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Editorial

Patent indicators: a window to pharmaceutical market success

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Abstract

Pharmaceutical success in the market is the best reward for pharmaceutical investors undergoing the lengthy, costly and risky process of pharmaceutical Research and Development (R&D). Drugs with high market revenues trigger fierce competition between pharmaceutical enterprises, as is demonstrated by the increasing Mergers & Acquisitions (M&A) cases focusing on seizing the best-selling products. On the other hand, patents, as the best shield for innovative drugs against generic drugs, become a powerful weapon for pharmaceutical enterprises to win the substantial returns generated by market exclusivity. Patents seem to be directly responsible for the commercial success of new medicines. In this context, it is of great significance to find out the empirical associations between pharmaceutical commercial success and patents. By comprehensively analysing 127 drugs marketed in the USA and their 621 American patents, this article identifies the evidence to link various patent indicators with pharmaceutical sales in actual market.

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 influence of patents on market success. These scholars have found significant relationships between the number of patents, R&D activities and the stock market value of firms [3-7]. Meanwhile, the further relationships between market value and specific patent indicators, such as citations and claims, have been studied on the basis of empirical evidence of patent indicators and patent value [8,9]. As far as the specific pharmaceutical sector is concerned, a few articles have identified the significant influence of quantitative and qualitative patent indicators with respect to the technological strength and market value of the pharmaceutical companies in the USA [10-13].

However, most of the aforementioned studies were conducted at the company level and focused more on enterprise decision making, and as of now, little research has been conducted in this field specifically at the level of therapeutic pharmaceuticals.

system and accurately reflect the associations between patents and market success with extensive application in pharmaceutical product decision making.

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.

Table 1. Definitions, rationales and sources of all variables.

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First, the market success of actual drugs could be reflected by their sales in the market. Thus, the authors use the sales in the US market in 2009 (SUS) as a dependent variable in the model to measure the market success of pharmaceutical products.

Moreover, patent indicators are constructed in the study in order to validate the associations between pharmaceutical patents and market revenues. They include the number of claims (NC), backward citations (BC), forward citations (FC), family size (FS)

and portfolio size (PS), all of which have been empirically tested in previous literature on patent valuation. These patent indicators are explained one-by-one 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 in each country. The group of patents protecting the same innovation is called its ‘family' [19,22,23]. In the study, the FS denoting international coverage of the patent is counted as the number of patents in extended international patent family defined by the International Patent Documentation (INPADOC).

5. PS. Big pharmaceutical companies usually create a patent portfolio, within which patents are all interlocking. Building a patent portfolio around a product-clustering is a way to hamper competitors [24,25]. The variable PS refers to the number of patents in the pharmaceutical patent portfolio defined by IMS Health. IMS Health provides pharmaceutical patent portfolio information to disclose all types of patents relevant to a drug, for example, composition, process, method of use and drug delivery system. These different types of patents construct a comprehensive protection network against the entry of generic drugs. The PS is used to measure

the strength of the pharmaceutical patent protection network and is supposed to affect the market success of drugs positively.

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].

Concerning operational process of data retrieving, the data on PS, OS, CD, TP, MS, TA and MY of sampling drugs are firstly collected from the IMS Health, while DT data of drugs from the DrugBank, a public database containing a unique bioinformatics and cheminformatics resource that combines detailed drug data with comprehensive drug target information. Moreover, the data on the NC, BC, FC and PY are collected from the US Patent and Trademark Office (USPTO), while the FS data achieved from the INPADOC provided by the European Patent Office (EPO).

After constructing original dataset, the authors employ the ordinary least squares (OLS) regression method to model pharmaceutical sales by patent indicators, while model robustness is tested by gradually adding technological and commercial factors in the models.

3. Results

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 to have no significant association with market revenues. The estimations of NC and BC seem slightly unexpected and will be further analysed in Section 4, whereas the remaining patent indicators show rational results. Moreover, the positive effects of FC, FS and PS demonstrate that higher quality, wider international coverage as well as a more rigid protection network of pharmaceutical patents may be meaningful hints to the potential higher market revenues of pharmaceuticals.

On the other hand, technological and commercial factors and time variables appear to control relevant variances with basic, significant parameters. Moreover, the regression results indicate the negative effect of OS and positive effects of DT, CD, TP and MS. The relationships between the technological and commercial factors and pharmaceutical sales reflected by the models are absolutely reasonable, according to the definitions and rationales of the variables in Table 1. Meanwhile, MY seems to be an unstable factor and PY has a positive effect on the response variable.

The robustness of the model estimation is clearly shown by the basic, consistent parameters of the patent indicators in the three models. Meanwhile, the fitting 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 therefore become less important than independent claims [16,17]. Thus, the simply aggregated number of various types of claims may be responsible for the ambiguities on this indicator. In further study, it is necessary to count them separately in order to ensure a better distinction between different categories of claims.

Moreover, the negative associations of backward citations with drug sales seem contradictory, if they represent the comprehensive basis and accumulative feature of inventions. On the other hand, an innovation with more backward citations is more likely to be a derivative innovation and thus less valuable [31]. Some research has pointed out that a patent with many backward citations may show low monetary value due to the diversity of classifications assigned to the backward citations [19,32]. However, the positive effect of this estimator has been observed in other empirical studies [18]. Therefore, backward citations may be a double-edged sword that has

On the other hand, all of the tested patent indicators in this study are available at an early stage of their pharmaceutical lifetime, drawn from publicly available information, 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 drug candidates.

Nevertheless, there are a few limitations worth noting in this research. First, the patent indicators could only provide a rather rough reference for the pharmaceutical market revenues as compared with the market benchmarking approaches of accounting and financing, although this method, based on the retrospective statistical analysis, could be used as a low cost highly efficient means of analysing a large number of drugs at one time. Second, the total sales of products in the real business world are affected by various complex technological and commercial factors, in addition to patents. The technological and commercial variables considered in the models are obviously insufficient for controlling all influences from the technological and commercial characteristics in light of the limited available data.

5. Expert opinion

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 a promising business for monitoring and managing intellectual property (IP) capital from the commercial perspective. IP firms, such as Ocean Tomo®, are springing up everywhere and leading the new market [33].

In the near future, further studies will mainly focus on the aspects outlined below. First, more informative patent indicators, such as patent challenges, will be developed, while technological and commercial variances will be better controlled by introducing more effective variables. Second, this approach can be widely extended on the geographic and sectoral scopes. Localisation application in emerging economies seems worthwhile, while it is also possible to translate this kind of method into other innovation-driven industrial sectors, especially by replacing industry-specific technological variables. Finally, the development of relevant databases and software is indispensable with the increasing observations and variables and dramatically improving information techniques, in order to fully take advantage of early stage, high-efficiency and low-cost

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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