

REGENERATIVE MEDICINE - THE TECHNOLOGICAL EVOLUTION
TRACK OF *METATECH*

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Abstract

The study explores a single case study with capability development, technology strategy, innovation types and business innovation flowchart perspectives. Longitudinally the study traces the beginning and development of MetaTech's technology and its spreading process. Laterally the study would reveal and induce the innovative evolution track of MetaTech's technology transfers. The study mainly presents the current development of Taiwan regenerative medicine in international situation through the development experience of the beginning and establishment of MetaTech's regenerative medicine technology. The growth of industry not only need the support of national policy, it also needs flexible capability of industry adaption. Besides, the development of MetaTech still must rely on pushing force of technology and pulling force of market, and, in addition, the most importantly is how the company continue to hang round with the international regenerative medicine industry for the strategic position it plays in network division of labor.

Key words: regenerative medicine industry, organizational development, technology transfer, technology strategy, innovation type, innovation flow.

Introduction

According to medical research report, the occurrence of human disease all starts with cell damaging and aging. Thus, human is curious and yearning on the regenerating phenomena of the nature. For example, no matter how many times a salamander's leg breaks, it will grow out the same leg from the wound. A salamander's great regenerating ability not only can grow a complete set of limbs and eyes, it can even grow heart and part of brain, etc., making many scientists to develop new medical technology, hoping to restore damaged cells or tissue organs to their original states.

In viewing the history of regenerative medicine development, from the stem cell research experiment of Canadian scientists James Till and Ernest McCulloch in 1963 that proved stem cell of little mouse's bone marrow can renew by itself and grow to be platelets, red and white blood cells, to English researchers Martin Evans and Matthew Kaufman separated stem cells from small mouse's embryo in 1981, and at the same year that English scientist Gail Martin found technology that can reserve stem cells in petri dish, which became the foundation of subsequent stem cell experiments. In 1981 the research team of Eugene Bell published technique that use patient's own cells to make artificial skin in repairing wounds, Mr. Bell founded Organogenesis in 1998 and obtain approval from American Food and Drug Administration to become the first medical product company that can produce living cells. In 2010, multiple application of stem cell treatment came to existence. Patients with damaged cornea

can get transplant of stem cell extracted from healthy cornea tissues to damaged cornea to restore vision and spine damaged patients can also restore mobility after receiving ovary stem cell treatment. In 2013 human's stem cell was developed by the team of Shoukhrat Mitalipov of Oregon Health and Science University. The team used the same body cell transplant technique as the one in cloning Dolly the sheep and duplicated the first human stem cell by using baby's cell. In 2014 South Korea and the US developed technique to clone human adults' cell to create human stem cell and such stem cell reduced the extent of rejection in treatment. Stem cell treatment started to enter the market in 2015. The European Union approved using Holoclar stem cell from umbilical cord blood and bone marrow, developed by the team of Graziella Pellegrin in Regenerative Medical Research Center of Modena University, Italy, on treating blind patients caused by burned cornea. This is the first stem cell product to be commercialized successfully. (<https://heho.com.tw/archives/5205>)

In recent years the progress of medical engineering has brought about huge changes in medical treatment on human's illness. Especially the research of stem cells and progress in material and biological science have allowed the making of applicable tissues from a person's cell to repair body damage and illness. However, in comparing to the entire medical history, the knowledge of regenerative medicine is only in the initial stage, which needs doctors', engineers', and biology scientists' cooperative effort for Taiwan not to fall behind, but to lead other countries in creation

and medical application of human tissues. Therefore, in April of 2003 “Formosa Association Regenerative Medicine” was founded by Professor Sheng-Mao Hou, Professor Feng-Huei Lin, Professor Yi-You Huang, and Professor Lein - Tuan Hou. The association extensively invited clinicians and medical engineering related researchers to participate. The aim of the association is to promote progress of regenerative medicine and tissue engineering.
(<http://www.farm-taiwan.org.tw/>)

In governmental policies, the Ministry of Health and Welfare in Taiwan imitates Ministry of Health, Labour and Welfare in Japan to construct and relax relative laws and regulation on regenerative medicine. In comparing to “Three Laws of Regenerative Medicine” of Japan, Taiwan also has three laws on regenerative medicine, consisting of “Act for the development of biotech and new pharmaceuticals industry”, “Rules on execution or application of specific medical technology examination medical instrument”, and “Rules on regenerative medical remedy management”. The government hopes that under the relaxing of regulation and authority’s supervision, it will assure safety and effectiveness of regenerative medical technology and products, thus pushing forward and speeding up the development of regenerative medicine.

Technology innovation and successful commercialization will establish a business’s competitive advantage. Technology is a business’s key to survive and develop in the market. (Byrne, 1996) Technology is also a resource and

can even be seen as a core sharp weapon of operation in business organization and also a core resource that maintains a business’s competitive advantage. A business can obtain methods through all kind of technology and also must consider influencing factors in every directions to obtain core technology suitable to each business’s application, which also can reduce risk of failure. The advance of technology plays major role in creating a nation’s fortune. It affects people’s living standard and quality of life. (Khalii, 2000) Therefore, technology is the cornerstone of a nation’s economic growth and a business’s survival and development.

To take a comprehensive view on a business’s competitive strategy, the proposition of “from external to internal” strategic model in early years to subsequent “from internal to external” model both led the trend for awhile. However, how does a business focus basing on resources and capabilities from inside the organization? Or what kind of innovative type should a business search? It looks ordinary but has actually affect a business’s most fundamental operating strategy. Besides, following the relaxation of Taiwanese government in law and regulations and under excellent medical system, complex and tightly connected network relationship has made up current condition of regenerative medicine industry today. The origin of MetaTech’s cell sheet manufacturing technology in regenerative medicine started in technology transfers from CellSeed Company of Japan and took root ever since. How does MetaTech hang around with, compete and cooperate with big international re-

generative medicine companies surely triggered a further in-depth observation and exploration.

Theoretical Basis

Through discussions on technology strategy, technological transfer types, and innovation types, it can be the basis of fact description in helping this case study. This type of literature can provide to a business' developing process an instruction on static observation in certain event or strategy. On the other hand, according to theory of Miller and Morris (1999), the developing process of technology intensive business is a series of interconnecting activities and decisions that trigger process of innovation activities and organizational ability makeover. It provides an excellent fundamental structure on static observation on a business's developing process. The following would discuss aforesaid literatures.

