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AN INVESTIGATION OF KEY SUCCESSFUL FACTORS OF BIOTECHNOLOGICAL INDUSTRY PERFORMANCE IN TAIWAN ~ ALSO AN ANALYSIS OF TRADITIONAL CHINESE MEDICINE

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ABSTRACT

The ever-prospering development of information and communication technology (ICT) in recent years has changed how people conduct communication and their commercial behaviors. A large number of industries, such as semi-conductor and biotech sectors, find themselves in a high-velocity environment, wherein the market demands, peer rivals, and technologies are in a constant change, industrial structure and boundary are becoming blurred and intensively competitive. To survive in such a rapidly changing and highly competitive environment, all industries begin to map out winning strategies as their top priority. Taking biotech industry as an example, and by reviewing of related literature, analysis on the current industrial status, and through analytic hierarchy process (AHP), this paper intends to draw out the key elements that have the most impact on the success of operational performance on biotech industry in Taiwan, and shall conduct further interpretation of the correlation between these elements and the decision-making process. Since the traditional Chinese medicine is a valuable traditional knowledge and has an advantageous position of biotech industry in Taiwan. This paper is also intended to look into the difficult problems and choke points that the TCM met in industries, officials and academic circles in the past, and analyze the present information of them for the purpose of offering these issues with more appropriate suggestions to Taiwan government. In the past years, the learning studies of Chinese medicine have accumulated a number of research results, but such results are unable to be applied effectively to and become one of important industries in Taiwan.

Key words: Traditional Chinese Medicine (TCM), biotechnology industry, patent, intellectual property rights, R&D, Taiwan

INTRODUCTION

Advancement of biotech technology can upgrade our national competiveness, and serves to expand national hi-tech domain, which in turn ensure the continuous growth of the macro-economy. Given the scarcity of natural resources, it is undoubtedly that the development of Taiwan's industries should steer away from those with heavy reliance on energy and of high pollution rates. Therefore, the development of technology- and capital-intensive biotech industry has become an important issue that concerns both the government and the industry.

Since its high-tech-intensiveness, the lengthy developmental time-span, the astronomical R&D cost and high risk involved, plus the large gap in terms of invested resources we have made compared with those of advanced counties, Taiwan's biotech industry are now encountering a host of problems: weak research groundwork, insufficient R&D capability, lacking of global marketing network, and relatively smaller scale, among many others. In facing and overcoming the challenge, Taiwan still has a long road ahead.

A majority of the industry are either small or medium businesses, to which the stickiest problem required to be tackled is operational performance. This leads to the imperative issue of developing effective countermeasures; including (1) Key success elements impacting the operational performance of Taiwan's biotech industry. (2) Impact of human resources has on the operational performance of Taiwan's biotech industry

The manpower and capital involved in biotech industry usually exceed the limited capacity of other domestic industries. Therefore, the key elements for smooth development of the industry lie in the quality management, and R&D talents. In this way, the focus is on the human capital indices: management's capability, employee's capability, corporate cohesion, and the acquiring, cultivating, and recruiting of researchers, developers, and top-grade biotech professionals.

McCarthy E. Jerome divided marketing in his *The Marketing Mix of 4P's Model* into 4Ps: product, price, place, and promotion. He proposed, therefore, that the organization that can identify the best marketing strategy and followed by putting them into action, tends to own more competitiveness than others. Biotech is a cutting-edge technology featuring high

knowledge-intensiveness, technology-intensiveness, lengthy R&D time span, and high risk (Roberts *et al.*, 1989). D'Aveni (1994) points out in his *Hyper-Competition* that a world leading industry is the one who has in command of many intangible assets, especially professional knowledge and know-how. In this section, we will discuss several technologic indices, including acquisition and transfer of technology, partnership alliance, and technologic uniqueness.

