A Comparison Analysis between Manufacturing & Service Approaches in the Medical Device Industry

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Abstract–**Medical device industry is an industry with obviously interdisciplinary characteristics and suitable for manufacturing and service approaches study. A manufacturing approach of industrial portfolio model, and a service approach of IIS (innovation intensive service) platform model are used as analytical tools for industrial innovation.**

From the perspective of manufacturing side, an industry portfolio has been conducted and it consists of two dimensions– industrial value chain and technology life cycle. On the other side, the IIS platform has been considered with innovation strategies, externalities and value activities. This research focuses on the industry level of policy making for medical device industry development in oncoming years of Taiwan.

The result reveals that the industrial innovation requirements of "Market Information", "Management Skills" and "Financial Resources" should be emphasized for Taiwan's medical device manufacturing. This research also indicates that "connectivity", "receiver competence" and "Nature of Knowledge and Spillover Mechanisms" in the dimension of technological system will be essential; meanwhile, "Factor Conditions", "Demand Conditions" and "Firm Strategy, Structure, and Rivalry" in the dimension of industrial environment are indispensable. Not only does the conclusion provide a mechanistic comparison of manufacturing and service approaches, it also allows strategic suggestion of resource allocation for medical device industrial development.

I. INTRODUCTION

The trend of globalization, regional coopetition and Industry 4.0 pushes the industry structure transformation; however, the tide also makes Taiwan in a critical situation in which it suffered from capital shortage, technology chasing, regional competition and rivalry which need to leap over the swamp of original equipment manufacturing (OEM) and cost competition. In the past, the industry development model in Taiwan was usually based on national innovation system and mostly considered form manufacturing point of view.

For many emerging industry and technology, born global and interdisciplinary characteristics make the boundary of manufacturing and servicing blurred. Thus, an analysis from manufacturing and service approaches assists to look inside the industry in a relatively comprehensively way.

The medical device industry is a strategically emerging industry for many countries and matches the character of industry boundarylessness. This research tries to analyze the medical device industry in Taiwan from a manufacturing approach (the industrial portfolio model) and a service approach (the innovation intensive service platform model) to understand the similarities and differences and to provide industry-level and firm-level policy suggestions.

II. LITERATURE REVIEW

Based on industry life cycle theory, Utterback [1] separated three periods of industrial development with different product stages as floating, transition and profession. Technology plays distinct roles at each period. Porter's [2] competitive advantages theory put the competition to national level. Technology progressing and innovation will enhance national competition advantages. Porter's theory didn't point out how the industry could achieve innovation through suitable planning. Rothwell & Zegveld's [3] research summarized three dimensions with 12 innovation policy tools which provide a concrete analysis tool for government support technology and innovation development in national level.

For the analysis of the service industry, Kellogg and Nie [4] defined the service package by the degree of customization and divide it into four categories: "generic," "restricted," "selective," and "unique" services. Five types of service innovation sources are identified: product innovation, process innovation, organizational innovation, structural innovation, and market innovation [5, 6, 7]. Design, validation of testing, marketing, delivery, after services, and supporting activities are the value activities that represent the internal knowhow in the value chain of service innovation [8, 9, 10].

TABLE 1. TRADITIONAL MANUFACTURING MODEL VS. INNOVATIVE SERVICE MODEL.

	Manufacturing Model	Service Model
Roles of Government	Construct S&T research institution, clusters, planning, investment and regulations.	Market mechanism building, interface management, platform, education &consulting system support.
Operation Model	Internal value chain integration and external supply chain.	Networking integration of internal & external resources.
Product Features	Mass production.	Customized to professional products.
Core Competence	Economy of scale and marketing.	Core resources control and leverage effect.
Marketing Strategy	Traditional 4Ps strategy and market share competition.	Holistic monopoly and intermediation product expansion.
Competition Types	Oligopoly competition.	Professional monopoly.
Market professionalization	Market needs or technology driven customization.	Network driven and customer oriented customization.

Source from: This research summarize, Yang & Shyu. (2009)

Service providers could externalize their core competence within networking to serve different types of customers through service process, which requires network interaction of seven externalities, including "Complementary asset supplier", "R&D", "Technology", "Production", "Servicing", "Market" and "Other users" [11, 12].

Though manufacturing and service industries are regarded as independent, yet manufacturing can offer services and base entire competitive strategies on service innovation [13].

III. THEORY MODELS

A. Manufacturing Approach–Industry Portfolio Model

Portfolio Approach was developed by Jose (1996) to explore the relation of enterprises' strategies corresponding to circumstances and set up environment-strategy matrix, then he used various portfolio conducted from the matrix to analyze and to modify strategy positions resulted from circumstances in different period.

