Globalization and Transnational Corporations: Innovative Transnational Business Model for Medical Device Industry in the 21st Century

BY

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M.S. NEW YORK UNIVERSITY (Polytechnic Institute of,) (2007)

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ABSTRACT OF A THESIS SUBMITTED IN PARTIAL FUFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF

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Abstract

This thesis is the continuation of my quest for an innovative international business model that is apt to the dynamically transforming 21st century global business environment which began when I oversaw an operations of a transnational medical device corporation in Asia earlier in the new millennium. The exotic cultures, emphatic traditions, idiosyncratic processes, collusive practices, aspirations for fairer business, a curious desire to explore the business practices in the advanced economies, and sincere devotion to patient care by physicians I had witnessed at hospitals in China, Japan, Korea, India and the rest of Asia after decades of absence from the land where I had originally come from drove this study.

The thesis inquires into how and under what conditions a business enterprise transforms its resources into superior productivity and profitable growth through an empirical study of the medical device industry's international business operations. The research focuses on the industry's consignment management, operational dissimilarities between an *indirect* business model that medical devices corporations employ in Asian markets and the regular *direct* business model employed in the US and European markets. It also delves into the theoretical logic of the organizational boundary decision that enumerates what factors affect the business enterprise to internalize a necessary capability or to outsource it.

This unconventional dissertation, blended with the empirical evidences acquired from hands-on global work experience, includes vivid real-world examples and facts that are not easily accessible to ordinary academic researchers for much of the information is internal to the practitioners in the industry. The study employs *"The Theory of Innovative Enterprise"* to gain theoretical insights into the underlying economic phenomena that affect the growth of economic organization and the determinants of organizational boundary decision making.[1]

[1] The Theory of Innovative Enterprise. (2015, Rvsd.)., Foundation of Economic Analysis University of Massachusetts, The Academic-Industry Research Network. The Theory of the Innovative Enterprise is an economic theory, that argues the growth of business enterprise is enabled in the presence and on the basis of the "social conditions" namely "strategic control, organizational integration and financial commitment" within the enterprise, which was built and originated by economist William Lazonick.

Acknowledgements

There are many people I must acknowledge. First, I want to recognize my wife, Chi Yon, who has been understanding and applauded my quest for intellectual logics I wanted to seek in academia even by leaving my corporate position. I also want to recognize Alex and Christine, my son and daughter who helped me with the proofreading of the manuscript.

I am deeply grateful to Professor William Lazonick who taught me invaluable intellectual logics of the economy, academic theories and enterprise innovation. Most importantly, Professor Lazonick graciously allowed me to utilize The Theory of Innovative Enterprise, an economic theory he had built over decades, as a logical foundation of the dissertation and mentored me with precious comments throughout the process. I thank Professor Phillip Moss who had guided me to understand the critical importance of governance institution in the economics and provided me with rich resources pertaining to various states and stages of economic developments. I am greatly thankful to Professor John Wooding for his invaluable comments, directions and guidance with the dissertation. His mentoring based on his superb academic intellectuality and constructive criticism had honed the text and improved the quality of the thesis.

I also want to thank the faculty members at the Economics Department and Global Studies Program at the University of Massachusetts Lowell who had provided great advice and encouragement to complete this dissertation. I appreciate the business organizations that I had worked for where I was able to experience the real-world challenges of global business operations and thank them for providing me the opportunities to explore, learn, execute hands-on global business operations in different parts of the world and, most importantly, led me to understand the global economy as the social amalgamation of capabilities, skills and innovations. I am indebted to my former colleagues I have worked with during my corporate careers who had provided me with rich data, information, insights and gladly agreed to participate in the survey and interviews for the thesis.

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Figure and Tables

List of Abbreviations

CLS	Consignment Logistics Specialist
CMS	Consignment Management System
CS	Consignment Site
DC	Distribution Center
DES	Drug Eluting Stents
ERP	Enterprise Resource Program
GDP	Gross Domestic Product
IC	Interventional Cardiology
OPS	Operations
QA	Quality Assurance
RA	Regulatory Affairs
TMDC	Transnational Medical Device Corporation
TNC	Transnational Corporation
UPN	Universal Product Number

Introducing the thesis

What fuels the growth of an economic organization? How does an organization decide to make or buy a capability it needs? The economics in the global medical device business is subtle and often invisible on the surface but is tacitly present alongside and in between the borders of the intertwined relations of the peoples at the medical device firms, hospitals and government offices. As a manager in charge of international operations I had to shuffle between the company mandated spot results and the desirable longer-term performances. As I experienced the gaps between the sustainable quality business operations and the real-world realities, I began envisioning a business operations model that could generate sustainable, superior economic performance regardless of culture and geographies. The socioeconomic phenomena observed in the medical device industry during my sojourn in Asia and around the globe for nearly eight years had both given me insights into the underlying dynamics that influence the growth of the firm, and inspired me to seek answers to the questions for what really affects the growth of economic organization in the rapidly transforming diverse marketplaces around the world.

After four years of passionate and profound engagement in the management of a transnational medical device corporation at the front lines of the hospital industry in Asia, I was given an opportunity to work at its global headquarters in Massachusetts with a greater capacity to oversee the company's entire operations in its emerging markets, i.e. Asia-Pacific, Africa, Middle East and Latin America. The move from Asia to Boston,

Massachusetts, the Mecca of academic intellectuals and institutions, in 2011 has provided me an opportunity to begin an academic journey into exploring the intellectual logic for the superior international business operations model. Henceforth I had begun a privileged living of two different lives simultaneously for the first couple of years, that is a real-world global operations manager at a transnational corporation (TNC) and an academic novice at a research university.[2] Then I decided to devote myself to full-time social-science training in the International Economics PhD program at the University of Massachusetts to expedite the intellectual exploration into the long-sought inquiry more formally.

Through analysis and theorization of the accumulated knowledge and historical evidences gathered in medical devices industry, this thesis seeks to demonstrate how and under which conditions business enterprises innovate to generate superior productivity and growth as well as what determines a business organization to make or buy a necessary capability it needs based on an intellectual academic logic. In doing so, it examines the evidences of a case study that deeply investigates the operational complexities of two inherently different international business models of medical devices, namely the *direct* and *indirect* business models along with the determinants that affect organizational decisions in selecting the respective model.

[2] Transnational Corporations., Encyclopedia.com. COPYRIGHT 2001 The Gale Group Inc. A transnational corporation (TNC) is "any enterprise that undertakes foreign direct investment, owns or controls income-gathering assets in more than one country, produces goods or services outside its country of origin, or engages in international production" (Biersteker 1978, p. xii). Variously termed multinational corporations (MNCs) and multinational enterprises (MNEs), transnational corporations are formal business organizations that have spatially dispersed operations in at least two countries. One of the most "transnational" major TNCs is Nestlé, the Swiss food giant; 91 percent of its total assets, 98 percent of its sales, and 97 percent of its workforce are foreign-based (UNCTAD 1998, p. 36).

The primary source of the data and information presented in the thesis, by and large, is based on my personal work experience, observance and knowledge accumulated over time during my career in the medical device industry as an 'insider' of a transnational corporation. The empirical and personal nature of the acquired knowledge of the subject compel me to write certain information without exact citation unlike standard academic papers. In addition, I have deliberately decided to exclude citations of certain data and information due to the highly discrete nature of the ways in which those data and information had been learnt, i.e. via one-on-one interviews, personal interactions and direct engagements with the subjects with a full understanding that such omission is an unordinary practice in academic papers. The inclusion of such information with omitted citation has been limited only to where it makes up the constitutive part of the dissertation and absence of it was thought to vitiate the work.

In accordance with the compliance requirements of the Institutional Review Board and the governmental statutes, I am committed to protect the privacy and confidentiality of the individuals and organizations that have participated in the study. Hence, I shall not disclose the source of data or information which can possibly invade the privacy or confidentiality of the contributors. Furthermore, I have eliminated all possible elements of the data and information that may be inferable or traceable by readers except for publicly available information.

CHAPTER ONE

The Summary, Research Problems and the Methodology

The Summary

The global medical device market is expected to grow to $410 billion by 2023.[3] The market has been steadily growing from $391 billion in 2017 and aging populations, particularly in advanced economies, are fueling this growth.[4] In this general expansion, the '*minimally-invasive surgery'* sector is one of the fastest growing and the most lucrative sectors in the advanced high-tech medical device industry.[5] The devices used in

[3] CISION PRNewswire.,https://www.prnewswire.com/news-releases/global-medical-device-market-2018-with-forecasts-to-2023---driven-by-healthcare-expenditure--technological-development--aging-population--chronic-diseases-300634442.html

[4] Select USA.gov, https://www.selectusa.gov/medical-technology-industry-united-states

[5] The innovative minimally invasive surgeries or surgical procedures are performed through tiny skin incisions about or less than 1 cm. The procedures are widely performed across the different specialties of interventional medicine, e.g. in interventional cardiology, neurology along with peripheral interventions and cardiac rhythm management procedures. The minimally invasive procedures continue to expand the applications in the various surgical interventions for parts of human body. Due to the facts that the patients who received minimally invasive surgeries tend to recover from surgeries much quicker and experience much less discomfort than conventional surgery with the same benefits the innovative surgical procedures are becoming explosively popular among physicians and patients, quickly replacing the conventional open surgeries in hospitals around the globe. John L. Ochsner, MD, (Jul 2000) Minimally-invasive surgical procedures, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3117518/ Mayo Clinic, (Dec 2017) Minimally-invasive surgery https://www.mayoclinic.org/tests-procedures/minimally-invasive-surgery/about/pac-20384771

advanced surgical procedures are high-end medical products that require long-term investments from the initial phase of R&Ds with uncertain outcomes all the way to the manufacturing and the post market phases of the finished products. As such, the global manufacturing of minimally invasive surgery devices is almost exclusively dominated by capital-rich US-based transnational corporations. The major global players in this industry are Abbott Laboratories, Boston Scientific, Medtronics, Stryker, GE, Johnson & Johnson and more, all US-based multinational or transnational device manufacturers. The minimally invasive devices market is estimated to reach USD 21.47 Billion by 2021 globally (from USD 13.89 Billion in 2016).[6] For the purpose of the study, the transnational medical device firms refer to the manufacturers of the *'minimally invasive'* medical devices and the medical devices refer to the *'minimally invasive'* medical devices.[7]

The US-based medical device manufacturers are also the global leaders in sales, marketing, state-of-the-art distribution, logistics system of the medical devices as well as in the post-sales customer and patient-care services. The foundation of such overwhelming dominance of the industry is rooted in the US-based transnational medical

[6]MarketsandMarkets™ https://www.marketsandmarkets.com/Market-Reports/minimally-invasive-surgical-instruments-devices-market-682.html?gclid=CjwKCAjw8ajcBRBSEiwAsSky_W0_9r9E8KRh3uSYnzzoovGiYjkqlkSjKbm4rb3QdBzgc87O5uvAzRoCy4MQAvD_BwE
MarketsandMarkets™ provides B2B research on high growth emerging opportunities/threats. There are aggressive statistics that reports the $21 billion has already been well past in 2019. The gap comes from the difference between the statistics that only reports the traditional minimally invasive medical device markets namely cardiological, neuro and peripheral intervention markets and those that include wider, newly added minimally invasive surgical device markets such as oncology, endoscopy, women-health specialties in the stat.

[7] Definitions of Medical device and Medical Equipment used here are based on the widely accepted WHO(World Health Organization) Medical Device: An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose.
Medical equipment: Medical devices requiring calibration, maintenance, repair, user training and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices. https://www.who.int/medical_devices/definitions/en/

device corporations' (TMDCs) competitive advantages in research and development capabilities that enable continuous innovation in technologies, and their ability and resources to execute the stringent multiphase-clinical experiments and human trials of medical devices required by government agencies.[8] The superior organizational and financial capabilities enable the US firms to pass through the rigorous governmental processes for human use until approval and their well-established sales and marketing apparatus compared to those of their global competitors are also important factors for the success of the US-based transnational corporations. Despite such an absolute dominance in every aspect of the industry, there is a distinctively perplexing phenomenon in one area of their business operations: the stark contrast ways in which they distribute (sell) the finished products in the '*international markets'* as opposed to their distribution in the US or European markets[9] (see footnote for definition of *'international market'* for the purpose of the study).

The TMDCs distribute the medical devices '*directly*' to hospitals in North America and Europe through their own sales and distribution apparatus built in-house (hereunder *"direct operations model*" or *"direct model*"). But they distribute products '*indirectly*' in '*international markets'*, i.e. markets outside North America and Europe, through third parties, namely the local country dealers or distributors (hereunder *"indirect operations model"* or *"indirect model"*). Under the *indirect* model, TMDCs

[8] TMDCs or MDCs., (Transnational Medical Device Corporations or Medical Device Corporations) In this research TMDCs and MDCs refer to the US-based transnational or multinational medical device corporations that manufacture, market and distribute the minimally invasive medical devices around the world. Only a handful of US device makers manufacture the minimally invasive surgery devices and dominate the world market. Those US-based TNCs compete among themselves for the market shares in almost every country around the world.

[9] International Markets, For the purpose of this study, I shall call the markets outside North America and Europe, the 'international markets' to avoid confusion with the global market which the study refers to the entire global markets including Europe and North America.

give up approximately 35% of the revenues (ranges vary between 20~45%) as commissions paid to the local country intermediaries, the dealers and distributors.[10] There are even harsher, more lopsided terms and conditions put forth by the local intermediaries. For instance, the TMDCs provide complete services from A~Z to the end using hospitals including delivery, replenishing and invoicing the consumed devices in *'consignments'* whilst the intermediaries do not take part in any activity or transaction between the TMDCs and hospitals, i.e. no buying, no selling, no physical receiving or no delivering of products, none whatsoever.[11] Despite such vastly disproportionate loss of revenues and the strange arrangement of paying the "do-nothing" middlemen, the *indirect* model continues to be the dominant business operations model outside the US and European markets. In fact, the *indirect* model is so ubiquitous that it is not an exaggeration to say the *indirect* model has become an 'official' *modus operandi* for international business of TMDCs. The seasoned managers at TMDCs with decades of international business experience uniformly insist the *direct* model is not only less profitable in *international markets,* but also a risky proposition due to the corrupt practices permeated in the hospital industry.[12] TMDCs' management adheres to this traditional industry '*dogma*' that expounds the *direct* operations model does not work in *'international markets'*, particularly in Asia.

[10] TMDCs' range of commissions paid to local dealers or distributors in Asia vary depending on country, medical specialty. The average range, however, is 20%~45% of the gross sales price. It could go as high as 47%~48% in Korea.

[11] ''Consignment" refers to the prevalent selling method for medical devices in international markets. From the product inventory standpoint, it refers to the device makers' shipped inventory to hospitals for potential consumption but not yet used or sold. In other words, it is an unpurchased, not-yet-paid-for medical devices still owned by medical device firms but stored at hospitals for usage by physicians.

[12] "International Markets" refer to markets outside North America and Europe to distinguish and avoid confusion with the global markets which the study refers to the entire global markets including Europe and North America.

Yet one US-based medical device corporation had ambitiously launched a '*campaign*' to establish direct operations worldwide in 1990s as its strategic global business model for the upcoming new millennium. Indeed, the company's concerted efforts to establish *direct* operations model worldwide had failed as predicted by the experienced managers in the company as well as pundits in the industry. But the model had '*oddly*' survived in one country in Asia. In fact, it was hugely successful in the country. The firm was AMC corporation and the only country where the direct model succeeded was South Korea (hereunder "Korea").[13] The firm's *direct* model had outperformed its competitors' *indirect* models for almost five years until the firm also had reversed the model back to indirect in 2010. Why did the direct model work only in one country? Why did the firm subsequently try to reverse the successful direct business to indirect? The phenomenon of continuing dependency of the resource-rich, mega transnational corporations on local country intermediaries in international markets remains a chronic puzzle in the medical device industry.

The study postulates that there is an intrinsic force that cultivates organizational innovation which enables a transformation of the resources into superior productivity and hence the superior growth of the enterprise takes place. That force of innovative enterprise is not easily or instantaneously formed but is forged over time under a suitable environment where necessary conditions are present. Through an in-depth case study of the '*odd*' case in AMC Korea, and its subsequent attempt to reverse the model to indirect and the ensuing results, by utilizing Lazonick's "*The Theory of Innovative Enterprise*"

[13]AMC (Acme Medical Company) is a pseudonym for a US based TMDC that operates in Korea and Asia-Pacific region. The pseudonym has been used for the study to protect the privacy and confidentiality of the participants who had contributed to the study by providing invaluable data and information.

(TIE), this thesis attempts to understand and identify what causes the innovative capability that turns organizational resources into superior products or services as well as to locate the underlying factors that affect the organizational boundary decisions, i.e. the choice to keep inside (make) or outside (buy) the organization. In the case of the medical device industry, it would be the question of what determines firms to choose the direct (make own distribution capability internally) or indirect model (buy distribution capability in market).

The Minimally Invasive Medical Device Business

While the US-based transnational medical device manufacturers lead the global 'minimally invasive' medical or surgical device industry, a specific device called "Drug Eluting Stent" (or DES)[14] used in cardiological procedure known as Percutaneous Transluminal Coronary Angioplasty (PTCA)[15] is one of the most highly-demanded and by far the most lucrative device amongst all minimally invasive medical devices due to its low production cost but high selling prices protected by patents (U.S National Library of Medicine.) In addition to the 'interventional cardiology'[16] procedure that requires high quantities of DES, there are other frequently performed procedures that require multiple sets of high-cost minimally invasive devices, e.g., 'carotid endarterectomy' procedures,[17]

[14] Tamburino, Corrado; Salvo, M. E. Di; Manna, A. La; Capodanno, D. (2009-08-29). A Drug-eluting Stent (DES) is a peripheral or coronary stent (a scaffold) placed into narrowed, diseased peripheral or coronary arteries that slowly releases a drug to block cell proliferation. (Stent: MedlinePlus Medical Encyclopedia". www.nlm.nih.gov. Retrieved 2015-05-13) This prevents fibrosis that, together with clots (thrombi), could otherwise block the stented artery, a process called restenosis. The stent is usually placed within the peripheral or coronary artery by an interventional cardiologist or interventional radiologist during an angioplasty procedure. (Tamburino, Corrado; Salvo, M. E. Di; Manna, A. La; Capodanno, D. (2009-08-29). Left Main Coronary Artery Disease: A Practical Guide for the Interventional Cardiologist. Springer Science & Business Media. ISBN 9788847014305. Retrieved 2015-05-13) Examples of DES can be found here: http://www.medtronic.com/content/dam/medtronic-com/products/coronary/stents/resolute-onyx/documents/us-resolute-onyx-brochure-1702.pdf

[15] U.S. national Library of Medicine, Percutaneous transluminal coronary angioplasty (PTCA) is a minimally invasive procedure to open up blocked coronary arteries, allowing blood to circulate unobstructed to the heart muscle. The procedure begins with the doctor injecting some local anesthesia into the groin area and putting a needle into the femoral artery, the blood vessel that runs down the leg. A guide wire is placed through the needle and the needle is removed. An introducer is then placed over the guide wire, after which the wire is removed. A different sized guide wire is put in its place. Next, a long narrow tube called a diagnostic catheter is advanced through the introducer over the guide wire, into the blood vessel. This catheter is then guided to the aorta and the guide wire is removed. Once the catheter is placed in the opening or ostium of one the coronary arteries, the doctor injects dye and takes an x-ray. If a treatable blockage is noted, the first catheter is exchanged for a guiding catheter. Once the guiding catheter is in place, a guide wire is advanced across the blockage, then a balloon catheter is advanced to the blockage site. The balloon is inflated for a few seconds to compress the blockage against the artery wall. Then the balloon is deflated. https://medlineplus.gov/ency/anatomyvideos/000096.htm

[16] An interventional cardiology procedure is a non-traditional surgical procedure, a minimally invasive treatment used to open narrowed coronary arteries to improve blood flow to the heart.

[17] Carotid endarterectomy- a minimally invasive surgical procedure to open or clean the carotid artery for stroke prevention.

carotid angioplasty' and similar 'stenting procedures'[18] in the 'peripheral intervention'[19] and 'neurological aneurysm'[20] involving minimally invasive 'catherization.'[21]

A physician, when performing a minimally invasive surgery, selects suitable sizes of stents after a screening of each patient's blood vessels has been completed in a Cath-lab because the device size that needs to be placed vary for individual patient, i.e. inner diameters, size of lesions, lengths of the effected blood vessels etc., vary from patient to patient.[22] Because doctors decide the suitable device sizes for each patient after screening of the blood vessels gets done, the hospitals must have large quantities of varying sizes of stents and a wide range of accessorial devices stored on the premises for doctors to choose from. The usual accessorial devices that must be present on the premises together

[18] MayoClinic, Carotid angioplasty and stenting- this procedure is performed by physicians instead of carotid endarterectomy in case a carotid endarterectomy isn't the best option for a patient. In this procedure, doctors thread a long hollow tube (catheter) with a small balloon attached through a blood vessel in your neck to the narrowed artery. The balloon is then inflated to widen the artery. A metal mesh tube (stent) is often inserted to decrease the chance of the artery narrowing again. https://www.mayoclinic.org/tests-procedures/carotid-endarterectomy/about/pac-20393379

[19] UNC Health Care (North Carolina Heart and Vascular), When patients suffer from hardening of the arteries, or atherosclerosis, their arteries are partially blocked by a substance called plaque. When these blockages occur in the legs or arms, they are called peripheral artery disease. Peripheral vascular interventions remove the plaque and restore the flow of blood through the artery. These interventions are medical specialties that treat peripheral artery diseases without surgically opening the leg or arm. Instead, the doctor uses small tools and at least one catheter. A catheter is a thin tube that is inserted into a blood vessel through a small cut, usually in the leg or arm, and threaded to the site of disease. Once in place, it acts as a tunnel, enabling the doctor to efficiently guide the tools to where they are needed. The muscles and other tissues of the arms and legs need oxygen and nutrients to work. If the arteries that feed the arm or leg are blocked by plaque (a mixture of cholesterol, fat, calcium and other substances), the leg will not work well and may experience pain or numbness. In extreme circumstances, they may require amputation. By using a catheter, doctors avoid making large surgical cuts when they remove the blockage. As a result, procedures that rely on a catheter generally decrease pain, pose less risk of infection, avoid large scars and shorten recovery times. http://ncheartvascular.com/services/peripheral-vascular-interventions/Peripheral Vascular Interventions

[20] Aneurysm, "*An aneurysm is an abnormal bulge or ballooning in the wall of a blood vessel. An aneurysm can burst (rupture), causing internal bleeding and often leading to death. Aneurysms usually don't cause symptoms, so you might not know you have an aneurysm even if it's large."* https://www.mayoclinic.org/diseases-conditions/aneurysms/symptoms-causes/syc-20354633

[21] Mayo Clinic, Jan 5, 2018 Catheterization is a procedure used to diagnose and treat cardiovascular conditions. During cardiac catheterization, a long thin tube called a catheter is inserted in an artery or vein in your groin, neck or arm and threaded through your blood vessels to your heart. https://www.mayoclinic.org/tests-procedures/cardiac-catheterization/about/pac-20384695

[22] Cath lab, A catheterization laboratory or Cath lab is an examination room in a hospital or clinic with diagnostic imaging equipment used to visualize the arteries of the heart and the chambers of the heart and treat any stenosis or abnormality found. https://en.wikipedia.org/wiki/Cath_lab

with the stents for ordinary cases of interventional surgeries include, at minimum, guiding catheters, balloons, and guidewires amongst others. Thus, pre-purchasing large quantities of minimally invasive devices of all sizes are financially burdensome for hospitals not only because of the magnitude of the required device quantities of various sizes but also because of the relatively short shelf-lives of the devices that add to the prohibitively high carrying costs of the devices when expire. In fact, the combination of these multiple attributes makes it extremely difficult or nearly impossible for ordinary hospitals to pre-purchase all stents and all accessorial devices of every size for all the surgeries hospitals undertake daily basis.

What medical device firms do to alleviate such financial burdens on hospitals is the *"consignment"* arrangement.[23] The device firms would first send or *'consign'* large amounts of DES, balloons, catheters, guidewires, and full sets of related accessorial devices of all sizes to hospitals without charging or invoicing them and then bill the hospitals only for those devices that have been used in surgery after the usage has been confirmed. This way, operating physicians have a large inventory of required devices of every size from which they can freely choose from on the premises without financially over burdening the hospitals. The medical device companies call these inventories of un-invoiced medical devices that are shipped and stored at client hospitals on a long-term basis the '*consignment'* inventory or field inventory (as opposed to the device makers

[23] ''Consignment" - the predominant selling method of medical devices. From the product inventory standpoint, it refers to the device makers' shipped inventory to hospitals for potential consumption but not yet used or sold. In other words, it is an unpurchased, not-yet-paid-for medical devices still owned by medical device firms but stored at hospitals for usage by physicians. The selling method of minimally invasive devices in international markets is 100% consignment. The only exception would be direct-global-orders received at TMDCs' global customer service centers in the US, placed directly by individual hospitals in countries around the world where the selling TMDC neither has its own presence nor has any of its representing partners (dealers or distributors) in the country. In such cases, the sale volumes are negligible.

inventory in their warehouses). The minimally invasive medical devices are largely sold through *consignments* in the United States, Canada and Europe, but these devices are sold 100 percent through *consignments* in the international markets.

The Research Problems

There are two central problems the thesis tries to understand through the dichotomy of the two differentiated international business models, *direct* and *indirect*, of the transnational medical device corporations. One problem is what really makes the business enterprise grow. The other is what determines the business enterprise to internalize a capability (make) or outsource it(buy) which, in this study, is the distribution capability of the transnational medical device firms.

What makes a business enterprise generate superior growth?

The uncanny penchant on the revenue-slashing indirect business model is a popular choice the TMDCs make based on the industry tenet, that is "sell through local guys in markets outside the US and Europe," a widely adapted industry rule after decades of failed attempts to eliminate the middlemen in international markets by numerous medical device corporations. Today the managers at the global headquarters of TMDCs interpret the recurrent failures of direct model as a *de facto* proof for the inoperability of the model in international markets. Nevertheless, the case of one transnational medical device firm's *'odd'* success of *direct* business model in South Korea (hereunder "Korea") in the early 2000s baffled managers in the industry. The firm's direct business kept on generating superior revenues and profits compared not only to its competitors in the market but to its own previous performances year on year until it had reversed the distribution to an *indirect* model by its new management in 2010. The company still runs a direct business in Korea today although it has scaled back from 100% direct to a

compromised 'hybrid' model.[24] The success of the direct business model in Korea remains as an extraordinary case even within the firm's Asia-Pacific region to date because the firm's direct model attempts have either miserably failed or barely broke even everywhere else in Asia. This case raises a series of fundamental questions about the validity of the traditional industry rule that rejects the direct operations model in international markets outside the US and Europe, particularly in the Asian market. Thus, this study inquiries into this very question, i.e how and under what conditions the organization's resources were transformed into superior direct operations that generated superior growth.

Make or buy?

The main difference between the direct and indirect business models in the medical device business lies in its product distribution method. The direct model internalizes the distribution capability whereas the indirect model outsources it. In other words, the central difference from the managerial standpoint is whether to make (build, own) or buy (outsource) the product distribution capability. Normally an organization would prefer to keep a capability within its boundary (make) when it is more efficiently performed by the organization than market and it would rather purchase the capability in market (buy) when someone else can perform it more efficiently. The TMDCs' distribution capability within each international country (subsidiaries) is not merely

[24] Hybrid Business model (Hybrid Model) refers to a mixed TMDCs' distribution model that combines direct and indirect models in a same market or country.

shipping products to hospitals but it also includes the management of the *"consignment operations"* which is the actual selling of the consigned products in the hospitals. Since the buying of the distribution logistics capability in TMDCs' country operations encompasses the buying (outsourcing) the organization's selling capability also, the decision whether to make or buy distribution capability is extremely important, probably the most important, strategic decision in the medical device corporations' international management.[25] Therefore, the issue of whether to make or buy distribution capability in the international medical device business and how and what decides this crucial decision becomes the central problem of the thesis.

[25] The distribution capability of TMDCs from the global headquarters or manufacturing' standpoint is the shipping logistics of the finished products, usually international shipping, from manufacturing facilities to the importing countries where the products are to be sold.

The Research Questions

The study inquires into the causes of sustainable productivity and growth of economic organization through an in-depth investigation of an actual case of success and failure of the direct business model in international markets. The two main questions that this thesis inquires and the relevant sub-questions to assess the valid causes are as follows.

The Main Questions:

1. What causes business enterprises to generate superior growth?
2. What factors influence TMDCs' decision to internalize or outsource distribution capability? (or to choose direct or indirect model)

The Sub-questions:

- Why is the indirect model prevalent despite the fact that it is extremely costly?
- At least one firm's direct model succeeded in one Asian country, Korea. Why did it work in Korea only?
- Why did the company attempt to reverse the successful direct business to an indirect model?
- What are the operational complexities, e.g. practices, processes, procedures of the medical device distribution in international markets, that may conflict with or not aligned with the local environment?
- Are the operational complexities of the direct model high enough to hinder the establishment and management of the direct model (endogenous barriers)?
- Do corruptions or collusive market practices (exogenous barriers) prevent the adoption of direct operations?
- Are the main barriers of direct operations structural (internal), market-oriented (external), or both?"

The Methodology

The methodology employed in this thesis amalgamates theory, empirical experience, surveys, a case study of a transnational medical device company's country-operations in Asia, and logical economic judgements that discern whether the evidences are merely constraint-optimizing or truly affecting the underlying causes of innovation based on the application of TIE's logic. The study analyzes the organizational structure, functional departments, distribution and consignment management and the business activities of country operations of transnational medical device firms to identify the details of the endogenous barriers that are implicit and tacit in nature residing within and alongside the processes and procedures of TMDCs.

The case study conducted for the thesis, i.e. a country business operations of a major transnational medical device firm in Asia, examines and compares the company's respective performances under the two different models, direct and indirect, that the firm had employed for a ten-year period in Korea, from 2005~2014. The study also reviews the country's market environment, customary practices, and corruptions to identify the endogenous and exogenous barriers along with the general business environment of Asian market. The reasons for selecting medical device companies' Asian country operations are, first, the author personally has extraordinary insights in the medical device industry gained from working at a major TMDC at various capacities in Asia and around the world. Given the author's work experience, the characteristics of the medical device industry in Asia best represent the common dilemma of transnational corporations' global operations in the dynamically transforming markets around the world irrespective of the industry, i.e. a regulatory challenges plagued with large cultural

and practical gaps in host countries that clash with the standards and requirements of the headquarters in home countries, and overly relationship-based, collusive commercial practices, implicit protocols by the home country standards that are considered 'normal' or 'usual' in host countries. TMDCs' Asian offices routinely face such large gaps in their day-to-day business operations and must compromise between the requirements of headquarters and the practices of host countries. Second, Asia is the fastest growing global market for goods in general, including medical devices. Third, Asia is the largest continent both in land-area and in population, constituting widely diverse cultural and regulatory environments such as North East and South East Asia, the distinct subcontinent of Australia, India, as well as the Middle East.

