevant to crafting successful product innovations, we will also examine the degree to which the firm's invention rate explains the effect of doctor collaborations on product innovations. To the extent that these are separable effects of doctor collaborations, as we suggest, collaborations will contribute to new product introductions above and beyond any effect captured by the firm's inventions.

## **CONTEXT: THE MEDICAL DEVICE INDUSTRY**

*"No medical device has ever been developed without collaboration between a medical device company and doctors,"*

*Scott Ward, President of the cardiovascular business at Medtronic<sup>3</sup>*

The medical device industry is comprised of over 6,000 companies<sup>4</sup> that spend significant sums on R&D (greater than 11% of sales<sup>5</sup>) and produce increasingly rapid product innovations

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<sup>3</sup> <http://www.nytimes.com/2006/10/27/health/27cnd-stent.html>

<sup>4</sup> Advanced Medical Technological Association, AdvaMed Website, (<http://www.advamed.org/MemberPortal/About/Industry/>) Last accessed June 5<sup>th</sup>, 2007.

(with product cycles sometimes lasting as short as 18 months<sup>6</sup>). Intellectual property rights on inventions in the medical device industry tend to be crucial and strong. In fact, R&D managers in medical equipment, report the highest degree of appropriability through patents of any industry surveyed – even higher than that reported by R&D managers in the pharmaceutical industry (Cohen et al. 2000).

### **Collaboration Between Physicians and Medical Device Companies**

As evidenced by the quote above, innovation in this industry requires significant interaction between physicians and device companies at all stages of development. From product conception to clinical testing to dissemination, medical device companies devise strategies to tap into the knowledge of their most important customers, practicing physicians (Chatterji et al. 2008). Prior research has demonstrated that practicing physicians are valuable sources of new ideas in the medical device industry (Chatterji and Fabrizio 2008).

In this paper, we focus exclusively on physician-industry collaboration at the earlier stages of product research and development. There are typically two general scenarios by which doctors and companies collaborate on innovation (Carlin 2004). In the first instance, a physician or team of physicians will patent a new invention that generates interest from a medical device company. If both parties agree, a license or a transfer of patent rights from inventor to company can be arranged. A famous example of this case was Dr. Thomas Fogarty, a prolific medical device inventor, who licensed the patent for his revolutionary balloon catheter to Edwards Life Sciences (White 2006). While these arrangements are quite common in the industry, they do not always represent collaborative innovation between doctors and companies.

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<sup>5</sup> Advanced Medical Technological Association, AdvaMed Website, (<http://www.advamed.org/MemberPortal/About/Industry/>) Last accessed June 5<sup>th</sup>, 2007.

<sup>6</sup> The Food and Drug Administration Website, (<http://www.fda.gov/cdrh/ocd/mdii.html>), Last accessed June 5<sup>th</sup>, 2007

Under the 2<sup>nd</sup> scenario, which we will focus on in this paper, the physician inventor is consulting or co-developing an idea with a medical device company, resulting in a patented invention (Carlin 2004). A common arrangement is a consulting agreement whereby a contracted doctor automatically assigns any resulting intellectual property to the firm. In this case, any resulting patents will list the physician as an inventor but will be assigned to the medical device company. These “co-invented” patents, with listed physician inventors, represent products of collaboration between innovative doctors and medical device companies.

### **The Regulation of Medical Devices**

To bring a new medical device to market, an application must be approved by the Food and Drug Administration (FDA), specifically the Center for Devices and Radiological Health (CDRH).<sup>7</sup> CDRH divides products into 3 classes. Class I for very low risk products such as crutches or bandages, which normally do not have to obtain pre-market approval and will be excluded from our study.

Class II devices are more risky products that are most often approved through a process called Pre-Market Notification, commonly referred to as the 510k process. 510k approval requires demonstration of equivalency to a device currently on the market, called a predicate device, so the process often takes less than 3 months (Singh 2007). As a result, products on the 510k track can sometimes be brought to market as little as year from conception (Lawyer et al. 2007).

Class III devices are the most innovative and riskiest products (Singh 2007). Class III devices undergo a much more rigorous Pre-Market Approval (PMA) process which involves animal testing and human clinical trials (Singh 2007). Recent research has found the average

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<sup>7</sup> Although it is technically correct to say the application has been approved rather than the product itself, we will refer to product approvals throughout the paper for simplicity.

review time for a PMA application to be approximately 409 days between 1998 to 2005, and significantly longer for orthopedic devices (Singh 2007). In 2006, the FDA granted 39 PMAs and 3210 510ks, in rough accordance to their ratio over the last several years (Lawyer et al. 2007). A recent study by the Government Accountability Office found that between 2003-2007, the 510k process had a 90% approval rate and the PMA process had a 67% approval rate.

## **DATA AND METHOD**

The goal of our empirical analysis is to estimate the impact of firm collaborations with doctors on inventive performance and new product innovations. Specifically, we explore the variation in levels of firm co-inventions with doctors and compare the subsequent rates of generation of inventive and product market outcomes. As described in detail below, we make use of patent data commonly used to measure inventive outcomes, and also compile FDA data on products approved through the 510k and PMA processes. This approach has the advantage of allowing us to consider separately the impact of user collaboration on both inventive and product market outcomes. Following Hausman et al. (1984) and Griliches (1990), we employ a production function model to estimate the elasticity of inventive and product market outcomes to doctor co-inventions, controlling for other inputs, including the firm's own R&D and accumulated knowledge stock.

