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The Impact of the R&D Expenditure and Patent Rights towards Operating Performance in Medical Device Industry – An Empirical Study

Yuzhou LUO¹, Zhaoyan HU², Kaijun YU³

Abstract

In face of the emergence of knowledge-based economy and global competition, countries in the world have actively increased sci-tech resources inputs and accelerate R&D innovation. Medical device industry is the emerging star industry under the time. Medical device industry with higher technology, large market potential, high added value of output products, low pollution, emphasis on sci-tech integration, and broad application presents higher risks but higher profits, is a knowledge intensive industry, and will become a star industry leading global economy. Medical biotechnology industry requires constant innovation that it has long-term invested in large amount of R&D expenses for various patent rights and R&D results to enhance the competitiveness. R&D expenses and patent rights are therefore the key factors in medical biotechnology enterprises maintaining the competitive advantage. The managerial level and employees of medical device companies in Shanghai, as the research object, are distributed 300 copies of questionnaire. Total 232 valid copies are retrieved, with the retrieval rate 77%. The research results show positive relations between R&D expenditure and patent right, patent right and operational performance, and R&D expenditure and operational performance. According to the results, suggestions are eventually proposed, expecting to assist medical device industry in acquiring various patent rights for the R&D inputs and maintaining the competitive advantage.

Keywords: medical device industry, R&D expenditure, patent, operational performance.

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Introduction

Since the 21st century, countries in the world, in face of the emergence of knowledge-based economy and global competition, have actively increased the sci-tech resource inputs, accelerate R&D innovation, and develop high-tech industries. High-tech industries focus on invention and innovation, and medical device industry is the emerging star industry under the time. It reveals that the function of medical device industry to human society and humans would far exceed it of information technology industry in the future decades. Medical device industry, with higher technology, large market potential, high added value of output products, low pollution, emphasis on technology integration, and broad application, presents higher risks but higher profits and is a knowledge intensive industry that it will become a star industry learning global economy in the future. The industry features to develop innovative products with intellectual property protection and ability to compete in global markets. Innovation capability of an enterprise refers to the activity of R&D development. Aiming to explore the innovation capability of enterprises, a lot of research devotes to the effect of R&D activity on companies.

Under current market environment, customer needs have become diversified to shorten the life cycle of new products in the market. An enterprise without continuously promoting new products or services would rapidly lose the competitiveness. It results in enterprises investing in R&D activities for new products. Under such a new economic model, R&D activity has gradually replaced physical assets to become the key success factor in business operation. Several research results revealed that more investment in R&D activity would result in better performance for enterprises. Medical biotechnology industry appeared the same situation that they had to constantly pursue innovation and long-term investing in large amount of R&D expenses for various patents and R&D results to enhance the competitiveness. R&D expenses and patent rights are therefore the key factors in medical biotechnology enterprises maintaining the competitive advantage. Overall speaking, enterprises in medical device industry with large R&D investment present better business performance. Apparently, R&D activity is a critical factor in the profitability of medical device industry. The effect of R&D expenditure on patent rights and operational performance in medical device industry is therefore studied.

Literature and hypothesis

R&D expenditure

Huyghebaert & Luypaert (2013) explained research as the search with plan or the strict survey to find out new knowledge for developing new products or new technologies, or improving current products or technologies. Development, on the other hand, referred to transforming research results or other knowledge into new products or new technologies, or improving or designing old products or old technologies. In other words, R&D expenditure was the input in the pursuit of new knowledge, while development was the application of new knowledge, expecting to have research results appear commercial value. Belz, von Hagen, & Steffens (2015) defined research as the survey or test, with the exploration of unknown event as the object, to seek for facts and principles, or the experimental survey. Development was defined as to promote affairs from a stage to another stage with natural or fixed methods or programs, which was related to the evolution of events and emphasized the promotion result. Kshirsagar, Nwala, & Yaohang (2014) explained R&D expenditure as the input to systematic creative activities for enhancing knowledge stock. Such knowledge covered science, culture, and society and could be developed new application routes. Eadie *et al.* (2016) regarded R&D expenditure as the efforts made for acquiring new knowledge. In general, the basic research findings were made further application and the work properties presented specific practical goals, which were normally the theoretical research on specific products, production programs, production methods, or systems with commercial objectives.