The thesis contrives the combination of the author's knowledge, hands-on work experience, empirical evidences of endogenous and exogenous barriers of transnational medical device corporations in Asia and around the world ascertained as an insider of the industry during the eight-year period 2007~2014.[26] The subsequent survey was conducted between the summer of 2018 and March 2019 in order to identify possible changes in practices, regulations or market environments in the region since 2015, the year the author had left the industry for academia. The survey was participated by five sales and operations managers who currently work at two different TMDCs in Korea, China and Singapore (See the foot note for the author's career details).[27]

[26] All information in the thesis regarding market environments, industry practices, consignment business management, inventory controls, regulatory (specifically the import licensing of the medical devices) requirements and compliance had been analyzed, confirmed and crossed-verified by professional analysts and seasoned managers of different functions at TMDC who are by and large the author's former colleagues.

[27] The author oversaw a country-operations of a transnational medical device corporation in Asia for four years from 2007~2011 as an American expatriated manager. During his assignment in Asia, he had worn two hats during the period of 2009~2010: the operations director for Korea and the interim operations director for China and Hong Kong simultaneously. Subsequently from 2011 until the end of 2014 he oversaw the entire consignment business operations of the corporation's emerging market, i.e. Asia-Pacific, Africa, Middle East and Latin America at its

CHAPTER TWO

Theoretical Framework

A theoretical framework that logically supports the application of relevant reasoning to the core issue of the study is central to building sound academic work. The challenge today, however, is the increasingly widening gap between traditional economic theories and the dynamically transforming socioeconomic phenomena of the 21st century. Neoclassical economics theories that dominate current discourse assume the outdated macroeconomics notion of so-called 'perfect competition'. As Joseph Schumpeter has already said in 1942 that "*the large-scale enterprise had come to the most powerful engine of economic progress*", the 21st century global markets are no longer where large number of small firms compete with similar products with a little or no barriers for entering and exiting markets and no one firm can influence the market outcomes, which are the theoretical assumptions of the 'perfect competition'.[28] However, the reality of the 21st century markets is utterly different. In 2014 "the 500 largest publicly listed U.S.

global headquarters. During this period, his main duties were to conduct meetings, interviews with country directors, directors of operations, finance, regulatory affairs, quality assurance, distribution and warehousing to advise and consult general country-operations matters such as hiring, training operations managers, strategizing consignment management of the countries in Asia-Pacific region. He also oversaw the collaboration with the local third-party logistics partners on "in-country operations" throughout Asia. The author's responsibilities included, but were not limited to, hiring, training, evaluating directors of operations, distribution, logistics mainly on consignment sales operations, import process and distribution center management as well as to oversee and reward contracts to third-party logistics subcontractors in local countries in the emerging markets. The list of countries the author was directly responsible for operational oversights and/or he had coordinated the country-operations in a dotted line reporting relationship with the local country heads of operations are Australia and New Zealand, China, Japan, Korea, Hong Kong, India, Indonesia, Malaysia, Philippines, Singapore, Taiwan, Thailand and Turkey. He travelled to these countries at the average interval of every three ~ four weeks for four years to oversee consignment operations by conducting regular in-person discussions, meetings with country directors, department directors of different functions of the subsidiaries throughout Asia-Pacific.

[28] Schumpeter, Joseph., (1950), Capitalism, Socialism and Democracy (Harper & Row Publisher 1950, Schumpeter, Original Pub.1942), p106

companies by revenues (the Fortune 500) had a combined $12.5 trillion in revenues (over 71% of the US GDP), $945 billion in profits, and 26.8 million employees worldwide."[29] The market power of large business organizations fueled by the continually expanding scale and scope further aided by advancing technologies have been increasingly influencing industrial output in increasing number of industries, hence the economics of market outcomes throughout the 20th century. Such oligopolistic phenomena in the economy exerted by large corporations has been increasing and spreading more potently in the 21st century. For examples, Microsoft has grown to become an over one trillion dollars enterprise in its market capitalization in 2019. Apple also has already hit one trillion earlier in the same year although it has since gone down a little bit. Amazon, Google are closely following suit to join the "Trillion dollar" club in market capitalization in the foreseeable future. (US Dept. of Commerce, 2019)[30]

To put it into perspective, one trillion dollars is larger than the annual GDP of Turkey, Netherlands, and Switzerland respectively and it is roughly equivalent to the annual GDP of Indonesia, the world's 16th largest national economy. (World Bank, 2018)[31] Economists must now accept the fact that a single business organization's market value can grow to be a greater than an annual GDP of more than 90% of the countries around the globe. Nevertheless, the Pareto-perfect or Pareto-efficient neoclassical economists utilize a convenient economics jargon, 'market failure', to explain economic phenomena that do not fit the rules and laws of economics they had formulated.[32] For

[29] William Lazonick (2016): Innovative Enterprise or Sweatshop Economics? In Search of Foundations of Economic Analysis, Challenge, DOI: 10.1080/05775132.2016.1147297., p2.
[30] US Dept. of Commerce http://www.iweblists.com/us/commerce/MarketCapitalization.html
[31] World Bank. World Gross Domestic Product ranking https://databank.worldbank.org/data/download/GDP.pdf
[32] The Pareto efficiency or Pareto optimality is a theoretical state of allocation of resources from which it's impossible to reallocate so as to make one preference criterion better off without making at least one preference criterion worse off. https://en.wikipedia.org/wiki/Pareto_efficiency

such reasons, this thesis employs the "*The Theory of Innovative Enterprise*" (TIE), which is built upon an incessant principle, i.e. technology and market change over time, as the main base of the intellectual logic in composing the theoretical framework. The *'historical-transformation'* methodology of TIE makes it the germane economics theory for the 21st century economy that continually transforms in ways that economists in the past did not foresee. (Lazonick, 2002, p4)[33] TIE presents a novel economic theory regarding the costs of doing business, i.e. fixed and variable costs of a business enterprise. TIE argues that "the organizational capability of the business enterprise influences the extent to which the enterprise can transform the high fixed costs of its innovative investment strategy into high-quality products (or services) at low unit cost."[34]

The framework begins with an introduction of the TIE and its *social conditions* which are the theoretical tools to analyze the case in hand, i.e. economic factors that may affect the productivity, growth and the organizational decisions to make or buy a required capability in a business enterprise. Then the next section will review Oliver Williamson's *"Transaction Cost Theory"*, the most important and the closest economics theory that's directly relevant to one of the main problems of the thesis, i.e. what leads TMDCs to employing the direct or indirect model in the international business operations, which the theory refers as the organizational boundary decision. (or make or buy decision)[35] Then

[33] Lazonick, William, 2002, "Innovative Enterprise and Historical Transformation," Enterprise & Society, 3-47, The *historical-transformation* methodology is the analytic approach used in developing Lazonick's economics theory, *The Theory of Innovative Enterprise.* Its theoretical postulates are derived from the study of the historical record and the resultant theory is used to analyze history as an ongoing an unfolding process. (For details see page 4 of Lazonick's (March 2002) "Innovative Enterprise and Historical Transformation," Enterprise & Society, 3-47) The Academic-Industry Research Network.

[34] Lazonick, William, 1991, Business Organization and the Myth of Market Economy, Cambridge University Press., p198

[35] Williamson, Oliver., 1973, "*Markets and Hierarchies: ORGANIZATIONAL FORMS AND INTERNAL EFFICIENCY".* He has published updated versions in 1975, 1981 and 1985. Williamson theorized the organizational decision making by providing reasoning as to why some economic transactions take place within a firm and why some other transactions take place outside a firm. He won Nobel Prize for the theory in 2009. https://www.nobelprize.org/prizes/economic-sciences/2009/williamson/facts/

the section will be subsequently followed by comparison of the "Transaction Cost Theory" with the "Theory of Innovative Enterprise." The author will make the case that Lazonick's TIE is the superior theory which is applicable to the real-world operations of business today as opposed to the limitations of the transaction cost theory in transforming the resources into superior products or services. The framework will help the study to understand the perplexing phenomenon of TMDCs' penchant on using the indirect model in Asia and explain the related evidences observed in the case study as to why and what determines TMDCs' direct and indirect model.

Then the chapter concludes by listing some related theories with succinct descriptions of the respective theories. Whilst employing TIE as the base framework, the study has also explored the wide range of conceptually related literatures and theories that focus on productivity, growth and marketing of the business enterprise as well. The chapter has included, at its end, several examples of those under subtitle, "other literatures reviewed" either because of the respective theory's intellectual comparativeness or interrelatedness with TIE or simply because of the noteworthiness of the work as a business or marketing theory. The list comprises of "*The Theory of the Growth of the Firm*" (Penrose, 1959), "*The Visible Hand*" (Chandler, 1993), Dynamic Capabilities and Strategic Management (David Teece, 1997), *'Value Migration'* (Adrian Slywotzky,1996) a contemporary marketing and managerial theory.

The Theory of Innovative Enterprise

Any firm would need initial capital or investment to start a business. The capital gets invested in the means to produce products or services and becomes the fixed assets or *'fixed costs'* of the firm such as the building, equipment and so on. Then *'variable costs'* are added to the fixed costs to make up the total cost of the firm.[36] "If an immediate financial return of the investment is expected through enough output, then the costs, both fixed and variables combined, would not become a financial problem of the firm."[37]

> *"Then we would probably not call the assets underlying these costs investments. Indeed, we might not even deem it appropriate to call these costs "fixed". The problem of fixed costs occurs because the production and sale of the enterprise output occur neither instantaneously nor with certainty." (Lazonick,1991, 198)*

It may be argued that even *variable costs* can decrease too in the short-term due to causes such as technological advancements in production mechanism (less human labor), decreasing raw material cost, declining energy cost prompted by discovery of, for example, new oil reserves, or lower labor cost in surplus labor market, etc. In real-world operations management, the total cost of an organization does not have to or is not destined to go up. Even in a case where variable costs do not decrease, for instance when

[36] Collins Dictionary of Business., *Variable Cost* - Any COSTS that tend to vary directly with the level of output. They represent payments made for the use of variable factor-inputs, notably raw materials and direct labour. A firm will leave a market if in the short run it cannot earn sufficient SALES REVENUE to cover its total variable cost. If it can generate enough total revenue to cover total variable cost and make some CONTRIBUTION towards total FIXED COST then it will continue to produce in the short run even though it is still making a loss. variable costs. (n.d.) Collins Dictionary of Business, 3rd ed.(2002, 2005). Retrieved April 15 2019 from https://financial-dictionary.thefreedictionary.com/variable+costs

[37] Lazonick, William, 1991, Business Organization and the Myth of Market Economy, Cambridge University Press., p198

variable costs were to remain constant or when variable costs increase slowly at a negligible rate as output increases, the average total cost curve would slope downwards as fixed costs are spread over increasing units of output. The mainstream economics theories, however, do not consider these real-world operational possibilities and maintains an outdated neoclassical assumption that justifies the perpetual and continuous increase of variable costs.

The base for such neoclassical cost theory is fixed on two variables: labor and management costs. These anachronistic assumptions are first, the increasingly crowded factory conditions (increasing labor cost) and second, the management's "control loss" (increasing management cost) that incurs by the increasing number of workers as business grows (Lazonick, 2015, 7). Unfortunately, economics textbooks based on the neoclassical economics still contain these outdated assumptions that insist all firms' variable costs rise invoking the 'law' of diminishing productivity return as the business grows. In the business world of corporations, the fundamental duty of managers are to transform the investments (costs) into revenue-generating products or services to realize financial returns. In doing so the managers can choose to run the business either in an *optimizing* manner or in an *innovating* manner.[38] The ordinary managers focus on '*optimization*' to maximize the revenues and profits rather than taking an '*innovative*' route that could generate sustainable superior productivity and long-term growth through transforming its resources and challenges into new values because such *innovating* route requires long-term investments and much greater managerial, organizational efforts.

[38] Lazonick, William., 2015, "The Theory of Innovative Enterprise: Foundation of Economic Analysis" , University of Massachusetts, The Academic-Industry Research Network. Rvsd. Aug 2015, p7.

The Social Conditions

The continuous innovation that promotes the process of superior economic performance is critical to the success of an enterprise. However, all innovation theories including the "*Diffusion of Innovation*", arguably the most widely known innovation theory, explain how innovation occurs in organizations which means occurrence of innovation gets treated as given theoretically, as the theories implicitly posit innovations do occur.[39] However innovations do not occur automatically. The '*social conditions*' of innovative enterprise explain under what conditions innovation gets first conceived and then nurtured to the fulfilment phase of innovation in enterprise. Hence, the paramount importance of TIE's *'social conditions'* must be understood on the base of conception, not inception, of innovations. The core principle of *the Theory of Innovative Enterprise* is the fact that innovations that lead firms to superior economic performances do not just occur by accident but occur as the result of long-term investment in the organizations' productive capabilities. The theory argues that there are three '*social conditions*' of an innovative enterprise and they are related to strategy, organization, and finance all of which jointly enable a business to generate higher quality products or services at a lower unit cost than those that had previously been available.[40]

[39] Rogers, Everett, 2003., *Diffusion of Innovations*, 5th Edition. Simon and Schuster. ISBN 978-0-7432-5823-4. A theory that seeks to explain how, why, and at what rate new ideas and technology spread. Everett Rogers, a professor of communication studies, popularized the theory in his book *Diffusion of Innovations*; the book was first published in 1962, and is now in its fifth edition (2003). Rogers argues that diffusion is the process by which an innovation is communicated over time among the participants in a social system. The origins of the diffusion of innovations theory are varied and span multiple disciplines

[40] Lazonick, William., *The Theory of Innovative Enterprise: Foundation of Economic Analysis** Revised 2015. * Revised and elaborated version of an essay that appeared as "*The Theory of Innovative Enterprise: Methodology, Ideology, and Institutions*" in Jamee K. Moudud, Cyrus Bina, and Patrick L. Mason, eds., Alternative Theories of Competition: Challenges to the Orthodoxy, Routledge, 2013: 127-159.

> *"The Theory of Innovative Enterprise states that the "strategic control, organizational integration, and financial commitment" enable a firm to confront the "uncertain, collective, and cumulative characteristics of the innovation process".(*Lazonick, 2015, 4)

TIE identifies the three "social conditions of innovative enterprise", *strategic control, organizational integration, and financial commitment,* enable a business to generate higher quality products at lower unit costs than those that had previously been available by enabling the firm to confront the uncertain, collective, and cumulative characteristics of the innovation process. The respective three *social conditions* of the TIE are as follows;

Strategic Control – is the determinants to make necessary investments, allocates resources in developing human and physical capabilities. It enables the firm to compete for chosen markets.

Organizational Integration – enables the ways in which organizational learning about transforming technologies and accessing markets, and thereby a firm develops and utilizes the value-creating capabilities.

Financial Commitment - sustains the processes in the prophase of uncertainty with developing technologies and accessing markets until they can generate the competitive products or services that yield financial returns.[41]

TIE accentuates the uncertain, collective and cumulative nature of innovative processes. As Lazonick states: "First, innovation is uncertain because when investments in transforming technologies and accessing markets are made the financial returns cannot

[41] Ibid., p4.

be known, even probabilistically. As we shall see, "optimization" is the enemy of innovation. Hence the need for strategy. Second, innovation is collective because, to generate higher quality, lower cost products than were previously available, the business enterprise must integrate the skills and efforts of large numbers of people with different hierarchical responsibilities and functional capabilities into the organizational learning processes which are the essence of innovation. Hence the need for organization. Third, innovation is cumulative because collective learning today provides the foundation for collective learning tomorrow, and these organizational learning processes must be sustained over time until, through the sale of higher quality, lower cost products, financial returns can in fact be generated. Hence the need for finance." [42]

With regards to the strategic decision-making process of ordinary business corporations, we can reasonably assume that decisions are made after conscious, educated considerations of available alternatives by decision making managers of the organization. Right decisions will lead an organization to productive results for growth, but wrong decisions can lead an organization to less or unproductive results and can possibly take an organization down. The point is that business enterprises are inherently man-made, social institutions created and managed by conscious wills with the purposive objectives of human beings where stakeholders, namely employees, managers, or investors coordinate together for common objectives of continuous and profitable growth.

Economic organizations are not *biological organizations* that go through destined lifecycles as significant number of corporate managers often colloquially and mistakenly describe the fate of collapsing business organizations. Since Alfred Marshall had

[42] Ibid., p.4

compared the organizational life to the biological lifecycle of trees in 1890, economists as well as industrial leaders began comparing economic organizations' longevity to the biological organisms.[43] One example is Adrian Slowtzky, the author of *Value Migration* which is listed at the end of this chapter.[44]

Those organizations that continually make the right strategic decisions to integrate organization by investing in productive capabilities continue to be in existence or even continue to be leading in the industry for centuries such as Lloyd's of London, IBM, Western Union, Merck, Mitsukoshi Group, and Towle Silversmith, to name a few. But those that continually make wrong strategic decisions in organizational integration and investments ultimately demise into the history. It is not so uncommon to find business enterprises that are operating well over several hundred years or more in the U.K., Netherlands, and Japan, even over a thousand years in the case of Japan.[45] There is no age limit to economic organizations, unlike biological organisms. The longevity or lifespan of an economic organization can be infinite, and it depends on humans that manage the organization although those humans who manage it may have finite longevities depending on the health conditions of the organization.

For a business organization to achieve the common objectives of its stakeholders,

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[43] Marshall, Alfred (1890)., *Principles of political economy*. London: Macmillan and Co. Since Alfred Marshall famously compared the organizational lifecycle to the biological lifecycle of trees in the 19th century, there have been considerable number of scholars who expanded the biological notion to explain the '*natural'* demise of business enterprises. Even today, there are scholars, let alone lay people such as corporate managers, who believe in the "lifecycle" theory of business enterprises, i.e the belief that business corporations go through similar phases of lifecycle as humans or other species of biological organisms from birth to death. In the inception phase, the theory argues that business organizations are established, grow and expand with novel ideas and products, then organizations reach peak phases as they become dominant players, then experience following lag phase as they start losing steam in competitiveness, which leads to falling behind competitors and eventually getting pushed out of the market as if the organization were a human that goes through life cycles of infancy, childhood, youth, adulthood, and then death.

[44] Slywotzky, Adrian. J.,1996, Value Migration: How to Think Several Moves Ahead of the Competition, Harvard Business School Press.

[45] https://en.wikipedia.org/wiki/List_of_oldest_companies

i.e. the continuous and profitable growth, the managers of the organization must have effective strategy that develops, nurtures and encourages its workforce to continually innovate to stay competitive in continually changing markets and technologies. TIE defines this enterprise action as *strategic control* – "a set of relations that gives decision-makers the power to allocate the firm's resources to confront the technological, market, and competitive uncertainties that are inherent in the innovation process." [46] TIE argues the strategic process as follows "For innovation to occur, those who occupy strategic decision-making positions must have both the abilities and incentives to allocate resources to innovative investment strategies. Their abilities to do so will depend on their knowledge of how the current innovative capabilities of the organization over which they exercise allocative control can be enhanced by strategic investments in new, typically complementary, capabilities. Their incentives to do so will depend on the alignment of their personal interests with the interests of the business organization over which they preside in attaining and sustaining its competitive advantage." [47]

Strategic control is only the starting part of the long road to achieving common objectives. The effective controlling of the strategy is another essential part to achieve the common objectives which requires *organizational integration.* TIE defines the *organizational integration* as – "a set of relations that creates incentives for people with different hierarchical responsibilities and functional capabilities to apply their skills and efforts to strategic objectives."[48] The critical factors in *organizational integration* is the

[46]Lazonick, William., *The Theory of Innovative Enterprise: Foundation of Economic Analysis** Revised 2015. * Revised and elaborated version of an essay that appeared as "*The Theory of Innovative Enterprise: Methodology, Ideology, and Institutions*" in Jamee K. Moudud, Cyrus Bina, and Patrick L. Mason, eds., Alternative Theories of Competition: Challenges to the Orthodoxy, Routledge, 2013: 127-159.
[47] Ibid.,p5
[48] Ibid.,p5

well-balanced alignment of the personal interests of the organization's individuals with the interests of the corporation. The applying balanced compensation system is important for integrating individuals into the organization. "To generate innovation, the compensation system must motivate employees as individuals to engage in collective learning. Hence the balanced compensation in the form of promotion, renumeration benefits and recognition must also be part of a reward system that manages the learning processes that are the essence of innovation."[49] The business organizations are inherently human-made, social organization where individuals from all walks of life with different functional responsibilities and capabilities apply their skills and efforts to the common objectives of sustainable growth of the organization. Hence the conditions to foster organizational innovations should be aligned with the beneficial growth of the constituent individuals of the organization which connect and incentivize individual people across the width and the depth of the organizations, i.e. the *social conditions* of the theory of innovative enterprise.

[49] Ibid.,p6

The Transaction-Cost Theory

Oliver Williamson's transaction cost theory has its roots in the concept argued by R.H. Coase in "*The Nature of the Firm*" (Coase, 1937).[50] The following quote epitomizes the central point of the initial inquiry on why firms exist and Coase's own answer to the inquiry at the time.

> *"We may sum up this section of the argument by saying that the operation of a market costs something and by forming an organization and allowing some authority (an "entrepreneur") to direct the resources, certain marketing costs are saved. The entrepreneur has to carry out his function at less cost, taking into account the fact that he may get factors of production at a lower price than the market transactions which he supersedes, because it is always possible to revert to the open market if he fails to do this." (Coase, 1937)*[51]

Coase argued that firms exist because of "*marketing costs*" which is the term economists later changed to "*transaction costs*". It argues that the efficient production of goods takes place inside a firm because markets are costly to use and, if there were no cost to use market, the firms would not exist. Coase asserted that it is always possible for a firm to revert to open market if an entrepreneur fails to maintain the cost lower than market. Since then his '*cost*' to use market became a foundation for transaction-cost theories that had since been refined and expanded. Williamson, since his initial publication "*Markets and Hierarchies: Organizational Forms and Internal Efficiency"* (1973), also has published elaborated versions of the transaction cost theory in 1975, 1981 and 1985, i.e. "*Markets and Hierarchies: Some Elementary Considerations*" (1975), "*The Economics of Organization: The Transaction Cost Approach*"(1981) and then "*The Economic*

[50] Coase, Ronald H., (1937) "The Nature of the Firm" http://www3.nccu.edu.tw/~jsfeng/CPEC11.pdf
[51] Ibid., p5.

Institutions of Capitalism" (1985). The Williamsonian Transaction-Cost Theory considers the transaction costs of activities within the boundaries of a firm in deciding whether a transaction can be executed more efficiently within a firm (hierarchy) or by someone else outside the firm (market).

Williamson's arguments that are directly relevant to the thesis are: first, firms decide what to keep inside firms (build, make) and what to keep outside firms (buy, outsource) based on the *transaction costs*. Second, firms naturally attempt to build efficient borders in the competitive world of commerce by deciding what to make and what to buy. Third, market uncertainty may induce firms to internalize resources or work. (Williamson, 1981, 558)[52] The Williamsonian Transaction Cost Theory is a well-known, directly relevant economics theory to the core problem of the thesis which is what affects TMDCs' management to keep their distribution capability inside the organizational hierarchy (direct model) or to keep it outside (indirect model).

Williamson initially divided the attributing factors of the theory into two large categories in 1975, the 'human' factors and the 'transactional' factors. The human factors are "*bounded rationality, opportunism and atmosphere*" and the transactional factors are "*uncertainty, small numbers and information impactedness*".[53] Subsequently Williamson had replaced his original "Transactional" factors, the "*Uncertainty, Small Numbers and Information Impactedness"* with *"Uncertainty, Transaction Frequency and Asset Specificity"* later in 1985 version. The bounded rationality, in his own words, is the "*rate and storage limits on the capacities of individuals to receive, store, retrieve, and process*

[52] Williamson, Oliver E. 1981. "The Economics of Organization: The Transaction Cost Approach." American Journal of Sociology 87:548-577.
[53] Williamson, Oliver E., 1973, Markets and Hierarchies: Some Elementary Considerations., Is this a journaVol. 63 No. 2, p317-318

information without error".[54] The Opportunism is "*an effort to realize individual gains through a lack of candor or honesty in transactions*."(Williamson 1973, 318) In a later version he has further refined the "*opportunism*" as a human nature of "*condition of self-interest seeking with guile*" in "*The Economics Institutions of Capitalism*". (Williamson, 1985, 30) Williamson described *"atmosphere",* one of the human-related transactional factors in his 1973 version of Markets and Hierarchies, as "individuals are not all given to the strict maximization of pecuniary gain but also consume *'atmosphere'*. Preferences for '*atmosphere'* may induce individuals to forego material gains for nonpecuniary satisfactions if the modes or practices are regarded as oppressive or otherwise repugnant." [55]

The core argument of the theory in short is that a mixture of human factors and transaction factors lead firms to choose between the hierarchy (make) or market (buy). Williamson asserts economic actors in business transactions are 'boundedly rational' and some actors are 'opportunistic'. He argues a firm would use market when both *bounded rationality* and *opportunism* are present because opportunism becomes problem only when bounded rationality is present. But the existence and combinations of certain aspects of transaction factors, i.e. "asset specificity, uncertainty or transaction frequency", can raise transaction costs and create 'market failure' which ultimately enables vertical integration more efficient than market. The *a priori* assumption of Williamson is that market is more efficient than hierarchy because a vertically integrated firm maybe not be under competitive pressure of market and is subject to internal bureaucratic process. The central point he contends is that only an idiosyncratic

[54] Williamson, Oliver E., 1973, Markets and Hierarchies: Some Elementary Considerations., Vol. 63 No. 2, p317
[55] Ibid., 318

relationship of human factors tied by any of the four asset specificities, i.e. "*human asset specificity, physical asset specificity, site specificity, and dedicated assets*" would have 'lock-in" effects to choose hierarchies because an alternative cannot be taken without incurring loss. (Williamson, 1985)[56] Hence the desire to continue an internal transaction is superior to the choice of exchanges in market in the absence of asset specificity.

In entering transactions, "one would have incomplete access to information and a limited ability to absorb the information to which he or she has access. The economic actors try their best to minimize cost (or make decisions intended to be rational) but they have a limited cognitive competence to do so."[57] Bounded rationality is the condition of being "*intendedly rational but only in limitedly so*."[58] If rationality were unbounded, "the changing environment would not create cognitive uncertainty and pose problems of adaptation."[59] Because "it would be feasible to develop a detailed strategy for crossing all possible bridges in advance."[60] An uncertainty is the factor that connects an opportunistic actor and a boundedly rational actor in economic transactions. An uncertainty, however, is a broad concept that different aspects of it can *"lead to both a desire for flexibility and a motivation to reduce transaction costs."* (Klein, 1989, 256)[61] The transaction frequency is the number of times the transactions take place. If the transaction were to take place only once, the transaction cost would be inefficient or higher than the market. But if it were to take place many times over a long period of time the cost for such transactions

[56] Williamson, Oliver., "Contractual Man" in The Economic Institutions of Capitalism, Free Press, 1985, 43-63. http://faculty.babson.edu/krollag/org_site/org_theory/Scott_articles/william_contract.html
[57] Lazonick, William, 2002, "Innovative Enterprise and Historical Transformation," Enterprise & Society, 3, p.9
[58] Williamson, Oliver E., 1985, The Economic Institutions of Capitalism, Free Press., p.45
[59] Lazonick, William, 2002, "Innovative Enterprise and Historical Transformation," Enterprise & Society, 3, p.9 .
[60] Williamson, Oliver E., 1985, The Economic Institutions of Capitalism, Free Press.,57-58.
[61] Klein, Saul., 1989, A Transaction Cost Explanation of Vertical Control in International Markets, Journal of the Academy of Marketing Science, 17: 253-260

are justified or lower than the market because of the economies of scale effect. Williamson argues the presence of uncertainty, bounded rationality, and opportunism hinders the process of negotiating and maintaining contractual commitments. Therefore, "it becomes even more important for contracting parties to '*work things out*' via governance structure and organization."(Williamson, 1985, 79)[62]

The problems with the transaction cost theory are, first it takes "the behavioral, cognitive and technological conditions of business enterprise as given." (Lazonick, 2002, 12). Second, it is an extension of neoclassical economics that employs constraint-optimization as its principle which seeks to optimize the given constraints rather than seeking to overcome those constraints through innovation. In the theoretical world of Williamson's transaction-cost where the behavioral factor of *opportunism* interacts with the human factor of *bounded rationality*, one would be better off with saving transaction costs through markets rather than through internal hierarchies. However, he did recognize that asset specificity, uncertainty and transaction frequency and the combinations of certain dimensions of those respective factors may possibly enable hierarchy more efficient than market. Williamson fails to answer under what conditions a firm can develop and maintain internal capabilities that are superior to markets.

[62]Williamson, Oliver (1985). "*The Economic Institutions of Capitalism"*, Free Press, 1985. P.79
http://faculty.babson.edu/krollag/org_site/org_theory/Scott_articles/william_contract.html

The Theory of Innovative Enterprise vs The Transaction Cost Theory

As explained in the beginning of the chapter, the superiority of TIE over any existent economics theory comes from its novel economic concept of embedded operational '*costs*' in business operations as well as the *'social conditions'* of innovative enterprise. What follows explain these main points of the TIE in comparison to the central points of Williamson's transaction cost theory. Williamson's "*Transaction Cost Theory*" delineates an efficient organizational boundary decision, given *bounded rationality, opportunism, and asset specificity*, whether or not an internally making or owning a necessary capability would be more efficient than buying it from market.[63] The transaction cost theory is a highly elaborated economics theory that views the cognition of endogenous conditions inside the hierarchy as given, while the Theory of Innovative Enterprise offers operational solutions for challenging those cognitive and behavioral conditions in the real-world corporate management, i.e. *social conditions*, to bring about breakthrough innovations that transform organizational resources into generating superior economic results.

The neoclassical adherence of the transaction cost theory limits its theoretical logic on organizational and managerial sources of breakthroughs to the interactions among *bounded rationality, opportunism, and asset specificity* rather than broadly considering how and under what conditions the individual human capability, intellectuality and aspirations are unleashed in economic organization. The transaction

[63] Williamson, Oliver E., (1975) *Markets and Hierarchies: Some Elementary Considerations*, Semanticscholar.org https://pdfs.semanticscholar.org/51e0/624399096cb1bbf76f358f1fc790b274d4cd.pdf

cost theory delineates organizational boundary decisions by exploring the causes and effects of managerial coordination within organizations. However, Williamson's argument, based on his explanation of the relationship between economic organizations and economic outcomes, reverses the causes and effects of the economic phenomena. Williamson's *human factors* and *transaction factors* or any combination of the components of the two factors that lead an organization to make or buy are inherently causes for economic effects or results no matter how the individual components of the two factors are mixed and matched. The organization's resultant products or services for market or its failure to produce anything due to internal inefficiency is the result of those mixtures. In other words, what's available in market at lower cost for an organization to buy than making it within its own internal hierarchy is also a result of someone else's efficient organizational mixture of the two factors in the economy, be it national or global. Thus, market is the result and the organizations are causes of available products and services, not the other way around.