### **Sample**

We construct a large, unbalanced panel of public medical device companies with data from 1985-1997. The sample includes all public firms in a primary medical device Standard Industrial Classification (SIC) code that were granted at least 10 patents between 1980 and 2002. This approach purposefully excludes large conglomerates and firms that are primarily pharmaceutical firms in order to focus on medical device firms and their activities. This method

also purposefully excludes firms with only rare inventions in order to focus on firms that are following a strategy based on innovation. The resulting dataset includes 127 firms and 767 firm-year observations.<sup>8</sup> The dataset includes information on the firms' FDA approved products from the CDRH, granted patents from the Hall et al (2001) dataset, and firm-year level data from the Standard & Poor's Compustat database. In order to identify collaborations with doctors, we rely on the AMA Masterfile data, which includes biographical information for all licensed physicians in the U.S..

The construction of our dataset proceeded as follows: For the set of firms that meet the criteria described above, we identified all successful U.S. medical device patents applied for between 1980 and 1997 using the NBER patent data (Hall et al. 2001). We use the patent data to identify all of the inventors on each of these patents, including data on inventors' first, middle, and last name, and the city and state location. The AMA Physician Masterfile contains the name, demographic information, address, history of prior locations, type of practice, and medical school information for all licensed U.S. physicians. With this information, we are able to identify which of the inventors listed on medical device patents of the sample firms are doctors.

We perform this match in several steps. First, we identify any doctors with the same last name, first name, and state location as an inventor listed on a medical device patent. We use the historical and current location and the address data for each doctor in the AMA masterfile for this match. Once these possible matches are identified, we evaluate them more closely to assure a true match. For each record, if there is a middle name or initial available from both sources (the patent data and the AMA data), we verify that these match and eliminate any for which they do not match. When one or both of the middle initial observations is missing, we verify that the

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<sup>8</sup> In order to observe a five year window of forward citations for patents in the sample, we are only able to include patents through 1997 in the analysis. Likewise, our identification of doctor inventors only extends back to 1980, so in order to include lags of up to 5 years in the analysis, our analysis can not use data before 1985 in the analysis.

observations match according to the city. Those observations lacking sufficient middle name data that do not match exactly based on city are flagged for closer evaluation to determine a true match.

## **Measures**

### **Inventive Output**

We capture each firm's rate of inventive output using the (forward) citation-weighted count of patents in each year (CiteWtdPats). Patents and citations weighted patents have been employed consistently as measures of inventive performance in recent literature (Griliches 1990; Trajtenberg 1990; Henderson and Cockburn 1994; Brockhoff et al. 1999; Harhoff et al. 1999). Previous studies have found that the count of citations received by a patent is a good indicator of invention value (Trajtenberg 1990; Harhoff et al. 1999; Hall et al. 2005).

We include all patents by sample firms in the 19 technology classes corresponding to medical devices, as per the U.S. Patent and Trademark Office<sup>9</sup>. We date the patents according to the application date to more closely approximate the date of invention. Using the Hall et al. patent database, we count the number of follow-on patents that include a citation to each of the sample patents (forward citations).

We also employ a modified measure to deal with two concerns. First, one might be worried that firms that co-invent with doctors in the recent past are likely to do so again, and that doctor co-invented patents receive more citations, as demonstrated in Chatterji & Fabrizio (2008). Second, one might be concerned that doctor co-invention might be correlated with the firm's propensity to generate future patents citing their own work, artificially inflating the

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<sup>9</sup> We use the US PTO's definition of medical device patents, as reported in the Technology Profile Report for Medical Devices (U.S. PTO, 2005).

forward citation count. To alleviate these concerns, we develop a modified count of forward citations excluding doctor co-invented patents and excluding forward citations from patents generated by the focal company (self citations).

### **Product Market Innovations**

Many studies that rely on counts of patents or citation weighted patents do so due to a lack of information on actual product introductions. We are fortunate to also have data on product innovations. We construct a firm-year count of the number of FDA-approvals (NumInnov) based on the CDRH data. To date the product innovations, we use the year that the application is received by the FDA.

### **Physician Co-invention**

Our primary independent variable of interest is firm-doctor collaboration, which we proxy for with the count of patents assigned to the firm that are co-invented with a physician in a firm-year observation. If at least one inventor on a firm's patent is a doctor, we count this as a doctor co-invented patent. In our base specification, we include the one year lagged value of doctor co-invention ( $DrPats_{t-1}$ ). As discussed below, we also test for robustness to including five years of lags.<sup>10</sup>

### **Controls**

Control variables include the firm's own research and development expenditures in millions of dollars (R&D) and the firm size, measured by the number of employees in thousands (Employ). We expect that more R&D expenditures will lead to more inventive output and more product innovations. We include a control for the firm's accumulated technical knowledge stock

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<sup>10</sup> We also experimented with a depreciated stock of doctor co-inventions over the previous 5 years. The coefficient on this variable was positive but not statistically significant. As results reported below make clear, the one and two year lagged co-inventions are what really matter in this case. As such, the five year stock measure was generating a lot of noise in the estimation.