Technology strategy

Technology management is the cornerstone of technology supervision system. It provides opportunity to business during intense competition but at the same time contains risk. (Ernst, 1998) Technology strategy is to invest technology resource to develop and apply technology and management required knowledge capability to achieve goals and create shortcut to competitive advantage. (Huang, 2012) Technology strategy is often seen as a dimension of a business strategy. The definition on technology strategy is different, but generally it is seen to surpass research and development strategy. (Danlia, 1989)

Technology strategy is also a shortcut for investment on technology resource to develop and apply technology and management required knowledge capability to achieve organizational goals and create shortcut to competitive advantage. (Clarke, 1989; Zahara, 1996) Thus, technology strategy is a method and process of using resource that considers both internal and external environment in enhancing competitiveness. It also explains close relationships among time stages, organizational ability and technology development strategy. (Tsai, 2001) Scholars also use different methods to apply technology strategy dimensions in strategic groups, such as classifying companies by order of entering markets to: market leaders, market leaders followers, applied engineers, imitators, (Ansoff and Stewart, 1967) and by coping behaviors when facing technology changes to: attacking strategy, defensive strategy, dependable strategy, imitating strategy, conventional strategy, and speculative strategy. (Freeman, 1982)

Technology transfer types and models

From business perspective, Harvey (1987) pointed out that technology transfer is an act that enable business introducing technology from external organization and benefitting from it. Rogers (1972) viewed that technology transfer usually is a process that an organization's innovation result introduced into and implemented by another organization. Technology transfer can have different types based on processing method and classification of transferring models. Scholar Mansfield (1975) believed that based on perception technology transfer

can be classified into the following two types, vertical technology transfer: points that it is a series of behavior process in which technology information is transferred from basic research to application research, or transforming application research and development to actual production; horizontal technology transfer: points to the same production technology, a behavior process used by one country or organization to transfer technology to another country or organization. Steel (1989) pointed out that technology must be classified into three categories based on the technical works that a business actually do: products technology; including product planning, product engineering, application and service engineering, etc.; manufacturing technology: including material selection, material processing or suppliers evaluation, and yield rate of manufacturing process and additional processing, equipment and tools selection, quality control, manufacturing system and maintenance, etc.; information technology: including information software and hardware, applied information system, real subject and cognition procedures connection and higher level supervisors' support systems, etc. Solo and Rogers (1972) based on technology receivers to classify processing methods of technology transfers to the following three kinds: single track transfer: technology is introduced entirely without any alteration; new track transfer: technology transfer is introduced after modification based on special environmental requirement; cross track transfer: modify technology receiver's technology and apply to usage for different purposes.

Innovation type

When a business face ruthless pressure, it must generate new wave of innovation to obtain profit and continue to exist. Almost every business shows Darwin style evolution process to maintain growing momentum. Many knows disruptive innovation, which is legend and lore, but we must not overlook a more ordinary innovation type that is equally effective. Thus, Moore (2004) proposed the following eight types of innovation. The first, disruptive innovation: draws much attention, as if coming from nowhere, as a source that create large volume of fortune. It leans toward the origin of technological discontinuity. The second, application innovation: Use existing technology on new market to achieve new purpose. The third, product innovation: Lead supply of products with stable market to higher layer. The fourth, process innovation: Allow supply process of products with stable market to become more effective or efficient. The fifth, experiential innovation: Do some surface modification to improve customers' experience on products. The sixth, marketing innovation: Improve method in contacting clients. The seventh, business model innovation: Redefine a value proposition of solid foundation with clients. The eighth, structural innovation: Use disruptive changes to reorganize industry relationship.

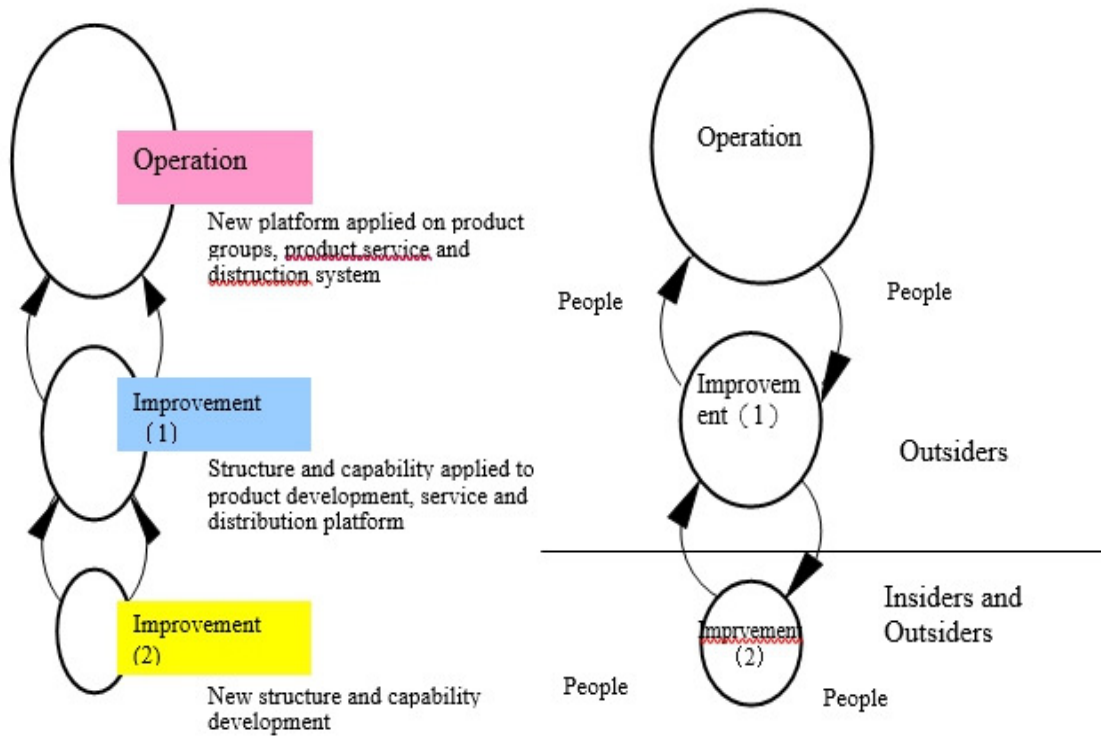
Development of organizational capability

Miller and Morris (1999) stated that for organizational structure there is an innovation cycle, in which innovation starts in competitive structure and develops organizational capability so that creation can provide platform foundation to

innovation in product, service and distribution system. “Organization creating driving force” and “creative tacit nurturing process” can guide organizational knowledge in lasting innovation. (Hung et al., 2010) Prahalad and Hamel (1990) believed that for companies to improve their competitiveness, they must first correct higher level supervisors’ incorrect operating idea that overlook core capability. They also proposed that the basic reason of the weakening competitiveness of US does not come from unfavorable “environmental factors”, but the overlooks on “core capability” of the interiors of business organization. Thus, the development of organizational capability will affect driving force and form of business growth or innovation.