Lazonick argues that the innovative firm improves its value-creating capability "*by unbounding its cognitive competence and by transforming the behavior of its participants, technologically by committing itself to the development and utilization of organization specific-assets."*[64] As TIE asserts "the innovative firm's *strategic control* determines to challenge the uncertainty by *organizational integrity* to overcome cognitive and behavioral limitations to create value where market coordination cannot."[65] Lazonick's examination on how Williamson used Chandler shows transaction cost

[64] Lazonick, William, 1991, *Business Organization and the Myth of Market Economy*, Cambridge University Press., p229
[65] Ibid.

theory's inability to explain the organizational innovation. Such explanatory failure of the transaction cost theory is well illustrated in Williamson's argument about the managerial evolution of railroads in "*Business Organization and the Myth of the Market Economy*". (Lazonick, 1991) According to Lazonick's citation from *The Visible Hand* (Chandler, 1977), Williamson recognized that "transformation from market coordination to administrative coordination occurred in American overland transportation between the 1840s and the 1880s." (Lazonick, 231)[66] The railroads in the eastern United States before 1850s were built to connect existing commercial centers or to supplement existing water transportation. Thus, the railroads were rarely more than 50 miles long in 1950s. (Chandler, 1977, 82) In theory, if those short units of railroads were unified by contract rather than ownership, a massive concentration of connected routes of railroad could occur.

Williamson argued that, because of "site specificity", the bilateral contracts linking between any two railroad companies' tracks in a linked chain of the railroads was fraught with *opportunism* and subject to high transaction cost. The member firms (that agreed to jointly use the each other's tracks by contract) cheated the weights in amounts shipped or distances sent, and used improper classifications of freight moved to attract more traffic by evading the published rates.[67] In Chandler's *The Visible Hand*, however, "there is no evidence that the inability or inefficiency of separate, end-to-end operation of longer routes gave rise to the unified ownership." (Lazonick, 232) The only possible explanation for Williamson's arguments is his dependency on neoclassical ideas that

[66] Williamson, Oliver E., 1985, *The Economic Institutions of Capitalism*, New York: Free Press., p.279, quoting from Chandler, The *Visible Hand*, 103. Requoting from Lazonick's *Business Organization and the Myth of Market Economy*., p231

[67] Ibid.277-8., quote from Chandler p.141

interpret any existence of market coordination (buy) as a result of an internal opportunism and any existence of internal coordination (make) as a result of market failure in the presence of asset specificity. Williamson stated that:

> *"There is more to railroad organization than physical coordination. Otherwise the natural railroad units of fifty miles in length would have remained intact. And there is more to railroad organization than unified ownership. Thus, the Western and Albany road, which was just over 150 miles in length, and was built in three sections each operated as a separate division, experienced severe problems."* [68]

There is no plausible evidence that the transaction cost played a role in Western's decision to invest in internal hierarchy. Western was the very first intersectional railroad in the country and it had transformed from three separate operating divisions.[69] The problems had nothing to do with internal opportunism or separate divisions of the railroad tracks. The problem was running three trains a day in each direction over a single track – "*the western suffered a series of serious accidents culminating in a head on collision of passenger trains*."[70] The management of Western decided to invest in administrative structural improvement rather than laying a second track. Western had incurred high operating costs by choosing to invest in administrative structure. Western saved money, however, by choosing to remain in a single railroad. The investment in organizational structure made the safer train travels possible.

Obviously, the theory of innovative enterprise didn't exist in the 19th century but what Western had done was an example of fulfilling of the *social conditions* of TIE, i.e., the strategic control to improve the administration of a single railroad (instead of laying another track) by committing financial investment in administrative structure to

[68] Ibid., 96-7, Lazonick., p.232
[69] Lazonick, William, 1991, *Business Organization and the Myth of Market Economy*, Cambridge University Press, p.233
[70] Chandler, Jr., Alfred D., 1977, The Visible Hand: The Managerial Revolution in American Business, Harvard University Press. P.96-7

overcome the safety challenges to achieve safer railroad travels through innovative organizational integration.

Organizational Process Integration

The process integration between the production and the distribution, namely vertical integration, was probably the one of the most important developments during manufacturing boom in the Unites States which was sped up by rapid advancement in transportation at the turn of the 19th century to the 20th.[71] Williamson asserted, referencing quotes from Chandler's *The Visible Hand*, that *"vertical integration is more consistent with transaction cost economizing than with the leading alternatives, in particular, the condition of asset specificity is the main factor to which a predictive theory of vertical integration must appeal."*[72] Williamson stated that *asset specificity* is the most important factor for forward integration into distribution and then second comes the externalities.[73] The greater the asset specificity and the externalities, the more far-reaching the forward integration into wholesaling and retailing. *"Scope economies may give rise to integration into relatively minor wholesaling activities, while economies of scale are probably even less relevant to a decision to integrate forward into distribution than economies of scope."*[74] Williamson included the cases of Duke (cigarettes), Swift (meat packing), Eastman Kodak(cameras and films), and Singer(sewing machines) for

[71] Lazonick, William, 1991, Business Organization and the Myth of Market Economy, Cambridge University Press.,p238
[72] Williamson, Oliver., 1985, *The Economic Institutions of Capitalism*., p103
[73] Ibid.p111-112
[74] Ibid., p112

forward integration, citing Chandler.[75] For backward integration into raw materials, also citing Chandler, are the examples of Pabst (into timber and barrel), Singer (into timber, iron, transportation), McCormick (into timber, minerals, hemp, twine) and American Tobacco, Campbell, and Heinz into bulk buying and storage of agricultural products.[76] Williamson argued that all the backward integration of these manufacturers must have been *mistakes* because *asset specificity* did not appear to be present (with an exception to the backward integration into perishable and agricultural products that may have been economically rational even though more details would be needed to assess the nature of the market breakdown even in those case)[77]

Williamson also contended that the main factor for forward integration is the 'economies of speed'. He argued as a proof that not all manufacturers of durable goods were integrated into distribution, i.e., the fact that small standardized producer durables were sold through independent distributors while manufacturers directly sold and serviced large unique producer durables themselves.[78] "*It is this rather than economies of speed differentials that explain the pattern.*" said Williamson. [79] Williamson views the forward integration as a response to opportunism. His analysis on vertical integration, backward and forward, is based on the neoclassical notion that limitedly views the existence of hierarchy as market failure. Instead from the theory of innovative enterprise viewpoints, these great examples could very well be propounded as innovative organizational integration made possible by strategic investment in distribution

[75] Lazonick, William, 1991, *Business Organization and the Myth of Market Economy*, Cambridge University Press.,p239.
[76] Ibid., p239
[77] Williamson, Oliver., 1985, *The Economic Institutions of Capitalism*.p120n. quoting from Lazonick, p.240
[78] Williamson, Oliver., 1985, *The Economic Institutions of Capitalism* p.126
[79] Ibid.

capabilities.

Eastman Kodak's invention of continuous process for making negatives opened the opportunity for creating a mass market for photographic equipment. The masses of consumers had to be willing and able to buy the products to make the mass market. Eastman Kodak had to come up with means to deliver high quality products at reasonable prices.[80] If the distribution had been left in the hands of distributors the easy-to-use innovative products might have never seen the light. Eastman Kodak was not concerned about the possibility of opportunism or bounded rationalities. Instead the company went ahead with process integration into mass distribution by creating a worldwide network of branch offices with managers to supervise salesman, demonstrators to coordinate inventory flows.[81]

The integration of production and distribution at Eastman was an innovative strategy that required a large investment upfront. The forwardly integrated distribution "*was managed by salaried administrative structure to ensure the throughput - the volume of Kodak sales per unit of time - would be large enough to transform high fixed costs into low unit costs*." [82] Like the Eastman Kodak's case, Duke in cigarettes, and Swift's mass meat marketing, Singer manufacturing's strategies were equally great examples of the forward integration of their products with distribution for masses of customers. All four cases had uniformly employed the strategy to invest a large amount of financial resources in forward integration to secure smooth and rapid distribution and employed salaried

[80] Lazonick, William, 1991, Business Organization and the Myth of Market Economy, Cambridge University Press.,p242
[81] Chandler, Jr., Alfred D., 1977, *The Visible Hand: The Managerial Revolution in American Business*, Harvard University Press. P.297
[82]Lazonick, William, 1991, *Business Organization and the Myth of Market Economy*, Cambridge University Press.,p242

workers to manage the product flows to ensure that a large enough volume of throughputs would transform the high fixed costs into low unit costs.[83] These examples of Williamson's analysis on forward integration into distribution proves the limitations of theoretical framework of the transaction cost theory. The increased output of a firm caused by the growth of the firm's business increased the competitive uncertainty in input markets as the growth generated firm-specific costs. It is clear, however, that the very success of the firm's business growth causes an output increase, and the committed high fixed costs to enable the increased output are the underlying reasons for the firm-specific transaction costs that prompted the backward integration. Thus, the increased transaction costs related to vertical integration is a calculated firm-specific cost increase which can later be decreased on per unit level by increasingly greater output.[84] Williamson's transaction costs theory explains what causes the backward integration, but it does not explain how the integration contributed to organizational efficiency once it has been completed. The theory of innovative enterprise, however, explains that

> *"a growing enterprise will integrate backward to transform relatively unmanageable competitive uncertainty into more manageable productive uncertainty. Then it uses its organizational capability to achieve the economies of speed that can transform its fixed costs into low unit costs in sustained competitive advantage. The incentive and the ability to engage in vertical integration are both therefore outcomes of the successful expansion over enterprise beyond its original core activities."* [85]

Having thoroughly analyzed the transaction cost theory, the following will contrast the main points of the theory with the theory of innovative enterprise, including a summary of important differences between the two theories. The transaction cost theory attempts to explain why hierarchies (corporations) exist and even grow when the

[83] Ibid.,p240
[84] Ibid.,p246
[85] Ibid.

economic transactions can take place in markets. Its argument is very similar to agency theory in which an agent will have the incentive to follow the principal's direction.[86] Williamson argues that it is the agents' behavioral *opportunism* that tries to hide information from principal that creates moral hazards, and the principal's cognition (*bounded rationality*) that contends with the agents' opportunism creates an adverse selection problem in hierarchies.[87] Hence the costs go up in the hierarchies, making organizational hierarchies inherently more inefficient than a market arrangement. The question remains: why is hierarchy still chosen over the market despite the inherent inefficiency of behavioral and cognitive problems of hierarchies? Williamson argues that it is because of the presence of "asset specificity" and the ability to "*work things out*" in hierarchies.[88]

[86] Agency Theory - The study of the relationship between an agent (such as a broker) and a principal (such as a client). Agency theory seeks to explain the relationship in order to recommend the appropriate incentives for both parties to behave the same way, or more specifically, for the agent to have the incentive to follow the principal's direction. Agency theory also seeks to reduce costs in disagreements between the two. Agency theory. (n.d.) Farlex Financial Dictionary. (2009). Retrieved July 2 2019 from https://financial-dictionary.thefreedictionary.com/Agency+theory

[87] A Principal in agency theory refers to any internal client who could be the boss of an agent but not necessarily the boss only. A principal could be any person who the agent needs to serve as an internal client such as colleagues in other functional departments that you need to provide with information, data or materials and so on.

[88] Williamson, Oliver., 1985, *The Economic Institutions of Capitalism*.p.60, 79

The Theoretical Comparison of the Key Concepts

Table. 1

Theoretical Comparison of the Key Concepts
Transaction Cost vs Innovative Enterprise

The Transaction Cost Theory	**The Theory of Innovative Enterprise**
Given Constraints	**Organizational Transformation**
Asset Specificity (Technology)	Investment Strategy (Develops Specific-Assets)
Bounded Rationality (Cognition)	Unbounds Rationality through Organizational Learning
Opportunism (Behavior)	Overcomes Opportunism through Organizational integration and Incentives

Origin: Lazonick(2016) "*Ennovative Enterprise or Sweat Shop Economics*?", p35

It is evidently clear that the transaction cost theory views corporate strategy as exploitative behavior that raises costs for products and services. The theory of innovative enterprise views corporate strategy as a collective process of continuous innovation to achieve higher quality and lowering prices of products and services by creating value to expand the output.[89] Williamson's notion of "*working things out*" in hierarchies is based on constraint-optimization methodology and seeks to *optimize* constraints according to the given constraints of technology, cognition, and behavioral limits. The theory of innovative enterprise's "working things out" focuses on strategy to invest in technology, organization to *challenge and transform* the given constraints for the asset specificities to

[89] William Lazonick (2016): *Innovative Enterprise or Sweatshop Economics?:* In Search of Foundations of Economic Analysis, Challenge, DOI: 10.1080/05775132.2016.1147297, p34

generate superior economic performance than previous performances.[90] The innovative enterprise uses strategic control to make a financial commitment to organizational integration for the purpose of producing higher quality, lower price competitive products or services. The innovative enterprise that overcomes these challenges succeeds by providing the *social conditions*, the proper strategic control, organizational integration and financial commitment in the organization.

The transaction cost theory inherits many aspects of neoclassical economics. The ideological penchant of the theory to adhere to *perfectly competitive market* inherently limits the interpretation of economic phenomena to the confinement of market-centric view. Hence Williamson labels any transaction occurring in hierarchies as 'un-market' or 'non-market' transaction that occurs as a result of market failure. The reason for business corporations to exist, strictly from a Williamsonian view, is because of market failures.[91] The transaction cost theory is *a priori* stretched by an anachronistic view of the market as a celestial sphere for economic activities, whereas the theory of innovative enterprise precisely reflects the phenomena of the real-world operations of the 21st century business corporations. Specifically, the operational aspect of the cost management that high fixed costs, strategically invested together with variable costs, can eventually get lowered in per unit cost bases as output expands to a large scale. Furthermore, the social conditions integrate the organization and enable collective and cumulative learning across the organization's personnel both vertically and horizontally throughout the hierarchy, resulting in a novel value that would not otherwise come about.

[90] Ibid
[91] Ibid

Other Theories Reviewed

As explained at the beginning of the chapter, the study, in framing the intellectual logic, has explored the wide range of conceptually related literatures and theories which focus on the productivity, growth and marketing of the business enterprise in addition to the base theory of TIE and transaction cost theory. The four theories listed in this section from those literatures reviewed, due to the respective importance in intellectual comparativeness or interrelatedness with TIE or simply because of the noteworthiness of the work are; 1) "*The Theory of the Growth of the Firm*" (Penrose, 1959), 2) "The Visible Hand" (Chandler, 1993), 3) "*Theory of Dynamic Capabilities*" developed by David Teece, and 4) 'Value Migration', a contemporary marketing and managerial theory (Adrian Slywotzky,1996).

These theories, except the Theory of the Growth of the Firm by Penrose", have two theoretical approaches that compel me to repudiate them. The first common approach that is rejected in this thesis but that all three theories uniformly employ is the methodological principle of 'constraint-optimization' which regards the constraints as given. The second, what is lacking in all three theories above is the innovative approach to 'overcome' the identified constraints. The Theory of Innovative Enterprise is the very theory that rejects the constraint-optimization approach and treats the constraints as organizational objectives for business organizations to overcome through innovation.

The Theory of the Growth of the Firm (Edith Penrose, 1959)

In undertaking an analysis of the growth of firms, Edith Penrose sought an answer for whether there was something inherent in the very nature of any firm that both promoted its growth and necessarily limited its rate of growth.[92] In "*The Theory of the Growth of the Firm,"* she views firms as bundles of resources, for production of goods and services, sold in markets for profit. The important Penrosian intellectual concepts that this study makes use of are:

- Firms are not defined in terms of products but in terms of resources.
- Effective use and mixture of resources within an enterprise leads to an innovation.
- There are economies of growth, quite apart from any economies of size.
- There are limits to growth, but not to size, and these are determined by the rate at which experienced managerial staff can plan and the capabilities to implement the plans.
- The services of 'inherited' managerial resources control the amount of new managerial resources that can be absorbed, and thus the rate of a firm's growth.
- The external environment is 'image' in the minds of the entrepreneur.
- Firms' activities are governed by their 'productive opportunity.' This involves a dynamic interaction between the internal and external environments and includes all the productive possibilities that its entrepreneurs can see and take advantage of.

[92] Penrose, Edith, E.T. (November 15, 1914 – October 11, 1996), "*The Theory of the Growth of the Firm"* (2009. Fourth Edition. org.1959) Penrose.E.T., an American-born British economist who is the author of *The Theory of the Growth of the Firm.* She sought answers for whether there's something inherent in the very nature of any firm that both promoted its growth and necessarily limited its rate of growth. "*The Theory of the Growth of the Firm"* (1959) describes the ways in which firms grow and how much and how fast they do. She viewed firms as bundles of resources, under internal resources, for production of goods and services, sold in markets for profit.

- In the long run, the profitability, growth, and survival of firms depend on their ability to establish '*relatively impregnable bases*" from which to adapt and extend their operations in an uncertain, changing and competitive world. (Penrose,1959, p.121)

As Lazonick has accurately critiqued in his 2002 publication. "*Innovative Enterprise and Historical Transformation*," the weakness of the seminal work of Penrose on the growth of the firms has implicitly assumed that "*organizational learning is inherently managerial learning*" in making of the innovative enterprise growth theory. (Lazonick, 2002, 25) During 1995~2000 the author of this thesis has personally experienced an organizational learning process that Lazonick asserts in TIE. At Yusen Logistics Co. Ltd, a Mitsubishi affiliated international logistics management company where the author had worked as export department supervisor, the newly assigned Japanese managers, the author's new bosses who were promoted or appointed to lead the export department assume the new responsibility by working on the warehouse floor first as a transportation dispatcher and distribution clerk for minimum of three months or even longer until they become completely and independently able to function as a fulltime professional dispatcher and a warehouse inventory clerk. It was an eye-opening live experience that the author had witnessed the organizational integration of Japanese corporations that is achieved through collective learning process that connects the hierarchy vertically (the shop floors and the management) or in other words, the blue collar and white-collar workforce.

The Visible Hand: The Managerial Revolution in American Business (Alfred Chandler, 2002)

This chronological study of business history that shows the transformation of the American business enterprises (7th Edition, 2002) from the late 19th century to the first half of the 20th century is a great resource for the study to learn how the successful managerial transformation of American enterprises helped the US become a dominant power in the global economy. The thorough depiction of the process of the industrial corporations' developmental efforts and the managerial revolution in the United States was particularly helpful to understand the historical transformation of the enterprise from owners to managers. The *Visible Hand*, which is filled with details about how men, events, processes, policies and procedures about changing technologies and markets, explains the transformational development of American enterprises from the family owned businesses to modern managerial corporations.[93] The work does not test or validate hypotheses, or theories. Rather, the primary focuses of Chandler's work are on why and how the "Visible" hand of management replaced Adam Smith's "Invisible" hand of market mechanism over time. The main arguments or propositions are:

- Modern business enterprise appeared when the volume of economic activities reached a critical level that made administrative coordination more efficient and more profitable than market coordination.
- Modern multi-unit business enterprises had replaced small traditional enterprises when the administrative coordination between multiple departments and divisions

[93] Chandler, Jr., Alfred D., (2002) Original printing in 1977, The Visible Hand: The Managerial Revolution in American Business, Harvard University Press.

within firms permitted greater productivity, lower costs, and higher profits than coordination by market mechanism.

- The advantages of internalizing the activities of multiple business units within a single enterprise could not be realized until an effective managerial hierarchy had been created.
- Once a managerial hierarchy had been formed and had successfully carried out its function of administrative coordination, the hierarchy itself became a source of permanence, power, and continued growth.
- As the modern business enterprises grew in size and diversity and as its managers became more professional, the management of the enterprises became separated from ownership of shares.

Chandler argues the well-orchestrated coordination of the managerial hierarchy in the first half of the 20th century became the source of the growth. He emphasizes the organizational innovation that enabled business enterprises to organize and manage diversified, multi-units of different expertise under the management of large firms. He emphasizes the advantages of internalization of costs through large scale, multi-unit businesses as opposed to the previous single business unit. The main drawback of Chandler's analysis in *The Visible Hand* is his treatment of the economic transformation in the US enterprises as only an organizational evolution from managerial perspectives. He fails to see the underlying economic transformation in the corporations, i.e. the changes in hierarchical relationship from the proprietary ownership to professionally managed social institution. The study does not include the process of evolution at the operational or production level. Even when he emphasizes the "*economies of speed* " for

production, he only focuses on the changes in technology and organization, not human assets, as the requirements for the speed.(Chandler, 281)[94] Greater *economies of speed* in production cannot be achieved only by changes in technology and organization (management) without the proportionate changes in the workforce at the operational or production level. The Visible Hand lacks the transformational dynamics of hierarchical interrelations of the work forces that shaped the modern American enterprises.

Dynamic Capabilities and Strategic Management (David Teece et al., 1997)

Advancing and maintaining the capabilities to compete successfully in markets is one of the most important requirements for a business enterprise to remain profitable. The fundamental principle of the 'dynamic capability' theory is that the 'firm-specific' combinations of competence and resources that can be developed, deployed, and protected in the changing market environments can be the sources of advantage.(Teece, Pisano, Shuen, 1997, 510). A new technological base may require the firm to achieve competence in some significantly different area of technology.[95] For an example, as Motorola corporation had successfully transitioned from a radio and TV manufacturing company to a semiconductor and telecommunications equipment company in the 1950s. (Slywotzky,1995)[96] Teece and Pisano argue the firm-specific differences in dynamic capabilities are rooted in three factors, namely "Asset Positions, Processes and Paths".[97]

[94] Chandler, Jr., Alfred D., (2002) Original printing in 1977, The Visible Hand: The Managerial Revolution in American Business, Harvard University Press., p281

[95] Penrose, Edith., *The Theory of Growth of The Firm* (Edith Penrose, fourth edition 2009)

[96] Slywotzky, Adrian J, (1996) - *Value Migration: How to Think Several Moves Ahead of the Competition,* Harvard Business School Press

[97] Pisano, Gary P.,(2017) "Toward a prescriptive theory of dynamic capabilities: connecting strategic choice, learning, and competition", August 201, Oxford university Press on behalf of Association ICC. P.750

The "Asset" in *Asset Positions* refers to the legacy resources of the firm such as knowledge, technical skills and core competences.

It argues that a firm's ability to change its future capabilities is constrained by its current capabilities. This argument is very similar to the Penrosian argument that contends the services of 'inherited' managerial resources control the amount of new managerial resources that can be absorbed, and thus the rate of growth of firms. (Penrose, 1950, 58-77). The second factor, *the Processes*, argues that *asset positions* can be reconfigured by investment and other managerial interventions but the capacity to do so depends on "high-order" of a firm such as governance, resource allocation, etc. *Paths*, the third factor, argues that a firm's capabilities are cumulative and built over time. Therefore, the top issue for management is to be vigilant in identifying the capability that will lead the firm to competitive advantage and to commit to that *Paths* for capacity creation. However, managerial discretion needs to select the right Paths, "along with constraints imposed by pre-existing asset positions and processes for configuration, can lead to differences in capabilities." (Pisano, 2017, 750) Pisano views the firm's capability problem as the matter of '*choosing*' among different types of capability-enhancing investments. The innovative capabilities do not happen automatically but need to be nurtured and proactively promoted by the management or they will stifle or die out. The dynamic capability theory lacks a consideration of the environments under which innovation can occur and the fundamental conditions for conceiving such capability.

Value Migration (Adrian J Slywotzky,1996)

The theory of value migration is a business strategy theory that argues a modern corporate strategy should be built 'outside-in' rather than 'inside-out' which means

strategic thinking should begin with the customer and work its way back into firm.[98] Slywotzky originated this 'reversed' strategy approach in 1983 with his partners who viewed the dominant corporate strategy in the US that focused on cost and total quality as self-limiting and had thought the fast-changing market environment required strategy that's sustainable for long-term growth. The core argument of the value migration theory is that business designs go through cycles and reach economic obsolescence. He argues that customer priorities, the most important issues to the customers, have a natural tendency to change in any business over time but business designs of firms tend to stay fixed. As the fabric or mechanism that tightly match the firm's business design to the structure of customer priorities begins to have gap or break down, and then *Value Migration* occurs. Slywotsky asserts a prospering company such as Nucor, in potentially an unattractive steel industry, as an exemplary case of successful business design change:

> *"Nucor's primary focus has been on producing non-flat rolled steel for construction applications. Its customers demand a minimum acceptable quality level and otherwise care only about price. The company built its entire business operations design around this central reality of its customers' priorities. It may appear Nucor's success is the use of low-cost technology and raw materials, but it is only one element of the business design change. The critical components of design change include low-cost(rural) and flexible labor(nonunion) and low overhead. (a headquarters staff of 23 for $3Billion dollar revenue) Through employing an explicit policy of reliance on external sources of technology, Nucor has also achieved low-cost position in R&D and technical development. It employs a superb business design to serve a customer group whose decision-making system is dominated by price." (Slywotzky, 1996, 4)*

There are great historical examples of business enterprises that were able to reconfigure and extend their competences and have effectively evolved into a different company with a new competency by being able to identify the *migrating value* ahead of the competitors. One great example is IBM, which was established in 1911 as Computing-Tabulating-Recording Company (CTR). Since its inception, it has been

[98] Slywotzky, Adrian. J.,1996, Value Migration: How to Think Several Moves Ahead of the Competition, Harvard Business School Press.

continually transforming from a manufacturing company of business machines for sale and lease (ranging from cash registers, commercial scales, meat and cheese slicers, industrial time recorders, tabulators, and punch cards) to effectively becoming a computer manufacturing and leasing company, IBM in 1950. It introduced the first practical artificial intelligence computer, IBM704, and programing languages such as FORTRAN, and the SABRE (Airline reservation system) in the early 1960s. IBM went on to become a mainframe-computer producing and leasing company in the1970s, practically dominating the computing service operations at major universities, scientific labs and even NASA with general computation, data analysis and management.[99] Today we know that Blockchain technology, a base-technology for crypto currencies and foundational software for other crucial future applications and software technologies, is an IBM invention. Another great example of a firm that was able to transform itself by detecting *value migration* at an earlier stage is NBC. In the 1950s NBC was a radio network but it had successfully transformed into a TV network as the listening consumers of the radio were becoming viewers of TV. (Slywotzky,1995)

On the other hand, there are equally as many examples of opposite cases, i.e. the consequence of failure to detect the migrating value in a timely manner. For one example, Motorola, once a dominant player in the industry in the 20th century, had lost billions of dollars in revenue in 2007-2009 and eventually ended up dividing the company into pieces and selling its several pieces to Google and Lenovo. The remainder of the business, which is Motorola Solutions, has become a much smaller company in the 21st century.[100] A&P grocery chain, an American icon that permanently closed its business in

[99] IBM, https://en.wikipedia.org/wiki/IBM
[100] https://en.wikipedia.org/wiki/Motorola

2015 after 156 years is another great example of the consequence of failure to detect the value migration.[101]

Slywotzky argues *Value* can migrate out of only one division of a company, a whole company or even out of a whole industry, as customers' choice on the business design that best meet their priorities changes. He asserts values may also migrate to another business designs within an industry or flow out of one industry moves into another. "In the steel industry example *Value* flowed within the industry from the integrated steel makers into alternative business designs like those of Nucor and the next generation integrated mills in Japan and Korea." (Slywotzky, 1996, 5) The author argues that business that predicts the coming change before the *value migration* begins will prevail or otherwise the business will fail. For example, *value* that resided in the steel industry for centuries had migrated out of the entire steel industry in the late 20th century as the companies which consumed large amounts of steel, such as canners and auto manufacturers, developed new technologies to use hybrid or substitute materials, i.e. plastic, aluminum or synthetic materials. Nucor, because it changed its business design to accommodate the changing priorities of customers, has not only survived but successfully transitioned its business to success but the rest in the industry demised or succumbed to integrated mills of Japan and Korea.

Slywotzky argues that predicting *Value Migration* before it moves is possible. There is a prescription for value migration so that firms can predict ahead of time and to proactively reconfigure the business design to satisfy the changing priorities of

[101] Verdon, Joan (14 November 2015). "A&P granted extension to file bankruptcy plan", *NorthJersey.com*. USA Today Network. Archived from the original on 27 December 2015. Retrieved 10 November 2016, https://en.wikipedia.org/wiki/The_Great_Atlantic_%26_Pacific_Tea_Company

customers. He offers the total of 12 points as the prescription for movement of *Value* as he described below. (Slywotzky, 1996, 265)

Customers (Identifying Value Migration)

1. Who is the customer? Are decision makers and influencers changing? If so, how do their buying criteria differ?
2. What are the customers economics and process flows?
3. Which customers' needs are mature and requires are more effective solutions? Which needs are emerging and require a performance solution?
4. Given the customers economics and needs profile, how are their priorities changing?
5. What do you think will be the customers most important future needs?

New business designs

6. How many distinct new business designs has been introduced in your industry in the past 5 years?
7. What is the customer and economic rationale?
8. How do their economics do, compared to yours?
9. How do their customer ratings do, compared to yours?

Value Movement

10. Map the Value Migration that enabled you to gain you are present position. Who was the vanquished incumbent? Why?
11. What is the total market value of your industry? What is your share of that value? Who is gaining share of value most rapidly?
12. Which industries our economic neighbors of your own (e.g. steel, aluminum, plastics)? is your industry losing value to them? Why? How rapidly?

The *Value Migration* theory may be a valid business strategy for profit maximization, but it has fundamental problems as a sustainable long-term corporate strategy. As shown in the 12-point questions above, *Value Migration* is not any different than the typical theory of optimizing firm in its virtue of viewing the organizational

constraints as given.[102] It emphasizes building the 'intelligence' function of firms so that they can proactively detect the changing trends in the market, particularly those in the customer tastes and priorities, and link them back into the company management in preemptive manner. In this way a company would quickly and flexibly change its business design making it suitable to the changing tastes and the priorities of the customers. One of the typical characteristics of optimizing firms is to "choose the industry in which it wants to compete because of the exogenous appearance of a disequilibrium condition that offers firm supernormal profits to be made" rather than creating opportunities to make new profits. (Lazonick,2015, 7) Additionally, there are two more theoretical problems with the *Value Migration.* One is its reversed understanding on the cause and effect of the market. The market-centric ideology of *Value Migration* views the market as the cause for economic activities of firms, not as the effect of economic activities of firms. The other problem is that it assumes the lifecycle theory on man-made organizations. Slywotzky says "*It is widely acknowledged that products go through cycles, from growth through obsolescence. It is not as well recognized that business designs also go through cycles and reach economic obsolescence*." (Slywotzky, 4) [103] What Slywotzky contends is a "viability" analogy, one of the popular biological cycle analogies.[104] The "viability" argument was originally set forth by Armen A. Alchian who had asserted that firms must make positive profit to

[102] The theory of optimizing firm is a term coined by Lazonick to describe firms that focus on maximizing profits rather than investing to create new values for future to use it as a counter to his 'The Theory of Innovating Firm' that Lazonick uses in his main economics theory "*The Theory of Innovative Enterprise"*

[103] Slywotzky, Adrian. J.,1996, *Value Migration: How to Think Several Moves Ahead of the Competition*., Harvard Business School Press., p.4

[104] Marshall, Alfred (1890)., *Principles of political economy*. London: Macmillan and Co. Since Alfred Marshall famously compared the organizational lifecycle to the biological lifecycle of trees in the 19th Century, economists often use different types of biological analogies to the growth or demise of business enterprises.

survive.[105] It argues that the firms that successfully adapted to the environment to generate profits do survive, but those that failed to be adapted to the environment demise. "This argument is analogous to Darwin's natural selection theory where positive profits are treated as the criterion for natural selection. In essentially argues that the profitable firms are selected by the environment and the firms that don't make profits are rejected by the environment." (Penrose 1952, 810)[106] The "life" of a business organization is fundamentally different from that of humans, animals or any type of biological organism. It can't be any more logically eloquent than the following quote in refuting the biological analogy to man-made business organization.