Referring to Chen *et al.* (2015), R&D density, R&D intensity, and innovation speed are used for measuring R&D expenditure in this study. 1. R&D density: Large and continuous R&D inputs are the key factor in the survival of semiconductor industry. The R&D inputs of the industry appear in the R&D expenditure that R&D expenditure could reveal a company's knowledge inputs. 2. R&D intensity: R&D intensity would not necessarily have a company succeed in the business competition, but the company inputting large amount of R&D activity is more possible to acquire major breakthrough in innovation and technologies. 3. Innovation speed: To out performance the same trade and remain the competitive advantage, the promotion of products and technologies in the same trade is important for an enterprise. In this case, the faster innovation speed would result in better competitive advantage in the same trade.

Patent right

Enomoto, Kimura, & Yamaguchi (2015) regarded patent as an intellectual property right (IPR). Rights declared in Intellectual Property Right could be referred to the contents of "Convention Establishing the World Intellectual Property

Organization” Article 2(8) in 1967. Nguyen & Ashish (2014) explained that, in order to protect the rights of an invention or a creation, the application could be proposed in local intellectual property protection institute; when it was confirmed to conform with the regulations in Patent Act, the patent right was authorized that the patent assignee, within a certain period, could exclude the manufacturing, sales, sales contract, use, or import for above objectives of others without the agreement. Such a right was patent right (Cohen, Gurun, & Kominers, 2014).

Referring to Gao *et al.* (2017), patent right is classified into invention, utility model, and design in this study.

(1) Invention patent: Referring to the creation of technological thoughts with natural law. That is, an invention regulated in Patent Act should present technology and is the creation at least satisfying the utilization of natural law and technology to be performed on the object or method (Matvos & Seru, 2014).

(2) Utility model patent: Referring to the creation of the shape, structure, or device of an object with the technological thought of natural law. It could define utility model as innovative shape, structure, or device of an object with the technological thought from natural law to generate certain new function or enhance effectiveness (Jeon, 2015).

(3) Design patent: Referring to the creation of the shape, pattern, color, or the combination of an object through visual appeal. It defines design as to enhance the visual effects of quality, affinity, and high value with the shape, pattern, color, and the combination of objects to enhance the product competitiveness and visual comfort (Sun & Liu, 2016).

Operational performance

Herger & McCorrison (2016) regarded performance as the degree of an enterprise or an organization achieving specific goals. Majumdar (2016) pointed out operational performance as the different standards for different needs of groups and organizations. Performance evaluation allowed understanding the result of past resource operation to guide an organization’s future direction of business strategies and resource allocation. Arora, Belenzon, & Rios (2014) considered operational performance as the actual performance and result of an organization. Simply speaking, a well-performed organization could effectively apply resources, satisfy member needs, achieve preset goals, and adapt to external environment changes. Krstanovic & Buljan Barbaca (2016) indicated that operational performance was the measurement of an organization achieving the goals. Business performance considered in general industries was the account return in financial statements, including return on total assets, return on stockholders’ equity, or return on investment. However, in addition to maximum profits, enterprises also pursued multiple goals of market share and employee satisfaction. Dahm & Boicey (2014) pointed out operating performance as the performance of operating activity, which

contained the creation of operating revenue, the control of costs and expenses, and the presentation of profit results. O'Connor (2014) stated that a company generally used financial performance and marketing performance for representing the operational performance; the former contained return on investment, return on sales, pre-tax income, sales amount, and sales growth rate, while market share was the representative of the latter.

Referring to Zeng's (2015) points of view, the measurement of operational performance of an organization is divided into three categories: (1) Productivity, including employees' productivity, capacity utilization and defective rate of products; (2) Profitability, containing return on investment and return on assets; (3) Growth, covering market share growth rate and sales growth rate.

Research hypothesis

Reisinger & Tarantino (2015) defined R&D expenditure as the R&D activity inputs, and the number of patent rights and the sales amount of innovative products as the outputs. A model was established to prove the positive effect of R&D expenditure on patent right output and the positive effect of patent right output on operational performance. Vithessonthi & Racela (2015) proved that the R&D expenditure input would generate patent rights for a company to become excess market returns. Chen *et al.* (2015) considered that the input research and development costs could enhance the number of patents to become the technology capability of a company. The empirical results revealed significantly positive correlations between R&D expenditure and the number of patent rights. VanderPal (2015) indicated that some companies invested large amount of money in R&D activity, i.e. high R&D expenditure, to have the company present new products with profitability or acquire patent rights; R&D expenditure therefore accompanied with better number of patent rights. From above literatures, the following hypothesis is inferred.