(KnowledgeStock), measured with the depreciated stock of patents over the prior five year period using a depreciation rate of 20%. We also include a control for the firm's accumulated product market knowledge (ProductStock), measured analogously with the depreciated stock of FDA-approved innovations over the prior five year period. These measures controls for time varying heterogeneity in firms' knowledge base.

## **Method**

Both of our dependent variables (CiteWtdPats and NumInnovs) take on integer values and are bounded at zero. OLS estimation would provide inefficient and potentially bias estimates. We adopt a poisson quasi-maximum likelihood estimation procedure to account for the discrete nature of these outcome variables. This estimation procedure is similar to the familiar poisson model, but does not depend on the (oft-violated) assumption of constant dispersion (i.e. variance equal to the mean). This method also allows for conditional firm fixed effects and the calculation of robust standard errors with clustered correlation structures to generate appropriate test statistics.

In general, we include the natural logs of the explanatory variables with a one year lag. Thus, we are estimating the relationship between, for example, last year's R&D expenditures and this year's inventive and product innovation outcomes. This is consistent with prior literature (Jaffe 1989; Dushnitsky and Lenox 2005).

Since we do not have strong priors about when the benefits of user collaborations will be evident in the firm's inventive outcomes, we test two alternative specifications. Our base models include only the one year lagged count of doctor co-inventions. The alternative is the most flexible specification: We include each of the prior five year lags as five separate variables.

Rather than including a cumulative stock or depreciated stock of recent collaborations, this has the advantage of not imposing an assumed pattern of depreciation.

### **Empirical Concerns**

As in any study of firm behavior, we have important empirical concerns to address. First, there is likely to be considerable firm heterogeneity not captured by the variables in our model. Second, the choice and opportunity to engage in co-invention with doctors is potentially endogenous to the inventive performance outcomes studied here.

To explicitly account for unobserved heterogeneity, we include firm-level (conditional) fixed effects in our model. To the extent that there are inherent differences in firm inventive performance that are constant across the period studied, the fixed effects will condition these out of the model. In the discussion of results, we also consider a random coefficients model that allows for persistent differences across firms and also estimates individual (firm-specific) coefficients for each explanatory variable.

The potential endogeneity of firm-doctor collaboration is more difficult to account for. The firm fixed effects help alleviate this potential source of bias to the extent that the drivers of endogeneity are constant across the time period studied. For example, if “better” firms attract doctors interested in engaging in collaborative research, and this is a permanent characteristic of the firm, then exploiting changes over time for each firm avoids bias associated with endogeneity. If, however, the drivers of collaboration change over time in a way that is correlated with our outcome measures, estimation that fails to account for this may produce bias estimates. As we return to in our discussion of limitations of this study, we would like to implement an instrumental variables approach to estimate predicted collaborations in the first

stage, based on exogenous factors, and then use this estimate to generate unbiased estimates in the second stage. We have not yet found instruments that meet the criteria for this approach.

## **ANALYSIS & RESULTS**

Sample summary statistics are presented in Tables 1-3. There is considerable variation across all of the variables in the model. Doctor co-invention is common for the sample firms, representing 24% of the firm's patents, but the degree of co-invention varies considerable across firms. Table 3 provides summary statistics for a few of the companies in the sample in order to provide additional insight into the data. Medtronic, a well-known medical device company, is one of the largest firms in our sample. This firm co-invents 15% of its patents with doctors. Smaller firms may invent more of their patented inventions with doctors, such as Biomagnetic Tech., or fewer, such as Luther Medical Products. It is important to note that the substantial differences *across firms* are not what our empirical analysis depends upon for identification – these differences are conditioned out in the fixed effect. Instead, our estimation makes use of within-firm variation over time to identify the effects of doctor collaborations on inventive outcomes.

In order to provide more quantitative evidence about the doctor-firm collaborations represented by the co-invention activity in our sample, Tables 4a and 4b summarize the primary employment settings and specialties of the doctor co-inventors in our data. Note that many of the doctor co-inventors are employed in group practice (38%) or solo practice (24%). Only 5% are in medical schools. The doctor co-inventors come from a diverse set of specialties. Doctors in various surgery specialties are represented, so that the total percentage of doctors in any kind of surgical specialty represents the largest contingent in the data (about 15%).

Results testing out hypotheses are presented in Table 5 (for the citation weighted patent count) and Table 6 (for the number of approved product innovations). Models 1 and 2 in Table 5 use the total forward citation count and the dependent variable; Models 3 and 4 use the modified count, excluding doctor co-invented patents and forward self-citations. For each dependent variable, we report our base specification, using the one year lagged value of doctor collaborations, and also an extended model including five lags of doctor collaborations in order to examine the time profile of the effects. Note that the use of the poisson maximum likelihood fixed effects model necessitates dropping firms with either only one observation (i.e. one year of data, which is the case for 26 firms) or with all zero outcomes (i.e. firm's patents never receiving citations or firm never generates an FDA-approved product innovation). For this reason, the number of observations and firms included varies across the dependent variables.