> *"The characteristics such as birth, youth, maturity and death are characteristics of biological organisms that reproduce sexually. "Organisms whose reproductive process are primarily asexual have in general a very different pattern of development in which death plays no part, and certainly the development of firms shows no pattern similar even to that of organisms that reproduce asexually. We have no reason whatsoever for thinking that the growth pattern of a biological organism is willed by the organism itself. On the other hand, we have every reason for thinking that the growth of a firm is willed by those who make the decisions of the firm and are themselves part of the firm and the proof of this lies in the fact that no one can describe the development of any given firm or explain how it came to be the size it is except in terms of decisions taken by individual men." (Penrose, 1952, 808)*

[105] Alchian, Armen (1950), "Uncertainty, Evolution and Economic Theory," *Journal of Political Economy 58*: 211–21. Alchian explored the " role and nature of purposive behavior in the environment of uncertainty and incomplete information" but he's adoption of a biological model to explore the causal relations underestimates the man-made social phenomena.
A member of the Chicago school of economics, and one of the prominent price theorists of the second half of the 20th century. His writings have touched on topics conventionally viewed as macroeconomic: money, inflation, unemployment, and the theory of business investment. https://en.wikipedia.org/wiki/Armen_Alchian

[106] Penrose, Edith Tilton (1952), *Biological Analogy in the Theory of the Firm*, American Economic Review, XLII (5) December 804-19, based on Organizational Capability and competitive advantage (1995) by William Lazonick and William Mass, *Edward Elgar Pub Co.*

CHAPTER THREE

The Barriers to Direct Business

As explained in Chapter One, medical devices are sold through '*consignments*' in Asia regardless of business models.[107] To accurately analyze the business models of the medical device business, the prerequisite is to understand what the 'consignment' business is and what its operations entail. This chapter takes deep dives into the operational complexities of the consignment business management and thoroughly reviews the findings of the consignment-borne barriers to direct business (endogenous barriers) as well as the market barriers (exogenous barriers) such as the collusive and corrupt practices that make TMDCs' direct business allegedly *'impossible'* in Asia.

The chapter enumerates the endogenous and exogenous barriers to the direct business in the next two separate sections. The first, The Endogenous Barriers section, examines the infamous complexities of the consignment operations. It lists "Quality and Regulatory Barriers" separately within the section because the Quality and Regulatory barriers are self-imposed barriers caused by policies that are not aligned with business operations, not caused by operational complexities. Then the second section of the chapter, The Exogenous Barriers, will discuss the market barriers that are external to the managerial domain of the TMDCs. The section reviews the different types of business models and the complex relationships intertwined among the intermediaries, hospitals

[107] The device maker-owned devices (consignment) and hospital-owned devices (devices pre-purchased and owned by hospitals) coexist in hospitals in the US, Canada and Europe whereas consignments in international markets are 100% owned by device sellers.

and the transnational medical device corporations. The chapter will end with a summarizing analysis of the enumerated barriers based on the theoretical framework of the theory of innovative enterprise.

The Operational Complexity of Consignment Management

The 'maximum selling prices' or the 'maximum reimbursement prices' of Drug Eluting Stents (DES) used interventional cardiology, are the highest among all stents used in interventional procedures.[108] The main problem of the consignment business begins with the billing of the used devices at hospitals. Billing in consignment occurs only upon actual usage of devices, and only those specific units used are billed. The magnitude of the consignment inventory at midsize hospitals in terms of dollar value could be as much as half a million to a million US dollars on average in sales prices. In the case of large hospitals with frequent inventory turns, the value of the rolling consignment inventory can be well over $2 million per hospital at any given point in

[108] The maximum selling price or maximum reimbursement price. The maximum reimbursement price refers to the highest possible selling price for a medical device that a registering device maker is permitted to charge customers, hospitals by government. The maximum reimbursement price is reviewed and approved by each national government in Asia. The product's present price ranges in the origin country market is one of the considering factors for determining the adequate price range for a newly registering device in a local country. In review and approval processes encompass activities such as the introduction of new device, its functions, and the usage, availability of substituting and complementing products and etc. The entire process of tug-of-war is conducted between the TMDCs and the importing government to 'negotiate' the MRP price for every new product being registered for importation in Asia. The DES, which are exactly the same as bare metal stents but produced with coated layers of drugs on the suffice of the stents, cost approximately $1,500~$3,600 per unit as opposed to a bare metal stent which runs in the range of $300~$600 a unit, depending on the maximum reimbursement prices approved by the each country government. A Drug Eluting Stent(DES) is a peripheral or coronary stent (a scaffold) placed into narrowed, diseased peripheral or coronary arteries that slowly releases a drug to block cell proliferation "Stent: MedlinePlus Medical Encyclopedia". www.nlm.nih.gov. Retrieved 2015-05-13. This prevents fibrosis that, together with clots (thrombi), could otherwise block the stented artery, a process called restenosis. The stent is usually placed within the peripheral or coronary artery by an interventional cardiologist or interventional radiologist during an angioplasty procedure. Tamburino, Corrado; Salvo, M. E. Di; Manna, A. La; Capodanno, D. (2009-08-29). Left Main Coronary Artery Disease: A Practical Guide for the Interventional Cardiologist. Springer Science & Business Media. ISBN 9788847014305. Retrieved 2015-05-13 https://en.wikipedia.org/wiki/Drug-eluting_stent

time. The single largest problem in consignments is the fact that the usage information of the devices (or sales) is solely dependent upon customers' (usually nurses') goodwill to promptly inform the usage to the consignors or the sellers. There is no other practical way for the device sellers to know if or when any device has been used unless a sales rep goes around the hospitals to check the usage in person. This is what sales reps must do once a week or at minimum once a month at every hospital to identify and realize the monthly sales revenues. From the device firms' managerial standpoint, *ex post facto* detection of the sold products becomes the main duty of sales reps instead of making *ex ante* efforts to sell the products. While a consignment provides full line of devices with no financial burdens to hospitals in advance, it creates huge administrative and logistical challenges to the device sellers' back offices. In addition to identifying the usage, billing the used devices according to varying rates and payment terms agreed between the sellers and each hospital are huge challenges as well. The billing terms vary from weekly, bi-weekly, monthly, bi-monthly, three months or even longer. This means even if an accurate device usage information has been obtained in timely manner, the used device will be billed in 90 days from the day it was used if the agreed payment terms were 90 days. A device that's been informed as 'used' today could have been used days or weeks earlier. The device sellers simply do not know. The sellers' inability to access the usage information leaves them no choice but to bill based on the dates provided by the customers. In addition, other classic examples of operational challenges of consignment management include frequent shipping and returns of devices between the device sellers' warehouses and hospitals, lost devices (or devices unaccounted for) within hospitals, the inability to issue billing invoices even if a usage has been confirmed because of insufficient or

incomplete manufacturers' lower level product data which are required by law to be printed on the billing invoices, etc.

The Endogenous Barriers

The endogenous barriers to the direct model are synonymous to the consignment barriers since the medical device sales in Asian markets are conducted only through consignments at hospitals. Thus, accurate and complete understanding of every administrative and operational problem of the complex consignment operations are the central importance for correct analysis of the barriers to direct business model. This section enumerates only the main problems with granularity of higher-level description of the operational challenges to condense the extensive and lengthy explanation required for the individual problems. The full descriptions of the respective endogenous barriers (Operational Barriers and Quality and Regular Barriers) with the detailed explanations have been separately listed and attached as an appendix to the thesis.

Operational Barriers (See Appendix)

A) The Detection of Device Consumption

B) Insufficient Data from Hospitals

C) Manual Matching of Unmatching Records (Mismatches)

D) Timely Replenishment of Consumed Devices.

E) Unbilled (or consumed-but-not-yet-billed).

F) High Inventory to Sales ratio.

G) Inefficiency in the Distribution Center.

H) Lost Devices (the devices unaccounted for at hospitals)

Quality and Regulatory Barriers (See Appendix)

A) Damaged

B) Expired and Near Expiry

C) Complaints

D) Frequent and Repetitious Shipping and Returns

E) Mandatory Product Scraps

Any business organization has a write-off procedure, but normally write-offs are determined as a last resort in case of *force majeure* or inevitable cases of business losses. In medical device companies that operate consignments, however, have very large regularly repeating irregularities as mentioned above, i.e. Complaints, Damaged, Expired, Lost and more that lead to eventual product scraps which get financially settled by frequent write-offs.[109] In addition to the most common Regulatory, Quality and Operational problems listed above, there are other issues of tacit and latent nature of consignment operations that occur at the back-offices of TMDCs. The common examples of such challenges include, in addition to the infamously known "used-but-not-yet-billed" issue (or unbilled), customized invoicing according to various discount rates, differed payment terms for each hospital that're longer than six months in some cases, unreported

[109] The definitions of Complaints, Damaged, Expired, Lost and other categories explained earlier in the chapter from p70

usages, additional or double issuance of the government mandated “Official” invoice in addition to issuing commercial billing invoices, e.g. separate VAT invoices and the list goes on. The magnitude of consignment problems and the back office administrative work to reconcile the differences, including cyclical and frequent write-offs, are so overwhelming that managers at MDCs view the magnitude of these problems as the main attributes for abandoning the direct business model and ultimately resort to the indirect model that utilizes distributors or dealers in Asia.

The Exogenous Barriers

This section reviews the market environment that TMDCs are operating under in Asia. The collusive and corrupt practices in medical device markets are external to firms' managerial domain but the firms must deal with these challenging realities in doing business. When different parties with interest in business deals or transactions make secret agreements to achieve their objectives, we can generally say it's a collusive act or a collusion. In the medical device industry, like other industries, collusive practices exist. These practices are by and large not illegal but unethical behaviors that create inherent barriers in the market for TMDCs in doing direct business. The first part of the section reviews the collusive collaborations between the device makers and the local intermediaries. Then the following part discusses the collusion between the dealers and the hospitals. The third part reviews the imposition of minimum purchase quantity on dealers and distributors by large corporations. The fourth part analyzes the collusion within hospitals. The fifth part of the section analyzes the conscious parallelism or pre-coordination on bidding prices among dealers and distributors of TMDCs' products.

Collaborative Collusion between TMDCs and Their Dealers

The collaborative collusions between the TMDCs and their intermediaries exists in all countries to varying degrees. The most classic and usual collaboration observed is a pattern of large quantity product returns from dealers to device makers that take place few days after quarterly sales closings at TMDCs. These cyclical product returns from

dealers back to TMDCs are frequently matched by the similarly large quantities sales that were transacted several weeks prior to the returns. The remuneration of sales reps and managers, including incentive pays, are calculated based on actual sales compared to the planned sales on a quarterly basis. Dealers help TMDCs achieve their quarterly sales targets by placing artificially large purchases 1~2 weeks prior to a quarter's end. Then, subsequently after a reasonable amount of time has passed from the quarterly closing at TMDCs and after confirming the sales numbers have been reached the planned target, the collaborating dealers return certain percentage of products from the large orders they placed right before the quarterly closing, so the dealers' financial burden would be alleviated. The reason for returning only portions of the large orders instead of returning all the ordered quantities is because normally over the course of several weeks a certain percentage of the artificially placed order does become a real order since the consignment sales occur at hospitals daily basis. The 100 percent return of the artificially placed order becomes no longer necessary by the 2nd or 3rd week into the following quarter's end. This phenomenon was observed for eight years during 2007 ~ 2014. The phenomenon was observed in China and Korea in relatively higher in frequencies than other countries, while the phenomenon exist in all other countries to varying degrees.

Bonding between the Dealers and the Hospitals

This practice of strong bonding between the local dealers and hospitals on a regional basis is particularly strong in Japan, although the phenomenon is observed in all countries in Asia. In Japan it is extremely difficult or practically impossible for TMDCs to sell products directly to hospitals except in rare independent cases in large metropolitan cities

like Tokyo or Osaka. This traditional bonding between the hospitals and the dealers in Japan is not practiced for helping each other's balance sheets in collusive manner but to maintain the tight business relationships between the hospitals and their preferred dealers. The tight alliance between the hospitals and dealers inherently blocks the penetration of the local markets by 'outsiders', not necessarily the foreign companies only but it also effectively blocks the domestic dealers from outside the regions. The local dealers maintain long-established commercial relationships with hospitals in regional prefectures throughout the country. The Japanese medical device market is a hospital-designated dealer business model. For this reason, it always has been dealer model since the inception of all TMDCs' establishment in the country.[110]

Pushing-Out Practice

This dictatorial commercial practice of large corporations exerted upon dealers and distributors is widespread in Korea. The literal translation of Korean word, *"mil-uh-nae-gi"* to English is *"pushing out"* which connotes the large companies' sales practice of allocating 'minimum sales quota' to distributors against their will or irrespective of their sales capacities. Large corporations or manufacturers of popular products, usually *"Jaebol"* or conglomerates, impose 'minimum sales quota' on each individual distributor. If a distributor fails to achieve the required minimum sales in a given period, the distributor is expected to purchase the 'balance' with their own money, or the

[110] The information regarding Japanese regional bonding phenomenon between the dealers and hospitals are well known fact in the medical device industry. The author has hands-on, personal experience and acquired knowledge in the characteristics and practices in Japanese medical device business through his almost eight years of direct and dotted-line professional and reporting relationship with his Japanese colleagues from 2007~2014 holding various levels of managerial capacities in sales, distribution and logistics.

distributor will be under threatening pressure for involuntary termination of the distribution contract by the large corporations. The headquarters of TMDCs are not keenly aware of their own participation in this unethical "mil-uh-nae-gi" or "pushing-out" practice in Korea. The act could even be illegal depending on technicalities such as degrees of coercion, duration, severity that have been forced upon. TMDCs' Korean subsidiaries do practice 'Pushing-out' despite their headquarters' strict compliance requirements. However, it is less likely for a transnational corporation to engage in the practice when an expatriated manager from headquarters runs the country business. It is not to imply that no American or European manager would commit any unethical practices in commerce, but it's unlikely or less likely for an expatriated manager to engage in collusive activities such as "Mil-uh-nae-gi" than locally hired managers, largely because of their unfamiliarity with local culture, practices and language. In addition, the expatriated managers eventually return to their home countries and can be held liable retroactively upon his or her repatriation. They can even be prematurely repatriated by their employers for a disciplinary action depending on the severity of the conduct.[111] On the other hand, locally hired general managers are more likely to participate in the customary business practices of the land due to their close familiarities and kinships with the local customs, practices and language. It is particularly so when

[111] The Foreign Corrupt Practices Act of 1977 (FCPA) (15 U.S.C. § 78dd-1, et seq.) is a United States federal law known primarily for two of its main provisions: one that addresses accounting transparency requirements under the Securities Exchange Act of 1934 and another concerning bribery of foreign officials. All American persons (individuals and corporations) are subject to "The Foreign Corrupt Practices Act" of 1977 (FCPA) when an act involves local government officials. [1] The Act was amended in 1988 and in 1998, and has been subject to continued congressional concerns,[2] namely whether its enforcement discourages U.S. companies from investing abroad.[3] ^ Funk, T. Markus (September 10, 2010). "Getting What They Pay For: The Far-Reaching Impact Of the Dodd-Frank Act's 'Whistleblower Bounty' Incentives on FCPA Enforcement" (PDF). White Collar Crime Report. Bureau of National Affairs. 5 (19): 1–3. ^ LeRoy Miller, Roger (2011). Business Law Today: The Essentials. United States: South-Western Cengage Learning. p. 127. ISBN 1-133-19135-5. a b Graham, Bradley, Stroup, Caleb (2016). "Does Anti-bribery Enforcement Deter Foreign Investment?" (PDF). Applied Economics Letters. doi:10.1080/13504851.2015.1049333. https://en.wikipedia.org/wiki/Foreign_Corrupt_Practices_Act

such practices are considered unethical but not illegal in the country. Even when a local country manager is caught in unethical or corrupt conducts forbidden by the headquarters' policy, there is not much the transnational employer can do locally if the act is not illegal in the country. The most severe disciplinary action the employer can take is to let the person go for violating the company's compliance policy. Usually if a situation comes to that point at a subsidiary it becomes too late and the damage has already been done to the organization.

Paper Companies

Hospitals in China and South Korea are permitted to register and run only as non-profit organizations although the Korean government is examining a feasibility to allow "for-profit" hospitals within a specialized Free Trade area at the country's southernmost island of Jeju, mainly targeting foreign medical tourism. Hospitals, like any other organizations, must maintain a healthy financial balance or at least maintain the financial solvency to continue to be in existence. In any organizational operations, certain miscellaneous expenses such as employee training, seminars, luncheon meetings, business travels etc. inevitably occur. These costs are not direct input costs for production but are still considered necessary expenses in operating ordinary organizations. Thus, business corporations allocate budgets for discretionary expense accounts to support such peripheral activities. Unfortunately, there is a little to no expense accounts for discretionary spending in 100% non-profit hospitals in Korea although the hospital operations inevitably incur such miscellaneous operating expenses. Therefore, in order to secure the financial resources to fund such expenses Korean hospitals create their own

'paper agents' who are responsible to supply hospitals the funding for miscellaneous expenses that can't be reimbursed by government so that hospitals can maintain black ink or at minimum to keep the non-profit organization financially balanced. These *paper agents'*, empowered by hospitals, generate money by forcing the medical device makers and pharmaceutical suppliers to surrender a certain percentage of their revenues made from sales to the hospitals to the paper agents. In other words, the paper companies charge medical device and pharma suppliers a certain percentage of their sales as a required condition for doing business with the hospitals. The agents then fund the miscellaneous discretionary expenditures of the hospitals with the percentage taken from the medical and pharma suppliers. Its original intention perhaps was to just cover the miscellaneous discretionary expenses under the inflexible non-profit accounting system of the country, but the practice has been blown out of proportion over the past several decades and became a de facto money-making means for hospitals in Korea today along with the funeral services the hospitals render to the families of deceased patients on the premises. (In Korea, virtually all hospitals run for-profit funeral service at the same time) It is not an exaggeration to say the Korean hospitals became de facto for-profit organizations by expanding these practices while technically remaining 100% non-profit by law. This issue will be elaborated in the case study (Chapter 5) because the practice is far more *systematically* permeated among hospitals in Korea than anywhere else in Asia.

Conscious Parallelism

The pre-coordination of bidding prices among dealers occur usually during the tender processes at government-owned hospitals in Asian countries because privately-owned

hospitals usually do not purchase devices through the competitive bidding processes. This "conscious parallelism" occurs because the minimally invasive surgical device market is an oligopoly of several US based medical device corporations. When medical devices being procured by a hospital supposedly come from four local dealers each of whom represent four TMDCs, for example, they could possibly pre-agree not to bid any lower than certain amount in tender process. There are multiple benefits the dealers gain by participating in such activity in a concerted manner. First, the dealers jointly lead hospitals to pay higher prices by eliminating the competition, otherwise a proper tender process would naturally lead the bids to lower prices, as the competing dealers try to undercut one another. Second, the dealers coordinate to help one dealer win a contract at a certain hospital when a specific dealer has a winning edge with a hospital anyway due to specific advantages, e.g a logistical or location specificity or an advantageous personal relationship of a dealer at a specific hospital over other dealers. The dealers who helped one dealer in one tender expect the beneficiary to return favors next time around at another hospitals' bidding processes. The dealers take turns in doing such "you scratch my back and I will scratch yours" type of collusive practice jointly at different hospitals around the country whenever such multi-coordination makes sense for all of them.

Corruption

The single biggest source of corruption the medical device makers and pharmaceutical firms face is the physicians who request monetary kickbacks in return for products, i.e. for using medical devices of specific companies or prescribing drugs of specific pharma companies. Sales reps confess that a significant number of doctors ask for under-the-table

money in exchange for prescribing drugs or using medical devices. Such proposals are usually made in very discrete and secretive manners. Some doctors who are emboldened and immunized by the accustomed practice, even request sales reps to pay specific amount for each device they've consumed. The most expensive devices used in minimally invasive surgeries are drug eluting stents or DES for cardiology procedure which the reimbursement price ranges approximately between $1,000 ~$3,600 per stent depending on the countries' maximum reimbursement prices. Often doctors specify the kickback amount they want per stent. The usual ranges of kickbacks per one DES are somewhere between $200 ~$500 in Korea. The number of DES required for a cardiovascular procedure or PTCA differs on the size of lesion but normally requires more than one stent.[112] Considering the average number of stents consumed per procedure is about 2~3 stents, doctors want over $1,000 per one procedure they perform.[113]

This type of corruption may also exist in America and in Europe. However the extremely subtle ways in which Korean dealers or distributors approach physicians, the complex customary practice of giving *"duhm"* or "extra" when literally translated (see the footnote), delicate and idiosyncratic relationship dynamics among doctors, paper agents, hospitals and the language barriers make the TMDCs' direct involvements in the practice very difficult.[114] This is the single largest reason, besides the operational

[112] U.S national Library of Medicine, Percutaneous transluminal coronary angioplasty (PTCA) is a minimally invasive procedure to open up blocked coronary arteries, allowing blood to circulate unobstructed to the heart muscle. https://medlineplus.gov/ency/anatomyvideos/000096.htm

[113] This information was obtained through personal interviews with number of sales reps during 2007~2014. They indicated that there are significant number of doctors who view sales reps from pharmaceutical and medical device companies as 'business' partners and try to negotiate the kickback amounts for drug prescriptions or for medical devices.

[114] "*duhm*" is a Korean word for 'extra' or 'additional' if directly translated. The "duhm" giving or "additional" giving culture is a traditional practice in Korean society that's deeply permeated in personal relationships, private and public protocols, commercial exchanges. The duhm giving practice in Korea refers to the practice of seller

complexities of consignment sales, why the transnational companies prefer to employ the indirect business model that keeps the end-customers in arm's length in Asia despite the significant loss of revenues to middlemen.

Complaint Returns. As explained in the previous section, the term 'Complaint' in the medical device industry refers to governmental regulatory measures intended to reduce patient risks. Once a complaint case is reported, the medical device manufacturers must follow through all of the procedural steps mandated by FDA regulatory compliance requirements. For example, when a physician claims a catheter is overly flexible at certain degree, then it's defined as a 'Complaint'. Even when an employee of a medical device company hears or notices a certain trend or a pattern of failures on a device, then it also meets the definition of 'Complaint'. When a complaint is detected or seen by a medical device company employee, the employee must report the incident to RAQA department and the device in question must be called back to the device companies' warehouse for QA examination. Then the report triggers QA to follow the ensuing steps in accordance with standard operating procedure (SOP) for 'Complaints' which may include CAPA[115] or report to FDA if QA determines such escalations are appropriate depending on the nature and severity of the case.

As a rule, when the device in question is taken back to device maker's warehouse

giving something additional to buyers who buys frequently or a large quantity. In hospital industry, the cultural practice causes the doctors and nurses who frequently use a lot of devices of a specific device maker to feel that they are entitled to receive something extra from the seller. Conversely, the sellers feel obligated to give "duhm" or something extra to those doctors and nurses who frequently use their products.

[115] CAPA (Corrective Action Preventive Action), USFDA "The purpose of the corrective and preventive action subsystem is to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence. Verifying or validating corrective and preventive actions, communicating corrective and preventive action activities to responsible people, providing relevant information for management review, and documenting these activities are essential in dealing effectively with product and quality problems, preventing their recurrence, and preventing or minimizing device failures. One of the most important quality system elements is the corrective and preventive action subsystem." https://www.fda.gov/iceci/inspections/inspectionguides/ucm170612.htm

as a ‘complaint’, the device maker replaces the unit with a brand-new device. The strict compliance for handling ‘complaints’ cases may be inappropriately used by customers in direct business model. For examples, 1) extraordinarily large numbers of ‘Complaint’ cases can emerge (actually do emerge at times) only at certain hospitals, or in certain regions or a country while ‘Complaint’ returns of the same product in other locations (hospitals, regions or countries) were extremely rare. 2) the unnatural timing of sudden surges of ‘Complaints’ in the same locations, e.g. a sudden increase of ‘Complaints’ that begins with the changed (new) physician at a hospital or surge that begins with business model change in the same geography. When dealers or distributors want to get a free replacement unit for a damaged or expiring DES, all they need to do is to ask a collaborating doctor to sign a device manufacturer’s Complaint Form. The signed Complaint Form with some blemishing or tainting description of the device entered by dealers or distributors gets submitted to the TMDC. When sales reps and dealers outsmart the employees in customer service and distribution departments at the TMDC, free units get shipped to the dealer as complaint-replacements.

To summarize the chapter, the findings confirm the insurmountable magnitude of complexities in consignment operations including constant usage data and documentary reconciliations, infamous unbilled accumulation, frequent product scraps are so overwhelming that the level of endogenous barriers actually do reach the point that hinders the efficient back-office administration of TMDCs, even severely affecting the lower level daily routine duties. Indeed, the managers at TMDCs view the intensity of the operational problems along with frequent write-offs as the main endogenous barriers that hinder device makers to build their own direct operations.

On the other hand, the difficult to understand cultural peculiarities of local countries, idiosyncratic processes and procedures at individual hospitals, corrupt and collusive commercial protocols and practices between the sellers and buyers are the common exogenous barriers for TMDCs in accessing markets directly. Even if the magnitude of the endogenous barriers is immense, the endogenous barriers are inherently within the managerial domain of the firms and such problems can be overcome depending on the managerial capability of the organization. The exogenous barriers are, however, external attributes to the TMDCs that come from outside the domain of the managerial controls of the firms. While the severity of the endogenous barriers alone is believed to sufficiently high to hinder the direct operations of TMDCs, the exogenous barriers too are equally problematic barriers for TMDCs to overcome directly. The combination of the endogenous and the exogenous barriers provide potent base for managerial decision for TMDCs to abandon direct business and ultimately resort to indirect model that utilizes distributors or dealers in Asia.[116]

From the Williamsonian transaction cost theory's standpoints, the TMDCs resort to indirect model (use market) due to the internal presence of bounded rationality and opportunism and the absence of any transaction factor that may enable hierarchies more efficient than market by raising transaction costs to create market failure. Hence, the vertically integrated hierarchies are inefficient in building their own capability to distribute medical devices which ultimately compels TMDCs choose dealers and/or distributors in market to sell products on their behalf. Williamson may also say TMDCs

[116] For examples, the infamously known "used-but-not-yet-billed" issue (or unbilled), customized invoicing according to varying discount rates and differed payment terms per hospital, unreported usages, issuance of the government mandated "Official" invoice in addition to commercially used billing invoices, e.g. separate VAT invoices and the list goes on.

even lack an asset specificity that effectively locks them to build its own a distribution capacity within the organizational boundary because doing otherwise can't happen without incurring a loss.

From the standpoint of Lazonick's theory of innovative enterprise, the neoclassical approach of the transaction cost theory limits the interpretation of the economic phenomenon, i.e. the medical device firms' penchant for indirect model, within the confined notion that excludes any possibility that may affect the behavioral characteristics, cognitive limitations of economic actors. It does not consider the technological changes that occur over time either. The logic of TIE would first questions the presence of the firms' strategic decision that allocates the resources to develop capability that enables the firms to compete. TIE would then check the TMDCs' organizational learning and developmental processes of the necessary capability with transforming technologies, i.e. the in-house distribution capability in the countries where TMDCs conduct or plan direct business, that create value which may enable the firms to access market directly. Then TIE would examine whether TMDCs have financially committed to sustain these entire processes or not until the established competitive capability begins yielding financial returns. In other words, the presence or absence of the *social conditions* of the TIE, namely *strategic control, organizational integration and financial commitment*, must first be examined to identify the causes for TMDC's penchant for direct model in Asian market.

CHAPTER FOUR

The Organizational Structure and the Business Models of TMDCs

This chapter reviews the transnational medical device corporations' organizational structure in Asia as well as the respective duties and responsibilities of their functional departments in operating direct model as well as the intertwined relationships with their local intermediaries and hospitals. The chapter discusses the vivid details of the cross-departmental issues and the tacit knowledge residing on the borderlines between the different functions and departments as well as the relationships between the processes and procedures of the different types of business models and the areas of potential improvements in the TMDCs' subsidiary management.

Transnational corporations run business in Asia through their locally established subsidiaries except in the 'small' markets or countries where they do business via local affiliates or associates.[117] As the minimally invasive device businesses grow in Asia, so do their strategic challenges. The managers must deal with the vastly different cultures, customary practices, and hierarchical dynamics in each country. The tacit business practices and evasive processes rooted in complex interrelations among transacting parties in Asian markets are not easily understandable or even visible to transnational or multinational corporate managers. It is, however, not only the managers at global

[117] 'Small Markets' or small countries refer, for the purpose of the study, to the countries where healthcare spending is negligibly small for TMDCs' business operations, i.e. less than $500 per capita or $10billions in total such as Indonesia, Philippines, Malaysia, Vietnam and etc.
(World bank, IBRD, IDA., https://www.emergobyul.com/resources/worldwide-health-expenditures)

headquarters who do not understand the varying practices of the different countries but also the local managers in the subsidiaries who face information asymmetry, particularly in day-to-day operational details at hospitals.

Departmental Walls

The supply-chain or distribution managers (or operations managers) in direct model may know the administrative process or procedural details, logistical idiosyncrasies at the various levels of functions and hierarchies within the client hospitals. For example, the medical devices for consignments must be delivered to hospitals' purchasing or receiving departments first in certain hospitals according to their internal procurement procedures whereas the devices are normally delivered directly to the consignment locations in Cath-labs in almost all hospitals. Other examples of distribution idiosyncrasies are the varying best time ranges to perform consignment cycle counts, best routes and shortcuts between one consignment site to another within a maze of the same hospital. This is true especially when the consignment sites are located at old, annexed, redesigned or restructured buildings. The supply-chain staff may also know the best time and day to run the second consumption check of the week or of the day to quickly replenish the consumed devices at each hospital. These are critical information for the sales and marketing managers. But sales and marketing do not necessarily know such data or information because sales reps are closely associated with physicians who are ordinarily not interested in or privy to ins-and-outs of the hospital-logistics processes or procedures. The operations managers, however, are privy to such information through daily routine activities and dialogues with consignment analysts, inventory analysts or

logistics specialists. These employees' primary duties are to check, replenish, and manage the consignment inventory by interacting with nurses, technician and purchasing staff in the hospitals. The managers of the two different functional departments (sales and distribution) don't necessarily talk to each other or share such the information often enough because they work within their respective departmental boundaries. The information asymmetry or informational gaps between the critical functions or departments in the subsidiaries are not just a matter of improving the cross-departmental communication. Rather, it is a chronic structural problem borne by inherent systemic imbalance created by the disintegrated '*financialized'* organizational structure of the subsidiaries influenced by the global and/or regional headquarters.[118] The incentives, responsibilities and authorities within subsidiaries are often not assigned or aligned according to the corresponding performance, and relevant functions and duties. These points will be further examined in the following sections.

