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Editorial

Patent indicators: a window to pharmaceutical market success

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Keywords:: backward citations family size forward citations market success patent claims patent indicators patent portfolio pharmaceutical industry

1. Introduction

Pharmaceutical success in the market, in the sense of compensating the long, costly and difficult process of drug Research and Development (R&D), raises tremendous concerns for scientists, managers and decision makers in the pharmaceutical industry. Patents seem to be responsible for dramatically increasing or decreasing the market returns of pharmaceuticals, in particular, innovative drugs. For example, Lipitor®, the former world's best-selling drug underwent a sharp decrease in sales in recent years [1] caused by the expiration of its patent protection. Moreover, top drug makers have to cope with the so-called ‘Patent Cliff' when their lucrative drugs are replicated in the form of low-cost generic drugs on the expiration of relevant patents, especially in the next few years [2]. Thus, it seems to be a significant research issue to observe pharmaceutical market success by tracking patent protection.

So far, many academic and commercial articles have been published that reflect the influenc ant relations market value of alue and specific on the basis of empir the specific pharmac ficant influenc e technol n the USA [10-1

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This research aims to identify the associations between patent indicators and pharmaceutical market revenues at the product level and, further, to explore the applications of patent indicators in pharmaceutical product decision making in a real-world commercial setting.

2. Methods

IMS Health, a leading provider of information, services and technology for the healthcare industry around the world, lists the sales data of important pharmaceuticals in main therapeutic areas in its Knowledge Link database purchased by the authors in 2010. Based on the data availability in the Knowledge Link database of IMS Health, the authors collected the sampled pharmaceuticals in the study comprising 127 drugs with leading sales in 15 main therapeutic areas in the USA in 2009, including 96 brand and 31 generic drugs. Moreover, the IMS Health provides the information of diversified types of patents relevant to drugs, while the sampling pharmaceuticals involve 621 American patents [1].

In total, 14 variables are constructed in the research. Their definitions, rationales and sources are concisely shown in Table 1, while they are elaborately explained as below.

1. NC. A patent comprises a set of claims that delineate the boundaries of the property rights provided by the patent, and hence the number of claims may be indicative of the ‘scope' or ‘width' of the invention [14-17]. The NC is used in the models to measure the scope of patent protection.

2. BC. In practice, patent examiners judge the fulfilment of legal requirements of patents, for example, the novelty by looking at the state of the art as reflected in existing publications, especially former patent documents. Relevant state-of-the-art documents are quoted by subsequent patents. These documents are called backward citations [18]. In the study, the BC refers to the number of patent references that are quoted by the patent and is used to measure the state of the art.

3. FC. Instead, the FC is the number of quotations a patent receives itself during subsequent granting procedures of younger patents. A high rate of FC implies that scientists have a greater interest in a particular innovation, which is interpreted as more likely to have commercial applications [9,19-21]. Specifically speaking, the FC in this research is referred to by the number of citations received by a patent during the period from its grant year to 12/28/2010, the deadline for the data collection.

4. FS. In order to protect an innovation in multiple countries, a patentee must secure a patent ion is called overage of the pa patent family

5. PS. Big n which patent lustering is a wa nber of pa Health provid of patents releva drug deliver sive protec neasure the str osed to affect

On the other hand, the origin of the substance (OS), the number of drug targets (DT) and chronic diseases (CD) are considered, in order to control the influence of pharmaceutical technological features on the market revenues. These technological factors are theoretically associated with pharmaceutical market revenues and empirically tested in previous studies [26-28]. Their specific definitions and rationales are shown in Table 1.

Moreover, the number of top products in same therapeutic class (TP), the market share of therapeutic class (MS) and total assets of relevant drug company (TA) are introduced in the models as commercial factors for fixing the effect of commercial characteristics on the market returns. These factors are selected based on basic principles of pharmaceutical market and limited data availability. The measurable definitions and supporting justifications of them are described in Table 1.

In addition, the marketing year (MY) and granting year (PY) are added in the models for avoiding the noise from the time effect. Specifically speaking, the MY defined as the year to launch a drug in the US market is considered because drug sales gradually evolves with the lifecycle of pharmaceutical products [29]. Meanwhile, the PY, the grant year of patents, is used in the models in order to control the different durations of the patent to collect forward citations [30].