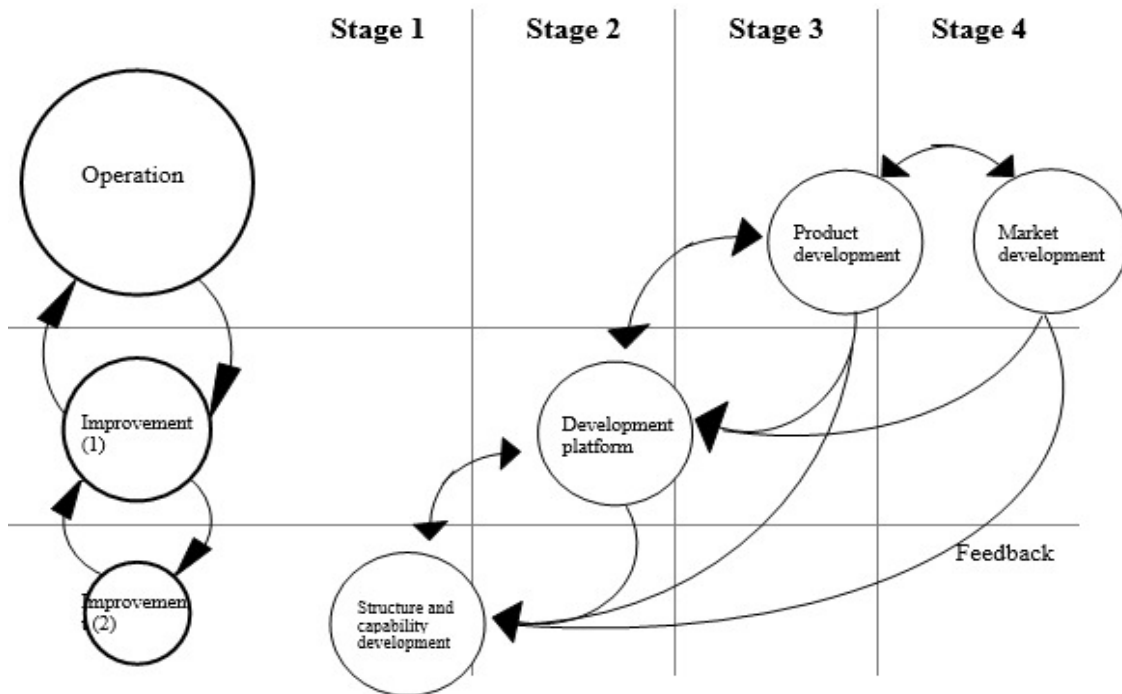
Miller and Morris (1999) brought up a capability development model, consisting a three-level organization and connection, as shown on Figure 1, for organizational capability development. The key connection is people themselves. When people leave works, because knowledge only exist in their brain, knowledge also follow people to flow and participate in different activities of three layers. Every core commercial activity, improving role of (1) is for better performance of operating activity, improving role of (2) is to improve (1) to be more efficient, while the main purpose of improving (1) is to shorten product cycle and make a more precise, fast and high quality core operating activity to run. Therefore, regardless of which

layer one works in business organization, those who work on improving (2) and (1) activities must understand relative core operating activities and tangible and intangible resources inside the company. In order to establish interdependent understanding, develop personal capability and extensively share and accumulate knowledge inside the organization, organizational members scatter among groups, moving freely and executing tasks. Through people’s moving participation among groups, it would induce generating “new knowledge”, which is then used to support source of innovative knowledge. People’s flowing around and common participation can build trust among each other. For the business’s core operating activities, improving (2) and (1) can also connect concepts of external structure, internal structure and employees’ capability, etc., meaning that relatively, internal and external structure on core activity is that employees’ capability is for the core of improving (1), while technology and procedures are core of improving (2). Thus, improving (2) is mostly for reducing cycling time of improving (1), and also for finding more valuable method, including possibly overlooked details, hidden system dynamics, and new rule and regulation on function and value. Improving (2) group does not necessarily need many people to effectively execute “enhancing improvement”, it emphasizes more on interdependent “knowledge production” process.



Data source : William L. Miller & Langdon Morris (1999), "4th Generation R&D : Managing Knowledge Technology, and Innovation". , Published by John Wiley & Sons, Inc. , p233 & p241 .

Figure 1 Capability development process and people moving among groups



Data source : William L. Miller & Langdon Morris (1999) , "4th Generation R&D : Managing Knowledge, Technology, and Innovation". , Published by John Wiley & Sons, Inc. , p281 ◦

Figure 2 Business innovation flowchart

Business innovation flowchart

The business innovation flowchart proposed by Miller and Morris (1999) is shown on Figure 2. It explains that organizational structure and capability development in Stage 1 can guide to enter Stage 2, in which with technology on developing platform of product, service and distribution system can then enter product development of Stage 3, then entering market development of Stage 4. When a project is under research and development, the new knowledge created can impact entire organizational model. Therefore, in a chaotic environment, good feedbacks from each stage is a necessary cohering guarantee.

Research Method

The study would explore on one case study, longitudinally tracing the origin and development of MetaTech's regenerative medicine technology and its spreading process; horizontally, showing the summary of innovation evolution track of MetaTech's technology transfers.

Study strategy

Based on Yin's (1994) study strategy classification, the study is "single industry case study method", studying a certain object in a certain period of time, through analysis on case behavior to find the reason or process that form present

situation. The study takes regenerative medicine industry as analyzing unit to obtain organizational capability development, technology strategy dimensions, innovative types and view point of business innovation flowchart, to develop theoretical model, further exploring MetaTech's historical development track of technology transfer in regenerative medicine through disruptive innovation during the years from 1998 to 2020.

The study mainly based on the concept proposed by Miller and Morris (1999) on the changes produced when organizations follow technology development track and the keys that must be decided and found that under different stages an organization must be able to complete some crucial activities that can prolong organizational growth. In addition, based on innovation type proposed by Moore (2004), it can be clearly pointed out that business grows in different stages must choose appropriate innovation model to finish tasks of certain stages, which is vital important in technology innovation intensive industry. The logic induction of this study started from the cycling evolving process of organizational capability development, after went through Improvement (1) and Improvement (2) to accumulate organiza-

tional resources and capability, then further affecting business's operating direction strategy and followed the time to move toward to choose what types of technology strategy, technology transferring type and model, bases of innovative type in that stage. The concept structure of this study is shown in Figure 3, which would separately explore case company's industry technology transfer and innovative types formed by evolution power in each stage.

Source of data

The study conducted in-depth interview with high level operating team and managers of MetaTech and collected secondary data, plus primary author's personal practical experience in related industry to obtain organizational related evidence from historical review angle and present aspects of study theme. Explanation from history is not an ambition attempting to establish theory, but simply valuing individually different research orientation under different time, space and environment thread of thoughts, which in micro research basis has performed some degree of integration or comprehensive explaining tasks on time phenomena. (Hsieh, 1994)