Financialized Structure

The organizational structure of subsidiaries is not free from their US headquarters' or parent companies' popular corporate ideology of *maximization of shareholder value (MSV).*[119] The *MSV* spirit of the headquarters cascades down to the

[118] Financialization refers to an economic pattern of making money through maximized financial means rather than through production of goods and services or exchange of trade. William Lazonick in his 2010 "Innovative Business Models and Varieties of Capitalism: Financialization of the U.S. Corporation." Harvard Business History Review, 84(4), 675-702. doi:10.1017/S0007680500001987ok Volume 84, Issue 4 (Business History and Varieties of Capitalism) described, in Abstract of the article that, the Financialization as "The financialization of corporate decision-making under the new paradigm has been the prime source of inequity and instability in U.S. economic performance over the past three decades. As manifested in outsized executive pay and massive stock buybacks, the financialization of the U.S. corporation threatens long-term economic prosperity."

[119] William Lazonick & Mary O'Sullivan, Maximizing Shareholder Value: A New Ideology for Corporate Governance, ECON. & SOC'Y 13, 14 (2000); Lazonick, Fragility, supra note 1.

internal structure of their subsidiaries in Asia. The first-in-command in a TMDC's Asian subsidiary is typically called 'country director' or 'general manager' referring to the head of subsidiary. Then the second-in-command in each country and in regional headquarters are the heads of finance. For the organizational structure of regional headquarters that oversees entire continent's business in Asia, there could be legitimately justifiable reasons for a finance person to be the second in command to coordinate and oversee the financial activities of all countries in the Asia-Pacific region. For example, the importance of strict compliance of subsidiaries with various country, regional and international taxation laws, and foreign exchange laws in the region as well as the planning, executing and coordinating the regional revenue targets along with financial oversight of each country in the region.

However, it makes less sense for a finance person to be the second-in-command in every country office where the primary duties are inherently to 'import and distribute' products. The main activity of subsidiaries is selling the imported devices via 'consignment' operations. The organizational structure of the subsidiaries in each country appears to be the identical duplication of the administrative structure of their global and regional headquarters where there is no sales or distribution operations take place. This proves the headquarters' unfamiliarity with the core activities and main duties of the respective functional departments in the subsidiaries in each country. There seems to be no other logical explanation for why a finance head uniformly holds the second position in the hierarchy of every country. Nevertheless, all TMDCs' country-offices (subsidiaries) are organized in such manner, i.e. a country director as the head of the country, finance director as the second-in-command, and then the rest of the directors or

manager such as sales and marketing directors, supply chain directors, distribution officially report to the country director according to the organizational chart but, in practice, they often report to finance director within countries.

The problem with this arrangement, especially in very submissive Asian culture, is that even the employees in other non-finance departments such as sales and marketing, supply-chain, customer service, distribution, consignment management and RAQA view the finance head as the *de facto* general manager or president of the subsidiary.[120] The reason is that top bosses in East Asian organizations, more so in China and Korea than in Japan, often delegate their routine duties to the second person in command. To a heightened degree in East Asian culture, the top boss is reserved for '*really'* important decisions or final decisions while the daily routines, almost all administrative decision makings and approvals, are delegated to the second in command. In such culture, the entire employees in subsidiaries naturally regard the second-in-command as the ultimate authority in the country and submit to or subordinate to the finance manager over their own department managers, especially when there are differences in opinions or directions exist in carrying out their departmental duties although such duties are not related to financial functions or responsibilities.

This finance-centered organizational structure inadvertently sets up the '*real'* organizational hierarchy and creates a structural imbalance in the organizational checks and balances among the functions and departments across the subsidiary. A number of TMDCs' Asian subsidiaries' reporting structure formally require other functional departments report to the head of finance. For example, distribution manager reports to

[120] RAQA- a widely used colloquial expression describing the combination or Regulatory Affairs and Quality Assurance departments in medical and pharmaceutical industry.

finance manager instead of reporting to the general manager of the country. In case of a direct business model, the consignment managers are the de facto business pillars of the organization that import, distribute, including actual sales, products to bring revenues into the organization. Having the departments or managers who oversee sales or consignments report to the finance manager who are responsible to calculate numbers after the facts (sales) is detrimental to the health of organizational integration in the long run. The disproportionately dominating role of the finance department, which is not involved in any revenue-generating activity, is one of the main causes for the chronic departmentalism and consequential interdepartmental conflicts in the subsidiaries.

Finance Department and its Operational Relevance

The department name "Finance" and the title "Finance Manager" or "Finance Director" do not accurately reflect the actual duties and responsibilities of the position or the department at the country level. In fact, the title "Finance Manager or Director" distorts and exaggerates the actual duties finance managers undertake in country-operations. First, there is a little to no 'financing' activities in the subsidiary operations. The finance departments at corporate headquarters engage in real 'financial' activities and assume financial responsibilities such as planning and executing capital investments, taking short-term and/or long-term loans from lending institutions to finance the company namely the debt financing or even perform equity financing through issuing share of company stocks and so on.

The finance departments in Asian subsidiaries do not issue shares of company stocks or repurchase shares of company stocks. They are not charged with responsibility

of sourcing capital to fund the company either. They do not perform either equity financing or debt financing of the company. They are almost never responsible for capital sourcing of any kind, not even in the form of bank loans of any significant amount. The subsidiaries are seldom responsible for capital financing through any investment banks at the local country level. The subsidiaries are allowed a very limited amount of financial flexibility to make local investment from the reserves. For example, purchase of corporate sports club or golf club membership for internal use, such as to reward outstanding employees by letting them use it for once or multiple times a year instead of offering cash bonuses or to entertain customers with a golf rounding in East Asia.(see the foot note for the peculiarities of the golfing in East Asia).[121] It is a well and widely known fact that corporate golf club memberships are often used as incentives to recruit local executives in Japan and South Korea where golf is extremely popular but prohibitively expensive for ordinary people.

The point is that, if purchasing sports club or golf course membership is considered a capital investment, such activities are the only types of limited "finance" activities the subsidiaries perform with a little flexibility to use the local reserve accounts.

[121] In 2007, an ordinary golf club membership (low to middle level courses) cost in Korea was around $US300,000. High-end golf club membership in the country was and still is well over $1million dollars. The average green fee for one rounding was around $150 per member and $250 per nonmembers at the low-end golf clubs. All golf courses in the country were member-only private clubs in Korea until early 2000s. The only way for an ordinary person who doesn't own a golf club membership to play golf in Korea was to be invited by a member as his or her guest. Unlike in the US where one can play golf by himself or herself often during off-peak hours, even a member is not allowed to play golf alone in Korea. It is still a mandatory for a member to book a rounding for a four-person group only which cost about US$1,200 per rounding, usually more than 7~8 weeks prior to the intended rounding date. A member is allowed to play in a three-person group (the member and his two guests) by paying penalty (about $100-$250) to the club and a two-person rounding is never allowed whatso ever. It is a well-known and a very common practice for corporations in East Asia (China, Japan and South Korea) to offer private sports club membership or golf club memberships as a part of the renumeration package to recruit executives. Companies use corporate golf membership to incentivize or to reward outstanding employees by allowing them to use it for one-time or several times with fees paid by the companies. Large number of companies subsidize green fees to their employees up to $100-$150 per a rounding up to 4 times a year.

There is almost no *'real'* finance activity that subsidiaries undertake at local country level. The primary "*financial*" duties and responsibilities of finance managers at subsidiaries, at best, are overseeing Account Receivables and Account Payables, deploying long-term capital locally so that they can secure certain level of financial liquidity, planning cash flows from the principal deposits including possibly some insignificant amounts of interest income and account receivables and to compare, identify and ready for future expenditures for variable costs such as incentives, events and projects. These duties and responsibilities are fundamentally "appropriating" or "planning" funds and budgets rather than capital investment or financing. The more appropriate name for finance departments in the Asian subsidiaries of TMDCs would be the Accounting and Budget departments.

The more appropriate title for the heads of finance departments at TMDCs in Asia would be "Accounting" manager or "Accounting and Budgeting" director depending on the size of the individual subsidiary. There is no argument on the importance of sound and balanced financial controls in business management. For that reason, the structural positioning of the finance head in one of the highest executive positions can be justified at regional headquarters level but not at the level of every subsidiary in each country whose main activities are to "import and distribute" the finished products. The financial and expense oversight of the subsidiaries can be administered by the reginal finance comptroller. Or organizational adjustments can be made in subsidiaries to have an independent comptroller whose duties are to inspect, supervise and investigate all in-country finance related activities including the general managers conducts. The finance managers, who are neither sales and marketing experts nor consignment business or

distribution experts, to be the second in command may tighten the organization financially but discourages growth potentials.

Regulatory Affairs and Quality Assurance

The quality and regulatory affairs departments are one of the most important departments in medical device firms because of the paramount importance of human safety which is regarded as a 'divine' duty in the heavily regulated healthcare industries. To achieve this 'divine' duty, medical device firms allocate large resources to operate Regulatory and Quality Affairs departments. Regulatory Affairs department (or RA) is inherently a government affairs department because of its nature of duties and responsibilities. All regulated industries such as banking, energy, pharmaceuticals and medical devices place RA as one of the most important corporate functions within the organization. The successful RA operations, however, is the effective application, interpretation and communication of the regulatory requirements with the relevant government agencies and also with the internal customers, namely the folks at sales and marketing, manufacturing, distribution etc.

The duties of RAs at international subsidiaries are inherently different from those of RAs in the global headquarters. The regulatory affairs at headquarters or in the country of origin of the products must execute and follow through the complex, lengthy development process of R&D and manufacturing of devices by supplying, communicating and complying with the discovery, development data, dossiers managing all the accumulated clinical tests and registration approvals including post market follow

ups. But the RA duties in subsidiaries in the importing countries are fundamentally "*ex post facto"* follow-up documentary work with the local government for the already approved devices at origin. Even a 'shelf-life extension', which is one of the most important post market duties of RA in headquarters, is not relevant in subsidiaries because all governments in Asia adapt "honoring the origin" rule.[122] The general rules of "honoring the origin" in considering a shelf-life extension for medical device in importing Asian countries are explained in the footnote.[123] Therefore, the single most significant RA duty in the importing subsidiaries in Asia is to register the already approved devices with the local government to secure import licenses. To achieve it in timely manner, RAs in subsidiaries coordinate the planned dates for import or launch with local Sales and Distribution departments and administratively link the RA at headquarters and the local country government agency at best.

The fundamental functional base of Quality Assurance (or QA) is derived from the corporate improvement process. QA makes sure of the internal and external alignments of management, products, processes and procedures and including the suppliers' quality compliance to the quality standards of the company. QA oversees

[122] Shelf-life extension is a set of process and procedure that device makers may take at FDA to request an extension of a shelf-life of a product after the product's shelf-life has already been determined by FDA. The extension can be applied for a product that's been previously approved with a shorter shelf-life by FDA when newly proven data and lab records that support and justify the longer shelf-life of the product become available.

[123] The "honoring the origin" means that a consideration for shelf-life extension of a device in Asia depends upon the cases of precedence at FDA for the same device in case of US-origin products. The governmental agencies in importing countries follow and exactly repeat what FDA did or didn't do. It means if FDA has approved the extension of a device, the equivalent agency in the importing country can consider an extension for the same device. If FDA has rejected an extension for a device, an importing country's equivalent agency will also reject the extension request for the same device.

CAPA,[124] product recalls, product stoppage, obsoletes, QNs,[125] mandatory scraps of products that do not meet the Quality requirements to ensure the human safety is not compromised because the devices get inserted or implanted into human body. For such reasons QA, along with RA, is also undoubtedly one of the most important functional departments in the medical device companies. The catch, however, is that all of QA activities required for production of the devices (including the sterilization, final outer packaging for selling) have already been completed at the origin before departing the manufacturing site for international destinations. The same *ex post facto* applies in local QA affairs, as it does in RA, except the 'post market' follow-up processes which are mainly managing product complaints, recalls, obsoletes, expired, damaged, nearing expiry, and making sure such products are scrapped in timely manner so that such devices would not be circulating in the market. The post-market centered RA and QA functions are usually combined as one department in subsidiaries. Often, not always, one person wears two hats as the head of RA and QA. The head person, supported by one or two person-staff, is the entire department of combined RAQA in subsidiaries where the total annual revenue is generally less than $100 million. The consequence of combining the two different but related functions into one department creates an enormous concentration of authority. The managers at two different departments of RA and QA at headquarters, who are not keenly familiar with the nature of RA and QA duties in

[124] CAPA – Corrective Action Preventive Action (CAPA) FDA "The purpose of the corrective and preventive action subsystem is to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence." https://www.fda.gov/iceci/inspections/inspectionguides/ucm170612.htm

[125] QN or Quality Notification- a process, that all medical device firms perform in accordance with the FDA regulations, to see if there has been any new alert, warning, stop order or recall order issued for post market products either by FDA or by the device makers internal RA/QA to take appropriate actions including product recall if necessary.

importing countries, provide very strong direct administrative, managerial supports to RAQA departments in subsidiaries thinking that their duties and tasks may be as stringent as those in the origin country. The mixture of the strong industry culture of human safety endowed with the direct authoritative supported by the headquarters and the submissive Asian culture, creates managerial abnormalities in local country-operations. The common problems borne by the disproportionately warranted local RA and QA are as follows;

A) Premature returns on near expiry products from consignments Medical device expiries are often expressed in 'months' rather than 'dates', e.g. as "July 2020" instead of "July 25, 2020". The absence of 'date' in expiration prompts RA/QA to call the products nearing expiry into the warehouse several months prior to the actual month of expiry. RA/QAs claim that in order to be compliant with RA and QA policies the products nearing expiry must be called back to the warehouse at latest by the end of the preceding month of the month of expiry. Because RAQA managers believe the device shouldn't be used in the very month of expiry even though it is perfectly acceptable both legally and medically to use the device by the last day of the expiring month. As a rule, RAQA gives two-month notice to distribution and sales to coordinate the pulling back of the devices nearing expiry from consigned hospitals. In addition, logistics of physical gathering, actual arrangement of return shipping of those products at hospitals need another one month. Thus, operations department that arrange the return of the devices should consider "all of the above" and must issue return order at least 3~4 months before the month of expiry just to be on the safe side.

B) Making already short shelf lives even shorter The longest shelf life of DES is 24 months, rarely 36 months or longer, from the date of manufacturing. The manufacturing facilities are normally spread around the world mainly according to differing tax incentives of the different devices, such as Central America, Ireland, or several midwestern states of the United States. The international shipment flows are set up not only according to the logistical transportation flow but also according to the systemic flow of commercial relations that's been arranged via intermediate shippers (internationally incorporated entities to receive and re-ship products between the origin and destinations) to save tariffs and taxes even though all parties involved are owned by the same TNC. The flows are usually from Origin (manufacturing) – the Global Distribution Center (normally in Europe or US) – Final Destination in Asia. For this reason, it is not unusual that the remaining shelf life of a 24 month-item becomes 18~12 months or less by the time the products arrive in Asia. Hence Sales reps bears the burden of selling products with shorter shelf lives. However, such operational issues are usually not the main concerns of RA/QA personnel. Their main concern is to scrap the devices at least one month prior to the expiring month or even earlier to be compliant.

C) Overly Obsessive Cosmetic Appearance of Packages. The list of scrap reasons and the amounts shown in Table 2 are actual examples of typical monthly scraps of a transnational medical device company in 2015.[126] The types of scrap reasons, such as missing box, opened box or pen marks are mostly caused in hospitals, can be

[126] The examples in Table2 are the actual data of a major TMDC operating in Asia. For the purpose of protecting the privacy and to honor the confidentiality agreement with the research participant, the actual name of the company is not disclosed. The data, however, can be released upon request under a conditional confidentiality agreement.

reduced through customer education. But sales reps who face customers view such instructional comments to customers as taboo because sales reps view it as telling nurses and physicians what to do.

D) Demo Scraps When sales reps plan a product demonstration to physicians, the reps request the distribution center (DC) to release products for "demo" purposes. Then DC staff would pick products and modify the inventory status of the products from "saleable" to "demo" which gets processed through a virtual scrap procedure in the computerized warehouse management system (WMS) so that such products cannot be sold for human use. The monthly average demo sample scraps shown in the Table 2 is over $11,000 at manufacturing price.[127] People outside the company don't know the actual manufacturing cost of medical device due to the complex methods of calculating various costs. It is an internal rule, even within device manufacturers, for operations staff privy to the price details to keep the manufacturing prices to within the operations and the finance departments so that the business units, sales, and marketing would not know the actual manufacturing costs. This prevents the sales reps from offering large discounts to clients. Demo scraps are normally event-based scraps that happen irregularly according to arising needs, thus one cannot assume over $11,000 demo scraps are happening every month in an organization. Nevertheless, when converting the $11,000

[127] Manufacturing price or (expressed in '$ in mfg' or 'mfg$' in the industry) are the net production cost of a medical device calculated at manufacturing cost level. This doesn't include tariff, taxes, transportation costs of international shipping and in the destinations' domestic trucking costs and other international and local logistics costs, e.g. customs clearance brokerage fees, airport transfers, bonded storage, stowage and other miscellaneous logistics costs at destination countries. The gap between the manufacturing price and the selling price of medical devices are known to be very large. It is estimated that price gaps of the minimally invasive devices particularly are large, with industry consensus of ranging approximately 3~30 times between the two prices depending on the devices and price calculation methods of the individual devices. The price differences of DES or drug eluting stent are estimated to be 10~30 times and other non-core, accompanying devices for PTCA, angioplasty procedures are estimated to be 3~10 times between the manufacturing price and selling price according to the research.

manufacturing price to an average range of selling price, which is estimated 10 times the manufacturing price, it becomes $110,000. [128] The total monthly average of $125,000 can be translated to a $1.25million dollar loss in sales revenue in a month which is a significant number at a country or subsidiary level.

The purpose of the stringent RAQA standards is to ensure the patient safety by making sure only the medical devices in supreme condition get supplied to hospitals. When products return to MDCs' warehouses for any reason, QA performs strict inspections and scrap products mercilessly for nonconformity, i.e. small pen marks on the outer packaging, open box, no 'local labels',[129] no 'localized instruction' document[130] and even near-expiries. The issue, however, is that TMDCs do not apply the same stringent QA standards to the devices transferred to dealers and distributors even if the products' quality and safety responsibilities remain with TMDCs until expiry. TMDCs enforce the Quality requirements only within the boundaries of their own organization. QAs look the other way once products have been shipped to dealers and distributors. Therefore, the products under dealers and distributors are being handled under less stringent QA standards, making is easier for the middlemen to sell.

[128] As explained in "Manufacturing Price" the range of price differences between manufacturing prices and selling prices of medical devices are difficult to estimate because the prices differ widely depending on the inclusion and/or exclusion of the miscellaneous base costs in calculation. For example, a company decides to include R&D cost in the calculation of manufacturing price, then the mfg. cost can rise very high. But if R&D cost gets excluded from mfg. cost by a manufacturer, mfg. cost gets decrease significantly.

[129] Local Label or localized label refers to additional product labels that are usually affixed on the outer surface of medical device packaging of TMDCs in local country language after importation into a country or even before formal importation (customs clearance) in Asian countries in accordance with the importing countries' government labeling requirements.

[130] Localized Instructions., Local countries' Health Ministries, same as the local labeling laws described above in footnote#129, require imported medical products to affix 'Usage Instruction' in local language outside the packaging or have such document inserted inside the outer packaging such as 'Tenpubunsho' of Japan.

Table 2. Scrap Reasons

Scrap Types	Scrap Reasons	Amount (mfg$)
Expired & Short Shelf Life 67%	Expired Product	(60,571.17)
	Expired	(13,058.04)
	Short Shelf Life (close to its expiration date)	(5,372.34)
	Consignment Returns	(3,769.92)
	Obsolete Product	(1,019.49)
	Missing Box	(130.73)
Damaged 21%	Crushed Box/Pouch	(7,120.11)
	Torn Box/Pouch	(6,169.30)
	Damaged	(2,982.82)
	Damaged Product Label	(2,818.94)
	Bent Box/Pouch	(2,107.66)
	Temperature	(1,378.70)
	Water Damage	(1,299.99)
	Dented Box	(493.85)
	Open Box/Pouch	(925.99)
	Pen Marks	(790.84)
	Punctured Box/Pouch	(14.45)
Recall & Ship Hold 1%	Ship Hold	(709.58)
	Recall	(90.78)
Demo & Samples 11%	Demo Sample Request	(11,284.09)
	Scrap for Demo	(2,892.21)
Total Scrap		(125,001.00)

In identical cases of non-conformities in indirect model operations, the dealers and distributors simply close the opened boxes, re-apply local labels and insert instructions in the boxes and ask physicians to use the expiring products before getting their expiration date. No product that is subject to ‘immediate scrap’ by RAQA requirements, is ever scrapped by dealers or distributers. RAQA departments turn blind eyes to dealers and distributors or condone such ‘non-conformities’ knowingly committed by intermediaries.

TMDCs do not inspect, audit dealers or distributors to ensure the RAQA compliance in handling process and procedure of products although they inspect their third-party logistics contractors. In fact, dealers and distributors do not even have secured, separate warehouses for storing medical products which is normally required under dealer or distributor contract. Dealers and distributors usually keep products at vacant corners or by the sales reps' desks in their offices as a rule.

Sales and Marketing

Ideally the bona fide marketing departments should conduct, engage and lead the activities and processes for communicating, creating, delivering values for patients, the physicians and nurses, and help company identify values that really help patients.[131] The marketing in TMDCs' Asian subsidiaries is typically a small functional part, consisting of one or two persons, usually belongs to a business unit such as within interventional cardiology or the peripheral intervention department reporting to the head of the respective business unit. Thus, the study focuses on sales function for marketing activities of TMDCs in Asia are by and large limited to basic activities such as compiling and analyzing data related to customer segmentation, competitors' market shares and performances, market outlooks and so on. Listed below are the classic examples of organizational integration issues in Sales & Marketing departments at TMDCs in Asia.

[131] Marketing, "is the activity, set of institutions, and processes for creating, communicating, delivering, and exchanging offerings that have value for customers, clients, partners, and society at large." defined by American Marketing Association., https://www.ama.org/AboutAMA/Pages/Definition-of-Marketing.aspx

A) Late Coordination between Sales and RA When Sales plans to launch a new product, it is important to pre-coordinate the plan with RA at an early stage. The bureaucratic procedures RA must go through, e.g. product registration, obtaining import license from the local country authorities, can take at least few months on average or possibly a year. Even after receiving an import license, there are additional bureaucratic approval processes and procedures RA goes through with local governments in order for a new product to be sold in market. For instance, the reimbursement price negotiations to get 'maximum reimbursement price', price approvals, and the insurance pricing code registrations at respective agencies are the most important tasks that RA needs to follow up with respective government agencies until all the necessary approvals are received [132] Subsequently the approved insurance codes (maximum reimbursement price codes) must be posted in the government reimbursement system in order for Sales departments to start selling the devices. These processes are time consuming. However, the sales or business units often inform RA when they (business units) have made final decision to sell new products or when they receive the new product allocation approved by the pertinent divisions at HQ. The delays in new product launches caused by such timing gap between distribution allocation at HQ and the local country import license approvals open leeway to competitors. To

[132] The maximum reimbursement price refers to the highest possible price for a medical device that a registering device maker is permitted to charge customers, hospitals. The maximum reimbursement price is reviewed and approved by each national government in Asia. The product's present price ranges in the origin country market is one of the considering factors for determining the adequate price range for a newly registering device in a local country. In review and approval processes encompass activities such as the introduction of new device, its functions, and the usage, availability of substituting and complementing products and etc. The entire process of tug-of-war is conducted between the TMDCs and the importing government to 'negotiate' the MRP price for every new product being registered for importation in Asia.

make the matters worse, RA, an inherently bureaucratic department by their nature, sets their own licensing registration schedules according to the preferences and priorities of the governmental agencies, or their own departmental priorities rather than to the priorities of the companies. No one questions the delays in governmental approvals for registration, licenses or permits when RA says "It's not approved yet. We will contact the government agency and will get back to you."

B) Demand Forecast In order to arrange product imports in timely manner, the global supply chain also must be preemptively alerted so that the entire process gets aligned by pre-feeding the demand planners or inventory planners with the adequate forecast data so that the data can be, in turn, uploaded to regional and global planning departments in a proactive or at least in timely manner. In Supply Chain Management, the demand management is synonymous with the response management because the demand-driven operations require a remarkably short response time throughout the supply chain links, both upwards and downwards. Customers expect unanticipated demand changes to be accommodated in real-time, while the device companies need to ensure the responses are aligned with the internal processes and procedures all the way to the manufacturing. To be successful, the demand forecast must be calculated based on the on-going and current demand signals gathered with present and future indicators rather than passive past data. The sales or business departments seldom act preemptively to provide the current and up-to-date demand forecast to planning. The demand

planning departments of TMDCs in Asian operations today are in fact supply-planning departments at best.

C) Absence of lower level product information Sales and Marketing use 'Level4' data in their duties including in business planning for their quarterly or yearly demand forecasts as they are trained to face clients.(see footnote for Levels)[133] The operations departments such as distribution, supply chains including manufacturing that actually execute the forecasted plans, linked via corporate ERP or other planning system, use Level 6 data. Therefore, even if the sales and marketing provide complete business plan with forecast data to operations for execution, it's always only a half the data. The sales and marketing plan must be retranslated into Level6 for processing in the corporate ERP or in demand planning system to activate the upward supply-chain to manufacturing. This problem persists and repeats every year across TMDCs.

D) Financialized Business Planning. All subsidiaries of TMDCs submit their respective annual business plans to global headquarters every year. This plan is also called 'sales plan' or 'sale and operations plan' (S&OP) depending on organizations. The intensity of the financialized corporate governance is better seen during this process than any other processes across the TMDCs. The S&OP plans are expected to show progressively increasing revenue numbers year on year. Prompted by such corporatewide drives and expectations, S&OP are

[133] The product data of medical devices of TMDCs, like the products in other many other industries, are normally consists of 5~6 different levels of information regarding the product. For example, Level 1: Country of Origin (or manufacture), Level 2: Name of Manufacturer, Level 3: Product Family, Level 4: Product Name, Level 5: Packaging, Level 6: Product specifications and so on. The author made these Levels 1~6 here for the purpose of providing an idea on what the product information Levels are to readers. The actual granularity of the data on each Level can differ from company to company.

prepared first by the finance and sales departments. The managers think or have been trained to think that sales and finance departments should prepare the 'sales' plan at TMDCs and then subsequently inform the finished plan to the rest of the departments in the company namely the supply chain or distribution (operations departments) so that supply chain would plan the production, import and distribution of the products accordingly. The problem with this finance-centric S&OP process is that the plans built by sales and finance departments are 'dollar' amount-based instead of 'unit' or 'product' based. The dollar amount based annual business plan is not executable in the ERP or planning system because it lacks device sizes, UPNs.

What repeats every year with the annual S&OP process at TMDCs is 1) sales & finance departments complete annual business plan based on dollar amounts, 2) demand planner who executes (enters) the plan in ERP or in demand planning system receives the plan with no size, quantity, UPN data and reports the deficiency to the operations director 3) The head of operations directs inventory analyst, inventory planner, demand planer (all three are Distribution/Logistics functions that report to the head of Operations) to run the historical sales data per size, unit, UPN per month, quarter and year and simulate the new business plan against the actual performances of the preceding 2~3 years, 4) Head of Operations informs the heads of respective business units (Sales) and Finance that the new business plan needs to be adjusted to the simulated demand per size, unit, product turn rates per hospital with the new prices into calculation, 5) sale and operations convene to hash out the new annual business plan according to the forecasted and

simulated demands analyzed based on the usage provided by inventory analyst and demand planner per product sizes, units according to the expected inventory turn rates per hospital. The financialized culture compels TMDCs to process the annual S&OP building in inefficient and reversed fashion.

E) No accountability for unsold products. Every year during the business planning process (S&OP) across TMDCs, the intense tug of wars repeat between Sales, who demand ambitiously large quantities of product allocation (imports), and the inventory planners who asserts the justifiable quantities to be imported based on multi-year product sales data. However, the result of the wars is predetermined, the victory always goes to Sales. It's largely because the financialized management that focuses on maximization of revenues and profits incline towards the possibility of larger sales rather than the 'probable quantity demanded' which is analyzed and forecasted by professional inventory analysts. As a rule, country directors or general managers, the heads of country-business operations, are the sales reps who grew up the corporate ladders in sales and marketing careers who tend to lean towards supporting the ambitiously large business plan. This organizational imbalance in check and balance in inventory planning causes chronic and repeated overstocking of inventory at TMDCs' warehouses across Asia that eventually cause large, cyclical yearly scraps of unsold devices. Nevertheless, sales and marketing, who fiercely fight to obtain the overly large quantities of products allocated (imports) into the county, are not held accountable for the unsold products that eventually get scrapped. Headquarters direct the reduction of product scraps to operations (supply chain or distribution) and hold

operations departments who opposed the ambitiously large quantity imports accountable, not sales who demanded the large quantity that's unsubstantiated by professional analysis. The incorrect alignment of accountability and responsibilities with regards to inventory imports appears to be a calculated and deliberate carrot and stick strategy practiced by headquarters of TMDCs. The financialized global headquarters fear a possible discouragement of ambitious 'sales sprits' among their global sales force. But, simultaneously, HQs understand the overstocking of inventory is requested by sales departments and supported by the country general managers whose performance evaluations are primarily based on sales revenues. HQs recognize both the carrots and sticks need to be applied to subsidiaries for maintaining the healthy inventory. Therefore, HQs do apply carrots and sticks to the subsidiaries' management without mentioning the root cause or without aligning accountability with the right departments in fear of possibility to 'discourage' the ambitious sales force. From the subsidiaries' standpoint, however, always the carrots are applied to sales and sticks are applied to operations in inventory controls. The chronic problem this practice causes is that the operations managers who know the game think the corporate driven product scrap reduction campaign or so-called right-size inventory planning efforts as hypocritical rhetoric of the top management and do not take them very seriously.

The Business Models

The relationships of TMDCs with their end-customers and intermediaries are complex and differ depending on the respective business models. Along with the critical importance of fully understanding the granular details of the consignment operations, it is also important to accurately understand the intertwined relationships among sellers, buyers and their intermediaries for the accurate analysis of the problems in hand.

