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What do patent-based measures tell us about product commercialization? Evidence from the pharmaceutical industry

Stefan Wagner[a,*], Simon Wakeman[b]

[a] ESMT European School of Management and Technology, Schlossplatz 1, 10178 Berlin, Germany
[b] New Zealand Productivity Commission, Level 15, Fujitsu Tower, 141 The Terrace, Wellington 6011, New Zealand

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ABSTRACT

Patent-based measures are frequently used as indicators in empirical research on innovation and technological change. Currently, there is little evidence as to what extent patent-based indicators relate to product market outcomes. Using a unique dataset that links outcomes from product commercialization in the pharmaceutical industry with detailed patent data, we relate patent-based indicators that capture either an invention's value or the uncertainty surrounding the patenting process to the outcomes of the product development process. Our findings suggest that the speed of commercialization increases with value but reduces with uncertainty. Using a variety of alternative indicators we derive implications for the use and the proper interpretation of individual measures. Moreover, our study has broader implications as it highlights the detrimental effect of uncertainty on the speed of innovation.

1. Introduction

Patent-based measures are frequently used in empirical research on innovation and technological change and have become increasingly popular in diverse topics such as studies of firms' strategies and organizational choices as well as labor mobility or team performance. Early work primarily relied on simple patent counts as a measure of innovation output (see Griliches, 1990 for a survey). More recently, the availability of comprehensive micro-level data has enabled the construction of more refined indicators aiming at characterizing the strength of the protective scope of a patent as well as describing the underlying inventions on a large scale. These indicators are derived from information contained in publicly available patent documents such as patent references, technology classifications or inventors involved. Refined patent-based indicators have been widely applied to study the outcomes and the functioning of the patent system itself (see Hall and Harhoff, 2012 for a recent survey). Going beyond the patent system itself, patent indicators are increasingly used to study firm-level phenomena such as R&D productivity (Jaffe, 1986), firm survival (Malerba and Orsenigo, 1999; Nerkar and Shane, 2003; Wagner and Cockburn, 2010), investments in young companies (Sorenson and Stuart, 2001; Cockburn and MacGarvie, 2009), entry into new industries (Cockburn and MacGarvie, 2011) and alliance formation (Mowery et al., 1996; Stuart, 1998).

As the use of patent-based indicators increases, it is important to establish that these measures actually reflect the more general facts that they are implicitly claimed to represent. Having a clear understanding of the relationship between these indicators and the underlying (mostly unobserved) phenomena that they purport to measure, such as an invention's value or the strength of patent protection, is important not only for their construction but also for a meaningful interpretation of their effects. Much work has therefore been invested in the validation of patent indicators. First, the positive correlation between the value of an invention and the number of citations the corresponding patent receives by subsequent applications has been clearly established (see Trajtenberg, 1990; Harhoff et al., 1999; Gambardella et al., 2008; Hall et al., 2005). Second, it has been found that patent indicators are informative regarding the uncertainties surrounding the patenting process. These uncertainties pertain to the timing, the scope, and the legal stability of patent protection. Patent indicators have been linked to uncertain outcomes such as patent grant, post-grant validity challenges or the occurrence of licensing (Gans et al., 2008; Harhoff and Reitzig, 2004; Harhoff and Wagner, 2009; Lanjouw and Schankerman, 2001; Régibeau and Rockett, 2010).

Despite these validation efforts, much less is known about which and to what extent patent indicators convey valuable information with regard to an invention's likelihood of commercialization. As

* Corresponding author.
E-mail addresses: stefan.wagner@esmt.org (S. Wagner), simon.wakeman@esmt.org (S. Wakeman).

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patent indicators are often used to describe firms' competitive situation in the product market, it is important to establish a clear understanding of how to interpret the results when these indicators are used to derive conclusions that reach beyond the patent system. In this paper we add new insights to this important question by investigating how frequently used patent indicators associated with an invention's value and uncertainty regarding the scope and strength of patent protection are related to actual outcomes from product commercialization processes.

The study is rooted in the pharmaceutical industry for two reasons: First, obtaining a clear and unencumbered patent position is essential for commercializing an innovation in the pharmaceutical industry (Cohen et al., 2000). Patent rights in this industry are generally strong, which should allow for an easier detection of correlations between patent indicators and outcomes of the product commercialization process. Second, the pharmaceutical industry is classified as a 'discrete' industry where a relatively small number of patents (often only one patent) can protect an entire product (Cohen et al., 2000). This allows us to clearly link product development projects to patents protecting the underlying invention. In particular, we exploit a novel dataset that combines detailed information regarding the commercialization of 5293 pharmaceutical development projects with fine-grained information on the underlying patents. Such a research design would not be possible in complex technologies where a large number of patents are associated with a single product.