In all cases, recent doctor collaborations are associated with an increase in the inventive performance outcome variable. The one year lagged doctor collaboration measure is significant and positive in all estimations. Firms that collaborated with doctors in the recent past generate more citation weighted patents and generate more new approved products. An increase of 1 doctor co-invention is associated with a 1.19 factor increase in the number of citation, or about 13 citations at the mean (based on Model 3 in Table 5) and a 1.24 factor increase in the number of innovations, or about 1 innovation at the mean (based on Model 1 in Table 6). In the models including 5 years of lags, joint tests for significance in each case support the joint significance of the five measures at the 1% level. Importantly, in all cases, it is collaborations in the most recent two years that have an effect on the innovative outcomes of the firm.<sup>11</sup>

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<sup>11</sup> The positive and significant coefficient on the 5 year lagged doctor collaborations is most likely picking up the underlying knowledge stock of the firm. We do not view this as an indication that collaborations from five years ago are a significant driver of current inventive outcomes.

It is interesting to note that the control for the firm's accumulated technical knowledge stock (KnowledgeStock), measured by the depreciated stock of patents in the prior five year period, is a significant predictor of new inventions generated by the firm (Table 5), but is not a significant predictor of new product innovations.<sup>12</sup> Likewise, the firm's product market knowledge stock (ProductStock), measured by the depreciated stock of approved innovations in the prior five year period, is a significant predictor of new product innovations, but not new inventions. This is confirmatory evidence that technical and product market knowledge are in fact different and contribute differently to the discovery (i.e. invention) and development and commercialization (i.e. innovation) processes.

Because the two outcome measures, counts of citation weighted patents and approved product innovations, are expected to be related, we pursued further analysis to examine the potential that the increase in product innovations was due to the increase in inventive outcomes, rather than being separately attributable to the collaborations with doctors. In other words, we tested for the mediating role of citation weighted patents in the analysis of product innovations. Results, reported in Model 3 of Table 6, demonstrate that although citation weighted patents do positively predict product innovations, the effect of doctor collaborations on innovative outcomes is not substantially diminished with the inclusion of this control. This finding is consistent with the companies gaining two different types of knowledge from doctors, technical knowledge that is most useful in developing new inventions, and product market knowledge that is most useful in crafting new innovations that are worth commercializing and will be approved by the FDA.

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<sup>12</sup> Note that the accumulated stock of technical knowledge is not significant in the equations including 5 years of lagged doctor collaborations because it is highly correlated with the five year lagged value.

As an additional robustness check, we estimated equations for our two dependent variables (Modified Citation Weighted Patents and Number of Innovations) together in a system of equations using Zeller (1962) seemingly unrelated regressions to account for possible correlation in the error terms across the two equations. Coefficient estimates confirm the results reported here, and significance levels are greater due to gains in efficiency from joint estimation. A Breusch-Pagan test of independence rejects the null of independent equations.

### **Empirical Extensions**

In light of the considerable recent literature describing and documenting the benefits of the firm's own research in generating the absorptive capacity necessary to make use of external knowledge sources, we also investigated the relationship between the research intensity of the firms in our sample and the benefits that they realize from doctor collaborations. In order to do so, we divided the firms into subsamples according to the firm's average (over time) research intensity (R&D expense divided by number of employees). The results of our base specification for firms in four quartiles of R&D intensity are displayed graphically in Figure 1. The effect of doctor collaborations on the modified citation weighted patent count are represented by the lighter grey bars and the effect of doctor collaborations on the number of approved product innovations are represented by the darker grey bars. Striped bars indicate insignificant coefficients. It is clear from Figure 1 that the more R&D intensive firms actually benefit less from doctor collaborations, in terms of generating important new inventions.<sup>13</sup> Firms doing the most R&D (relative to size) are benefitting the least (or not at all) from co-inventions with doctors. This is the opposite of the absorptive capacity argument, and instead suggests that firms are substituting between internal R&D and external sourcing of new technical knowledge. The results for the new product innovations are not as straightforward. The least R&D intensive firms

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<sup>13</sup> Results are the same if we use the total citation count including all patents instead of this modified count.

do benefit more from doctor collaborations than firms in the second and third quartile of R&D intensity. However, the most R&D intensive firms appear to benefit the most in terms of new product introductions. These are generally also the smallest firms, in terms of the number of employees, and may be engaged primarily in developing technologies sourced from doctor collaborations.

To further investigate the difference in the benefits gleaned from doctor collaboration across firms, we employ a random coefficients model (Ameniya 1978; Swamy and Tavlvas 1995; Knott 2008). This model is a general functional form model in which coefficients are allowed to vary across members of the panel. As described in Knott (2008), the common “fixed effects” model is a partial random effects model that allows the constant term to vary across member of the panel, but maintains common coefficients for the other explanatory variables. The full random coefficients model is similar, but allows a common and firm specific component for each of the explanatory variables. This allows not only the intercept but also the slope (for each explanatory variable) to vary by firm.