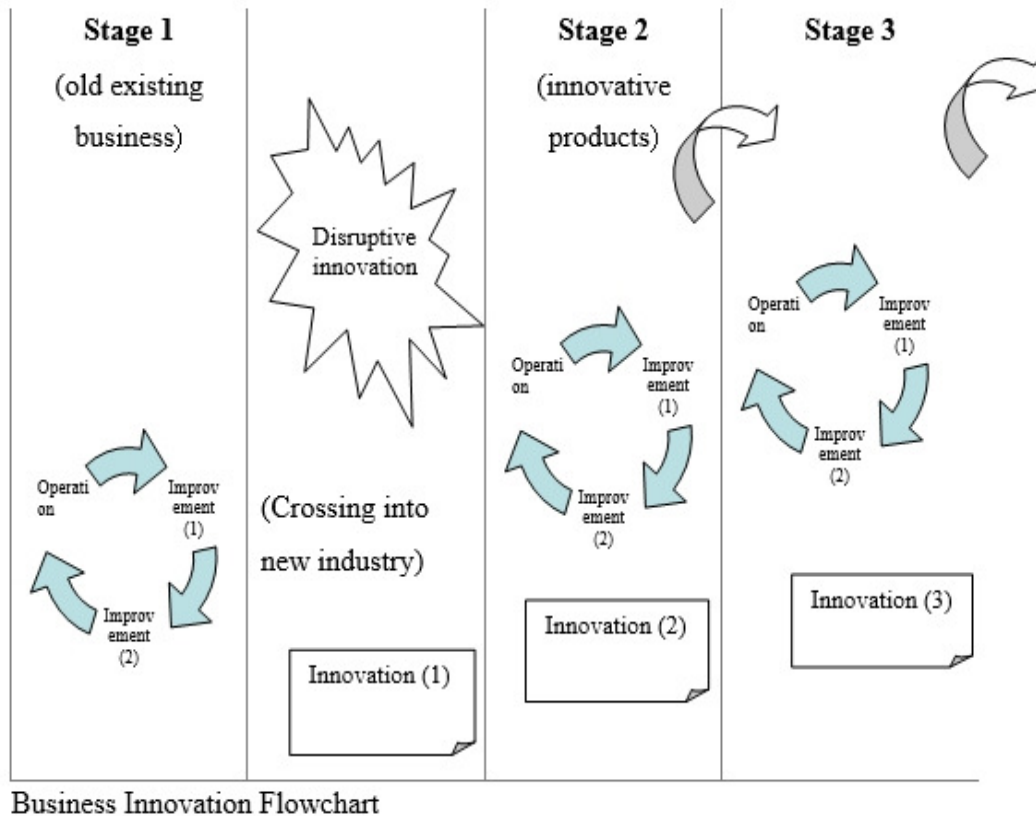


Figure 3 Research concept structure

Description of Case Company, MetaTech

Briefing on Company's Present Condition

Meta Tech (AP) Inc. was founded in September, 1998. Currently there are 90 employees in Taiwan and 39 employees overseas, with capital of NTD580 million. In addition to company's headquarter in Xizhi, New Taipei City, there are also overseas subsidiaries in Singapore, Hong Kong, and MetaTech Trade (Shenzhen), etc. The headquarter operates on production and sales while managing and controlling subsidiaries on

relative business. Subsidiaries not only sales to local domestic market, but also operate on marketing business in international market, implementing international division of labor with mother company in Taiwan.

The main operation of MetaTech is wholesale of electronics material and cosmetics. The products that the company represent are majorly consumer products, telecommunication products and connectors, plus biomedical products and others, etc.

In operating scale the company's total sales in 2019 is 1.412 billion NTD,

among which 64.41% is connectors, the most important sales item. The company' 2019 EPS after taxes is a loss of 1.59 NTD, a consecutive two-year decline due to the input on technology transfer of cell sheet in biomedical business in 2017, which just started and sales contribution cannot yet realize. However, since December 2019 four cooperative hospitals have passed verification by Ministry of Health and Welfare in special regulation on knee cartilage sheet and growth in sales is expected to turn loss into profit.

To view the sales market, in 2019 domestic sales occupy 21.33% of total sales while oversea market takes up 78.67%. As for market share, the company is a distributor of electronic parts and mainly represent sales of European and US brands, with products range covering telecommunication product, connectors and consumer products, and with the representation on sales of major brand Sametec and Everspin, etc., market share is stable. The company also actively search to represent brands in various application products, which will help to enhance market share in each product's industry in the future. Besides, the company has performed technology transfer with CellSeed Company of Japan and put clinical practice in developing biomedicine in Taiwan, with the first developing cooperative project in esophagus and cartilage repair, which can all be a brand new developing item in the future. The company also establish cooperative strategy in developing together with universities and collages and their affiliated hospitals, such as Taiwan University Hospital, E-Da Hospital, Taipei Medical University Hospital, etc., with

early stage to research, develop and test, and later stage to introduce into market, thus proceed with product sales and cooperation, to strengthen the company's competence niche.

History of biomedical technology development

With the opening of government regulation and encourage of policies, biotechnology business in Taiwan actively follows, reigniting market confidence. MetaTech put all effort on "regenerative medicine" development, not only has the newest "cell sheet" technology successfully transferred from Japan, but also put into effect in building cell manufacturing center in Taiwan and obtain the first domestic case of "cell treatment product three stages clinical trial permit". At the same time the company has gained approval from the Ministry of Science and Technology in special project verification to invest on building plant in Hsinchu Biomedical Park and entered joint venture with Hitachi, Ltd. of Japan to plan new generation of automatic cell treatment plant and will continue on innovative research and development, producing all kind of regenerative medical products. In sales strategy, the company cooperates with teaching hospitals of major top medical center levels, from charging treatment of current products, to completing research and development then entering clinical testing, even to development of newest application, all connect tightly with medical institutions. The company's cell treatment technology not only benefits people domestically, but also plans on international medical service for oversea patients that come to Taiwan for medical

treatment, and with integration on excellent medical techniques in Taiwan and expand MetaTech's international market, to build MIT high quality regenerative medical technique and service.

The study mainly researched and explored on technology development of MetaTech's regenerative medicine technology. After the company was founded, although related electronics products representation and sales was irrelevant to biomedical technology development, it is still an important cycle of organizational development process, which is also the driving force of disruptive innovation. Therefore, in summation of opinions from interviews with professionals, the study explored track of MetaTech's biomedical technology development in five stages.

The first stage: (Old) Electronic distribution industry (1998-2013)

MetaTech was founded in 1998 by Mr. Chen Hwa Liao, former manager of National Semiconductor Taiwan Region, and others, with management philosophy of "integrity, teamwork, challenge and optimistic", focusing on sales representation of electronic components, of which products application domain includes: industrial computer, server/storage, PC accessories, internet communication, power outlets and wireless communication products. The company's headquarter situated in New Taipei City, Taiwan and has established subsidiaries and branch offices in Hong Kong, Shenzhen, and Singapore, etc. Due to excellent operating performance in early years, the company was officially listed in OTC Taiwan in June,

2004. Until 2013 the company's main operation in electronic industry was still largely in consumer products, communication products, and connectors, without much changes. The company had stable growth every year, with accumulated earnings of 60 million NTD.

In July 2013, the original management team of the company decided to release their holding due to career planning and let Mr. Li San Hu and others to take over publicly. Under mutual agreement, the acquisition volume was 16 million shares of common stock, about 38.09% of total shares of outstanding common stocks.

After the change of management team, Mrs. Mei Yue Huang was appointed as chairman of the board of directors and was replaced by Mr. Li San Hu, the present chairman who still leads the company today. Because the new management team was certain about future biomedical market, in November 2013 biomedical business department was established, which based on existing electronic technology domain to develop biomedical distribution business, increase bio technology medical treatment, cosmetics, and care products, etc.

A brief summary: At this stage, back then in Taiwan the telecommunication network, DVD multi-media and cell phone application products continued high growth. With the addition of excellent performance of electronic industry and semi-conductors companies in Taiwan, and factor such as support of governmental industrial policy, electronic communication industry was developing vigorously, thus leading dis-

tributors of electronics and communication to high growth.

This stage is distribution business stage, there was no production, manufacturing, research and development. The main products are representing sales of consumer products, communication products and connectors. However, starting from November 2013 there appeared disruptive innovation strategy in the company with the introduction of biomedical distribution business. In market entering strategy, this stage played the role of following market leader and the contingent behavior strategy is conventional strategy oriented.

The Second Stage: Nurturing period of regenerative medicine technology (2014-2016)

To cope with the integration of electronic technology and medical bio technology for future development trend, in 2014 the new management team of MetaTech actively introduced professional biomedical team, hoping to base on existing electronic technology field to effectively develop business in biomedical distribution. Thus the company signed “Multi-functional image digitalization and biomedical chip testing integration technology platform” technology transfer authorization with Taipei Medical University in July, 2015. In September of the same year, the “biomedical VIP show facility” that was founded in Taipei 101 provided intelligent micro type functional sensor to take non-invasive method in providing system analysis on individual health. In 2016 the company signed tumor medicine related gene testing agency agreement with BGI Health

(HK) Company Limited and provide gene testing service to domestic cancer patients in Taiwan. The company also signed a cooperative memo with BGIK Health (HK) Company to co-find joint venture and laboratory and agree to proceed with personalized cancer medicine gene testing in Taiwan, realizing localization of cancer gene medicine screen. At the same year the company acquired Jen-Hwa travel agency inc. as subsidiary. In 2016 the company signed cell sheets regenerative medicine cooperative memo with CellSeed Company of Japan, planning to develop regenerative medicine, including transfer of cell cultivation technique and reconstruction and repair of human organ tissues (such as: inner wall of (o)esophagus), of which range include development plan, clinical experiment, manufacturing and product sales, etc. Both sides expand regenerative medicine development of (o)esophagus and knee cartilage in Taiwan together, to shorten research and development time and push regenerative medical products to complete commercialization as early as possible.