Kotler et al. [14] thought that strategy industry portfolio is to select several industries suitable for developing from industry pool based on the criteria in the Fig. 1, and at the same time eliminate the less weak ones. In the strategy industry portfolio analyzing procedure, we should define decision criteria to set up the target to select the suitable industries. Every nation would have its considerations rely on its situations and competences. Therefore, the nation could use instruments, polices and resources to enhance competence.

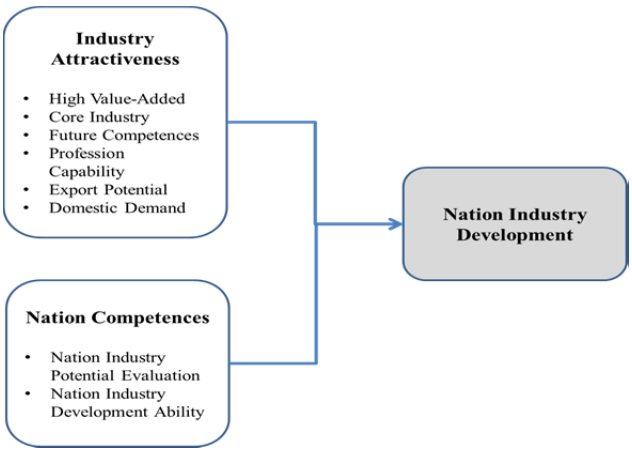

Figure 1. Strategy Industry Selection Model
Source: Kolter et al.(1997)

Shyu [15] indicated that an industry required different resources at different developing stages. Therefore, the authority could offer appropriate resources and aids, if they are properly planned by the authority. Kim [16] thought the government should assess its technology capability to match strategic industry developing requirement. Industry portfolio matrix covers these two concepts as Fig. 2 shows.

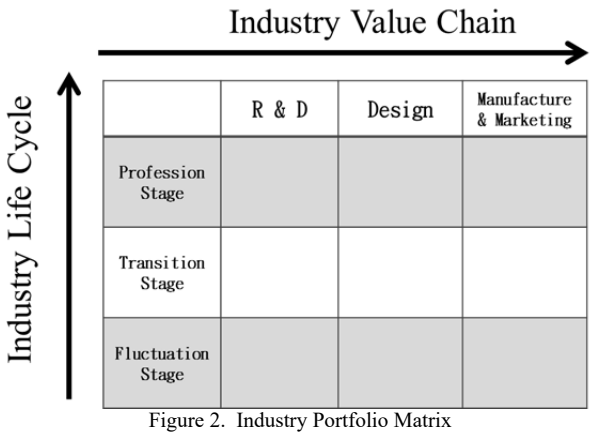

Figure 2. Industry Portfolio Matrix
Source: Shyu, 2000.

Industry value chain pointed out industry technology capability level: research and development, design, and manufacture marketing.

B. Service Approach- Innovation Intensive Service (IIS) model

In this research, we follow researches from the scheme of Kellogg and Nie [4]. Though it is simplified and uncertain in clarifying the customization, there are still lots of researchers who appreciated the categorization provided by the scheme and applied it to analyze knowledge intensive business service (KIBS). This model defines the service package by the degree of customization and divides into four categories, as the "generic," "restricted," "selective," and "unique" services.

TABLE. 2 CLARIFYING THE CUSTOMIZATION BY KELLOGG AND NIE

Package Name	Customization	Definition
Unique	Full	Most of the service package is customized. The customer has considerable discretion in defining the how, what and where of the service.
Selective	Considerable	While some parts of the service package are standardized, the customer has considerable discretion in selecting from a wide menu of options.
Restricted	Limited	Most of the service package is standardized. The customer can select from a limited number of choices.
Generic	Little or none	Most of the service package is standardized. The customer has little discretion in defining the hows, whats or wheres of the service.

Source from: Kellogg and Nie, 1995.

Sundbo and Gallouj [5] have found different fields of service innovations sources that can be categorized into four types: "Product", "Process", "Market", and "Organization." In accordance with the concepts of the service innovation sources, Hauknes and Hales [6] added "Structure" as five

categories. Gallouj and Windrum [7] also got the similar research results and indicated technologies introducing was getting involved. Therefore, this study adopts five type service innovation sources to build up the analytical framework.

To focus on the characteristics of KIBS, innovation intensive service matrix analysis model (IIS) follows the service innovation source defined by Hauknes & Hales [7], and the customization classification defined by Kellogg & Nie [4], to format a two dimensions of innovation intensive service positioning matrix. The X axis of the matrix represents four customization classification of service-generic, restricted, selective and unique, whereas the Y axis represents five innovation sorts- product, process, organization, structure and market innovation.