Due to degree-of-freedom constraints, estimation requires dropping firms with fewer than 8 observations, resulting in a loss of 249 observations, leaving 45 firms in the analysis.<sup>14</sup> Because this model estimates a coefficient for each explanatory variable for the sample as well as each firm, a table of results is not included in the interest of space but is available from the authors upon result. For the equation predicting the modified citation weighted patent count, the firm-specific coefficients on the doctor collaboration variable range from -85.88 to 90.78, and 16% are statistically significant, indicating substantial variance across firms in the impact of doctor collaborations. These betas allow us to examine the relationship between the firm’s own R&D

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<sup>14</sup> Because a firm-specific coefficient is generated for each included explanatory variable, including more variables quickly uses up the degrees of freedom. For this reason, we replaced the year dummy variables from our base model with one variable representing the year in the random coefficient model.

productivity (the elasticity of inventive outcome to firm R&D) and the benefits from doctor collaboration (the elasticity of inventive outcome to doctor collaborations) by comparing the firm-specific betas for the own-firm R&D variable and for the doctor collaboration variable. Figure 2 graphs the relationship between the firm-specific elasticities of citation weighted patents counts to the firm's own R&D and to doctor collaborations. The correlation is negative (-0.38) and statistically significant at the 5% level, suggesting that firms with *the least productive* own-firm R&D have the *most productive* collaborations with doctors. Again, this is consistent with specialization between internal and external sourced of new inventions.<sup>15</sup>

Results of the analogous model for the count of FDA approved product innovations also suggest considerable firm heterogeneity. The firm-specific coefficients on lagged doctor collaboration range from -17.44 to 2.89, and 18% are significant, suggesting variability in the benefits derived from doctor collaboration. Figure 3 graphs the relationship between firm-specific elasticities of new product innovations to own firm R&D and to doctor collaborations. The correlation between these elasticities is negative (-.90) and significant at the 1% level. As is evident from the plot, there is a substantial outlier. If this outlier is excluded, the correlation is still negative (-.47) and significant at the 1% level. Again, this suggests that firms with *less productive* internal R&D (in terms of generating new product innovations) *benefit more* from collaborations with doctors.

## **DISCUSSION**

In light of the substantial importance of users as sources of knowledge relevant to the innovation process (Cohen et al. 2002), corporate activities aimed at tapping this unique resource are particularly salient. This paper marks the first attempt to quantify the benefits realized from

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<sup>15</sup> This is consistent with the results in Knott (2008) with regard to the elasticities of sales to the firm's own R&D and other firms' R&D.

user collaboration by examining the effects of collaboration with doctors on the inventive performance and product market innovations of incumbent medical device companies.

Our work makes several important contributions to the existing literature on managing innovation and sourcing external knowledge. First, we highlight product users as an important and unique repository of outside knowledge that can be accessed by firms. Along with other firms and universities, users can now be included in a broader conception of “open innovation” (Chesbrough 2003) whereby firms take advantage of a variety of external sources of knowledge. Future research might wish to consider whether firms benefit more from accessing a variety of external sources with equal intensity or from concentrating on a specific source, for example other firms, universities, or users.

Next, we explicate two separable paths by which user knowledge benefits firms: 1) through technical knowledge leading to enhanced inventive performance and 2) through market knowledge leading to improved product market innovation outcomes. As Schumpeter (1934) first pointed out, there is a crucial distinction with between invention and innovation, and we find that user knowledge can be helpful in supporting both. This is an important theoretical distinction between users and other sources of external knowledge (Saxenian 1990; Mowery et al. 1996; Powell et al. 1996; Almeida and Kogut 1999; Stuart 2000; Ahuja and Katila 2001; Cohen et al. 2002; Grant and Baden-Fuller 2004) and is driven by the unique knowledge acquired by users through use of a particular product. Future research should explore whether the mechanisms for accessing user knowledge are dramatically different than those used to tap other sources. As discussed above, since user knowledge is often tacit and difficult to transfer (von Hippel 1988), companies may need to design new strategies to effectively source this variety of knowledge.

Furthermore, our empirical results demonstrate that firms may be strategically sourcing knowledge, in that firms with lower R&D intensity and own-R&D productivity appear to benefit more from knowledge accessed via user co-invention. This relationship suggests substitutability between internally generated and externally sourced knowledge. This finding runs counter to the absorptive capacity argument (Cohen and Levinthal 1990), where internal R&D and external knowledge acquisitions are complements (Cassiman and Veugelers 2006), but is consistent with recent empirical findings regarding inter-firm spillovers (Knott 2008).

## **LIMITATIONS**

There are important limitations to our work. First, FDA approval is not necessarily the best measure of market success. Future research should consider whether collaboration with users leads to increased sales or profits related to a particular product. Next, it is important to test these ideas beyond the medical device industry, where users are likely to be especially important. For example, it would be interesting to test for heterogeneity among firms in other industries in terms of their reliance on customer innovation. The results of this study indicate that this kind of “customer-centric” innovation may be an emerging business strategy that is perhaps especially important for firms that have weaker internal R&D capabilities. Additionally, we are unable to separate the aspects of user knowledge that are related to invention versus innovation. Rather, we are only able to observe the distinct impact on subsequent firm patents and products. Future research, likely based on field interviews with physicians, might uncover methods to classify various aspects of user knowledge reliably.