Table 3

Business Models of Transnational Medical Device Corporations in Asia

Business (Selling) Models		Definitions/Product Flow	In-Country Subsidiary Required	In-Country Warehouse Required	Selling through Consignment	Title of Ownership on products (commercial)	Title of Ownership on products (legal)	Direct Customer Contact	Complexity
Direct Model		TMDC imports and sells directly to local hospitals inside the country. (TMDC - Hospitals)	**Yes**	**Yes**	**Yes**	**TMDC**	**TMDC**	**Yes**	**High**
Indirect Models	**Global Distributor**	TMDC sells internationally to large global distributor(s) in a region of the world who then in turn sell to multiple countries in the region. (TMDC - Global or Reginal Distributors - Hospitals)	**No**	**No**	**No**	**Distributor**	**Distributor**	**No**	**N/A**
	Local In-Country Distributor	TMDC import devices and sells to local distributors in the country. Subsequently the local distributors sell to hospitals in the country. TMDC - Local Distributor - Hospital	**Yes**	**Yes**	**Yes**	**Distributor**	**Distributor**	**No**	**Low**
	Local In-Country Dealer	TMDC imports and conditionally sells devices to local dealers in a country.Then subsequently the dealer sells to hospitals. TMDC - Local Dealer - Hospital	**Yes**	**Yes**	**Yes**	**Dealer**	**TMDC**	**No**	**Medium**
	Selling Agent	Agents sell TMDC owned devices to hospitals for commission. TMDC - Hospital	**Yes**	**Yes**	**Yes/No**	**TMDC**	**TMDC**	**Yes**	**High**
Hybrid Model		Mixed selling model of partial direct and partial indirect model within a country.	**Yes**	**Yes**	**Yes/No**	**TMDC/Dealer**	**TMDC/Dealer**	**Yes**	**High**

Note: Distributors and Dealers are used interchangeably in the industry but there is a big difference in legal definition between the two subcontrators.

The Tables (Table3,4 and 5) have been made to show the different selling models of TMDCs in comprehensive manner as well as the complex '*real'* relationships of the parties in transactions to explain the operational challenges of consignment business amid the intertwined matrix of relationship among the parties in interests.

The Real Relationships

One of the most puzzling arrangements in the business practices in Asia is that TMDCs not only deliver products sold to intermediaries to the customers of the intermediaries, the end user, but also manage the product inventory of the intermediaries at the end using hospitals. Certainly the 'Bill to' and 'Ship to' parties can be different in shipping arrangement of goods in commerce. Normally when a dealer or distributor purchases products from a TMDC, the dealer or distributor who purchased the products own them as the shipping transactions are made. In such cases the intermediaries are shown as 'buyers' or 'sold to party' on documents (i.e. commercial invoices and packing lists) but in practice those intermediaries do not physically receive the products or don't even see the products throughout the entire process of the selling and delivery transactions from order placement to delivery of the products. (Note: not all cases are the same. There are variations to the arrangements which are explained in the Table 3)[134] The intermediaries in such arrangement are technical purchasers on paper but are not real purchasers of the products. The intermediaries are 'paper companies' that do not take any part in any actual transactions but still take commission from TMDCs.

Then the question becomes why would a TMDC pay such middlemen who do 'nothing' at all. Solving this puzzle requires an accurate understanding of their 'real' relationship by looking deeper into the details and their transactions among TMDCs - local country intermediaries - hospitals. One may think perhaps TMDCs can simply eliminate such paper companies and do business directly. But the matrix of relationship is

[134] The relationship matrix between the TMDCs and their intermediaries in local countries are complex, complicated multi-phased, multilateral relations. I devote a separate section exclusively for the definitions of different types of intermediaries as well as the complex relationship between and among all parties, i.e. TMDCs, dealers, distributors, agents, purchaser-designated suppliers, paper companies etc.

far more complicated than one may think. The ‘real’ relationship matrix of medical device firms with their dealers, distributors, paper companies and hospitals are complex and intertwined amongst all parties.

The relationship among transacting parties is simplified and summarized in Tables 4 and 5 on next page. The ‘official’ names of the paper companies explained in Table4 and Table 5 are either ‘billing agents’ or ‘purchasing agents.’ These paper companies are set up by hospitals as their front companies to generate profits out of hospitals’ purchasing activities. At times they could be independent agents who supposedly provide procurement service of medical devices, equipment and miscellaneous supplies for hospitals on the paperwork. However, these so-called ‘purchasing agents’ in fact do not engage in any purchasing or commercial activity on behalf of hospitals. Often the agent is a faceless, paper company that only exists in documents. Even when they have a physical location, their offices are located inside the very same hospitals that hired them, usually occupying a small space or just a desk at a vacant corner of the hospitals’ purchasing departments. At times there are independent billing agents that serve multiple hospitals and have their own offices outside hospitals. Usually, not always though, the heads or the owners of such agents are related to the owners or chairs of the serving hospitals’ boards of directors. How the system works is that a purchasing department at a hospital delegates billing service to its front company (paper company) but calls it a ‘purchasing agent’. The hospital directs TMDCs to issue billing invoices to its designated billing agent’s name instead of issuing invoices directly to the hospital.

Table 4

The 'Real' Relationships of TMDCs, Intermediaries and Hospitals in Indirect Model			
Parties in Transaction	**Roles (Who they are)**	**Officially sells to (technically on the book)**	**Really sells to (de facto sell to party)**
TMDC	Manufacturer, Importer of Medical Devices who clears through customs of local countries, paying duties, VAT when applicable	Dealers or Distributors	Hospital
Intermediaries	**Dealer** Contracted to sell medical devices to hospitals on behalf of TMDC	Paper company	Hospital
	Distributer Purchase and own products from TMDCs and sell to hospitals for profits	Paper Company	Hospitals
	Paper Company(Billing Agent) Does not really purchase any product but technically plays a role of purchasing agent on behalf of hospital between the seller(dealer,distributos or TMDC.) and buyer(hospital)	Hospital	No One
Hospital	End-User of medical devices, the ultimate purchaser of the medical device	N/A	N/A

Table 5

The 'Real' Relationships of TMDCs and Hospitals in Direct Model			
Parties in Transaction	**Roles**	**Officially sell to (technically on the book)**	**Really sell to (de facto sell to party)**
TMDC	Manufacturer, Importer of Medical Devices, Clears through customs of importing country, pay customs duties, VAT when applicable	Paper company	Hospital
Hospital	End-User (ultimate purchaser) of the medical devices	N/A	N/A

TMDC's billing invoices then get issued to the hospital-designated billing agent as 'sold to' party of the products and the hospital as 'ship to' party. Hence the paperwork reads as if the TMDC has sold the products to the billing agent instead of the hospital. In this process the agent negotiates the prices of products on behalf of hospitals. TMDCs are 'asked' to lower the selling price normally by 10% less than the government approved reimbursement prices or the prices TMDCs are willing to sell at. These agents are often, but not always, directly and wholly owned and managed by the hospitals that TMDCs supply devices to. Some of them could be independent agents hired by hospitals with an understanding to create money for the hospitals. No matter what their relationship may be, one thing is clear. The billing agents capitalize on parasitizing between the TMDCs and hospitals creates enormous inefficiency in market exchange of medical devices. There is no other way to sell devices without issuing invoices to the hospital-designated billing agent because the agent is the only party that 'officially' procures devices on behalf of the client hospital on the book. This exogenous barrier continues for it is technically difficult to prosecute the practice because even if it is clearly an unethical and corrupt practice, but its technical illegality of the practice is unclear. These paper companies exist in countries across Asia in unorganized, ad hoc basis except in Korea, where such paper agents are methodically organized nationwide. An estimated 65% of hospitals in the country utilize the such front companies to generate money and provide miscellaneous financial needs of physicians and hospitals including expenses such as travels, seminars and other discretionary expenditures.

This chapter focused on precise understanding of the operational, structural realities of the transnational medical device firms in Asia, rather than exploring the

theoretical aspect of the enterprise management, by scrutinizing their structure and the business models in detail. Such granular level of understanding in the organizational structure, the cross-departmental issues, the business models and the intertwined relationships are the prerequisites to the analysis and inquiries into the main problems of the study which will be conducted through the case study in the following chapter. The organizational structure and the organizational decisions to choose business models come from the organization's strategy that allocates resources to invest in organizational capabilities to compete in the market. The accurate analysis of the TMDCs' Asia strategy will lead the study to finding the potential root causes of the growth of business organization regardless of geographies and the TMDCs' penchant for indirect model in Asian markets.

CHAPTER FIVE

Case Study

The study selected a case of a TMDC's business operations in Korea because first, I have an extensive knowledge and personal insights in the case as well as the country's culture, practice and business environment. Secondly, the organization's Korean subsidiary is a great real-world example, probably the only example, that has gone through both the success and failure of direct and indirect business operations and finally settled on a hybrid model that combines direct and indirect models in Asia. Korea is the only country where the firm's direct model has survived in Asia since it had launched a worldwide campaign to establish direct operations in the 1990s although it has survived in a form of severely compromised 'hybrid' model today.[135] The case study provides rich details of business operations, uncovering the profound level of tacit practices and collusions in the medical industry. It analyzes the challenges facing the consignment business, particularly for inventory management at hospitals

[135] Hybrid Model (or Hybrid Business) refers to TMDCs' business operations model that employs a mixture of direct and indirect models within same countries. It is considered strategically, operationally an inefficient business model to employ for such mixture of models dilutes the market differentiation of direct business model and one model doesn't justify the merit and virtue of other in the same country. TMDCs tend to avoid the hybrid model. AMC corporation does maintain direct business models in Latin America and some 'small markets' in Asia which refers to, for the purpose of the study, the countries where healthcare spending is negligibly small for TMDCs, i.e. less than $500 per capita or $10billions in total such as Indonesia, Philippines, Malaysia, Vietnam and etc. (World bank, IBRD, IDA., https://www.emergobyul.com/resources/worldwide-health-expenditures)

(consignments), the regulatory and quality dilemmas and *'idiosyncratic cultural practices'* that are present in commercial exchanges.[136] It also examines corruption in the healthcare industry and the strategic, organizational, financial practices and processes at the in-country operations level. With the intellectual insights gained from TIE, the case study seeks to theoretically understand how and under which conditions business organizations innovate to generate superior growth as well as what determines business organizations to make or buy a necessary capabilities, specifically the distribution capabilities of the medical device in this study.

Geography and Business Environment of Korea

Korea is a great place to study the Asian market in general but it's particularly a great fit for studying the healthcare industry because 1) with 51 million population it represents average midsize Asian countries, not as huge as China or India, and not as small as Hong Kong or Singapore.[137] 2) Korea's contrasting urban and rural demographic and geographic characteristics represent the rest of Asia well. E.g., extremely high population density in cities vs sparsely populated rural areas, industrialized urban vs agricultural rural regions, and westernized cities vs traditional countryside, high education attainment in cities vs low education attainment in the provinces. 3) its

[136] Idiosyncrasies in Korean commercial, cultural practice in the study refers to the cultural practice of "*duhm*" which means in Korean, if directly translated, an 'extra' or 'additional'. The "duhm" giving or "additional" giving culture is a traditional practice in Korean society that's deeply permeated in personal relationships, private and public protocols, commercial exchanges. The duhm giving practice in Korea refers to the practice of seller giving something additional to buyers who buys frequently or a large quantity. In hospital industry, the cultural practice causes the doctors and nurses who frequently use a lot of devices of a specific device maker to feel that they are entitled to receive something extra from the seller. Conversely, the sellers feel obligated to give "duhm" or something extra to those doctors and nurses who frequently use their products.

[137] Korea demography., http://www.index.go.kr/potal/main/EachDtlPageDetail.do?idx_cd=1007

healthcare expenditures, which is approximately $2,900[138] per capita is median in OECD, not poor and not rich nation but represents middle to relatively high income countries that can afford advanced medical services, 4) $120 billion healthcare expenditure per year, 7.7% of its GDP, is the 4th largest healthcare spender after China, Japan and India in Asia.[139] 5) Geographically, as one of the three East Asian countries, its culture and customary practices are very similar to the other two largest markets in Asia, Japan and China. Half of the country's 51million population live in the capital region, the Seoul and Gyounggi-Do that surrounds the capital city ("Seoul region") which is highly advanced, industrialized, high income, highly educated region of the country. Among 25-34 years old, 66% held a college or graduate degrees in 2012, the highest share among OECD countries, compared with an average of 39%. In this age group, Korea ranks the first in the world for both men (62%) and women(69%). (OECD,2012)[140]

The Market Barriers for Direct Business

The widespread industry practice of collusive terms and conditions forced upon medical device firms through 'paper' companies and the corrupt physicians who expect or request to pay monetary kickbacks for using medical devices are the two biggest market barriers for TMDCs. Collusion through paper companies is a deeply embedded, systematic practice in the Korean hospital industry. Approximately 60~65% of sales are billed through billing agents ("gaan-naap-uhp-che" in Korean), costing TMDCs

[138] OECD Healthcare Expenditures (2017), https://data.oecd.org/healthres/health-spending.htm
[139] Statista., https://www.statista.com/statistics/647320/health-spending-south-korea/
[140] http://www.oecd.org/education/Korea-EAG2014-Country-Note.pdf

approximately 10% of the revenues, as discussed in the previous chapter. The physicians who request TMDCs' money in return for using their products is the single largest exogenous barrier (along with the endogenous barriers such as the paramount operational complexity of consignment management), which make up the main reasons of why TMDCs choose an indirect model that hires intermediaries to do the 'necessary' jobs so that TMDCs can stay clear of potential ethical and legal problems. The severity levels of corruption widely differ between the Seoul region and outside the Seoul region (hereafter "provinces"). The doctors in the Seoul region largely tend stay clear of such corrupt practices compared to those who practice medicine in the provinces outside of Seoul region. It is rare that sales reps are approached by doctors who request kickbacks in the Seoul and Gyounggi regions.

The situation outside the Seoul region is different, however. According to the people who are familiar with the subject, the corrupt practices in the provinces outside Seoul region in 2007 were widespread as a normal standard of practice in hospital industry. The doctors would suggest or even coerce sales reps of pharmaceutical and medical device firms to pay kickbacks in return for prescribing their drugs or using their devices. One sales rep, under a condition of anonymity, revealed that he was approached by several doctors who proposed specific amounts to pay for using one DES, ranging between 300,000~500,000 Korean Won (or US$300~$500) per every stent consumed in Gyunsang and Chonla Provinces. Another sales rep who had left a large transnational pharmaceutical company in Gyunsangnam-Do region in the summer of 2007 had '*confessed*' to author that his reason for departing the former employer in the region was because he was very wary of his routine, regular duty which was to deliver cash

kickbacks to doctors.[141] Such corruption in hospital industry in Korea is not widely known to general public because it's a taboo even to mention about it in the industry. Usually such matters are proposed, agreed and settled in a very discreet and secretive manner so that no one else knows about it other than the two parties involved. Even when the deal doesn't go through or is broken in the middle of negotiations there are coded understandings among parties to keep it secret. Once a deal is made between a doctor and a distributor, the doctor uses products from that specific distributor's consignment. It is very difficult or even nearly impossible in such circumstance for other sellers to penetrate the sales in that hospital. It is extremely difficult for transnational firms to directly compete in the market under such treacherous situations. Thus, TMDCs ultimately resort to the distributorship solution in Korea. TMDCs choose distributorship in Korea, not dealership, because even the legal title of the ownership of the products get transferred to the distributors as the products are shipped out of the warehouse. This eliminates a possibility to assume any and all types of legal responsibility over the products whereas the legal title of ownership of the products remains with TMDCs even after the products have been made and shipped to the dealers under dealership arrangement.

[141] The author has visited Daegu, Daejeon, Busan, Gwangju regions multiple times during 2007~2011. The author's very first live, one-on-one interview with sales reps regarding the corrupt practices in hospitals took place in August 2007. Since then the author had numerous interviews, meetings with sales reps not only in Korea but also with reps in China, Australia, Hong Kong, India, Indonesia, Japan, Malaysia, Taiwan, Thailand, Turkey and other Asian countries for nearly eight years. The author had met with countless number of physicians in Korea and in other Asian countries. The author also has an experience of being *'discreetly'* approached by a doctor in Korea. The doctor had told the author about how much a doctor he knew made in a month from a deal he had struck with a pharmaceutical company, indirectly implying that he was open to negotiate a similar deal with medical device companies too. The company the author had worked for had strictly enforced the ethical, regulatory compliance policies and forbade sales reps from engaging in any activity that could be just deemed as an unfair, unethical commercial practice. The company had spent large resources to educate and train employees on anticorruption, preventive measures for corrupt practices, and regulatory compliance and implemented a zero-tolerance policy on any collusive and corrupt practices. The company had trained its employees to give up the business if any type of collusive or corrupt collaboration is suggested or hinted by a physician.

AMC Korea

AMC (Acme Medical Company) is a pseudonym of the US-based TMDC used for the case study to protect the privacy and confidentiality of the participants who contributed in the survey and interviews. AMC's Korean operations, among the company's entire Asia operations, best demonstrates the classic examples of transnational companies' struggles with their strategies in Asia-Pacific. At the same time, the case also demonstrates that the enterprise innovations and superior capabilities stem from the amalgamation of strategic control, organizational integration and long-term investment. In 2005, AMC Korea was moderately competing in the country's US$200 million interventional cardiology market for tenth year since the inception of the company. Its total annual revenue, USD $56 million, was approximately 23% of the market share in terms of the country's total interventional device market value.[142] The interventional cardiology (IC) business, among all other interventional specialties, is the largest business that brings the largest revenues and profits in to TMDCs. USD $45 million (or 80% of the total revenue) out of AMC Korea's annual revenue ($56 million) came in from its IC business alone in 2005 as shown in the Tables 6 and 7.[143]

[142] Market values, adjusted industry estimates based on National Health Insurance Corporation's 2007 (NHIC, a Korean government agency under Ministry of Health) projected annual budgets for the years of 2008~2009 which took the planned reduction of the overall maximum reimbursement prices on minimally invasive surgery devices encompassing interventional cardiological, peripheral and neurological devices and accessories including but not limited to bare metal stents, DES (drug eluting stents) etc. The total interventional market value of Korea in 2005 is estimated USD$250millions.
Attached URL link, the graph and Excel spreadsheet reported by Statista for the Korea's interventional cardiology market and other interventional device market values of 2007, 2014 and the projected value of 2021(for the purpose of providing objective comparison against the industry produced stat.)
https://www.statista.com/statistics/648682/cardiovascular-devices-market-south-korea-by-category/

[143] See Table 6 & 7 for details

The case study applies the *'social conditions'* of the Theory of Innovative Enterprise in analyzing the firm's innovational transformations made during the period of innovative strategic controls in 2006 and the ensuing organizational integration and the financial commitment the firm had made. It also analyzes the period of organizational collapse that began in 2010 as the constituting elements that supported the social conditions were removed from the firm.

Establishment of Direct Business Model in Asia

AMC is a US-based transnational medical device corporation that specializes in R&D and manufacturing of advanced medical devices for minimally invasive surgeries. The company's world-wide drive to establish 'direct' business began in Asia in 1990s. The corporate-wide campaign to establish a direct business model was an unconventional move for a major transnational corporation in the international market where all other TMDCs were doing business indirectly via intermediaries. The move in the mid-1990s was considered rather an innocent trial doomed to fail not only by the seasoned managers at TMDCs but also by workers in healthcare and hospital industries, such as doctors and nurses. Sure enough, the company began switching its business model back to the indirect model country by country after approximately 10 years of failed attempts to establish a direct business in Asia.

Switching Back to Indirect Business Model

AMC China had switched its model to indirect in 2010, abandoning the direct model it had had employed over a decade. In India, the company's European entity had sold its products through a local distributor under an exclusive distribution contract until 1990s. Then in early 2000s the company had completely pulled its presence out of India after it had failed the years of attempts to establish direct business in the country, leaving a tiny warehouse in Okhla, South Delhi behind for the sole purpose of supplying its one and only distributor. In 2011 when the company returned to India to re-establish its business, after a brief initial testing of a direct model at handful hospitals in and around Delhi, it soon had put the full gear into establishing an indirect dealer model from 2012. Australia and New Zealand are exceptions. These two are culturally European countries although they are physically located in Asian continent. The company had begun its direct business since its inception in both countries and remains in direct model till today, the same as what it did in North America and Europe. Since the AMC corporation began trying to establish direct business model in Asia over two decades ago, the company's only direct business that survived in Asia is in Korea today, although it survived in a partial or hybrid form.[144]

[144] The company currently runs direct operations in 'small markets' where healthcare spending is negligibly small for TMDCs, i.e. less than $500 per capita or $10billions in total such as Indonesia, Malaysia, Philippines, Thailand, Singapore, Vietnam. (World bank, IBRD, IDA., https://www.emergobyul.com/resources/worldwide-health-expenditures) The total combined revenue of the firm from the six South East Asian countries was approximately $50Million in 2012 which is less than Korea's $64million in the same year.

The Innovative Enterprise

In 2005, AMC's global Enterprise Resource Program (ERP) project, intended to replace its fragmented web of various legacy systems with one unified worldwide system, was underway. As the company's worldwide ERP project was engulfing its subsidiaries in Asia, a seasoned manager with profound experience and knowledge in consignment business was expatriated from its US headquarters to Seoul as the country director to lead AMC Korea. The veteran with multiple decades of international sales and operations experience knew better than anyone in the corporation that the rapid *'detection'* and replenishment of the used devices in order to minimize "unbilled" was of paramount importance in the success of the consignment business model.[145]

Strategic Control

The country director and his local management team were devoted to build a strategy that could bring a breakthrough in the industry's chronic consignment problems. First, they had agreed to build a computerized consignment management capability that can scan consignment inventory, detect consumptions and place replenishment orders by PDA[146] (a handheld personal digital device) via internet while reps visit hospitals. The team wanted to take advantage of the corporate-approved ERP project and its budget in building the intended computerized consignment management system. It was pre-smart phone era and the idea was received as a remotely futuristic and very costly to managers

[145] 'Detection' refers to a process of 'finding out' or identifying the usage of medical devices in hospital consignments either by sending sales reps to hospitals to check the consignment inventory or by receiving the usage information by nurses from hospitals.

[146] A personal digital assistant (PDA), also known as a handheld PC, is a variety mobile device which functions as a personal information manager. Nearly all PDAs have technical functions to connect to the Internet and transmit data over internet. https://en.wikipedia.org/wiki/Personal_digital_assistant

in 2005. Nevertheless, the committed management in the subsidiary with a long-term vision had devised a plan to build the capability internally and decided to make a financial commitment to overcome the chronic problems of consignments once and for all. However, the bureaucratic Information Technology (IT) department and the financialized management at the corporate headquarters were against the idea of a computerized system built outside the control of headquarters (HQ). The disapproval was justified based on 'network security' and 'cost reduction'. HQ didn't allow even an interface of any external system to the corporate ERP either. At the same time the corporate finance didn't want additional costs other than the costs for the already approved ERP project.

Strategic Control through Partnership

Capability building requires resources. When HQ didn't approve the building of the visionary consignment management capability, the local management in Korea came up with an innovative idea to build the system by going around the HQ's bureaucracy. The distribution and warehouse staff had determined the capability didn't have to be built in-house as long as they could somehow own and operate the capability. The distribution team searched for a logistics company that would be willing to go around the client hospitals to check the consignment inventory for a fee. A descent size local logistics company, that was already providing transportation and logistics services to pharmaceutical companies, was intrigued by the idea that it could potentially expand its specialty logistics service into the medical device industry. AMC Korea offered to train the logistics company staff with the complex consignment inventory operations. The

logistics company wanted to invest in learning a novel genre of medical logistics which could potentially be a high-value specialty logistics service, making the company the first pioneer in the field in the country. The two companies had agreed to co-develop and co-own a 'consignment management system' but only for the exclusive use by AMC. This case of a 'double coincidence of wants' between the two companies in totally different competencies jointly gave birth to an innovative, pragmatic consignment management system (CMS) which could scan inventory, detect used devices at 'UPN level', reconcile, report inventory details and place replenishment orders via internet from the palm of the sales or logistics staff in the hospitals.[147] The synergetic strategy built on collective and cumulative knowledge in the respective professional competencies of the medical device consignment and the inventory logistics emerged as a very powerful capability to overcome the chronic complexities of medical device consignment. The necessity of strategic investment in technology for superior performance was understood by both companies.

Upon completion of CMS, the two companies agreed to jointly build an unprecedented 'consignment logistics specialists' (or CLS) team consists of the light freight van drivers of the logistics company who would go around to all of the 135 hospitals (or 380 consignment sites) in the entire country. The 40 young men of CLS team would be on the logistics company's payroll but paid and managed by AMC Korea through a 'Third-Party Logistics (or 3PL) contract.[148] AMC Korea strategically proposed

[147] The Universal Product Number (UPN) - The UPN is a product identifier used to uniquely identify products used in the health industry. See footnote#43 for additional information.

[148] Third Party Logistics, Third-party logistics providers (or 3PL) typically specialize in integrated operation, warehousing and transportation services which can be scaled and customized to customers' needs based on market conditions, such as the demands and delivery service requirements for their products and materials. Often, these services go beyond logistics and include value-added services related to the production or procurement of goods, i.e., services that integrate parts of the supply chain. https://en.wikipedia.org/wiki/Third-party_logistics

the logistics partner to jointly control the operations of CLS team including hiring, firing, training, compensation but AMC Korea would have the primary managerial and operational authorities on CLS team, not logistics firm. The two companies mutually agreed on the proposition. The 40-person team was formally organized as a separate, an autonomous unit within the logistics company but managed directly by AMC. The CLS team was given a name, "AMC Consignment Team" within the logistics company to function as a long arm of AMC Korea's distribution department even if the team technically belongs to the logistics company.

Strategic Control to Accessing Market

The joint project team of AMC Korea's Operations Department (OPS) had run into a major challenge in the initial phase of CLS team's takeover of the inventory management from the sales reps. The Cath-labs and the operations theaters (called consignment sites by MDCs) are off limits to all outsiders except the medical device sales reps who must check and replenish the devices and need to interact with nurses and physicians. Accessing the consignment sites, which are located deep inside Cath-labs and operations rooms, by the logistics staff who are basically freight van drivers were opposed by physicians and nurses. AMC conducted a series of joint brain storming sessions with cardiovascular, peripheral intervention sales managers, distribution staff and the managers from the logistics company to collectively devise an idea to overcome this unexpected monumental obstacle. The joint team came up with an *unconventional* idea which was to have the drivers clad with business suits and ties, the same attire as the medical device sales reps would wear, and have them introduced to hospitals as the

consignment specialists whose specifically assigned duties are to alleviate the burden on nurses by detecting, counting, and replenishing the consumed medical devices at consignment sites. The drivers had not only easily gained access to all hospitals in the country but also were whole heartedly welcomed, especially by nurses who no longer had to worry about the replenishing the used devices and miscellaneous consignment inventory control in the operating rooms. From the nurses' point of view, when it comes to AMC's products, as opposed to its competitors' devices, absolutely everything including the replenishment is done automatically by CLS so the nurses can just keep on using the devices with no worries of post-usage administrative hassles.

Organizational Integration

Even though the jointly built Consignment Management System (CMS) had been developed and with the logistics company taking over consignment management, the chronic issues of traditional consignment problems, e.g. unbilled, expiries, near expiries continued in 2006. The consignment write-offs reached over $2 million a year in selling prices and it was worsening in 2007. The country director's determination to eliminate the traditional consignment problems once and for all by using the capability built (CMS) had led to him to commit another *strategic financial investment*, this time in human resources.

An extremely unusual, a very bold decision, was taken to recruit a 20-year experienced logistics expert from aerospace industry in the United States who was overseeing just-in-time inventory of aircraft parts, components and jet engine repair service logistics to lead the entire consignment operations in Korea. The compensation

offered was nearly 10 times of the average local operations managers' compensation in the country at the time. AMC Korea's business was 100% direct consignment model so the newly recruited operations manager would be the de facto head of the entire Korean sales because entire consignment operations would be under his responsibility. The local managers at the subsidiary viewed this extremely unusual move with skepticism. The sales managers of each division were particularly skeptical because of the respective idiosyncrasies of cardiovascular, neurological, peripheral and endoscopic and endo-surgery businesses were never to be understood by an aerospace logistics expert, at least in a short term. However, the country director had made a long-term investment decision. The primary duty of the newly recruited operations director was to dramatically reduce, and ultimately eliminate, the increasing loss due to product 'lost' and 'scraps' from consignment operations that was reaching $2million a year.

Organizational Integration through Innovative Structure

The incoming operations (OPS) director understood the value of eliminating the effects of the financialized organizational structure of the company that hindered the innovative value creation that he was hired to unleash. During the recruitment process, he had negotiated to be in second-in-command, reporting only to the country director and have everyone else in the organization reports to him, which was unique proposition not only in AMC but also in any financialized TNC. The former request, of being second in command in the country, was granted but the latter request, of having all other department managers reporting to the Operations chief, was not granted. Although the negotiation was only half successful, the unusual organizational hierarchy where the

operations chief sits as second in command in the subsidiary had sent very strong messages to all employees in the country which resonated "operations first", not finance, to all rank and files in the organization. The global headquarters' *maximization of shareholder value (MSV)* spirit that cascades down to internal structures of the TMDC's international subsidiaries had stopped at least at its Korean subsidiary in 2007. The positive ripple effect of the extraordinary organizational structure was much greater than anticipated. The message began resonating in the management of partnering logistics firms and to the important stakeholders: the doctors and nurses in hospitals too. This innovative approach in organizational structure has effectively eliminated the financialized imbalance in checks and balances and had integrated the organization not only internally but also with external partners and hospitals which became the critical tipping point for innovative penetration of the market.

Organizational Integration through Innovative Operations

As the CLS learning curve in consignment operations was improving, and with the internal organizational integration at hand, another huge innovative act of strategic control took place. In the summer of 2007, the Operations-led (OPS-led) medical device business commenced at AMC Korea empowered by the strategic division of core competencies of the sales and the logistics professionals. The primary responsibility of a sales rep is to promote sales through engaging in clinical aspects of the products with physicians such as discussing device efficacy, technical issues of devices, compiling clinical advices, experience and opinions from physicians for continuous improvement and innovation of the device rather than counting consignment inventory which is a

secondary duty of a sales rep. The sales reps are great in performing their primary duties but not as great in performing the secondary or peripheral duty of inventory control. The logistics specialists' core competency is the inventory management and are trained to perform flawless inventory counts and replenish the used devices in a very short amount of time. The country director and the head of Operations had recognized these simple points and had drastically separated the respective duties of the medical device sales reps and the logistics inventory specialists according to the core competences of to an extreme extent. The sales reps had to completely do away with consignment inventory duty or inventory related duty of any kind. The sale reps were not allowed to discuss or speak about consignment inventory. Sales reps were even prohibited to place orders of the replenishing devices themselves. They were only allowed to take orders from customers and then turn them over to CLS for electronically placing the orders through the CMS system. The new order placement process, done only by CLS, had empowered the CLS to reign over an absolute and exclusive ownership of the consignment inventory control at all hospitals, and enabled them to bring the inventory and logistics expertise into the operating rooms of the hospitals in the country. The sales managers initially viewed this organizational innovation as a hostile act that undermined the importance of sale and marketing functions and had revolted at the onset of the implementation and some reps wanted to continue their own inventory counts by themselves. Those reps believed the CLS, who serves much greater number of hospitals per person than sales reps, couldn't perform the inventory counts at their client hospitals as often or as accurate as the rep wanted. Some reps simply worried that the importance of the sales reps in facing customers would diminish or the rapport built with each customer would be weakened as

greater number of hospitals would be assigned to per sales rep as their inventory counting duties have been eliminated.