A brief summary: This stage opened up technology nurturing period of MetaTech bio medical industry. According to cooperative memo, CellSeed Company of Japan would provide technology and relative equipment, thus pushing forward the establishment of MetaTech’s cell sheet foundation afterward. At this stage the biomedical technology in Taiwan was generally in sprouting period. Disregard other people’s sneering at, with input of huge amount of technology transferring fees, MetaTech management team still bravely innovated and expanded, actively

working for technology transfer so they were able to nurture the technology of cell sheet in Taiwan in later years.

As for the technology source of cell sheet in Taiwan, such stage of transferring model is planned by CellSeed Company to apply horizontal transferring method to Taiwan. At the same time CellSeed Company also provided entire set of equipment source and introduced production technology by one track transferring. At this stage biomedical products aim at cartilage repair technology and clinical esophageal cancer treatment, with technology source originated in technology capability development of CellSeed of Japan. In the strategy of market entrance, this stage plays the role of following market leader, while technology coping behavior strategy is still conventional strategy oriented.

The Third Stage: Technology taking roots stage (2017-first half of 2018)

In April, 2017 the company officially signed with CellSeed of Japan to cooperate in developing regenerative medical items in Taiwan, introducing CellSeed Company's esophageal and cartilage repair technique. Since the company cooperated with CellSeed Company, the leading technology company of cell treatment in Japan, in technology transfer, it has put full effort in developing regenerate medicine. Because regenerative medicine thinks outside the box of conventional western medicine in curing the symptoms and not the disease beaten track, it broke through from "symptom treatment" to "tissue/organ repair" and had become prominent subject in medical treatment.

The research and development experience of Japan in regenerative medicine has grown fast globally, of which favorable rule and regulation for cell treatment has been promulgated in more than twenty years, Japanese companies have long been in this business. The technology of "cell sheet" specialized by CellSeed Company can even be seen as the leap of advancing "single cell repair" to "tissue reconstruction". In viewing the cell treatment in Taiwan, it still stayed in developing the lower technology threshold of single cell injection and no product of cell sheet in the market yet. MetaTech management team quoted from Sir Issac Newton: "If I have seen a little further it is by standing on the shoulders of Giants.". Thus, in the critical period of taking a root and growing strongly in biomedical business development, MetaTech decided to cooperate with CellSeed Company, the forerunner of regenerative medicine in Japan. Back then it was the first regenerative medical technology transfer case in Taiwan and Japan, that introduced nurturing technique of "cell sheet" and developed "esophageal and cartilage regenerative medical treatment technology". The introduction of relative technology and equipment is like planting seeds in Taiwan for regenerative medical treatment development. In the same year MetaTech also obtained 100 million NTD of "Industry Innovation Transformation Fund" established by National Development Fund of Taiwanese government. Through the technology transfer speeding up the clinical trial timing in Taiwan, it assisted in pushing forward the development of regenerative medicine related medical treatment. In addition, with increase in cash capital of 1.4 million

shares, it has shifted the fund to the need of MetaTech's cell sheet in clinical trial experiment development in Taiwan, and allowed the starting of regenerative medicine development in Taiwan,

In the progress of research and development application, MetaTech's products are autologous cells and special tissue engineered regenerative medical products, which major function is to repair tissue damage and autologous tissue regeneration. One of the functions is to apply esophageal cell sheet in repair surgery of endoscopic submucosal dissection on esophageal cancer, which can reduce proliferation of healed tissue and maintain the space of Esophageal lumen, and in comparing to conventional drug and balloon expansion treatment, such method can be more effective in preventing esophageal stenosis symptom. The second one is to use cartilaginous cell sheet to induce rebirth of autologous chondrocyte, allowing damaged articular cartilage to heal, which, in comparing to conventional medical treatment technique, can significantly improve patients' quality of living. In present MetaTech has successfully transfer cell sheet nurturing technique. In the development of "esophageal sheet", the company has completed CDE preliminary in 2018 and the third stage clinical trial submitted in early 2019 has obtained approval by the Ministry of Health and Welfare to proceed with experiment and would cooperate with Taiwan University Hospital and E-Da University Hospital in clinical trial. The key to clinical trial success is the degree of progress in admitting cases and treatment effectiveness on patients. With the academic and clinical status of this two hospitals and par-

icipating doctors all have abundant experiences in esophageal cancer treatment and can be deemed as authority of esophageal cancer in Taiwan, it would be a plus for future clinical trial to finish fast and go on the market earlier. In the development of "articular cartilage sheet", there are a total of fourteen doctors from ten medical centers in Taiwan to work together. According to statistics, the number of people that need knee joint replaced is more than 40 thousand cases. Due to the large volume of cases taken, the company plans to take cases simultaneously with various medical centers so the products can be in the market sooner. Therefore, to train research and development staffs in cell sheet technology, the company sent technology seed troop to Japan for training and certification, so the technology of cell sheet in Taiwan can get to take roots subsequently. What is worth mentioning is that the initial researcher and developer of articular cartilage sheet is Dr. Masato Sato of Tokai University Hospital in Japan, whose advanced medical treatment technique of "autologous articular chondrocyte regrowth treatment" has obtained approval of the Ministry of Health, Labour and Welfare in Japan on October 18, 2018 and can already be used in treating patients in Japan by performing cartilage repair treatment and collect fees, which also prove safety and feasibility of articular cartilage sheet technology. Because in present only Japan and MetaTech in Taiwan own this technology, it is believed that the product of articular cartilage sheet going into the market can benefit people in Taiwan to be free from the pain of replacing artificial knee joint.

Besides, MetaTech management group strongly invited elites to join, such as having Dr. Ray Jade Chen (superintendent of Taipei Medical University Hospital), Dr. Hong Nen Her (former superintendent of National Taiwan University Hospital), and Dr. Chih Hui Yang (Associate Dean, College of Medicine, I-Shou University), most authoritative professional experts in medical biotechnology industry, as new supervisors, which would definitely lead the company toward regenerative medicine development and allow each research and development and clinical study to run smoothly, providing a more power growing kinetic energy to MetaTech. Group.

A brief summary: This stage is the period that MetaTech's biomedical technology took root. The company's management team not only undoubtedly revealed the toughness of small and medium enterprises in Taiwan, the technology expansion benefit generated during technology transferring process and its sharp market observation and flexible coping actions, but presented the entrepreneurship spirit. In complex economic food chain and the competitive nature law of winning and losing, the management team has maintained an entity's tough vitality. Although there is no large amount of operating capital, the management team has kept active and attentive working attitude, bravely moving forward to establish excellent foundations.