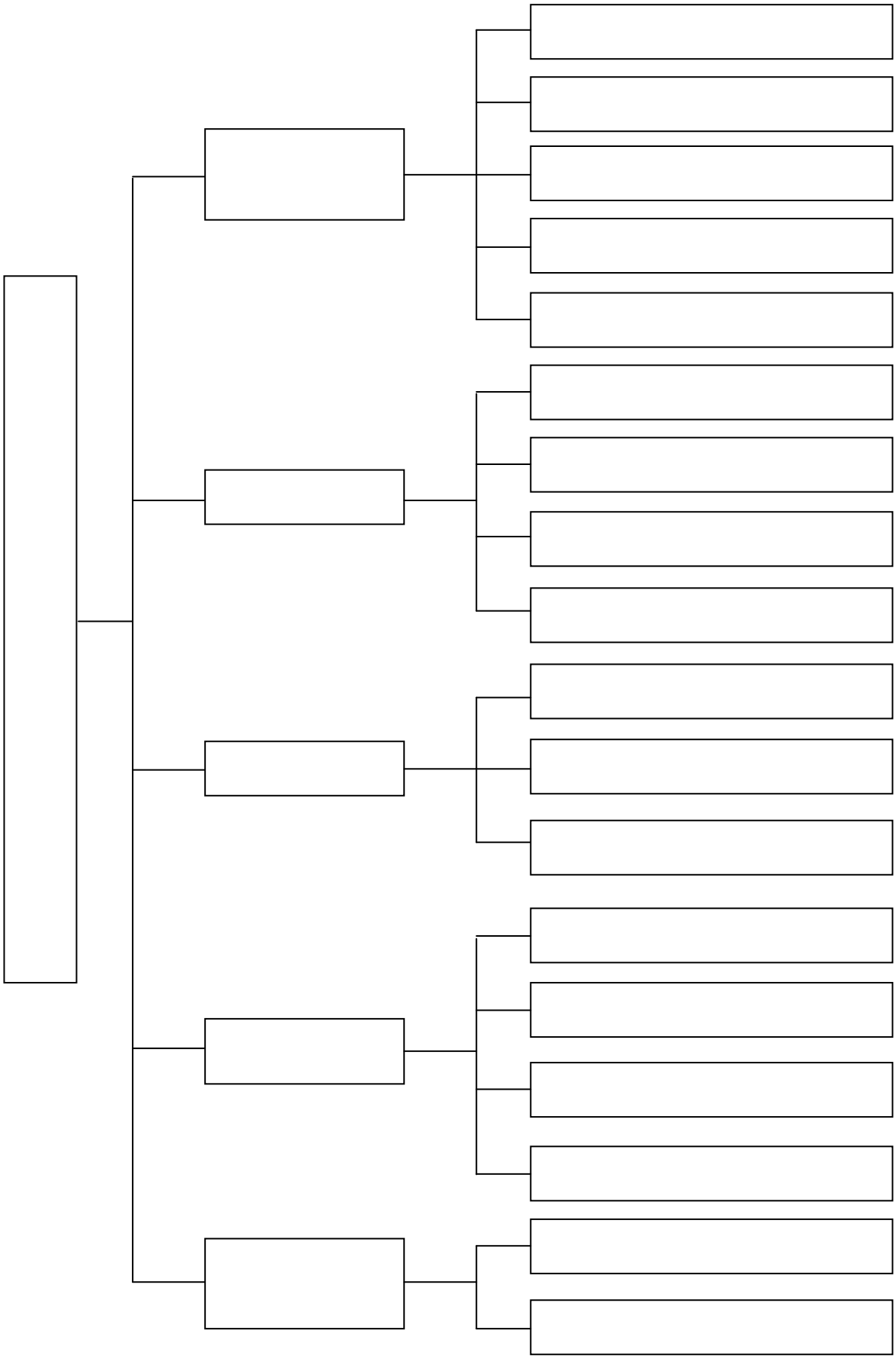
In his *Post-Capitalist Society*, Drucker (1993) argued that innovation is a new ability that can create wealth out of resources, makes resources realize the highest efficiency, and can change the value and satisfaction consumers derive from resources. The purpose of innovation lies in introducing new products, process, and service, to initiative systematic changes in order to increase customer satisfaction and product value. Innovation includes product innovation, new manufacturing process techniques, new structure and management system, and new market development project and management solutions.