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3. Res

The sales of the sampled pharmaceuticals vary widely within the range of 2 million USD for Mozobil® to 7.216 billion USD for Lipitor. Other drugs with leading sales include Nexium® (6.065 billion USD), Plavix® (5.340 billion USD), Seretide® (4.657 billion USD) and Seroquel® (4.411 billion USD), while the top five therapeutic classes with a high market share comprise cholesterol and triglyceride regulating preparations, antipsychotics, antineoplastics, antiulcerants and antidepressants and mood stabilisers.

The regression results of the three models with increasing independent variables step by step are shown in Table 2. Model 1 is the original one that only considers five patent indicators and two time variables, while Model 2 adds three technological variables and Model 3 further controls three commercial factors.

Table 2. Pharmaceutical sales modelled by patent indicators (OLS regressions).

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As shown in Table 2, BC is significantly negatively associated with pharmaceutical sales, whereas FC, FS and PS show significantly positive relationships. The NC, however, seems t tions of NC and BC s whereas the remainir fects of FC, FS and P well as a more rig l hints to the pote

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performance of the models gradually improves from Model 1 to Model 3 with the increasing R-squared. It seems that adding the variables in Model 2 and 3 not only significantly control the technological and commercial influences on pharmaceutical sales, but also indicate the robust estimation of the parameters of the patent indicators.

4. Discussion

First, it is worth discussing that there appear to be a few unexpected results in the models beyond the initial theoretical considerations. For example, NC should be positively related to market revenues if it truly measures the scope of patent protection. This indicator, however, shows insignificant and unstable effects on pharmaceutical sales in all three models. Hence, it seems necessary to rethink the true meaning of this indicator on the basis of the further analysis of previous literature. In fact, patent claims could be divided into different types, such as independent and dependent claims, process and subordinated claims, while different kinds of claims present different effects on patent value [18]. The number of independent claims seems to reflect the scope of patent protection more precisely, whereas dependent claims form a narrower protection boundary by refining independent claims and therefor e simply aggrega mbiguities on this i n order to ensure a

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and are computable at a low cost. The linkage between patent indicators and the sales of actual drugs identified in this study may be conveniently used in the analysis of the business revenues of pharmaceutical products, especially during the initial stage after a drug is launched in the market. Moreover, this kind of association would be an important complement to the financial and economic data used in licensing assessments, Mergers & Acquisitions (M&A) analyses, investment decisions and product planning and management, in view of the importance of pharmaceutical patents and market success.

Meanwhile, this kind of association implies that it is significant to further explore the importance of patent indicators to the market success of pharmaceutical candidates in the R&D pipeline. The drugs launched in the actual market and drug candidates in the R&D pipeline, however, have substantial differences in the context of the commercial setting. The market success of actual drugs could be reflected by their sales or revenues in the market, whereas the market success of drug candidates mainly refers to whether they are successfully approved by the drug authority to enter the market. In the lengthy R&D process including toxicity and efficacy testing, preclinical research, and clinical Phase I – III studies, the market success of drug candidates has higher uncertainty and needs to be modelled by different parameters, in comparison with marketed drugs. Hence, it is not appropriate to directly apply the results in this study to evaluate

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5. Exp

With the increasing R&D expenditures and difficulties associated with finding new drugs, pharmaceutical enterprises are competitively seizing products with substantial market returns, in particular, blockbuster drugs generating annual sales of at least 1 billion USD. For example, several of the most influential M&A cases in the industry happened with the main motivation of competing for best-selling pharmaceutical products. In this context, approaches that focus on identifying the association between the patent indicators and the pharmaceutical market returns are of great significance for helping pharmaceutical managers or investors comprehend more hints to the market success, especially during the period of the impending patent cliff, when large pharmaceutical companies face weak product lines. Meanwhile, this research fills the gap in the existing literature on patents and market success by exploring this theme at the product level rather than at the traditional corporate level.

As far as operational aspects are concerned, most data on patent indicators can be publicly retrieved at a low cost at the early stage of the life cycle of pharmaceuticals and their patents, while the information on newly approved pharmaceuticals and patents is regularly released by the US Food and Drug Administration (FDA) and USPTO. The continued observation of the indicators of target patents in the databases of the FDA and USPTO using the methodology applied in this analysis could provide valuable reference to the pharmaceutical market success. In practice, this kind of work has become perty (IP) capital f re springing up every

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However, accomplishing these tasks is not easy work. The success of further research essentially depends on how closely and intensively experts from various backgrounds collaborate in this field. It is of great significance to integrate the multidisciplinary resources from scientists, managers and lawyers because the market success of pharmaceutical products is determined by the complex combination of technological, commercial and legal factors.

Declaration of interest

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