Overall, our findings show that the effect of indicators related to an invention's value and the effect of indicators reflecting uncertainty regarding the scope and strength of patent protection are in line with expectations. We find that value-related measures such as the number of different patents surrounding a commercialization project, the number of countries in which primary patents have been applied for (family size), and different citation-based measures are all related to increased hazards and a higher speed of product commercialization. Further, our data reveal that uncertainty has a significant negative effect on the hazard of commercialization: Once a patent has been granted, and hence the scope of the IP protection of a potential drug has been clearly delineated, we observe that firms significantly speed up the commercialization process. This indicates that uncertainty regarding patent protection slows down commercialization.

Our contribution is twofold: First, to the best of our knowledge, our study is the first attempt to combine fine-grained patent indicators with product market outcomes on a large scale. Based on this unique research setting, we are able to derive statements about the extent to which patent-based indicators are informative about outcomes beyond the patent system itself. In particular, we distinguish between indicators that are based on endogenous applicant behavior such as family size and measures that lie beyond the influence of the patent applicant such as citation-based measures. Our findings suggest that indicators which depend on applicant behavior are more informative. Second, our findings bear relevance for the design of patent systems. While previous research has scrutinized the effect of patenting on follow-on innovation (Sampat and Williams, 2014; Williams, 2013) and the effect of patent terms on the direction of R&D (Budish et al., 2013), we derive insights regarding the effect of uncertainty on the speed of commercialization. Once uncertainty has been resolved the hazard of product commercialization increases significantly. This finding is in line with related work analyzing the hazard of licensing (Gans et al., 2008) and has broader implications regarding the negative effect of patent grant delays on the speed of innovation.

The remainder of the paper is structured as follows: In the next section, we briefly summarize the process of product commercialization in the pharmaceutical industry. In this section we also discuss how patent-based indicators have been used and interpreted in the existing literature and derive implications as to how different indicators might be related to the hazard of product commercialization. In Section 3, we describe our dataset and the constructed variables that are used in our analysis. Section 4 links important patent-based indicators to outcomes in the product commercialization process in line with their descriptions before we explain our multivariate regression approach and present the results from Cox Proportional Hazards models in Section 5. The paper concludes with a brief conclusion and discussion of the limitations of our study in Section 6.

2. Pharmaceutical product commercialization and patent-based indicators

2.1. Product commercialization in the pharmaceutical industry

The pharmaceutical industry is characterized by a high R&D intensity and developing new drugs is expensive. Estimates of the average cost of development per drug generally exceed US $800 million (DiMasi et al., 2003; Adams and Brantner, 2006) and research-active pharmaceutical companies (originator companies) spend about 17 percent of their revenues from prescription drugs on R&D (European Commission, 2009).[1] The commercialization process of inventions in this industry can be divided into three different phases: (i) the pre-launch period where R&D, clinical trials, and clinical tests take place; (ii) the marketing and sales period during which the originator company sells its product under exclusivity usually derived from patents; and (iii) a post-exclusivity period where competition by generic products copying the initial invention is possible (European Commission, 2009).

In this paper, we specifically focus on the pre-launch period as the duration between the invention of a compound and its market launch, which is of utmost importance for companies commercializing pharmaceutical inventions. Initial patents relating to a drug are typically filed during the basic R&D stage and have a fixed duration of 20 years from the original filing date (known as the "priority date"). Hence, the length of the period during which a drug can be sold by the originator company under exclusivity granted by the primary patent right is directly determined by how much time lapses between the filing of the patent and the market launch of a product. The shorter the duration of the pre-launch stage after the patent grant, the more time an originator company has to enjoy the exclusivity provided by patent protection and thereby recoup the investments made during drug discovery and testing without facing competition from companies selling drugs based on the same substance (Budish et al., 2013).

The pre-launch phase contains the search for molecular targets associated with a disease and the identification of novel pharmaceutically-active substances that interact with the target. Once a substance has been identified, various preclinical and clinical tests are carried out to ascertain the toxicity and efficacy of the new molecule. Finally, national regulators have to approve the drug before it can be sold on the market. The overall duration of the pre-launch period is of significant length. Sternitzke (2010) reports an average duration of about 11.5 years, while the European Commission (2009) reports a shorter period of only 8.6 years for a selection of 144 substances. After the initial discovery of pharmaceutically-active substances companies will usually file first patent applications related to the active molecules

[1] Note that 1.5% of the revenues made from prescription drugs is spent on basic research while the remaining fraction is spent on clinical trials and tests (European Commission, 2009).