H1: R&D expenditure presents positive relations with patent right.

Kumru & Kumru (2014) pointed out the inefficiency of the research and development costs invested by many enterprises that the number of patent rights was regarded as a proxy variable of the technology capability of a company. The empirical result showed the remarkably positive correlation between the number of patent rights and operational performance. Sawaki (2015) indicated in the research that 79% respondents regarded the protection of patent right as an important competition tactic of the company, and the protection of patent right could help a company present better advantage on sales services and pricing policies than the competitors (Cohen, Gurun, & Kominers, 2014). Trout (2014) predicted the future business performance of a company with the patent data and considered that a company with good business in the past could continue to the

future. Past research revealed that a company with good patent right was able to present favorable operational performance in the future. Gao *et al.* (2017) found out the positive correlations between operational performance and patent right in integrated circuit, computer peripheral, and photo electricity industries. The following hypothesis is therefore inferred.

H2: Patent shows positive relations with operational performance.

Weichieh & Tsang (2015) capitalized R&D expenditure and found out the notably positive effect of R&D capitals on the return on stocks of an enterprise. With factory as a unit, Lahiri & Narayanan (2013) proved that R&D expenditure could actually enhance performance. Taking the actual business data of domestic listed companies as the research objects to test the relationship between R&D expenditure and operational performance of an enterprise, Herger & McCorriston (2016) discovered that an enterprise with large R&D investment presented better operational performance. Saini & Saxena (2014) studied domestic listed manufacturers and proved the positive relations between R&D expenditure and operational performance. Zeng (2015) defined R&D expenditure as the R&D activity input, the number of patent rights and the sales amount of innovative products as the outputs to establish a model to prove the positive effects of the R&D activity input on the outputs and the positive effects of the outputs on operational performance. Sun & Anwar (2015) defined R&D output as knowledge capital to prove the significantly positive relations between R&D input and knowledge capital as well as the remarkably enhancement of company performance by knowledge capital. According to above literatures, the following hypothesis is inferred.

H3: R&D expenditure reveals positive relations with operational performance.

Sample and measurement indicator

Research sample and object

Aiming at medical device industry in Shanghai, the managerial level and employees of medical device companies, as the research objects, are distributed 300 copies of questionnaire. Total 232 valid copies are retrieved, with the retrieval rate 77%.

Reliability and validity test

Validity refers to the measuring tool being able to really measure the problems which a researcher would like to measure. Generally speaking, validity is divided into content validity, criterion-related validity, and construct validity. The questionnaire in this study is referred to the questions from domestic and

international researchers and is discussed with the tutor for the pretest before the distribution of formal questionnaire that it presents certain content validity. The dimensions of R&D expenditure, patent right, and operational performance in this study are tested the casual relationship of the overall structure with linear structure relationship model, and the data entry is based on the correlation coefficient matrix of above observed variables. The linear structure relationship model analysis results reveal the overall model fit reaching the reasonable range that it presents favorable convergent validity and predictive validity. Item-to-total correlation coefficient could be used for testing the construct validity of the questionnaire content in this study, i.e. reliability analysis. The acquired item-to-total correlation coefficients are used for judging the questionnaire content. The item-to-total correlation coefficients of the research dimensions are higher than 0.7 that they present certain degree of construct validity.

To further understand the reliability and validity of the questionnaire in this study, reliability and validity are further analyzed. The higher Cronbach's α reveals the better reliability. The formal questionnaire in this study is developed according to the standard, and the Cronbach's α reliability appears in 0.80~0.88, obviously conforming to the reliability range.

Results

Evaluation indicators in LISREL model

LISREL (linear structural relation) model combines Factor Analysis and Path Analysis in statistics and includes simultaneous equations in econometrics that it could calculates multiple factors and multiple casual paths. The model fit is evaluated from preliminary fit criteria, overall model fit, and fit of internal structure of model.

The research results are organized in Table 1. The preliminary fit criteria, fit of internal structure of model, and overall model fit of the model are explained as below.