TABLE 3. INNOVATION INTENSIVE SERVICE (IIS) MATRIX

	U-Unique	S-Selective	R-Restricted	G-Generic
P1 Product Innovation				
P2 Process Innovation				
O Organization Innovation				
S Structure Innovation				
M Market Innovation				

IV. INDUSTRY ANALYSIS–MEDICAL DEVICE INDUSTRY

The medical device industry is one of the most potential industries that many countries intend to develop for their future competition in the global market. It is a highly diversified industry that produces a range of products designed to diagnose and treat patients in health care system, and consists of companies engaged in the manufacturing and distribution of basic medical devices and supplies, which comprise products like surgical appliances and supplies, surgical and medical instruments, electro-medical equipment, in-vitro diagnostic substances, irradiation apparatus, and dental and ophthalmic goods. Medical devices differ from drugs in that they do not achieve their intended use through chemical reaction and are not metabolized in the body.

The definition of the medical device:

- An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory (U.S. FDA) [17]
- Articles which are intended to be used for a medical purpose that is assigned to a product by the manufacturer (EU) [18]
- Any instrument, apparatus, appliance, material, or other article whether used alone or in combination, including the software necessary for its proper application (China) [19]

In summary, a medical device is an instrument for the diagnosis, prevention, monitoring, and mitigation of diseases.

Unlike prescription drugs, the medical devices regulation and certification process are reviewed by FDA using two regulatory standards, they are premarket approval (PMA) and the 510(k) process [20]. The former requires clinical testing and inspections while the latter requires that the device be similar to a device already marketed (predicate device).

The product engineering product life cycle of the medical device can be divided into design, prototype and manufacturing [21], and the life cycle can be depicted as the figure below.

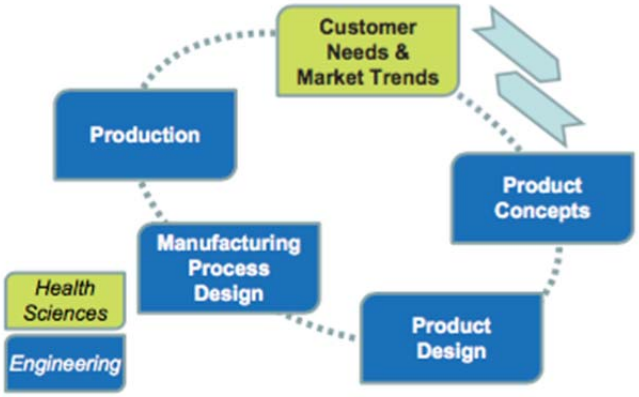

Figure 3. Life cycle development applied to medical services
Source: Ciurana (2014)

The life cycle is mainly dominated by expertise from engineering and health sciences, and customer needs and market trend will affect the formation of product concepts.

The global value chain of medical devices, from upstream to downstream, is comprised of R&D, component manufacturing, assembly, distribution, marketing and sales, and post-sales services. It is in industry that features elements of manufacturing and service and thus can be analyzed from the two perspectives.

V. RESEARCH RESULTS

Based on the industry analysis, the result of two approaches in medical device industry has summarized as below:

A. Overall comparison with two approaches:

According to our research structure, there are industry level and firm level with manufacturing approach and service approach as the analysis spindle.

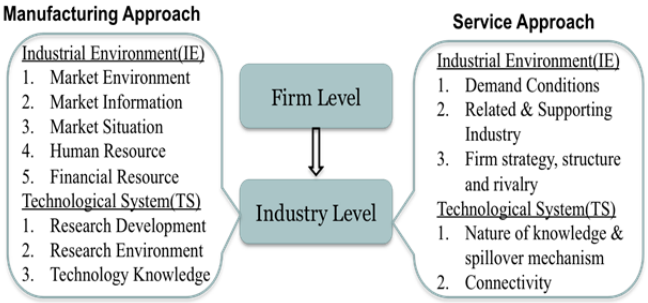

Fig 4. Manufacturing vs. Service Approach

Table 4. below shows the critical innovation resources or factors we should consider for medical device industry development.