In this stage, MetaTech officially brought in CellSeed Company's specialized "cell sheet" technology and related equipment. The transferring model type applied is the method of horizontally

transferring to Taiwan. Mr. Ming Shun Mo, manager of MetaTech's manufacturing research and development department and others, etc. were the pioneering seed troop of technology, which were subsequently multiplied and gradually accumulated technology foundation in lab manufacturing. At the same time the handling method of transferring technology has progressed from one track to new track method, which in medical application manufacturing technology has started diversified types. The development of MetaTech's business organizational capability not only gradually expand and accumulated internally and externally, its technology manufacturing capability also continuously research and develop and progressed. Due to the technology has taken roots, it started to grow strongly and applied to other tissue repairs and gradually stepped into "products innovation" stage. In marketing entering strategy, this stage still plays the role of following market leader and technology coping action strategy is dependent strategy.

The Fourth Stage: Technology innovation period (Second half of 2018 – 2019)

Although MetaTech introduced cell sheet nurturing technology of CellSeed Company of Japan to develop as main product, but the company does not limit itself. The company uses simulating innovation strategy to focus on extending the development of cell sheet nurturing technology and marketization. It will use existing technology basis to break through critical core technology and continue to bring in and learn advanced technology in the world and, in this stage, started to show research and develop-

ment result. In January 2018 the company signed cooperative memo with Dr. Niann-Tzyy Dai of Tri-Service General Hospital of the Ministry of National Defense in Taiwan to develop “study of skin cell sheet applied on healing wound”, and bring in the company’s innovatively researched and developed “skin cell sheet” product to clinic. At this time the third stage of experiment IND on autologous oral mucous membranes has been submitted to the Ministry of Health and Welfare.

MetaTech thought that will strategic alliance, plus cooperation from industry, government, academics, research, and medicine, are two main shafts that speed up biomedical industry in Taiwan to walk hand-in-hand toward international arena. Thus, in order to stand firm in Taiwan, the company not only must bring in foreign technology, it need more in building a cell manufacturing processing center that meet the standard condition of Pharmaceutical Inspection Cooperation Scheme (PIC/S GMP) to benefit research and development, manufacturing and products of subsequent product. In present the company has built the most well established cell sheet operating room in Oriental Science Park, which, in addition to cope with more productivity, can provide enough supporting space to optimize manufacturing process in order to save research and development time and provide more regenerative medical products’ capability. Inside the center there is also established the only one quality experiment, taking charge on quality control process of cell sheet and can effectively control time and cost management and control. The quality control center is used internally,

and will promote quality control related business externally in the future, to increase company’s business income. The cell production center (CPC) has been completed in environmental and equipment validation in October 2018 and has started products’ pilot run in November of the same year. The center is the production site of esophagus and cartilage clinical trial products to cope with foreseeable production capacity increase. In the same year the company’s been approved by the Ministry of Science and Technology Review Board to invest in building plants in Biomedical Park, with main purpose of bringing in automatic cell nurturing process and keeping pace with big biotechnology companies in Europe, US, and Japan.

In September 2018 the Ministry of Health and Welfare passed “Regulations on implementing or using special medical treatment technique examination inspection medical equipment” (Special Regulation), a heart-strengthening shot to regenerative medicine industry in Taiwan. The Special Regulation specially opened up six cell treatment items, consisting of peripheral blood CD34+ cells in autologous stem cell transplantation, autologous immune enhancement therapy, autologous stem cell enhanced fat grafting, autologous transplantation of cultured fibroblasts, autologous transplantation of bone marrow mesenchymal stem cell and autologous chondrocyte transplantation, among which autologous fat stem cell, autologous cultured fibroblasts and autologous chondrocyte are the items submitted by the company in 2019. The company also applied with various large medical research institutions for the application of autologous

cultured fibroblasts on skin regeneration, including wound healing, wrinkle evening and scar repair, etc., which plus the application of autologous chondrocyte on cartilage regeneration, including repair and regenerate damaged cartilage, would assist the company's growth in biomedical performance.

In January 2019 MetaTech signed cooperation contract with Superintendent Yuen Shen Tu of E-Da Hospital on cartilage sheet repair and plexus technology. In April of the same year the company signed three party cooperative memo with Tokyo and Hitachi group, to develop regenerative medicine market in Taiwan together. In December the company also announced with CellSeed Company of Japan that they would form a joint venture "Nissen Cell Biotec Inc." (Nissen Company) in Taiwan and invited Academia Sinica Scholar Dr. Andrew H.-J. Wang as Chairman of the Board of Directors. Nissen Company became MetaTech's subsidiary and would devote to research and develop clinical application of every kind of cell sheet. The first project is to cooperate with Superintendent Tu of E-Da Hospital, using MetaTech's "neuro cell sheet" to accompany Dr. Tu's uniquely created surgical method-regenerative treatment of brachial plexus and spinal injury. Nissen Company is the first cooperating projects of CellSeed Company and MetaTech since 2017 after the technology of esophageal cancer and cartilage sheet was authorized to MetaTech and the first oversea company that CellSeed Company invested. Thus, the human cell sheet technology researched and developed afterward would be owned by Nissen Company and for commercial patent

authorization. The president of CellSeed Company Setsuko Hashimoto also attended the founding news conference in person. She has more than thirty years of developing experience in industry and academic cooperation and commercialization of cell treatment. With the progress of Taiwanese law and regulation, Japanese company hopes to combine with MetaTech to accelerate development of regenerative medical treatment in Taiwan together and speeding up commercialization, wishing that Nissen Company's future cell application can be expanded to other areas of Asia to satisfy more potentially unfulfilled medical treatment demanding market.

A brief summary: At this stage MetaTech's technology has technology spill over effect. After the company's organizational internalized learning process, MetaTch has gradually accumulated and enhanced every kind of capabilities, especially the technique of "skin cell sheet" has entered production of "process innovation", different from their earlier method. In the processing method of transferring technology, the company applied cross track internal transferring method. As MetaTech appeared in the role of the network division of labor in international regenerative medicine industry, the strategic position that the company plays had shown to be more important. In the company's market entering strategy, in this stage, besides playing the role of applied engineers, the company has taken imitating strategy and cooperative developing strategy oriented in the its technology coping behavior strategy.

The Fifth Stage: Technology expansion period (2020 to present)

Clinically in present the mostly commonly seen cell products are single cell injection type, there has not been product of cell tissue or cell of 3D nurtured in the market, showing that cell sheet has its product innovation, market monopolization, technical differentiation, and clinical application. Cell sheet has its special standard and regulation in product specification and has its unique market and demand in clinical application.

In April 2020 Hitachi Group of Japan announced to enter joint venture with MetaTech to found a new company, with a plan to construct Asia's largest cell production factory in Zhubei, Taiwan. Construction of the factory is expected to be completed by the end of 2023, which will assist Taiwan further and accelerate development of global regenerative medicine. Before the Hsin Chu factory is completed, the production line in factory in Xizhi, New Taipei City, would firstly be expanded to manufacture and provide cell sheet for the demanding order of large pharmaceutical companies in the world. In fact, Taiwan and Japan has a large complementary and cooperative space. The introduction of the newest regenerative medical technology from Japan to train relative talents together, and combining the excellent medical treatment capability and innovative technology of Taiwan, together they initiate international competitiveness. MetaTech is the only company in Taiwan that obtained the approval of both to enter the third stage of clinical trial on cell treatment product

and "Special Regulation" of autologous chondrocyte implantation treatment. Especially that MetaTech's GTP laboratory was visited and inspected by Hitachi based on international standard of Europe and US to align with PIC/S GMP specification, so Hitachi chose MetaTech as their cooperating partner. This is following CellSeed Company's joint venture to establish Nissen Cell BioTech Inc. in Taiwan that the company entered another joint venture with Hitachi, which will bring in equipment, capital and technology to Taiwan to build Taiwan becoming an internationalized important cell capital, and through Hitachi's lead to enter international cell treatment industry supply chain together.