From Table 1, the dimensions of R&D expenditure (R&D density, R&D intensity, and innovation speed) show significant explanations on R&D expenditure ($t > 1.96$, $p < 0.05$); three dimensions of patent right (invention patent, utility model patent, and design patent) show notable explanations on patent right ($t > 1.96$, $p < 0.05$); and, three dimensions of operational performance (productivity, profitability, and growth) reach remarkable explanations of operational performance ($t > 1.96$, $p < 0.05$). Accordingly, the overall model presents favorable preliminary fit criteria.

In terms of fit of internal structure of model, R&D expenditure shows positive and significant correlations with patent right (0.823, $p < 0.01$), patent right reveals positive and remarkable correlations with operational performance (0.857 $p < 0.01$),

and R&D expenditure reveals positive and notable correlations with operational performance (0.801, $p < 0.01$) that H1, 2 & 3 are supported.

In regard to overall model fit, the overall model fit criteria $\chi^2/Df=1.427$, less than the standard 3, and RMR=0.007, showing the proper results of both χ^2/DF and RMR. What is more, chi-square value is extremely sensitive to sample size that it is not suitable for the direct judgment of fit. However, the overall model fit criteria GFI=0.978 and AGFI=0.921 are higher than the standard 0.9 (the closer GFI and AGFI to 1 reveals the better model fit) that the model presents good fit indicators.

Table 1: LISREL analysis result

Evaluation item	parameter/evaluation criteria		result	t
preliminary fit criteria	R&D expenditure	R&D density	0.633	7.44**
		R&D intensity	0.651	8.72**
		innovation speed	0.642	8.21**
	patent	invention patent	0.683	9.91**
		utility model patent	0.675	9.43**
		design patent	0.692	10.54**
	operational performance	productivity	0.711	11.82**
		profitability	0.724	12.16**
		growth	0.706	11.17**
fit of internal structure of model	R&D expenditure → patent		0.823	25.38**
	patent → operational performance		0.857	37.29**
	R&D expenditure → operational performance		0.804	23.46**
overall model fit	X2/Df		1.427	
	GFI		0.978	
	AGFI		0.921	
	RMR		0.007	

Note: * stands for $p < 0.05$, ** for $p < 0.01$, and *** for $p < 0.001$.

Table 2: Hypothesis test

Research hypothesis	correlation	Empirical result	P	Result
H1	+	0.823	$P < 0.01$	Supported
H2	+	0.857	$P < 0.01$	Supported
H3	+	0.804	$P < 0.01$	Supported

Conclusion

In the globalization time, enterprises are facing increasing pressure from international competition. It is worth of in-depth understanding how medical device industry outperforms in the capital market and attracts investors' attention. The research results find out the significantly positive correlation between R&D expenditure and patent right, revealing that medical device enterprises with higher R&D expenditure could acquire more patent rights. Such a result shows the positive effect of the R&D activity inputs on the outputs. The positive relations between patent right and operational performance present that the R&D activity outputs would affect operational performance. The positive and remarkable relations between R&D expenditure and operational performance show that medical device enterprises with higher R&D expenses present better operational performance. However, the effects of patent right on operational performance is larger than it of R&D expenses, revealing that outputs (patent), but not inputs (R&D expenditure), are the major effect, among R&D activity, on operational performance. In this case, after inputting R&D costs, medical device industry should acquire patents of new technologies or new products to effectively promote the business performance.

Recommendations

By concluding the primary results and findings, practical suggestions, aiming at the research results, are proposed as followings.

1. A large amount of R&D investment is not necessarily the guarantee of profits for medical device industry. Inputting R&D expenditure but not having actual results would be useless for medical device industry. Medical device industry should try to enhance the success rate of R&D inputs and obtain patents for the developed new technologies or new products to expand the international market share, stabilize the growth of the enterprise, and create good operational performance. In this case, R&D activity could present larger benefits for medical device industry.
2. Medical device industry is suggested to create value at different R&D stages, stress on the protection and operation of technology patent rights, combine teams in distinct professions to participate in the industrial value chain as a relay race, and facilitate the application of medical device industry to various fields for better conforming to the requirements. The developed products should focus on market orientation, the technology should be product orientation, and the sci-tech research should be technology orientation. The link with various levels could enhance the public acceptance of the products.
3. Medical device industry is suggested to engage in patent management, when improving the technology, to acquire the first-hand technology information as well as to explore the patent loophole from other competitors. By matching the prediction of technology and market and understanding

consumers' potential needs to establish core technology with niche, a company could prevent the overall revenue from being affected by supply-demand price fluctuation.

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