Finally, as noted above, firm-doctor collaborations represent a choice of the firm, and represent an endogenous choice. To the extent that the drivers of this choice vary over time and are correlated with the inventive outcomes studied here, our estimates may be biased. While

prior work has suggested that some firms may value external knowledge more highly than internal knowledge (Argote et al. 2003), there may be other reasons for the pattern observed in our data. Future research should explore why some firms draw on more external knowledge than others and whether the determinants of this strategic choice are primarily permanent aspects of the firm (such as location) or characteristics that change over time (such as research productivity). At a minimum, our results suggest that firms may be strategically seeking user-generated technical and product market knowledge when they recognize that their own R&D activities are not generating benefits in terms of new inventions and product innovations.

## **CONCLUSION**

Our paper highlights the importance of user innovators in the medical device industry. These practicing physicians play a unique role in the industry, not only as a customer for medical devices, but as a valuable source of insights for future inventions and products. As physicians and companies work closely together to generate new ideas and create life saving devices, conflicts of interest must also be managed carefully, since patients might not always be aware of connections between their doctor and device makers (Chatterji et al. 2008). In our view, policymakers must encourage transparency without reducing the incentives for collaborative innovation, which our work suggests can have significant benefits.

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Table 1: Summary Statistics  
N=767 firm-year level

	Mean	St Dev	Min	Max
Cite Weighted Patents	102.92	237.57	0	1893
Modified Cite Weighted Patents	70.14	164.46	0	1232
Number Innovations	3.94	7.71	0	70
Lagged Doctor Collaborations	1.15	3.42	0	40
Knowledge Stock	10.52	27.49	0	291.58
Product Stock	9.38	17.89	0	17.76
Lagged Employees	2.12	7.52	0.01	65.9
Lagged R&D	16.42	42.20	0.01	345.00
% Company Patents w/ DR	24%	33.25	0	100%

Table 2: Correlations

		1	2	3	4	5	6	7
1	Cite Weighted Patents							
2	Modified Cite Weighted Patents	.96						
3	Number Innovations	.57	.55					
4	Lagged Doctor Collaborations	.50	.43	.40				
5	Knowledge Stock	.61	.60	.54	.79			
6	Product Stock	.45	.46	.78	.42	.62		
7	Lagged Employees	.35	.35	.72	.25	.44	.71	
8	Lagged R&D	.40	.38	.68	.41	.63	.78	.84

Table 3: Statistics for Select Sample Companies

	Avg Annual # employees (M)	Avg Annual # Patents	Avg Annual # FDA approved Product	Avg Annual # Doctor Patents	Avg Annual % Pats w/ Doctor
Medtronic (101)	8.92	63.46	15.46	11.23	15.81%
Stryker (142)	2.80	4.31	6.92	1.00	17.79%
Biomagnetic Tech (20)	0.10	1.67	0.56	0.44	25%
Luther Medical Prods. (94)	0.04	2	0.92	0.08	9%

**Table 4a: Tabulation of Doctor Co-inventor Primary Employment**

<b>PE code</b>	<b>Present Employment</b>	<b>% Doctor Co-inventors</b>
30	Group Practice	38
11	Self-Employed Solo Practice	24
110	No Classification	13
40	Medical School	5
101	Other Non-Patient Care	5
50	Non-Gov't Hospital	4
13	Two Physician Practice - Owner	3
22	Locum Tenens	2
63	City/County/State Hospital	2
64	City/County/State Other	1
85	Vet Admin (Fed Govt Hospital)	0.5
86	Fed Govt Hospital Other	0.5
35	HMO	0.4
21	Other Patient Care	0.2
81	Army (Fed Govt Hospital)	0.1

**Table 4b: Tabulation of Doctor Co-inventor Specialty**

<b>Spec code</b>	<b>Specialty</b>	<b>% Doctor Co-inventors</b>
EM	Emergency Medicine	12
IM	Internal Medicine	11
CD	Cardiovascular Disease	9
DR	Diagnostic Radiology	8
AN	Anesthesiology	6
FP	Family Practice	6
ORS	Orthopedic Surgery	5
GP	General Practice	3
GS	General Surgery	3
US	Unspecified	3
TS	Thoracic Surgery	3
P	Psychiatry	3
PHP	Public Health & Gen Preventive Medicine	2
ICE	Cardiac Electrophysiology	2
A	Allergy	2
OBG	Obstetrics & Gynecology	2
OPH	Ophthalmology	2
GE	Gastroenterology	2
PD	Pediatrics	1
PS	Plastic Surgery	1
VS	Vascular Surgery	1
OS	Other Specialty	1
NS	Neurological Surgery	1
ALL OTHERS	ALL OTHERS	10 total