The Operation-led consignment business was being pushed through despite the resistance from sales. As the Operations-led consignment sales, which is unprecedented in any TMDC, was beginning to show improving operational efficiencies with increasing sales numbers in consignments around the country, sales reps started to show gratitude because sales were increasing at an unprecedented pace while the reps did not have to perform consignment counts (which is the most hated job of the sales reps). The logistics partner was happy because a novel expertise in a niche logistics market has been created for them. AMC Korea's management was happy because the long-wanted innovative capability that could manage consignments flawlessly has been built, although it was created externally. By the end of 2007, CLS would scan, detect, reconcile, replenish consumed devices daily at 70% of the hospitals in entire country, 25% of the hospitals every other day, and once a week at the remaining 5% of the hospitals. The entire 380 consignment sites at 135 hospitals got billed at minimum once a month from 2007. The regular write-offs of "Lost" in consignments, which is the single largest write-off category at medical device firms, that was over $1.5 million in early 2007 was completely eliminated by the end of 2nd quarters in 2008 or within 1 year of strategic organizational alignment of core competencies according to the expertise.

Organizational Integration of External Partner

The operations department understood the fundamental risk with the outsourced capability and needed to tighten the organizational integration, especially with its long

arm created externally at the third-party logistics company (3PL), the CLS team.[149] For example, possible interruption caused by the logistics partner, e.g. bankruptcy or its internal changes to less supportive management of CLS team etc. The worst possible scenario is the betrayal by the partner by providing AMC's competitors with the jointly built computerized CMS system, and the accumulated knowhow and skills built in the process. AMC's Operations proposed to the logistics partner the provision of continuous training of CLS staff on medical devices, a critical training to cope up with the continuing pipeline of new products. The 3PL appreciated the necessity of CLS member training on medical devices, medical nomenclature, jargon, etc. They understood such training can only be done by AMC. Both companies agreed to conduct the periodic trainings and crated a relevant performance evaluation matrix of CLS built based on the training and performance results. Both companies also agreed that the incentives, renumeration, promotion of CLS to be determined by AMC's evaluation matrix and recommendations. This mutual agreement had enabled AMC to retain the 'brain' part or 'software' of the greater Consignment Management System (CMS) including personnel management inside the AMC and it made sure that AMC's external dependency to the logistics partner would be only the 'arms and feet' of the 'hardware' of the joint system, namely the 'physical' part of the greater CMS that is replaceable. Thus, the greater CMS system, that is the combination of computer system, product knowledge, the invisible assets of tacit consignment management knowhows, became extremely difficult to imitate by

[149] Third Party Logistics, Third-party logistics providers or 3PLs typically specialize in integrated operation, warehousing and transportation services which can be scaled and customized to customers' needs based on market conditions, such as the demands and delivery service requirements for their products and materials. Often, these services go beyond logistics and include value-added services related to the production or procurement of goods, i.e., services that integrate parts of the supply chain. https://en.wikipedia.org/wiki/Third-party_logistics

competitors or even by the very logistics partner who executes the consignment operations duties of AMC daily basis.

Financial Commitment

The strategic decisions to build the capabilities to outperform competitors, e.g. the development of CMS and establishing an AMC Consignment Logistics Team (CLS) at an external logistics company were possible because of the financial investment the management had committed. The recruitment of an aerospace logistics expert from the United States to oversee the county-operations, by offering nearly 10 times greater compensation than average local salary for the profession is a huge financial commitment with large risks. The innovative organizational integrations of the company and the building of a joint autonomous AMC Consignment Team at a logistics partner firm were also possible because of the financial commitment the company had committed. The unprecedented Operations-led sales through separation of core competencies along the sales and logistics expertise, making sure the ‘brain’ or ‘software’ part stays within the organization by strategically controlling the utilization of the outsourced resources through on-going CLS training, evaluations, incentivizing renumerations were all possible because of the willingness to commit a long-term financial investment in human and technological resources.

Collective, Cumulative Innovations in Consignment Management

For collective learning to accumulate over time, the financial commitment that can sustain the long-term organizational learning is required according to the principles of the Theory of Innovative Enterprise. As Lazonick posits that

> "*The social condition that can transform finance into innovation is financial commitment: a set of relations that ensures the allocation of funds to sustain the cumulative innovation process until it generates financial returns*." (Lazonick, 2015)

The enterprise innovation from collective and cumulative knowledge, with the dynamic capabilities built through long-term financial commitment, creates superior economic performance compared not only to the competitors but also to its own previous performance - a TIE's core principle. The unprecedented Operations-led medical device sales brought huge success to AMC Korea from 2006 until 2009. The consignment inventory of the company at all hospitals in the entire country was scanned 100% at least once a week of which 70% of hospitals were scanned daily. The lower level operational details (consignment operations process protocol) are listed in the footnote.[150]

The previously *'unthinkable'* improvements at AMC's consignment operations began taking place from 2007 by the innovative operations-led sales supported by the

[150] The process protocol of the CMS system is 1) a consignment logistics specialist (CLS) scans consignment inventory at a hospital, 2) A hand-held PDA automatically detects the usage with product details, i.e. quantity, sizes in UPN level, 3) the data sent to CMS in AMC's customer service in real-time, 4) order gets entered into AMC's ERP system (purposely not linked to CMS to satisfy the corporate network security requirement), 5) warehouse picks the order, 6) the CLS pick up the products and goes back to hospitals for another round of replenishing products and scanning. Shipping cost was eliminated because CLS deliver products to hospitals in person. Each CLS was given 3-4 hospitals in average to visit and manage the inventory. Scanning frequency which was one scan per day at 60% of the hospitals in 2007 had increased to maximum of 4 scans per day at 10% of the client hospitals, two scans a day at around 30% of the hospitals in Seoul by 2010 where 50% of the country's hospitals are concentrated.

combined technological capabilities of CMS and CLS, which was hard to imitate by competitors. (See the List of Improvements in the footnote)[151]

[151]The list of improvements at AMC's Consignment Business Operations (enabled by the innovative operations-led sales equipped with the combined capabilities of CMS and CLS, which was hard to imitate by competitors, had begun in 2007)
1)The Real-time Detection of Usage. The previous passive and periodic consumption detection by sales reps had been replaced by proactive daily processing of consumption by Consignment Management System (CMS) (Seoul, Gyounggi region which is 60% of the firm's Korea business) (Republic of Korea demography., Seoul is the capital of South Korea and Gyounggi is the province that surrounds the capital city. The populations of Seoul (estimated 11million) and Gyounggi (16million) combined makes up more than 50% of the entire country's populations. http://www.index.go.kr/potal/main/EachDtlPageDetail.do?idx_cd=1007)
2)The Daily Replenishment. The consumed devices at 70% of the hospitals get replenished everyday by consignment specialist. (in 24hours from usage)
3)The Real-time Reconciliation of data. CLS sends the data for replenishment order based on detected consumption with all the necessary details such as manufacturer UPN, the unique information including size, batch number, origin and so on which enabled the generation of billing invoices including official government invoices.
4)Reduced Unmatching Records (Mismatches of Records) The consumption records between the AMC and hospitals get reconciled before each remittance. The mismatching or unmatching between the device firm and hospitals reduced by 70% in 2006, 80% 2007 was eliminated totally in 2008.
5)Elimination of Lost Devices. The consignment lost (the devices unaccounted for at hospitals) which was more than $1million a year prior to 2007 became $0 by the end of 2008.
6)Unbilled eliminated. Accumulation of Unbilled products (or consumed-but-not-yet-billed), the biggest headache of all TMDCs in consignment business dramatically reduced at AMCK from 16% of the revenue in 2006 to 10%in 2007, 8% in 2008, 4% in 2009, 0% in 2010.
7)Improved Inventory Reserves to Sale ratio. As the unbilled disappeared the inventory reserves which was traditionally 36%-37% of the annual revenue at the company had reduced to 25% in 2008 and to approximately 7% in 2011.
8)Efficiency in the Distribution Center. Prior to 2007 AMCK had maintained average 4-5months sales inventory at any given time. By the end of 2010 its average DC inventory level came down to the most sufficient level in the entire AMC worldwide, the DC carried six weeks' sales inventory.

Overcoming the Barriers

In addition to the known endogenous and exogenous barriers for direct business, there are unknown barriers neither endogenous nor exogenous. The removal of endogenous barriers inherently depends on a firm's managerial capability to improve internal organization so that the barriers could be replaced with incentives. The exogenous barriers are conditions outside the organization or market conditions. Thus, exogenous barriers or market conditions are assumed to be equally affecting other competitors in the market too. The two largest market barriers are the collusive business practices (cultural or structural) and corruptions (individual) in hospital industry. The third barriers, uncertain or unknown barriers, are the dynamic combination of evolving endogenous changes and exogenous conditions which is difficult to predict.

Overcoming the Endogenous Barriers

The Operations-led strategic, organizational and logistical innovations at AMC enabled by the combination of technology, human skills and knowledge (CMS and CLS) had taken the following actions to remove the internal barriers. Operations hosted regular interdepartmental meetings every month encompassing Sales & Marketing, RA/QA, and Demand Planning until the inefficiencies and barriers had been either improved, resolved or eliminated.

A) Sales & Marketing + Finance

   a. Totally new method of Annual Sales Planning implemented. Operations to initiate the annual S&OP process based on 'unit based' analysis with

planned inputs received from Sales and Finance.Demand planners trained sales and marketing staff on planning with lower level (UPN) product data.

b. Accountability on overstocking. Suggestion to charge the cost of unsold devices that have been scrapped or aging in the DC to business units (deducting the cost from sales commissions) had stopped the chronic overstocking by drastically reducing the unwarranted large imports.
c. Expiry. Offered sales rep extra incentives for selling expiring devices out of consignments. (extra $100 commission per every stent sold that was due to expire within 3 months) Expiry scrap from consignment reduced over 90%+
d. Stopped 'Demo" scrap. Utilized expired goods for demo instead.
e. Complaint Return. Informed the sales of operational management's intent to investigate the complaint returns with doctors reduced the complaint return to nearly zero in half year.
f. Proactive insurance coding updates and posting in the individual hospitals' reimbursement system.
g. Preemptive coordination with RA/QA for new product launch for registration (cross-coordination with Sales)

B) <u>RA/QA</u>

a. Created a Korea-specific local standard operating procedure (Local SOP) and Work Instruction (WI) to accommodate the idiosyncrasies in country operations replacing the standard corporate SOPs provided by HQ.
b. Redefined definitions of expiry, near expiry and damaged

c. Expiry- the terms and definition of expiry and mandatory scrap return locally changed from one month prior to expiry to the same month.

d. No more scrap of products with pen marks, writing on outer suffice as 'damaged' product.

e. Monthly interdepartmental sharing of registration and approval status.

f. Proactive insurance registration and reimbursement coding registration with respective Gov't Agencies

g. Preemptive coordination with RA/QA for new product launch for registration (cross-coordination with Sales)

C) Demand Planning

a. Implemented a mandatory prior approval by the Operations director for large quantities of inventory requested by sales.

b. Preemptive alignment of inventory planning with reginal, global planning organization all the way to manufacturing

D) Distribution

a. Streamlined the Customs clearance process, inland transportation logistics and warehousing.

b. Redefining the HTS (Harmonized Tariff Schedule) number traditionally used for neurological coils for tariff application.[152]

[152] The Harmonized System is an international nomenclature for the classification of products. It allows participating countries to classify traded goods on a common basis for customs purposes. At the international level, the Harmonized System (HS) for classifying goods is a six-digit code system. https://unstats.un.org/unsd/tradekb/Knowledgebase/50018/Harmonized-Commodity-Description-and-Coding-Systems-HShttps://www.census.gov/foreign-trade/schedules/b/index.html

c. Direct and preclearance of imports implemented for same day import. Eliminated costly bonded transfers between Incheon and Seoul resulting the customs clearance from 2 days to same day

Overcoming Exogenous Barriers

The exogenous barriers of the direct model reside in the market. The optimizing firms view market barriers as inevitable variables that apply to all companies doing business in the market. Thus, the optimizing firms resort to an indirect model. This case study shows a truly innovative enterprise can even positively influence exogenous market barriers when the innovative enterprise is fortified with the *social conditions*. AMC could not completely eliminate the exogenous barriers in Korean market. Those barriers, however, had been effectively dealt with by the ingenuity of the social conditions of an innovative enterprise. Unlike overcoming endogenous barriers, which gets done through the improved managerial capability, the overcoming of exogenous barriers needed external assistance, specifically the help of governmental institutions. At the end of 2007 the country director and the operations director, both the expatriated executives from the US, had decided to pursue an atypical campaign to deal with the on-going collusive practice of forcefully seizing part of the MDC's revenue (about 10%) by hospitals. The first part of the atypical campaign was to re-negotiate the percentage of the forced commission with the paper companies. The Operations director had led this aberrant campaign. He had assigned the company's six directors and managers to cut the 'commission' rates of 70 hospitals by half within one year. The head of operation took

himself the largest hospital group in Korea to negotiate himself. It was strategically important to have the most influential hospital group in the country to favorable terms for AMC because it could immensely influence negotiations with the rest of the hospitals in the country.

The second part of the atypical campaign was for the two top leaders of the company to officially bring the practices of the paper companies to the American Chamber of Commerce (AMCHAM) in Seoul. The company had requested AMCHAM to address the issue to the US Embassy in Seoul and to the Korean Ministry of Health and Welfare (MHW). The AMC's plea campaigning for fair business practices in the Korean hospital industry through the influential AMCHAM and the US Embassy in Seoul continued until 2009. This unconventional approach to tackle the market barriers by the TMDC, sent a strong message to the local industry as well as to the other US based TMDCs who were 'optimally' operating businesses under indirect models. This campaign was considered, however, a 'transgressing' act to many people in the industry because AMC had broken the '*secret*' tradition of the hospital industry of the country by 'publicly' talking about it. It offended even the AMC's own sales and marketing employees who had adamantly opposed the idea in the beginning of the campaign in 2007. They were afraid of possible adverse effects in their sales which could be touched off by angry physicians and hospital staff. They didn't think the deeply rooted traditional practice would go away.

AMC had continued the effort to reduce the impact of the forced commission practice of the paper companies with a target to lower the rate down to 1~2% until 2010. After about six months of continuous painstaking renegotiations, AMC finally had the

most influential hospital group in Korea agreed to lower the discount rates from previous 14% to newly agreed 8% in 2008. When the second round of negotiation ended in 2010, they agreed to lower it further down to average 6.5% which was an unthinkable victory to the company.[153] When the two expatriated managers had first suggested the plan to the management in 2007, the Korean managers had thought it was a 'crazy' idea. This campaign lasted until AMC Korea was completely localized in 2010 as the last expatriated American employee had turned the firm's management completely over to a locally hired Korean country director.

The second exogenous barrier, the corruption among physicians particularly in the provinces outside Seoul region, had assured the managerial 'pundits' at TMDCs that AMC's direct model effort would not prevail and would ultimately have to be switched to an indirect model. AMC's credo of '100% direct' business model with the highest ethical integrity, strict compliance to the laws, ending kickbacks of any kind, combined with its '*innocent*' challenge against the forced commissions involving Korea's regulating body (Ministry of Health) through AMCHAM, US Embassy started gaining a momentum by 2008. The clear-cut, efficient consignments that automatically replenished used devices and provide lists of consumed items weekly, monthly or whatever period hospitals wanted, supported by the innovative technology of CMS and logistics specialists were immensely appealing to nurses. The nurses who could continue to use devices without having to follow up the usage had welcomed the innovative Operations-led consignment

[153] The so-called commissions, which in fact is the forced kickbacks to hospitals via paper companies, widely vary in percentages against the maximum Reimbursement price depending on the devices and the specialties. For example, guidewires for neuro-intervention could be 18%, safety net for endarterectomy could be 15% while cardiological-stents (DES) could be 10~15%. Such discount percentage vary from hospital to hospital depending on products quantity demanded and supplied, severity of corruption, initial negotiation for consignment agreement with hospitals. Average commission rates refer to the average rates of the total commission rates of thousands of different devices with different rates at hospitals.

operations model of AMC. The novel design for consignment operations was becoming rapidly popular among nurses around the country. However, problem is that it is the doctors who select the devices, not nurses.[154] For this reason, the competitors of AMC had fervently believed that the growing popularity of the innovative Operations-led consignment model would have no effect or would have a very little effect on the ultimate sales outcomes of the firm. The competitors had banked on their optimal strategy of the indirect model based on their decades of market knowledge.

Surprisingly, the facts ascertained by implementing and running the Operations-led direct consignment sales countrywide were: First) the significant percentage of doctors in the provincial regions (outside Seoul and Gyunggi regions) were clean, not corrupt, hard-working doctors who devoted themselves to sincere patient care. Second) even outright corrupt physicians also use AMC's devices at times even if they know that they won't get any kickbacks. The seasoned sales managers who are familiar with the practice profess that the most likely causes behind the phenomenon would be either those physicians could be in temporary negotiation stage with the present distributors of 'cozy' relationship to raise their current kickback amounts, or because they felt an implicit pressure or suspicious atmosphere about their cozy relationships among other colleagues in the hospital.[155] It was evident that AMC's efficient, engaging, technologically

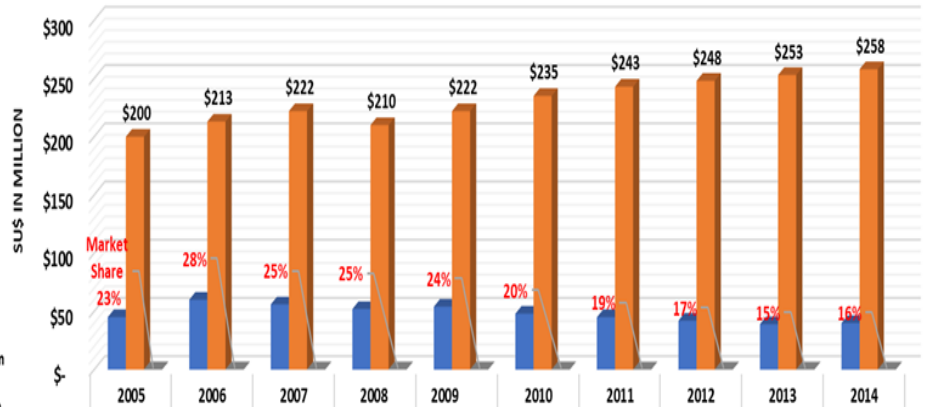
[154] The minimally invasive surgeries cane be performed by highly trained, experienced and skilled interventional cardiology surgeons. The most frequent cardiological minimally invasive surgery is Percutaneous transluminal coronary angioplasty (PTCA). It's a procedure to open up blocked coronary arteries, allowing blood to circulate unobstructed to the heart muscle. Such procedures require multiple injections of a needle, different sizes of guide wires into patient's blood vessel. In addition, multiple accessorial devices such a diagnostic catheter, guiding catheters, balloons of various sizes are used together in repeated manner depending on the size, location of the lesions which can only be determined by doctors. https://www.mayoclinic.org/tests-procedures/minimally-invasive-surgery/about/pac-20384771, https://medlineplus.gov/ency/anatomyvideos/000096.htm

[155] The author had interviewed over 50 sales reps and managers, some of whom had worked as medical device sales managers for over 3o years, to analyze this unusually interesting phenomenon of the corrupt physicians' usage of AMC's devices even if they know that they won't get any kickbacks between the years of 2007 through 2019.

proficient, straight forward and uncompromising direct model built on the fulfillment of the social conditions of innovative enterprise invites even corrupt physicians to consume the products of AMC as a mean to conceal their corrupt relationship with other distributors. Everyone in the industry thinks the physicians who use AMC products are clean because of an obvious reason – the direct operations by TMDCs does not and cannot pay kickbacks. The large TMDCs' direct business model makes it extremely difficult or nearly impossible to pay monetary kickbacks to customers due to its systematically inflexible, stringent compliance and accounting policies and practices. AMC was the only TMDC that ran on direct model in the country. These favorable conditions for AMC, however, had quickly changed in southern provinces after 2010 when the model had been switched to indirect in two southern cities, Busan and Daegu. It was no longer a concern of the new management because the hospitals in regions have been already turned over to the distributors. Under indirect model, products in the regions could be *'pushed out'* to the distributors. It is practically very difficult to compile numerical data on how many or what percentage of AMC's products are being consumed by corrupt doctors for concealment purposes, or as a negotiating tool for increasing their kickback from distributors who bribe them. What have been clearly proven, however, are the firm's superior economic performance under direct model and the inferior economic performance under indirect model both in revenues and market shares by the longitudinal survey results over the ten-year period as shown in the Tables 6 and 7.

Table 6

AMC Korea's IC Business Performance under Different Models 2005~2014



Source: The graph has been contructed based on data from "JaemooJepyo", a finaical statement reported to Korean government and made publicly available by law, similar to 10K-filing of the United States.

	2005 Direct	2006 Direct	2007 Direct	2008 Direct	2009 Direct	2010 Hybrid Direct 78% Indirect 22%	2011 Hybrid Direct 50% Indirect 50%	2012 Indirect Over 55% of the country	2013 Indirect Over 60% of the country	2014 Indirect Over 60% of the country
Interventional Cardiology	$45	$60	$56	$52	$54	$48	$45	$42	$39	$40
Total IC Market Value of Korea	$200	$213	$222	$210	$222	$235	$243	$248	$253	$258
IC Market Share% in Country	23%	28%	25%	25%	24%	20%	19%	17%	15%	16%

Historical Business Performance for 10 Years (2005~2014)

AMC Korea's most dramatic period was between 2005~2014 in terms of strategic, organizational aspects as well as in its financial performance measures, i.e. revenue, profits and market shares. It had gone through a period of strategic, organizational, financial excellence exemplifying the innovative enterprise from 2006 until the first half of 2010. Then its slump period began in the second half of 2010 when the firm began *'extracting'* the previously created values by converting the model to indirect in the southern regions of the country which had led the firm to a plunging economic performance until 2013, the year regional HQ instructed AMC Korea to stop

the further expansion of the indirect model into the Seoul region.[156] The company's business performance tables (Tables 6~7) have been built based on publicly available data, the "*Jaemoojepyo*" reported to Bureau of Taxation in Korean government by the company during 2005~2014.[157] Contrary to the fervent belief of the managers at the competitors, AMC's total revenue in 2006 had increased by 32% compared to the prior year (Table7) despite the traditional cozy 'relationship' between the physicians and the distributors that were hired by the firm's competitors. The market share of the firm's interventional cardiology business had increased from 23 percent in 2005 to 28 percent in 2006. (Table 6)

Global Restructuring

AMC's US headquarters had begun reorganization of its global management structure from headquarters-centric to decentralized three regional headquarters around the globe: Americas, Europe and Asia-Pacific regions in 2010. The Asia-Pacific's regional headquarters was being established in Singapore from 2010. However, the complete transition of managerial oversight including the transfer of the operations management from the global HQ to the Asia-Pacific took several years. The transfer of managerial oversight, business (sales & market) and operations (distribution, supply

[156]Lazonick, Williams., 2014 "*Extracting value*" vs "Creating value" mentioned in 2014 Harvard Business Review article "*Profits Without Prosperity*" that won the "Best HBR Award" of the year. HBR Sept.2014.
[157] "Jaemoojepyo"- a comprehensive financial reports filed annually to Korean government by every business corporation in the country and made publicly available by law. It contains much more than revenue, balance sheet, cash flows. It includes brief history, financial statements, earnings, compensation, investments, miscellaneous expenditures and all activities of financially relevant data. It is similar to the annual 10K filing of corporations the United States.

chain) had been done on incremental manner. The transfer of business (sales & marketing) oversight began first in 2010. Then, it was the end of 2014 when the operational (distribution, supply chain) oversight had been transferred completely from the global HQ to the Asia-Pacific region.

Localization of Asia-Pacific Region

Prior to the restructuring, AMC corporation's global headquarters in the US had directly oversaw the Asian business operations until 2009. The general managers in sizeable Asian subsidiaries (annual revenue of $50 million or above) were American employees expatriated from the US headquarters. The decision to localize all Asian subsidiaries, replacing the expatriated American country-directors in every Asian country with local nationals, was determined by the new corporate management in 2010. The decision was based on several convincing reasons such as 1) Often the family members of the US employees being expatriated experience severe and prolonged difficulties adjusting to the local culture, customs and environment, 2) the expatriation and the repatriation of the American employees and their families cost the company prohibitively large amount of money[158] 3) the expatriated managers may be experienced, knowledgeable in business and loyal to the US HQ but most of them, if not all, do not know the local languages. Thus, someone must translate the local affairs to the expatriated managers. 4) The

[158] The annual cost of expatriation per a US employee and his/her family to Asia differ from company to company. It also depends on individual employee's family size, ages of accompanying children, home value that needs to be either sold or left vacant in the US, spouse's annual income given up during the assignment as well as the host country's air quality, natural environment, availability and ease of access to American lifestyle amenities such as sports, golf courses, swimming pool and general hardship level. If age(s) of the accompanying child/children are K~12 grades, the tuition for American school or English-speaking international school in the host country gets added to the cost which runs $40,000 ~$50,000 per child per year in East Asia. The average expatriated employee cost of a US corporation was approximately $1millon dollars per family per year in 2007.

expatriated employees stay in a country only 2~5years on average. Thus, the knowledge gained on the local country business also leaves with the employee's repatriation. 5) When an expat is ready to return to the US, the position must be filled with another expat from the US and the vicious cycle repeats. There are debatable pros and cons about the expatriated managers from the US leading their subsidiaries in Asia which can be another important research subject in international management. Nevertheless, AMC made the decision to completely localize the Asia-Pacific region.

Back to Indirect Model

AMC Korea's incremental business model change from 100% Direct to Indirect began in the second half of 2009 by the new management led by the first locally hired Korean-national general manager. The newly hired Korean country director had argued and persuaded the global headquarters that the corrupt practices in Interventional Cardiology markets in Busan and Daegu regions were so potent and the company could no longer perform in direct business model. The model-change to indirect distributorship first took place only in Busan city where the sales volume was significantly low in proportion to the size of the city as an initial test case. The direct customers of AMC in the region were greatly disappointed at the news because the change was regarded as a capitulation of the long-endured effort to maintain the direct business model despite the difficulties of the market environment (which was regarded as a proof that AMC did not compromise) to the industry 'norms' of collusive practice to maximize temporary profits. The clear proof from the 10-year longitudinal data shows that AMC had performed superior in revenues and expanded market shares under the direct model. The model change from direct to indirect was done only for Interventional Cardiology (IC) business and none of the other franchises, namely Peripheral Intervention, Vascular and Endo-Surgeries, Electrophysiology, Oncology, Gynecology, Urology has changed the business model and all have always remained in direct model until today.

The reasons for maintaining the direct model differ per franchise or medical specialty. First, the most sales of Peripheral intervention and Endoscopy businesses, about 65%~70%, occur in Seoul regions which has been always under the direct model. Besides sales managers and sales reps in peripheral intervention business unit had

established very strong relationship bonding with clients in the provincial regions and had lock-in affects. Then the main reason for keeping the direct model for all other franchises (electrophysiology, oncology, gynecology, urology) are the insignificant market sizes and sales volumes. In case of Korea, an annual sales revenue per a business unit should be at least $1million or greater to hire a dealer or distributor without difficulties. Electrophysiology, oncology, gynecology urology businesses are less than $1miilon or barely $1million a year respectively. It's not easy to find candidates for dealership or distributorship for insignificant volume of business. The TMDCs' minimum cost to manage respective small dealers and distributors are unwarranted either. Besides the electrophysiology business is closely related with CRM (cardiac Rhythm Management) business which requires a special programmer that must be operated only by AMC trained sales rep in sync with the electrophysiologist for each surgery.[159] Thus, electrophysiology devices can either be sold directly by the attending sales rep or by CRM designated agents. It is usually the nurses, not doctors, who choose products in Oncology, Gynecology, Urology, Vascular and Endo-Surgeries or Endoscopy business.[160]

Table 7 shows the comparison of business performance of Interventional Cardiology (IC) that changed business model against "Other" businesses for ten years that have maintained the direct model. The company's 5% gain in IC market shares in

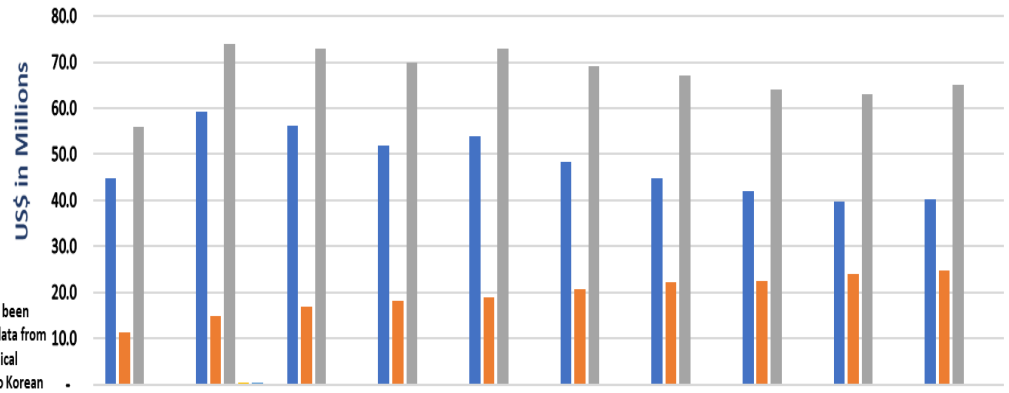
[159] This major service provides diagnosis and treatment for disorders that affect the heart's electrical system and cause rhythm problems. Heart rhythm disorders are managed in a number of ways, including medications, pacemakers, implantable defibrillators, invasive electrophysiologic procedures and biventricular pacemakers. PeaceHealth St. Joseph Medical Center's electrophysiology program uses sophisticated computer technology with advanced 3-D mapping. https://www.peacehealth.org/st-joseph/services/cardiovascular-center/cardiovascular-diagnostic-testing/Pages/Cardiac-Rhythm-Management-%28Electrophysiology%29

[160] https://www.asge.org/docs/default-source/education/Technology_Reviews/doc-b1e8b7c822f44a909688b313fce048f4.pdf?sfvrsn=8

2006 had sent the shockwaves to the industry, especially to competitors who had thought AMC couldn't sustain the direct model. AMC's 28% IC market share in 2006 was the company's highest performance ever achieved in the country. AMC's traditional market shares in Korea's IC market had been 15~23% per annum since its inception (1996) through 2005. The firm's four consecutive years of the superior performance of high growth ever recorded was from 2005~2009.