According to the report of Global Biotech Monthly, starting from 2017, Hitachi has continuously merge overseas cell plants, presently the company has owned six cell plants in the US, Germany and Japan, finishing its plan in three large markets of US, Europe and Japan, but the new plant in Taiwan will be the largest base of all. Hitachi will bring in fully automatic production technology, introducing automatic system that can "custom made" to cope with ordered products and production line will have different consideration and design. The building of Cell Processing Center (CPC) module equipment will not only reduce the risk of manual operating and ascertain product safety, it also can reduce cost due to meet unified standard specification of lot productions. In compliance with the plan, after the establishment of Cell Processing Center is completed and passed approval, the annual sales volume is expected to reach 100 million USD, such growth is highly anticipated. According to Mrs. Lian-Yu

Liang, General Manager of Asia Pacific, Taiwan Hitachi, the most importantly is to multiply fast, integrating the strength of Taiwan industry's flexibility in CDMO OEM and highly customization, plus Hitachi has many years of PIC/S GMP international standard experience, she believed that the company can fast achieve arrangement in global market. (Data source: <https://www.gbimonthly.com/2020/04/66700/>。)

With the vigorous development of regenerative medicine industry trend, at this stage MetaTech has large input in research and development expenditures, and plus unique ambition, the company has been in the equal pace with technology of large plant in the world, also established its leading position in regenerative medicine industry division of labor. It is expected that Taiwan government will legislate to pass "Regenerative Medical Preparation Regulation" this year, by then cell treatment product of European countries and US will be able to enter Taiwan smoothly. MetaTech would move toward establishment of human cell sheet bank in Taiwan, regenerative medicine research and development center and regenerative medicine innovation business incubators as aim. Through establishment of these units, the company can proceed with product education, higher level talents nurturing and products promotion, and at the same time develop innovative business channels, technology transfer or authorization to innovative companies, which can be charged for royalties, all can increase company's profits and growth.

A brief summary: At this stage MetaTech, through joint venture with Hitachi of Japan, has people from both companies to learn from each other, then applied vertical and horizontal transferring to enhance technology improvement of manufacturing process, using design and capacity transfers to reduce manufacturing cost and research and development of high added value new products. In this period MetaTech's cell sheet manufacturing technology has been relatively matured, so their handling method on transferring technology can be done by cross track transferring method. In marketing entering strategy, they have played the role of applied engineer in this stage. In its behavior strategy on technology coping, due to the company's joint venture with Hitachi, its behavior strategy is dependent strategy, but its existing technology strength is also with defensive strategy.

Analysis Result of Case Company

Summary of the above literature and induced to analysis of MetaTech's technology transfers is shown in Table 1. The first stage is electronic distribution industry, there was no production, manufacturing and research and development, neither was technology transfer. However, in November 2013, the company appeared disruptive innovation strategy, bringing in biomedical distribution business. In market entering strategy, at this stage the company played the role of following market leader and its coping behavior strategy is conventional strategy oriented. The second stage is biomedical technology nurturing period. According to cooperative memo, transferring model type is planned by CellSeed

Company to apply horizontal transferring method and by one track transferring to bring in production technology. In the strategy of market entrance, this stage the company played the role of following market leader, while technology coping behavior strategy is still conventional strategy oriented. The third stage is the period that biomedical technology took root, with transferring model type in horizontal transferring method. The handling method of transferring technology has progressed from single track to new track method. Because technology has taken root, it started to grow strongly and can be applied to other tissue repair. In marketing entering strategy, this stage still plays the role of following market leader and technology coping action strategy is dependent strategy. The fourth stage is technology innovation period. The handling method for transferring technology applied cross track internal transferring method. In the company's market entering strategy, in this stage, besides playing the role of applied engineers, the company has taken imitating strategy and cooperative developing strategy oriented in the its technology coping behavior strategy. The fifth stage is technology expansion period. Through joint venture with Hitachi of Japan, the company applied vertical and horizontal transferring to enhance technology improvement of manufacturing process and used design and capacity transfers to reduce manufactur-

ing cost. The handling method on transferring technology can be done by cross track transferring method. In marketing entering strategy, the company still played the role of applied engineer. In its behavior strategy on technology coping, due to the company's joint venture with Hitachi, its behavior strategy is dependent strategy, but it existing technology strength is also with defensive strategy in order to cope with environmental demand in both domestic and overseas.

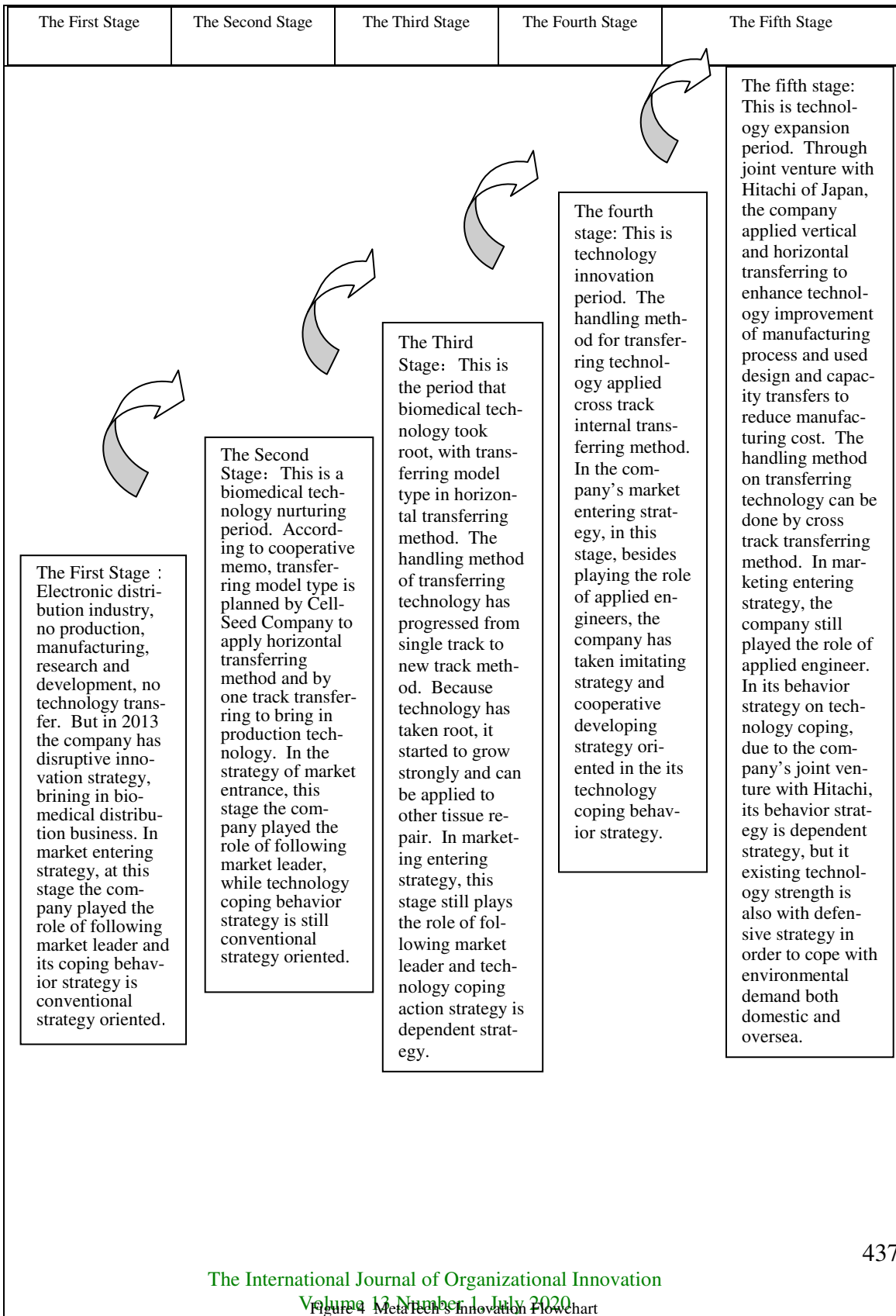
The evolution track of MetaTech's five stages of technology transfer type reveals that in the handling method of technology transfer, it has gradually developed from one track transfer method to cross track transfer method. In technology transferring type, stages of nurturing period and taking root period are mainly in horizontal transferring type. CellSeed Company of Japan is the technology source foundation of MetaTech. After continuous internal learning, the imitating strategy has worked that there is a breakthrough innovation in technology, thus the stages of innovation period and expansion period can apply vertical transferring type and applied to cell sheet new products on other tissues. Technology transferring media mainly use transfer of product equipment and people as dimension while MetaTech's technology transferring type mostly was processed via joint venture.