In an age of knowledge economy dominance, the economic profits and values created by intangible assets are innumerably tremendous. Governments across the world are putting full efforts in coping with the developmental needs of the industry through providing various subsidiaries and incentives to biotech R&D and innovation, and by amending IPR-related laws and regulations.

RESEARCH DESIGN AND METHODOLOGY

Targeting Taiwan's biotech industry, the present study adopts expert survey to conclude the key success elements. An AHP is used to analyze the returned questionnaires from respondent experts and scholars in the field, and eventually screens out the resultant key success elements.

The present study aims to explore the key success elements of Taiwan's biotech industry. Through reviewing of related literature and industrial analysis, we conclude the major elements, which are then divided into the following three hierarchic tiers as belows:



Sample

The Study group is composed of 45 participants who are representative experts and scholars of biotech industry in Taiwan. They were asked each to complete the questionnaire voluntarily during April-May 2009. 25 of the participants returned completed forms but 3 did not answer properly to the questions. They were later dropped from the analysis so that final study samples are made of 22 individuals.

Analysis results from experts and scholars

(A) Analysis results of success factors

After software analysis, the success factors of framework of this study has shown in table 1 as followings.

Table 1 Analysis results of success factors

KSF	Weight Value	Rank	λMax=5.11 C.I.=0.027 C.R.=0.024<0.1
Human resource factors	0.107	5	
Marketing strategy	0.165	4	
Technical factors	0.2	3	
Innovation Strategy	0.229	2	
Intellectual property rights and patent	0.3	1	

Based on the analysis result, experts and scholars regard IPR and patent rights (with a priority weight of 0.3) have the greatest impact on the operational performance of biotech industry.

(B) Human resources

Table 2 Analysis results of human resource

KSF	Weight Value	Rank	λMax=5.06 C.I.=0.015 C.R.=0.013<0.1
The ability of executives	0.137	5	
The professional competence of staff	0.172	4	
Centripetal force of staff	0.222	3	
R&D personnel's acquisition and cultivate	0.226	2	
Recruiting Outstanding talent	0.242	1	

(c) Marketing strategy

Table 3 Analysis results of marketing strategy

KSF	Weight Value	Rank	λMax=4.02 C.I.=0.005 C.R.=0.006<0.1
Product Strategy	0.289	2	
Pricing strategy	0.211	3	
channel strategy	0.31	1	
Promotional strategy	0.19	4	

Analysis results show that experts and scholars regard channel (with a priority weight of 0.31) has the greatest impact on the operational performance of biotech industry.

(D) Technology

As shown in Table 4 below, technology analysis with software yields the following priority weights:

Table 4

KSF	Weight Value	Rank	λMax=3.00 C.I.=0.002 C.R.=0.004<0.1
Technology acquisition and transfer	0.223	3	
Alliance Partnership	0.253	2	
Technical uniqueness	0.523	1	

Based on the analysis result, experts and scholars regard technologic uniqueness (with a priority weight of 0.523) has the greatest impact on the operational performance of biotech industry.

(E) Innovation strategy

As shown in Table 5, analysis of innovation strategy elements yields the following priority weights.

Table 5

KSF	Weight Value	Rank	λMax=4.01 C.I.=0.004 C.R.=0.004<0.1
Process innovation	0.191	3	
Product Innovation	0.366	1	
Managerial Innovation	0.302	2	
Market innovation	0.141	4	

Analysis results show that experts and scholars have regarded product innovation (with a priority weight of 0.366) as the most influential factor to our biotech industry.