Table 5: Citation Weighted Patents as a Function of Doctor Collaborations

	(1)	(2)	(3)	(4)
	Citation Weighted Patents		Modified Citation Weighted Patents	
<b>ln_DrPats<sub>t-1</sub></b>	<b>0.206</b>	<b>0.209</b>	<b>0.174</b>	<b>0.182</b>
	<b>(0.067)**</b>	<b>(0.064)**</b>	<b>(0.070)*</b>	<b>(0.066)**</b>
<b>ln_DrPats<sub>t-2</sub></b>		<b>0.151</b>		<b>0.174</b>
		<b>(0.065)*</b>		<b>(0.088)*</b>
ln_DrPats <sub>t-3</sub>		-0.013		0.025
		(0.055)		(0.064)
ln_DrPats <sub>t-4</sub>		-0.009		0.067
		(0.088)		(0.086)
ln_DrPats <sub>t-5</sub>		0.168		0.190
		(0.074)*		(0.075)*
<b>ln_KnowledgeStock<sub>t-1</sub></b>	<b>0.234</b>	0.136	<b>0.336</b>	0.170
	<b>(0.104)*</b>	(0.138)	<b>(0.102)**</b>	(0.134)
ln_ProductStock <sub>t-1</sub>	0.031	-0.025	0.015	-0.079
	(0.119)	(0.113)	(0.124)	(0.110)
ln_Employ <sub>t-1</sub>	0.192	0.242	0.210	0.280
	(0.160)	(0.164)	(0.197)	(0.206)
ln_R&D <sub>t-1</sub>	0.111	0.135	0.159	0.214
	(0.115)	(0.120)	(0.137)	(0.148)
Observations	739	739	733	733
Number of firms	100	100	99	99

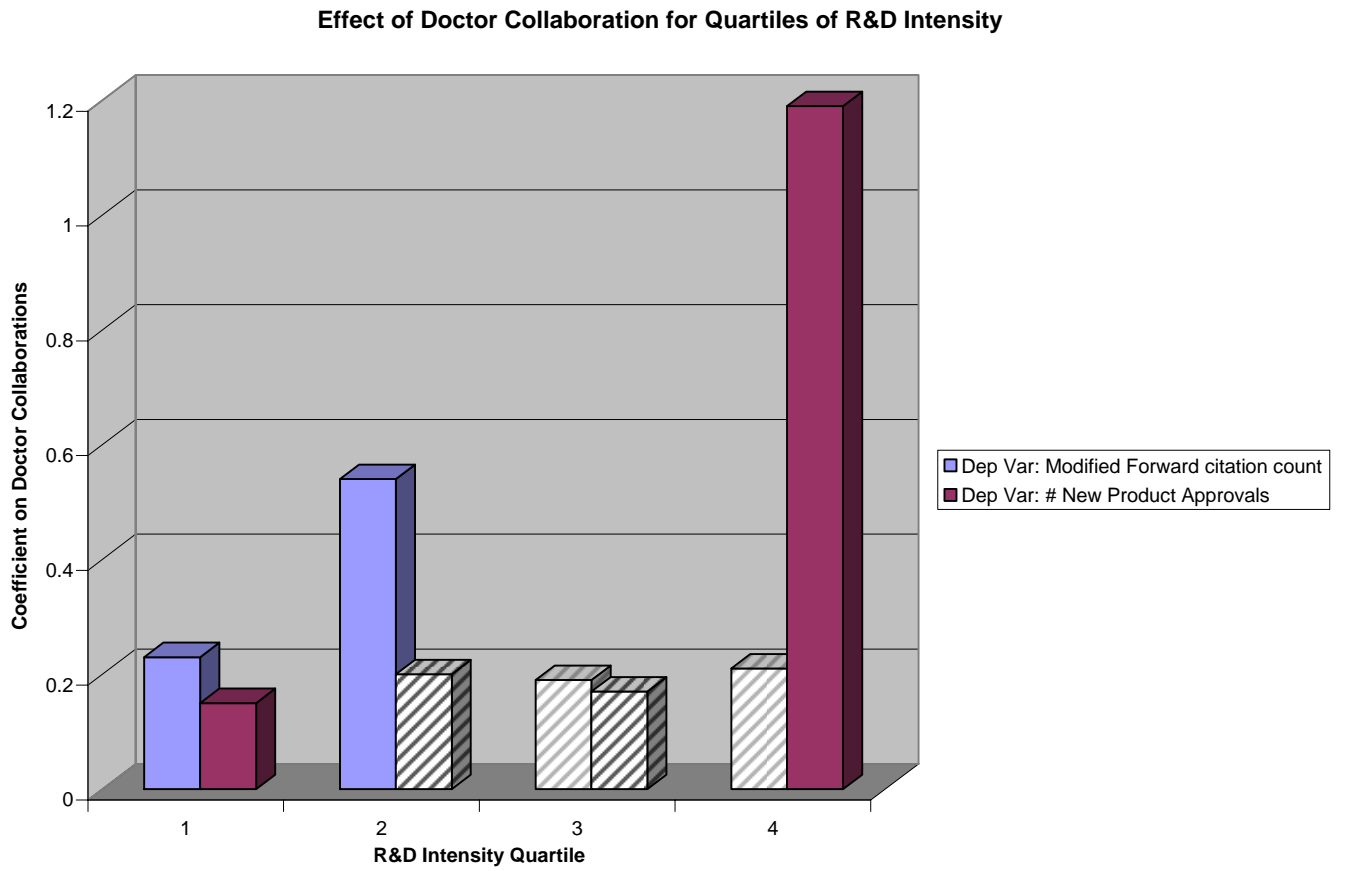
Standard errors in parentheses; \* significant at 5%; \*\* significant at 1%