Table 7

AMC Korea's Total Business Performance under Different Models 2005~2014



Source: The graph has been contructed based on data from "JaemooJepyo", a finaical statement reported to Korean gov't and made publicly available by law, similar to 10K-filing of the United States.

	2005 Direct	2006 Direct	2007 Direct	2008 Direct	2009 Direct	2010 Hybrid Direct 78% Indirect 22%	2011 Hybrid Direct 50% Indirect 50%	2012 Indirect Over 60% of the country	2013 Indirect Over 60% of the country	2014 Indirect Over 60% of the country
Interventional Cardiology	44.8	59.2	56.2	51.8	54.0	48.3	44.9	42.0	39.6	40.3
Other	11.2	14.8	16.8	18.2	19.0	20.7	22.1	22.4	23.9	24.7
Total Revenue	56.0	74.0	73.0	70.0	73.0	69.0	67.0	64.0	63.0	65.0
Growth Rate of I.C. Business		32%	-5%	-8%	4%	-11%	-7%	-6%	-6%	2%
Growth Rate Other Biz(Direct)		32%	13%	8%	4%	9%	7%	1%	7%	3%

The data in Table 7 indicates the rapid downfall of the IC business began as the business model changed from direct to indirect model in 2010. Since then IC business was continually losing revenues until 2014 while "Other" business was continually growing, year on year, at varying percentages.

The summary below, "The Major Historical Events at AMC Korea" is an abridged version of chronological events occurred during 2005~2014. It exhibits major landmarks that transformed the organization to a 'value-creating' firm and then its subsequent 'value-extracting' phase during the ten-year period.

Major Events at AMC Korea during 2005~2014

2005 - Established strategic partnership with a Third-Party Logistics company. Invested in capability building, i.e. Consignment Management System (CMS) project began.

2006 – CMS completed. Consignment Logistics Specialists (CLS) Group established. CMS and CLS operations cleared the accumulated Unbilled since its inception. Daily replenishing in consignments began. Interventional cardiology (IC) market share in the country skyrocketed by 5% in a single year from 23% in 2005 to 28% in 2006.

2007 – Operations-led consignment business commenced. Sales reps focused on clinical aspects of products and relationship strengthening with physicians. Negotiation to reduce the paper companies' forced commission began. Made the collusive practice public involving AMCHAM, US Embassy and Korean Government.

2008 – Ministry of Health and Welfare (MHW) reduced the medical device reimbursement rates by average 10%. (ranged 10%~15% depending on devices) MHW is the single payer for healthcare expenses in the country of 100% socialized medicine. The medical device reimbursement cuts by 10~15% across the board. Successfully negotiated paper company's commission reduction to average 7% (from avg10%) helped reduce the revenue loss from Gov't reimbursement cut. The 4% decrease in revenue in 2008 ($70M) from 2007 ($73M) was only about half of the planned loss. Estimated 4%~5% revenue loss had been avoided because of the newly negotiated lower rates with the paper company. Otherwise the total loss could have been estimated $6~7M instead of $3M.

2009- Localization. HQ decided to localize the Korean subsidiary which had been managed by expatriated country directors from the US since its inception. Locally hired a Korean national was to take over the management of the subsidiary at the completion of 1-year training. The second round of rate negotiation with paper companies completed. $1M gain in IC revenue is the result of paying lower commissions to paper companies, not resulted from increased sales.

2010- Localization 50% progressed. The last American country director had been repatriated. The locally hired country director took over the management in January. The Operations director, last remaining American expat, was still overseeing the operations during the transition. The new country director had changed the business model for I.C. in Busan and Daegu, the 2nd, 4th largest cities in Korea, to indirect distributor model

despite the opposition of the Operations director. IC market share of the firm shrunk to 20%, worse than 2005 which was 23% of the market.

2011- Localization 100% completed as the Operations director had been repatriated to the US. The business model changed to indirect distributor model for the entire country except Seoul region. The direct business in Seoul generated about 60% of the firm's revenue and the rest of the country generated 40% of the revenue by the end of 2011. The IC market share dropped to 19%.

2012 – A locally hired person filled the vacant head of Operations position as a third-in-command after finance director. Even several client hospitals in the center of the Seoul city were transferred to distributors. A decade old differentiation strategy of the uncompromising direct operations model had collapsed in less than two years since the first model change had begun in Busan and Daegu. HQ began questioning the aggressive expansion of indirect business model even into the advanced, westernized Seoul region. IC market share plunged to unprecedented 15%.

2013- The Asia-Pacific regional HQ directed Korean country director to stop the unwarranted nation-wide expansion of indirect model and terminated him.(or technically speaking HQ decided to not extend his contract in 2014)

2014 – The locally hired Korean country director left the company. Newly recruited country director in the US arrived in Korea and took over management.

The managerial oversight was being transferred incrementally from the global headquarters to the newly established Asia-Pacific Regional HQ slowly from 2010 through 2014. During the transitional period, all Korea experts at the US headquarters, such as former expatriated employees to Korea, had left the company. When all of them had left, the company had lost the Korea business operations knowledge that was cumulatively built over 17 years. No one at HQ was knowledgeable enough to question the aggressive and expansive transition of business operation model from direct to indirect in Korea. The new management neither at global HQ nor at regional HQ (which was being organized) in 2010 was aware of the strategically differentiated logistics capabilities of the business operations in Korea. In 2012~2013, as the regional HQ was beginning to grasp the strategic differentiation of indirect model that had been previously

implemented in Korea and the unique Operations-led direct sales model in Seoul, it began questing about the justification of the on-going aggressively model changes. When the reginal HQ realized that the poor business performance had begun with the business model change that began in 2010, it had ordered the country director of Korea to stop the continuing expansion of indirect operations model to the rest of the country in 2013. The company had let go its first and only locally hired country director thus far. The replacing country director had been recruited in the United States and sent to Korea in 2014.

CHAPTER SIX

The Thesis

This thesis, as a part of the author's continuing quest for an innovative global business model for the rapidly transforming 21st century economy, has inquired into the causes of the two important economic issues of a business enterprise: growth and efficient boundary of enterprise. These two main questions - first, what makes an economic organization grow and second, what determines an organization to internalize (make) a capability or outsource (buy) it - were examined through a case study of a transnational medical device company's business operations in Asia where they uniformly employ an *indirect* model as opposed to their preferred *direct* model in the US and in European markets. The penetrating sub-questions of the thesis have been answered through a thorough examination of the case in Chapter Five. In doing so the study employed Lazonick's *'The Theory of Innovative Enterprise'* as its intellectual framework to gain insights to understand the empirical evidences, observations and the socioeconomic economic phenomena witnessed in the Asian hospital industry.

The case analysis of AMC Korea focuses on how and under what conditions the innovation in its internalized distribution capability was conceived and nurtured. The case analysis also examines when and how those have dissipated over the course of a ten-year

period through the application of the three *"social conditions"* of TIE, namely the S*trategic Control, Organizational Integration and* "*Financial Commitment.* The first condition, "*Strategic Control*", determines to make necessary investments. Second, "*Organizational Integration*", enables the ways in which learning about transforming technologies and accessing markets not a sentence. Third, "*Financial Commitment*" determines how innovative investments made are sustained until they can generate the competitive products that yield financial returns.

Analysis of the Case Study

From an Optimizing Firm to an Innovating Firm

Prior to 2005, AMC was an optimizing firm trying to maximize short-term profits just like its competitors. The firm had made the strategic decision to invest in the capability building for direct operations in 2005 and since then it had transformed from an optimizing firm to an innovating firm during the years of 2005~2009.

> *"The theory of the optimizing firm posits that an "entrepreneur" chooses the industry in which he wants to compete by allocating resources to any industry in which, because of the exogenous appearance of a disequilibrium condition, there are supernormal profits to be made. In the theory of the innovating firm, in contrast, the entrepreneur's specialized knowledge of the industry in which he chooses to compete is of utmost importance for his firm's ability to be innovative in that industry."* (Lazonick,2015, 7-8)

AMC's management prior to 2005 had assumed that there was not much it could do to change or eliminate the barriers for business. It had assumed that endogenous barriers could be improved only up to certain level, but the overwhelmingly complex consignment problems could not be eliminated completely. The managers at AMC had assumed that there was absolutely nothing they could do to change the exogenous barriers, namely the cultural, commercial traditions of the land that might have been practiced hundreds of years, if not thousands. This is one of the two assumptions embodied in the neoclassical theory of the firm which is that *"the entrepreneur plays no*

role in creating the disequilibrium condition."[161] The other neoclassical assumption of the theory is that "*the entrepreneur requires no special expertise to compete in one industry rather than another. All that's required is to follow the principle of profit maximization in the chosen industry to compete."*[162] But in the theory of the innovating firm, "*entrepreneurs, by contrast, create new profitable opportunities and thereby disrupt equilibrium conditions."*[163] The management of AMC Korea understood the necessity of long-term investment to human and technological resources to develop the distribution capabilities that the competitors cannot easily emulate. The firm had begun integrating the organization by committing financial resources to development of direct operations capability, to access market from 2005.

First, *Strategic Control* - AMC Korea's strategic determination to build the visionary computerized consignment management system was an initiative launched by the firm's *Strategic Control*. The decision to search for a logistics partner who's willing to explore an untapped frontier of medical logistics and combined with the matching of 'double coincidence of wants', i.e. the wanted capability for consignment management at AMC and the desire to explore the novel areas of the medical device logistics business by the logistics company, had resulted the production of an innovative consignment management system (CMS). The synergy created by collective and cumulative knowledge in the respective competency of the medical device consignment and the inventory logistics turned into a powerful combined capability to overcome the chronic complexities of consignment management. The necessity of strategic

[161] Lazonick, William., 2015, "The Theory of Innovative Enterprise:Foundation of Economic Analysis" , University of Massachusetts, The Academic-Industry Research Network. Rvsd. Aug 2015.,p7
[162] Ibid.
[163] Ibid

investment in technology to solve the chronic consignment problem was appreciated by both enterprises, respectively for different reasons. AMC was willing to invest in innovative distribution capability to access the market to generate superior performance. The logistics firm was willing to invest in a novel area of the logistics business despite the existence of uncertainty. The establishment of the 'consignment logistics specialists' (CLS) team enable the unparalleled capability to flawlessly manage every consignment inventory at the firm's 135 client hospitals (or 380 consignment sites) on daily basis in the entire country.

The unprecedented Operations-led consignment sales in the industry had increased the firm's sales level that's impossible to copy by competitors. The CMS capability enabled CLS to scan, detect, reconcile and replenish used devices daily at 70% of the hospitals in the country, 25% of the hospitals every other day, and once a week at the remaining 5% of the hospitals. The entire 380 consignment sites at 135 hospitals were billed at the end of every month. The sales revenue had increased by 32% in 2006 compared to the previous year. 2006 was the very year CMS and CLS capabilities building had been completed and applied in the consignment operations. The regular write-offs caused by "Lost", which historically had been over $1.5 million annum, had been eliminated by the end of 2008. (See Tables 6~7) The unbilled amounts which had been approximately 16% of the firm's revenue throughout the year prior to 2006 had dramatically improved to only 10% of the revenue by 2007, 8% in 2008, less than 4% of the total revenue by 2009 and finally achieved the legendary 0% of *'unidentified unbilled'* by year 2010.[164] These *unthinkable* state-of-the art

[164] The "*unidentified* unbilled" (Unidentified UBB, or Unidentified UBD) refers to the "unbilled" devices that the consignor hasn't even yet aware of its existence or occurrence because it has occurred too recently or it's currently

improvements in direct distribution service were possible because the firm's initial strategic decisions to invest in the development of human and technological capabilities. Therefore, the firm equipped with CMS and CLS was able to challenge the uncertainties throughout the process and enable the organization to learn collectively throughout the cumulative innovation process until it was able to turn the high input cost into lower unit cost.

Second, *Organizational Integration* – The innovative re-organization of the reporting structure that placed the Operations director as the second-in-command enabled the company to access the market *directly* and grow business by utilizing the transforming technology(CMS). This organizational re-arrangement effectively eliminated the 'financialized' imbalance in managerial oversight of the firm and built the appropriate checks and balances that set the priorities right for continuous growth. It has not only integrated the organization internally but also created external ripple effects that has formed its linkage among the external stakeholders, i.e. the logistics partner, hospitals including doctors and nurses. These forward and backward integrations of the internal hierarchy became a critical tipping point for its innovative penetration of the market. The initiative to train, evaluate and compensate CLS members according to AMC's Operations department's merit-based matrix had integrated the external logistics provider into the de facto integral part of the company's Operations department. This enabled AMC to retain the 'brain' part (software) of the greater Consignment Management System (CMS) in-house and made sure the

occurring in real-time as opposed to the regular "Unbilled" which refers to those that have been used but haven't been billed yet because of missing or insufficient data but sellers are aware of the existence of the unbilled. Unbilled is also abbreviated as "UBB" or "UBD" in the industry short for "Used But not Billed" and "Used But-not-billed-Device"

outsourced dependency would only be limited to functions of 'hands and feet' (hardware) of the greater operational system. The internalized distribution logistics capability, namely the greater Consignment Management System (CMS) comprised of a combination of technologically advanced computer system that scans and replenish consignments in real-time via internet, fleet of vans with CLS, the invisible and tacit consignment management knowledge, became extremely difficult or nearly impossible to imitate by competitors.

Third, *Financial Commitment* - A decision to recruit an aerospace logistics expert with over two decades of experience from the United States required substantially large upfront financial investment. The local managers' strong skepticism on the incoming Operations director's lack of medical device business knowledge exacerbated the uncertainty surrounding the costly recruitment. Then country director, however, was committed to make a long-term investment decision to foster innovative breakthroughs in the chronic consignment operations problems. The strategic decisions to build the dynamic capabilities to outperform competitors, i.e. the development of CMS, establishing AMC Consignment Logistics Specialist team (CLS) at an external logistics company were possible because of the financial commitment of the management. The organizational innovation to build the CLS team externally and integrating it as part of the firm's Operations was possible because of the financial commitment. The unprecedented Operations-led sales executed through the strict separation of the miscellaneous consignment operations duties along the respective core competencies and expertise of the sales and logistics, effectively managing the entire CMS and CLS operations the way in which the competitors cannot imitate required

long-term financial commitment. These characteristics of innovative enterprise had been duly understood and the financial commitment had been provided throughout the development phase in spite of the existence of uncertainties until 2007.[165] The newly integrated AMC Korea internalized the increasing variable costs of inputs into its operations as part of its strategy until 2006. This strategic control placed AMC Korea, which had chosen to *innovate* instead of *optimize*, at a competitive disadvantage at low levels of output in the beginning, increasing the imperative that it attain a larger market share to drive down unit costs.[166] An innovating firm makes investment in high fixed costs in technology and in accessing markets, and thereby gains a large market share to convert high fixed costs into low unit cost. This transforms a potential competitive disadvantage into an actual competitive advantage as exactly as the social conditions of the TIE asserts.[167] These economic phenomena had occurred exactly in AMC Korea from 2005 through 2009 as the results of adequate implementation of strategic control, organizational integration and financial commitment. AMC Korea was an 'innovating' firm by definition that thrived on superior productive capability generated on the foundation of fulfilled *social conditions* during the years of 2005~2009.

[165] The chronic problems of unbilled, including the unidentified unbilled mentioned in the process of Strategic Control section, had reduced to the unprecedented 10% by 2007 and completed eliminated by the end of 2008. Thus, it can be said that a certain degree of uncertainty with the effects of huge financial investment made during the years of 2005~2007 had remained in AMC Korea until the end of 2008.
[166] Lazonick, William., 2016, "Innovative Enterprise or Sweatshop Economics?: In Search of Foundations of Economic Analysis, Challenge" DOI: 10.1080/05775132.2016.1147297., p.10
[167] Ibid.

From an Innovating Firm to an Optimizing firm

The transition from *innovating* firm to an *optimizing* firm at AMC Korea began from 2010 as the firm began focusing on maximization of short-term profits through an incremental expansion of indirect distributor model in the poorly performing southern regions of the country. When direct business operations are being switched to indirect models of dealership or distributorship, the firm would experience increasing revenues in the initial phase because the distributors must purchase initial stocking inventory to start the business. But those initial surges in sales will eventually disappear as the distributors' stocking orders reach the saturation level which is the point when the distributors filled every consignment site in their respective sales territories and when their own internal inventory get filled up. The AMC Korea's new country director (the first and last locally recruited so far) had launched the transition of business model back to indirect distributorship from the beginning of 2010 but its initial test to switch from direct to indirect distributors model had already begun from second half of 2009 in the southern region of Busan. The *optimizing* firms choose dealer or distributor model to avoid consignment complexities and go around the barriers in markets which was the business model employed by every TMDC in the country except AMC since 2005. AMC Korea during 2010 ~2014 was clearly an '*optimizing*' firm by definition which had *"extracted"* the previously created values during 2005~2009.[168] The *optimization* effort of the firm ultimately withdrew the capabilities it had implemented (CLS and CMS) incrementally region by region in the country's South in exchange for the maximization of the short-

[168] Lazonick, William., 2014., Profits Without Prosperity, Academic Industry Research Network (www.theAIRnet.org), University of Massachusetts, Lowell., p3

term revenues and profits as the financial gains would come in from the initial stocking orders by the newly onboarding distributors. As long as the model changes to indirect continue to expand throughout the country in incremental manner at certain periodic intervals, e.g. 1~2 new distributors every two ~ three months or so, the revenue would appear to be increasing or at least not decreasing on the firm's quarterly accounting reports for certain duration, likely 1~2 years. However, the revenues, profits and the market shares of the firm ultimately began plunging even as the indirect sales regions were expanding in 2012 ~2013 because the firm's innovative internalized distribution capability challenged the barriers to generate superior performance (differentiated, specialized capabilities to flawlessly handle consignment challenges) could no longer be applied in indirect markets. From 2010, it has become no longer the competition between "AMC's innovative internalized capability vs competitors' traditional distributorship" in the market. It became the competition between the AMC's distributors against the competitors' distributors in the market from 2010.

The theoretical economics logic that an *innovating firm* invests in uncertainties in market is based upon the fact that a market is an outcome, not a cause, of the productive activities of economic actors in innovative enterprise. On the contrary, the theory of *optimizing firm* does not invest in the organizational capabilities and an *optimizing firm* does not confront uncertainty because it views market as the cause rather than the outcome of the economic organization's activities. It regards exogenous conditions as given and '*extracts'* previously created values and keeps the safety-distance of disengagement from the 'risks' in market by employing an intermediary as an insurance. *"The optimizing firm chooses the industry in which it wants to compete by allocating*

resources to an industry in which, because of the exogenous appearance of a disequilibrium condition, there are supernormal profits to be made. The innovating firm, by contrast, entrepreneurs create new profitable opportunities, and thereby disrupt equilibrium conditions." (Lazonick, TIE 2015, 7)

Retain-and-Reinvest vs Downsize-and-Distribute

The *financialization* had transformed the governing principle of the US corporations from "*retain-and-reinvest*" to "*downsize-and-distribute*".(Lazonick, 2014)[169] AMC Korea had embraced "retain and reinvest" scheme as its governing principle in 2005. It had invested the retained earnings in building productive computerized capabilities (CMS) and building CLS team, including investing in human resources, e.g. a costly recruitment of an aerospace logistics expert from the US to revolutionize the consignment operations, increased training budget for import clearance courses and logistics seminars, establishing regular trained programs for CLS, raising operations budget for consignment analysis and management to achieve unbilled account accuracy down to an individual unit level granularity and just-in-time replenishment. This governing principle of "retain and reinvest" scheme created new values in the firm during 2005~2009.

Under the "downsize-and-distribute" regime that began in 2010, however, AMC Korea had voluntarily replaced the strategically differentiated, difficult to imitate, direct

[169] Lazonick, William., 2014., *Profits Without Prosperity, Academic Industry Research Network* (www.theAIRnet.org), University of Massachusetts, Lowell., p2-3
Lazonick, William., 2012 *The Financialization of the U.S. Corporation: What Has Been Lost, and How It Can Be Regained*., The concepts discussed in this paper were presented at The Future of Financial and Securities Markets: The Fourth Annual Symposium of the Adolf A. Berle, Jr. Center for Corporations, Law and Society of the Seattle University School of Law. The Symposium took place in London on June 14–15, 2012

model that generated superior economic performance to an indirect distributor model to maximize temporary profits that can't be sustained. It began *"mil-uh-nae-gi" or "pushing out"* of the products to distributors by tasking them compulsory minimum purchase quantities every quarter.[170] The firm continually laid off CLS starting 2010 until 2014 as it expanded indirect sales territories and turned over the client hospitals to distributors for the temporary merit of initial stocking order purchases. The 40-man CLS group shrunk to less than 20 men by middle of 2013, the skeleton crew who had been kept for Seoul region which was still being directly operated but its fate too wasn't clear at that point. The profit maximization regime was voluntarily abandoning the state-of-the-art distribution capability that had been internally built region by region starting from the provincial business, over the course of five years. The combination of CMS, CLS, tacit knowledge and skills of the consignment inventory controls is difficult to imitate dynamic capability, but the significant portion of the combined knowledge has been lost today.

The innovative operational capability was the key to the success of superior direct model of AMC Korea. The incoming leadership at the US headquarters in 2010 didn't even know the existence of the innovative Consignment Management System in one of its own subsidiaries in Asia, let alone its meritorious superiority. The global Country-OPS Group, the knowledge center of the global country-operations at the US

[170] *"mil-uh-nae-gi"* or *"pushing out"* is a dictatorial commercial practice of large corporations exerted upon dealers and distributors in Korea. The literal translation of Korean word, *"mil-uh-nae-gi"* to English is *"pushing out"* which connotes the large corporations' sales practice of allocating 'minimum sales quota' to distributors irrespective of their will or sales capacities. Large corporations or manufacturers of popular products, usually *"Jaebol"* or conglomerates, impose 'minimum sales quota' on each individual distributor. If a distributor fails to achieve the minimum sales volume in a given period, the distributor is expected to purchase the 'balance' with their own money, or the distributor will be under threatening pressure for potential involuntary termination of the distribution contract by the large corporations.

headquarters, was dissolved for 'cost' savings purpose in 2010. The managerial oversight of Asian business was being transferred from global HQ to the reginal HQ which wasn't fully established until 2013. The reginal Asia-Pacific HQ, upon establishment, was expected to '*optimize*' the business in Asia by the financialized global HQ. Even if the HQs found out the Korea's superior internalized operations-led direct model at the time, the maintaining the internalized distribution logistics capabilities could have perhaps appeared as a '*costly*' option to the incoming corporate and regional leadership who had to carry out the "downsize-and-distribute" mission.

During the hasty localization attempt, the business model change was approved by the financialized HQ that was persuaded by the locally hired director had brought the disastrous consequences. The "downsize and distribute" imperative undermined the *social conditions* of the innovative enterprise, the essential conditions for firms to generate superior growth. The financialized governing principle under new leadership also had changed the organizational reporting structure of the Korean subsidiary in 2013. It had re-organized to have the head of Operations report to the head of Finance. By doing so, the financialized regional management believed that the organization could plan and execute the business in financially *'optimal'* manners within the calculated limits of planned revenue targets. The study clearly proved the innovating direct model that engaged the market had outperformed the optimizing indirect model that avoids the direct engagement in the market as shown in Tables 6 and 7.

Conclusion

There are three economics principles that transcend time and space that I learned from studying and utilizing the theory of innovative enterprise as the intellectual framework for analyzing the economic phenomena in the thesis. These principles helped answer the main questions of the thesis which are 'what makes business organization productive and grow' and 'what determines organizations to internalize (make) a required capability or outsource (buy) it'. The first principle learned is the fact that technology and market change overtime. The second principle, economic organization including business enterprises are inherently man-made institution. The third principle, the market is the result, not the cause, of productive activities of business enterprise.

For a business organization to grow, it must continually innovate. For innovation to occur, the decision makers must take the uncertainties into strategic consideration in allocating resources to develop capabilities that are hard to imitate by competitors. Because technologies and markets continually change overtime, the first principle, the technological and market uncertainties continue during the capability development phase of an innovative firm. The firm may not be able to develop the intended higher quality capability, or the developed capability would no longer be a competitive capability by the time it completes if it took too long to develop or if it's easy for competitors to copy. The market uncertainty wouldn't allow the firm to be certain about how much market share will it be accessing. Furthermore, there are competition uncertainties too. A competitor could have invested in a strategy that

generates an even higher quality, lower cost product or service. Therefore, strategic decision making in an innovative firm requires to take these uncertainties into calculation and make financial commitment until the investment starts to return profit by transforming the high fixed cost into low unit cost through increased output by accessing the large enough market.[171]

The second principle learned is the fact that economic organizations including business corporations are inherently man-made, social institutions. The growth and prosperity of a man-made institution are dependent upon its organizational capabilities and integration that unite individual interests to the interests of the institution. There is no pre-determined fate or longevity for man-made institution unlike the life cycles of biological organisms. The life and prosperity of man-made institution may be indefinite although the lives of the people who manage the institution may be finite. Therefore, the *social conditions of* the innovative enterprise, "strategic control, organizational integration and financial commitment", must be present and fulfilled in economic organization to continually innovate to generate superior economic performance.

The third economic principle learned is the fact the market is the result, not the cause, of productive activities of a business enterprise. A market is where products or services are traded. The products and the services traded are the results produced by the amalgamation of collective, cumulative productive activities of economic actors at an economic organization. Hence, a market is the result, not cause, of productive activities performed by enterprises.

To identify the cause of the second problem of the study, i.e. what determines

[171] Lazonick, William., 2015, "The Theory of Innovative Enterprise: Foundation of Economic Analysis", p11

which organizational capability to internalize and which to outsource, the study has very thoroughly examined the theoretical arguments of Williamson's transaction cost theory, a renown economics theory that won 2009 Nobel prize in economics by theorizing the organizational decision-making process by delineating why firms decide what to keep inside the firms (make, own) and what to keep outside the firms (buy, outsource). The theory argues that firms naturally attempt to build efficient borders in the competitive world of commerce by deciding what to make and what to buy and the market uncertainty may induce firms to internalize resources or work. (Williamson, 1981, 558)[172] Williamson argues a firm would use market when both *bounded rationality* and *opportunism* are present because opportunism becomes problem when bounded rationality is present. He asserts the existence and combinations of certain aspects of transaction factors, i.e. "asset specificity, uncertainty or transaction frequency", may raise transaction costs and create a 'market failure' which ultimately enables firms' internal hierarchy as more efficient than market.

Transaction cost theory is an extension of neoclassical economics that employs constraint-optimization "which takes the constraints as given rather than seeking to overcome those constraints through innovation".[173] The *a priori* assumption is that market is more efficient than hierarchy because a vertically integrated firm maybe not be under competitive pressure of market and is subject to internal bureaucratic process. The combinations of the human factors and transaction factors in the transaction cost theory that leads organization to decide whether to make or buy are causes of economic

[172] Williamson, Oliver E. 1981. "The Economics of Organization: The Transaction Cost Approach." American Journal of Sociology 87:548-577. https://www.nobelprize.org/prizes/economic-sciences/2009/williamson/biographical/

[173] Lazonick, William., 2015, "The Theory of Innovative Enterprise:Foundation of Economic Analysis", p3

activities. The organization's resultant goods or services for market or its failure to produce them due to internal inefficiency is the result of a mixture of human and transaction factors. What is available in the market for purchase at a lower cost than for an organization to make it within its own hierarchy is also a result of someone else's productive economic activities in the economy. Thus, market is the result and the economic organizations are the causes of available products and services in the market, not the other way around. The Williamsonian behavioral, cognitive and transaction factors are constraints for innovative operations model to overcome. The asset specificities are not given to the firms but are rather outcomes of their investment strategies.(Lazonick, 2015,3) It is not a bounded rationality, an opportunism, or an asset specificity that affects a business organization's determination to internalize or outsource a capability it needs, i.e. the distribution capability in case of the TMDCs in Asian market. It is either the absence or the existence of a value-creating innovative capability, which challenges uncertainties and overcomes barriers inside organization, that affects organizations' decisions to make or buy.

The study learned from TIE that an innovating firm's value-creating capability can be improved by "*by unbounding its cognitive competence and by transforming the behavior of its participants, technologically by committing itself to the development and utilization of organization specific-assets."*[174] It was the combination of AMC corporation's *strategic decision* to make the *financial commitment* to develop distribution capabilities that challenge uncertainties and overcome barriers and its *organizational integration* that enabled accessing market to large enough extent to

[174] Lazonick, William, 1991, *Business Organization and the Myth of Market Economy*, Cambridge University Press., p229

which the high fixed cost could be turned into low unit cost which ultimately made its internalized capability in the hierarchy more efficient than market coordination-the clear presence of the social conditions in the organization. As TIE asserts that it is the innovating firm's *strategic control* that determines to challenge the uncertainty by *organizational integrity* to overcome cognitive and behavioral limitations to create value where market coordination cannot."[175] The treating the behavioral, cognitive characteristics of humans as given instead of challenging them to overcome and viewing the asset specificity as given rather than an outcome of the firm's investment strategy are classic examples of constraint-optimization principle of neoclassical economics. It is the value-extracting "downsize-and-distribute" regime focused on temporary maximization of the profit that led business organizations, including AMC Korea from 2010, to buy (outsource) the distribution capability in market.

[175] Ibid.

Recommendation

As the minimally invasive medical devices are being rapidly commoditized, product superiority alone no longer works as a competitive advantage for the advanced medical device manufacturers. The previously existing exogenous disequilibrium conditions in the lucrative global DES markets have already dissipated. The current price equilibrium in the global medical device markets will continually be under downward pressure as technological advances increasingly accelerate the commoditization process.

The dynamics of the converging 21st century economy require the business enterprise to continuously innovate by directly engaging end-customers and by investing in uncertainties regardless of the geographies. The capability to distribute the products in the most efficient and cost-effective manner to customers creates value in Asia-Pacific, Latin America and anywhere in the world as it already does in North America and Europe. The right business model in the fast-changing 21st global markets is a value-creating innovative enterprise model that invests in transforming technologies and accesses the market despite facing uncertainties in the local countries where the transnational firms conduct business employing sustainable "retain-and-invest" governing principle, not a "downsize-distribute" regime that focuses on short-term profits. Thus, the local customers in the respective countries can view transnational firms as an integral part of their local economies, not as foreign corporations that extracts profits out of their economies.

An innovating firm strategically invests in productive capabilities despite the

existence of uncertainties in markets because it views the market as the result, not the cause, of their productive activities. As the author has learned through the theory of innovative enterprise, the transactional asset-specificity is not given to organizations but is an outcome of its investment strategy. The neoclassical illogic that reverses the cause and effects in modern economic discourse dominates academia and its influence has permeated into the management practices of large corporations as well. I hope this principle that transcends time and space will contribute in rectifying the reversed notion of cause and effect of the economy in future economic researches as well as in the business designs of the corporate world.

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