(F) IPR and patent

Results of software analysis of IPR and patent rights show that patent rights (with a priority weight of 0.0667) have the most influential power on the operational performance of biotech industry in table 6

Table 6 Results of software analysis of IPR and patent rights

KSF	Weight Value	Rank	λMax=2.00 C.I.=0.003 C.R.=0.003<0.1
Intellectual property rights	0.333	2	
patent rights	0.667	1	

(G) Overall assessment of the key success elements

Based on the expert survey, we conduct an overall analysis on the AHP framework. Overall analysis and comparison between all priority weights show that patent rights, among all key success elements, is the most influential factor to the biotech industry considered by experts and scholars. These influential factors are shown in table 7.

Table 7 Overall assessment result of the key success elements

KSF for the second layer	Weight Value	KSF for the third layer	Weight Value	Overall Weight Value	Rank
Human resources factors	0.107	The ability of executives	0.137	0.015	18
		The professional competence of staff	0.172	0.018	17
		Centripetal force of staff	0.222	0.024	16
		R&D personnel's acquisition and cultivate	0.226	0.024	15
		Recruiting Outstanding talent	0.242	0.026	14

KSF for the second layer	Weight Value	KSF for the third layer	Weight Value	Overall Weight Value	Rank
Marketing strategy	0.165	Product Strategy	0.289	0.048	8
		Pricing strategy	0.211	0.035	11
		channel strategy	0.31	0.05	6
		Promotional strategy	0.19	0,031	13
Technical factors	0.2	Technology acquisition and transfer	0.223	0.044	9
		Alliance Partnership	0.253	0.051	7
		Technical uniqueness	0.523	0.1	2
Innovation Strategy	0.229	Process innovation	0.191	0.044	10
		Product Innovation	0.366	0.084	4
		Managerial Innovation	0.302	0.069	5
		Market innovation	0.141	0.032	12
Intellectual property rights and patent	0.3	Intellectual property rights	0.099	0.099	3
		patent rights	0.2	0.2	1

Findings of the study show that, regarding the cognition contents of operational performance, IPR and patent rights are the two most important factors considered by biotech experts and scholars, followed by innovation strategy, technology, marketing strategy, and human resources. This indicates the consensus of all experts and scholars that IPR and patent rights are the most important factors to Taiwan's current biotech industry. In addition to the protection provided by IPR and patent rights, it also takes the coordination of good innovation strategy, and well-developed and unique technique to attain a higher goal of operational performance. To reach even higher, the industry will have to strengthen its

marketing strategy and human capitals.

Besides these above survey results, the open questionnaires have resulted in a consensus point of view, that is, traditional Chinese medicine could be a best choice for Taiwan to develop its own industry

The Case of Traditional Chinese Medicine (TCM)

Taiwan is the first country in the world to include Chinese medicine in its national health insurance budget system. In a broad sense, "Chinese herbal drug" is an integrated term for Chinese medicine and herbal medicines that comprise natural ingredients, including various plants, animals, minerals, algae, and/or fungi, or extracts or composites of these ingredients. In Taiwan, no standard requirements that regulate the Chinese herbal drug industry currently exist. Chinese herbal drug manufacturers are generally categorized into three groups: (1) pharmaceutical companies that produce Chinese herbal drugs according to good manufacturing practice (GMP) procedures. The products primarily consist of traditional prescription drugs, including Chinese drugs, concentrated Chinese drugs, and Chinese prescription drugs with new indications or new administration routes. (2) Biotechnology companies that primarily develop new Chinese herbal drugs (including botanical new drugs). (3) Other companies that use Chinese herbal medicines as raw materials for various applications, including in health foods and cosmetics.