Table 1 Analysis of MetaTech's Technology Transfer in Every Stage

Technology transfer category		Electronic Distribution Industry(I)	Disruptive Innovation	Biomedical technology nurturing period(II)	Taking root period (III)	Innovation period (IV)	Expansion period (V)	
Technology transfer type	Vertical transfer						V	V
	Horizontal transfer			V	V			
Technology receivers on transfer handling method	Single track transfer			V	V			
	New track transfer							
	Cross track transfer					V	V	
Actual technology work differentiation	Product technology	V			V	V	V	V
	Manufacturing technology			V	V	V	V	V
	Information technology					V	V	

In addition, as shown in Figure 4, in the innovation flowchart of MetaTech's technology historical track, in technological strategical track: For market entering strategy from the First Stage to the Third Stage, the company mostly played the role of following market leader until the Fourth Stage and Fifth Stage that it changed to the role of applied engineer. In technology coping behavior, the First Stage to the Third Stage were conventional strategy oriented. In the Fourth Stage because the company has joint venture with CellSeed Company of Japan, the company's technological development tends to be dependent strategy. In the Fifth Stage due to the joint venture with Hitachi of Japan, the company's technological development almost inherited from Japanese

company, thus tends to be dependent strategy. In innovation type: In the First Stage the company directly jumped from electronic distribution products to establish new product business. It is disruptive innovation type; for the Second and the Third Stage, because of the technology transfer from CellSeed Company of Japan, product manufacturing is applied innovation type; in the Fourth Stage because the company's learning in technology manufacturing process has progressed, it is product innovation type; the Fifth Stage is strengthening structure product diversification, taking multiple role strategy to actively cooperate and ally with large international companies and striving to be in international cell treatment industry supply chain. This is construct innovation type.



Conclusion

Regenerative medicine is still a forerunning technology and application development. According to the study predication of Research and Markets of 2017 Global Market Research Institute, the market scale of global regenerative medicine can grow from 18.9 billion USD in 2016 to 35.7 billion USD in 2021, respectively. In 2015 US National Institutes of Health funded regenerative medicine (including stem cell) research approximately 67.3 billion NTD. In 2012 Japan promoted “Japan Regenerating Strategy” and input 30 billion Yen to develop induced pluripotent stem cells (IPS cells) research. In 2017 medical treatment research development agency in Japan also focused on practicality of regenerative medicine and industrialization, etc. by input 14.7 billion yen, hoping to accelerate research into clinical trial and pushing commercialization of study results. There are more than 700 companies in the globe on regenerative medicine field, all revealing that development of regenerative medicine continue to flourish and, under the drive of market demand and gradual constructing of the environment, there has been a production of a complete industry system structure. With the relax of governmental regulation, it will allow developing progress to speed up and Taiwan has great developing potential. In technology strategy and industry management field, evolution perspective is a flourishingly developed subject in recent years and different conceptual structures are continuously proposed. The main points in literatures described may have fundamental differences, they all emphasized that technology devel-

opment has its system and historical evolutionary track to be found. The study used regenerative medicine industry in Taiwan as analyzing unit, applying capability development, operating technology strategy, innovation type and business innovation flowchart perspectives, to explore further the historical track of MetaTech in technology evolution for the periods from 1998 to 2020. As shown in Table 2, it is the industry strategy and business innovation milestone formed by evolution power of case company in five stages.

In this study we find that in the first three stages MetaTech’s technology coping behavior applied conventional strategy and established technology transfer in one track and horizontal method. In innovation stage the company changed to joint venture type of dependent strategy to proceed cross track type of obtaining technology transfer. After accumulating internalized technology development to be matured and technology stables in present stage, the company has taken defensive strategy orientation in addition to dependent strategy. The regenerative medicine industry in Taiwan can rely on excellent flexible coping capability and active input in research and development of Taiwanese business to show their capacity in competing with large companies in international market of regenerative medicine field for Taiwan. The study presented the international situation of Taiwan regenerative medicine industry’s current development through MetaTech’s development experience in technology initiation and establishment. The growth of industry needs support of governmental policy, and, also need flexible coping capacity

of industry. In addition, the development of MetaTech's cell sheet not only must rely on technology push force and market pull force, the most important is how MetaTech continue to hang round

with international regenerative medicine industry in the strategic position that it takes in playing one role of network division of labor

Table 2 Milestone of capability development, operating strategy, innovation type in five stages of case company

	The First Stage	The Second Stage	The Third Stage	The Fourth Stage	The Fifth Stage
Capability Development	Electronic distribution industry, no production, manufacturing, research and development, no technology transfer.	According to co-operative memo, transferring model type is planned by CellSeed Company to apply horizontal transferring method and by one track transferring to bring in production technology.	The handling method of transferring technology has progressed from single track to new track method. Because technology has taken root, it started to grow strongly and can be applied to other tissue repair	This is technology innovation period. The handling method for transferring technology applied cross track internal transferring method.◦	This is technology expansion period. Through joint venture with Hitachi of Japan, the company applied vertical and horizontal transferring to enhance technology improvement of manufacturing process and used design and capacity transfers to reduce manufacturing cost. The handling method on transferring technology can be done by cross track transferring method.◦
Operating Technological Strategy	In market entering strategy, at this stage the company played the role of following market leader and its coping behavior strategy is conventional strategy oriented.◦	In the strategy of market entrance, this stage the company played the role of following market leader, while technology coping behavior strategy is still conventional strategy oriented.	In marketing entering strategy, the company still plays the role of following market leader and technology coping action strategy is dependent strategy.	In market entering strategy, the company played the role of applied engineers. In its technology coping behavior strategy, it is imitating oriented	In marketing entering strategy, the company played the role of applied engineer. In its behavior strategy on technology coping, it is dependent strategy, but it is also with defensive strategy oriented.
Innovation Type	Disruptive innovation	Applied innovation	Applied innovation	Product innovation	Construct innovation

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