TABLE 4. MEDICAL DEVICE INDUSTRY INNOVATION FACTORS BETWEEN MANUFACTURING VS. SERVICE APPROACH

	Manufacturing Approach	Service Approach
Firm Level		• Value Chain Activities ① Design: Spec, innovative technology design, IP and customization. ② Marketing: Brand, market penetration, customer response, price & quality control. ③ Validation of & Testing: Capability of modulation, flexibility and interaction with R&D. ④ Delivery: Logistic, channel and inventory management. ⑤ After Service: Market feedback mechanism, price, quality and speed of after service. ⑥ Supporting Activities: Organization structure, culture, training system, purchasing, legal and financial support. • Externalities ① Service: Customized service design, outsourcing, internal/external integration, customer interface building. ② Market: Competition structure, customer feature, CRM, channel management and market information control.
Industry Level		• Industrial Environment: ① Market Environment: Infrastructure ② Market Information: Consultant service, professional knowledge intermediation, CRM. ③ Market Situation: Market volume, strategic alliance, multivariant. ④ Human Resource: Foreign market expansion and integration R&D personnel. ⑤ Financial Resource: Comprehensive capital market and financing system. • Technological System: ① Research Development: National support on innovation, vertical integration, interdisciplinary integration & collaboration. ② Research Environment: Research institution, IP platform, license mechanism ③ Technology Knowledge: R&D Database system, process and cost control, spec and defect-free rate.	• Industrial Environment: ① Demand Condition: Domestic market features, scale, growing path and internationlization. ② Related & Supporting Industry: Related upstream & downstream industries, supporting industries. ③ Firm strategy, structure and rivalry: Strategies, scale, organization type and rivalry in the industry. • Technological System: ① Nature of knowledge & spillover mechanism: Related medical device knowledge and the spillover mechanism. ② Connectivity: Cluster, networking between supplier-buyer, firm-person.

B. Industry level comparison with two approaches:

Follow the overall comparison structure, there is the comparison of industry level on "Industrial Environment" & "Technological System".

TABLE 5. COMPARISON OF TWO APPROACHES IN INDUSTRY LEVEL

	Manufacturing Approach	**Service Approach**
Industrial Environment (IE)	**Market Environment**	**Demand Conditions**
	Market Information	**Related & Supporting Industry**
	Market Situation	**Firm strategy, structure and rivalry**
	Human Resource	
	Financial Resource	
Technological System (TS)	**Research Development**	**Nature of knowledge & spillover mechanism**
	Research Environment	**Connectivity**
	Technology Knowledge	

C. Industry level comparison with two approaches:

From the side of industrial environment, domestic market support, infrastructure include of research institutions, industry-university collaboration, medical device industry clusters and upstream-downstream industry insights, information, integration and strategic alliance are critical factors that now insufficient for Taiwan to stimulate medical industry development.

On the other side of technological system, no matter it's manufacturing or service viewpoint, basic research capacity, IP platform or transaction mechanism, integration of innovation-technology-commercialization and industry networking all need to be progressed and enhanced. Medical device industry is a industry with high interdisciplinary integration identity, the results shows there is still a gap on "industrial environment" and "technological system" for Taiwan to improve.

VI. CONCLUSION

Medical device industry is still in an emerging and growing period of industry life cycle in Taiwan. From the demand-side perspective, the market in Taiwan is subject to the scale-limited domestic market of Taiwan, and Taiwanese companies need to aim on regional or global market for demand-side support. Positioning medical device industry as a national key development direction may facilitate the development in Taiwan, and the government should allocate resources on industry infrastructure, research center/institution, IP transaction mechanism and industry-university collaboration. Financial supports such as multiple capital market, including venture capital, secondary market and subsidy, and related leasing, and financing activities of banking system, will accelerate the industry development. Compared with advanced countries such as USA, Japan, Germany and China, Taiwan plays a role of a follower in medical device industry and the technology development status shows the same result. The way to leverage the ICT research competence and capability into medical device industry is an issue for the Taiwanese government. Domestic market size is an inherent limitation for Taiwan, but from the service market side there are several ways for Taiwan companies to conquer this challenge. Industry connectivity from networking between suppliers and buyers and traditional manufacturing capacity upgrade are critical factors need to be concerned.

For industry level from the two approaches, the Taiwanese government could aim on "basic research" and "market." Basic research includes related research institution, collaboration between industry and university, and expert/profession education system. On the other side, market comprehensively covers from industry cluster, foreign market expansion, strategic alliance, financial support to tax privilege. Medical device industry has been seemed as a next critical emerging industry for many countries, Taiwan is no exception, the interdisciplinary feature of this industry leads to a chance to study not only from traditional manufacturing mindset but service one, and this research try to provide some attempt to combine two approaches and make several suggestions for industry facilitation.

This research was to combine two theoretical frameworks for the analysis of the characteristics of the service industry and manufacturing industry, given that the boundary between them is becoming so blurred. The medical device device is one of the industries that encompass this trait, and was chosen as the core of study in this paper. For further study, the national level of policy research, cross-nation comparison, case study and innovation policy viewpoint may all be considered and following.

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