Traditional Chinese Medicine (TCM) has a recorded history of at least five thousand years in Chinese society and constitutes a vast treasure of Indigenous knowledge useful for human health, but the protection of intellectual property rights necessary for its scientific development is not adequate due to the nature of TCM. As in Western countries, such as the U.S.A., E.U. countries, Australia, Canada and Eastern countries such as China, Singapore, and Japan, Taiwan's legislation to provide legal protection for intellectual property rights necessary for the scientific development and practice of TCM must be strengthened. Because intellectual property right protection is difficult to extend to Indigenous knowledge such as TCM, efforts must be made to develop new Indigenous knowledge from TCM, both products and procedures, to enable IPR protection. Alternatively, a new legal framework could be developed to encourage the scientific development of TCM which would be protected as Indigenous knowledge. China and Taiwan have a vested interest in seriously pursuing the development of innovative ways to protect intellectual property rights to ensure the on-going scientific development of TCM for the benefit of Chinese companies as well as for the interest of public health world-wide.

The proposed and existing policies and legislation regulating complementary, alternative, and traditional medicine in advanced industrial countries is designed to provide strategies for addressing "…issues of policy, safety, efficacy, quality, access and rational use of traditional, complementary and alternative medicine." Examples include the Guidance for Botanical Drug Products approved by the U.S. FDA in June 2004, the EU Traditional Herbal Medicinal Products Directive of April 2004 which amends the Directive 2001/83/EC and requires all members to promulgate their own national laws regulating TCM by October 2005, the Canadian Natural Health Products Regulations under the authority of the Food and Drugs Act, the Pharmaceutical Administration Law and the 1992 Regulations on the Protection of Traditional Chinese Medicines in the People's Republic of China, and the WHO Traditional Medicine Strategy, 2002-2005. These documents all address the practice and use of traditional, alternative, and complementary medicine (TM/CAM), particularly herbal medicinal products; however, they are not sufficient to provide intellectual property rights to researchers.

Thus, protection of intellectual property rights regarding all aspects of the practice of TCM is an extremely important problem today. Researchers in many countries are applying scientific analysis to traditional Chinese medical practices and herbal remedies in order to ascertain their effectiveness and safety as well as to develop new products and practices. They also aim to develop production methods which guarantee high quality, safe products. Due to the high material and time cost, investors and researchers are reluctant to pursue the development of TCM if they cannot adequately protect their results through trademarks and/or patents. (Brown . 2000)

For a long time, numerous patent applications for Chinese herbal drug products have been submitted, with only a small proportion receiving approval. For patent applications, Chinese herbal drug products are commonly assessed as chemicals. However, Chinese drugs or herbal drugs are generally products based on traditional knowledge that is widely circulated among people; thus, they lack the element of novelty required for patents. According to the Intellectual Property Office, by the end of 2007, 141 Chinese herbal drug patent applications were approved, and the proportion of applications filed by Taiwanese researchers/developers had increased from 50% to 70%. This increase benefits the development of Chinese herbal drugs and biotechnology industries in Taiwan.

CONCLUSION

Because of the high value of knowledge protected by intellectual property rights in the global market, the protection of IPR for research and development of TCM is an important policy issue for the Government of China and Taiwan in term of improving biotech industry. Hence, the Chinese people have a unique opportunity to protect and develop their Indigenous knowledge of TCM for the benefit of all people and at the same time to generate income and recognition for the China and Taiwan as well as for the individual researchers and investors whose intellectual property rights it protects. Thus, it is in the interest of the governments of China and Taiwan to ensure the protection of intellectual property rights in the development of TCM by continuing to innovate in the application of IPR to TCM.

Regarding the key success elements, Daniel (1961) points out in his *Management Information Crisis*, "Most industries usually have 3 to 6 key elements that determine their success." The study selects the top six elements listed in Table 7, and use them as the key success elements. They are, in sequence of order: patent right, technologic uniqueness, IPR, product innovation, market innovation, and channel,

Accordingly, in its pursuit of success, a biotech manufacturer must: (1) establish comprehensive safeguarding measures to protect its IPR and patents; (2) focus on R&D and continuous innovation; (3) conduct innovative reform both on its products and market to gain an competitive edge; and (4) choose the appropriate channels, so that it can promote the development of biotech industry, emulate the standards of advanced countries, and synchronize with the world's bi-tech development.

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