Table 6: New Product Approvals as a Function of Doctor Collaborations

	(1)	(2)	(3)
	NumInnov	NumInnov	NumInnov
<b>ln_DrPats<sub>t-1</sub></b>	<b>0.215</b>	<b>0.182</b>	<b>0.157</b>
	<b>(0.076)**</b>	<b>(0.075)*</b>	<b>(0.071)*</b>
<b>ln_DrPats<sub>t-2</sub></b>		<b>0.126</b>	0.045
		<b>(0.063)*</b>	(0.074)
ln_DrPats <sub>t-3</sub>		-0.069	
		(0.090)	
ln_DrPats <sub>t-4</sub>		-0.144	
		(0.078)	
ln_DrPats <sub>t-5</sub>		-0.081	
		(0.090)	
ln_KnowledgeStock <sub>t-1</sub>	-0.004	0.046	-0.030
	(0.094)	(0.109)	(0.094)
<b>ln_ProductStock<sub>t-1</sub></b>	<b>0.236</b>	<b>0.258</b>	<b>0.222</b>
	<b>(0.057)**</b>	<b>(0.065)**</b>	<b>(0.076)**</b>
ln_Employ <sub>t-1</sub>	0.375	0.329	0.266
	(0.156)*	(0.150)*	(0.153)
ln_R&D <sub>t-1</sub>	0.123	0.125	0.144
	(0.126)	(0.124)	(0.122)
<b>Modified Citation Weighted Patents</b>			<b>0.001</b>
			<b>(0.000)**</b>
Observations	698	698	698
Number of firms	88	88	88

Standard errors in parentheses; \* significant at 5%; \*\* significant at 1%

Figure 1:



Note: Striped bars indicate that coefficient is not statistically significant.

Figure 2:

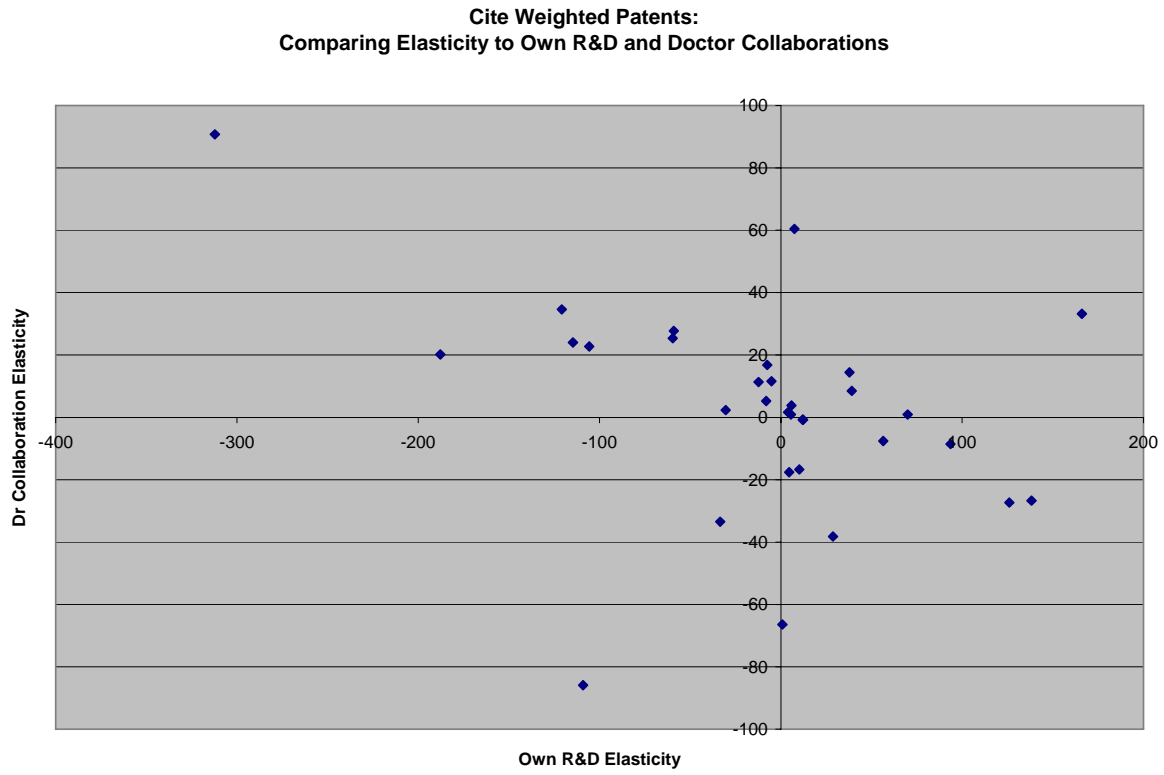


Figure 3:

