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A COMPARATIVE STUDY OF JAPANESE AND US AMERICAN MEDICAL DEVICE INDUSTRIES

Japan has an unfavorable balance of trade in medical devices, and large Japanese companies hesitate to enter the medical device industry. This paper investigates the process of the expansion of the American medical device industry. It was concluded that the propensity for risk in the U.S.A. and Japan is different; both countries have different industries and ways of thought which construct their manufacturing cultures. A system called Investigational Device Exemption (IDE) indicates that US Medical Industries are in a stronger position than their Japanese counterparts. The American system allows purchasing of developing medical devices before pharmaceutical acquisition. Japan has no foster policy for medical venture, nor are medical devices tested strictly before pharmaceutical approval. It is predicted that the Japanese economy will no longer be able to grow in a stable manner just by relying on the large corporation-led export of manufactured goods, whereas those SMEs with the sophisticated technology, by accommodating the needs of the medical institutions, will be highly competitive internationally in a narrow and specialized market. The author points out that promotion for the medical device industry may help Japanese economic revitalization. Japanese companies and their government will have to support developing "diversity" of the players.

1. BACKGROUND

1.1. THE CURRENT STATUS OF JAPAN'S MEDICAL DEVICE INDUSTRIES

Japan has recently suffered from an unprecedented scale of natural disaster, and a heated debate will arise on which industry will lead Japan's economic recovery most effectively. It is expected that in the new era, those SMEs that have been vital as subcontractors to the large corporations will act independently with their own technologies. These SMEs have been fostered with ideas and inventions to respond from large contractors' requests. They developed during the economic high-growth period with their unique, so called "only-one," technologies in each steady small enterprise without relying on the big corporations. One of the areas of such technology that would be most utilized will be the medical device sector. Until now, the only medical devices where Japan has had the international competitive edge have been the low invasive diagnostic devices especially the large-sized ones (CT, MRI) that generate large earnings and the fiberscope-style endoscopes using optic technology one of the technologies where Japan's strong

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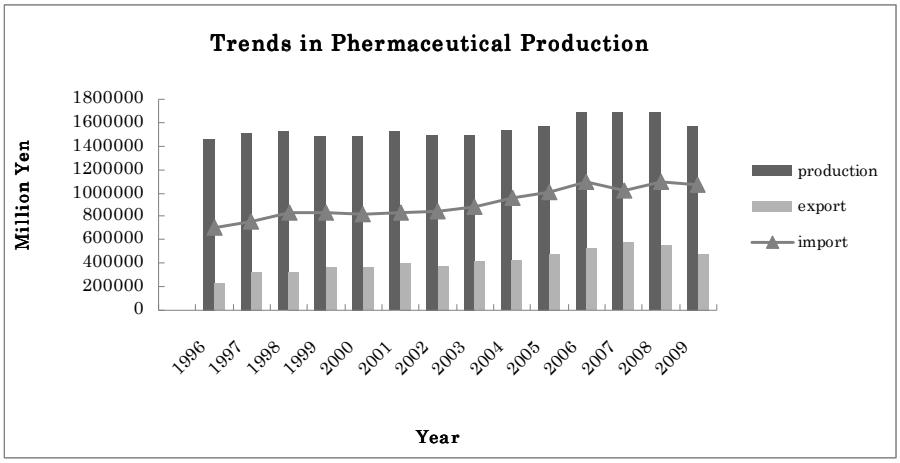
competitiveness lies because of its accumulated elemental technologies. As Dr. Professor Yoshimi Ito, the founder of the International Institute of Industrial and Manufacturing Culture (IMAC), has pointed out, Japanese manufacturing culture is different from that of America [1]. The author thinks, therefore, Japan seemed even to be going away from the medical industry. A few large corporations that have the medical device subsidiaries have been making profits cautiously by having the subsidiaries as independent entities in order to shield their main business from the risk of such sectors being liquidated.

Japan is following a path to an aging society in ways not being experienced by any other country. As the aging of the entire Japanese population progresses, the market covering the life science sector, such as prevention of disease and enhancement of the quality of medical care, is predicted to expand even further. According to the FY2005 edition of the Statistical Survey on Trends in Pharmaceutical Production, which the Ministry of Health, Labor and Welfare (MHLW) reported, the total market for medical devices in Japan was approximately 2.5 trillion yen in 2005 (domestic production 1.5 trillion yen and imports 1 trillion yen). The latest statistics which were announced by MHLW, "The Statistics of Production by Pharmaceutical Industry," show the market scale grew during the past 14 years; Japanese production of medical devices grew only 109.2%, whereas the imports grew 151%. In other words, Japan has been relying increasingly on imports each year. This trend shows that the domestic market has been expanding because of increased imports, or, in other words, the growth of Japan's medical devices market is dependent on imports from overseas. (The raw data with ratios are featured at the end of this paper in Appendix 1.)



Data from MHLW annual report of Statistics of Production by Pharmaceutical Industry

Fig. 1 Statistics on Pharmaceutical and Medical Device Industry

Clause 4, Article 2 of the Japanese Pharmaceutical Affairs Law which was revised in 2005 defines medical devices as "any instrument, apparatus, appliance, material or other article used for the purpose of diagnosis, treatment, or prevention of disease in humans or animals, or for the purpose of influencing the physical structure or function of humans or animals, and which are stipulated by government ordinances." Medical devices are furthermore classified into three types: (1) "High-level controlled medical devices" and (2)

"Controlled medical devices," both of which were designated by the Ministry of Health, Labor and Welfare after incorporating the views of the Council on Drugs and Food Sanitation, as well as (3) "General medical devices." Examples of (1) include dialyzers, pacemakers, and PTCA catheters, among others; examples of (2) include MRI, laparoscopes, electronic manometers, electronic endoscopes, and ultrasonic diagnostic devices; and examples of (3) include surgical knives, tweezers, X-ray film, and other items. Of these, companies wishing to manufacture and sell (1) and (2) must obtain the approval of MHLW for each item. Devices with high novelty value require the approval of the said Minister, even if they belong to Class (3).

What, then, is the scale of the global medical device markets? According to the 2000 edition of the European Medical Technological and Devices Industry Profile issued by the European Medical Technology Industry Association, or Eucomed, the market amounted to 18.7 trillion yen, with 41% of products coming from the US, 26% from the EU as a whole, and 15% from Japan. In other words, products made in the US boast an overwhelming competitive edge in global markets.

In consideration of the current status—Japan's domestic market being dominated by US-made products, and its international market share eclipsed by the US—in 2003, the Japanese Government drew up their Vision for the Medical Device Industry and worked to stimulate the market by means of an Action Plan. At a meeting of the Council on Fiscal and Economic Policy held in June 2007, among the several programs for accelerating growth potential featured in the Economic and Fiscal Reform 2007 "Basic Policies", the "5-year strategy for creating innovative drugs and medical equipment" was set forth as part of the Strategy for Expanding Growth Frontiers. However, because medical devices are closely associated with the patient's life and physical safety, the MHLW did not take an industrial oriented attitude. They apply the Pharmaceutical Affairs Law strictly, and the length of time for the acquisition of medical approval proved difficult. Therefore, the leading Japanese companies would not go into the medical device area. Regarding medical approval, MHLW established an independent professional organisation to speed up the approval. Although efforts are gradually being made, no real progress has been seen.

1.2. PROFILE FOR THE JAPANESE MEDICAL DEVICE POLICY

Medical devices under the Pharmaceutical Affairs Law include a diverse range of equipment, from high-level control medical devices such as pacemakers, which are therapeutic apparatuses implanted inside the body, to diagnostic devices such as MRI and CT, which are large-scale devices, and small items such as surgical knives and tweezers. When we hear the words automobiles, steel, and textiles, specific images readily come to mind. Medical devices, however, come in all sizes and shapes, so they are less easily categorized. Medical treatment itself directly influences the life of a living organism, so this may be a sector where industrial vitalization should not be discussed merely in terms of market forecasts and productivity alone. In any case, as long as the aging of the population accelerates at an alarming rate in Japan, the current situation, in which medical devices used domestically are dependent on imports from other countries, must be

re-examined seriously with a view to a public policy measurement. At the same time, the corporations that play the above mentioned roles must do so with the utmost commitment and caution, remembering that they are dealing with the safety of human life. Table 1 shows interesting data of a questionnaire survey conducted by the Japan Chemical Innovation Institute (JCII) [2], which was established with the objective of conducting research, planning and proposals on strategies related to chemical technologies, as well as implementing surveys and development on chemical technologies, and is studying making inroads into this industry. The Institute is a private-interest foundation that is organized with about 100 listed corporations, including major chemical companies.

Table 1. Status of Entry in the Medical Devices Industry

	All		Considering entry		Once entered then withdraw		Disregard medical	
	No.		No.		No.		No.	
Total	49	100	17	100	5	100	27	100
Considering New Entry	8	16.3	3	17.6	1	20.0	4	14.8
No interest in the Medical Industry	4	8.2	0	0.0	0	0.0	4	14.8
Hopeful Industry in the future	26	53.1	10	58.8	3	60.0	13	48.1
Business with doctors and medical institutions to be a nuisance	9	18.4	2	11.8	1	20.0	6	22.2
Have to go through endless administrative authorization and approval procedures	20	40.8	12	70.6	1	20.0	7	25.9
Business related to medical devices entailed huge risks	34	69.4	11	64.7	3	60.0	20	74.1
Difficult Industry for high technology	9	18.4	4	23.5	0	0.0	5	18.5
Complicated Industry for commercialism	9	18.4	4	23.5	1	20.0	4	14.8
Need large amount of money for R&D	22	44.9	10	58.8	1	20.0	11	40.7
Far from my company's area	8	16.3	0	0.0	1	20.0	7	25.9
Considering with collaboration	11	22.4	6	35.3	1	20.0	4	14.8
Others	1	2.0	0	0.0	0	0.0	1	3.7
No comment	1	2.0	0	0.0	1	20.0	0	0.0

JCII supported by Toray Corporate Business Research Inc. (2007)

In spite of Japanese economic stagnation, the JCII has been inviting committee members from member corporations to study the possibility of making entries into the most promising new business sectors. As a result, they concluded that the medical device industry had the highest potential for entry. This conclusion was reached based on a questionnaire survey that they conducted with member corporations from March to April of 2007. The Institute sent question sheets to 98 member companies, inquiring about their status of entry in the medical devices industry as well as advisability of entry, and they received responses from 49 companies. (Some of their answers are featured Table 1.) Their answers showed that over half the member corporations that responded to the survey felt that, although the medical device industry was a sector that had potential for growth in the future, it was

hardly worth the effort, since they would have to go through endless administrative authorization and approval procedures. They also regarded that the new entry of medical device area entailed high downside risks, since it was related to human health, and the uncertainty of new medical approval period could already have some business risk. Moreover, 5 out of 49 companies had the experience of entering the medical devices sector but had eventually pulled out. Many end users of medical devices are physicians and medical institutions, and representatives of the companies cited above said that they found doing business with doctors and medical institutions to be a nuisance. They also answered that business related to medical devices entailed huge risks. It is true that if a medical device is flawed, it carries the risk of leading to a fatal accident; and if incidents occurred, they would be covered extensively in the media, hurting the corporate image. Many companies that sent their replies belonged to the chemical industry group and had the experience of being labelled as polluters during the high economic growth period. Because of this, chemical companies are extremely sensitive and careful about their reputation and image [3]. This is why they worry that poor image alone can deliver them a disproportionately hard blow. Moreover, in the wake of one manufacturer in the pharmaceutical industry an adjacent business sector for medical device industry in terms of medical treatment being made a defendant in a drug-induced AIDS lawsuit case, the process of approval and review of medical devices under the Pharmaceutical Affairs Law has become even more rigorous. The issue of drug-induced AIDS: This refers to a series of drug scandals that were caused by blood coagulation factor preparations produced from HIV-infected donors' blood, which were used for treatment without first inactivating the viruses by heat treatment. Many of the patients given contaminated blood preparations developed HIV and AIDS, suffered immunodeficiency, and died of a variety of illnesses. The physician, the Ministry of Health and Welfare official who approved the product at the time and the chief executives of a pharmaceutical company were arrested and indicted on suspicion of professional negligence resulting in death. In this lawsuit, three defendants from a pharmaceutical company received jail sentences in 2000, a physician received a not-guilty verdict in March 2001, and a Ministry of Health and Welfare official was convicted in September later that year. The perspective of the products being labelled as "apparatus," even after they are released on the market, there still is a chance that the companies may be charged with product liability (under the PL Act).

Based on the author's own research, it can be concluded that chemical companies are best suited for entering the biomedical sector to help in its growth and development [4]. The reasons are that since chemical companies cover a wide range of fields, they have the greatest potential to accurately assess the diverse technologies involved; they excel in evaluating new technologies; and they also have the potential to absorb such technologies and commercialize them. The JCII survey mentioned above has revealed that chemical corporations themselves were studying the possibility of making inroads into the medical industry sector. The survey also showed, however, that although these companies recognized the potential of the medical device industry, they harbored concerns, including those mentioned above and were hesitant to enter the sector.

In this paper, the author explores how these reluctant attitudes held by a group of companies that are categorized as "the chemical industry" come about. The difference

between medical device companies and automobiles or steel manufacturers that aggressively carry out innovations in their technologies (although their innovation is restricted to their product field only) should be compared.

1.3. HISTORIC IMPEDIMENTS

As a battleground in World War II, Japan saw its land reduced to ashes. Technological development, therefore, was in a state of near devastation. As part of measures to shoulder the reparation fees charged to Japan as a defeated nation, a policy of import quotas was enforced and of introducing technologies in exchange for paying licensing fees to the United States. Japan had an immediate need for this technological introduction policy that was put into effect soon after the war to catch up with US technological levels. The Foreign Investment Law (the Law concerning Foreign Investment: Technical Assistance Agreement, Grade A) was established in 1950. Since then, introduction of chemical technologies has become subject to long-term assistance, with the remittance of technical fees to overseas companies being guaranteed for extended periods. These policies were drawn up based on "a healthy foundation for foreign capital investment" as a sophism. Could it be, however, this particular policy nipped voluntary development in the bud?

First, experiments conducted at the R&D stage entail costs. Japan's major chemical companies, which had previously belonged to *zaibatsu*-type business groups, found themselves no longer able to procure funds as easily as before WWII because of the forced dissolutions of the groups. On suffering this blow, each chemical company was compelled to carefully scrutinize their profitability. Therefore, they gravitated towards only those business areas where research could be carried out at a low cost [5]. Innovative medical devices had an uncertain future, so Japanese companies avoided this sector and instead opted for a low-risk approach. They were not spirited enough to look ahead to the future of Japan and help establish a medical devices industry unique to Japan. Instead, they managed to survive by resorting to incremental technological developments. As if to add insult to injury, at a US-Japan Summit Conference held in 1985, the US side pointed out that America's best products were being prevented from entering the Japanese market because of high entry barriers, and the following year, import quotas were discussed for each item. These were the Market-Oriented Sector-Specific (MOSS) talks. One of the items singled out was medical devices. Many personnel in the medical devices industry still vividly recall this incident today as "external pressure." The fact was they were finally about to venture into a new business sector, using the funds which they had accumulated as a result of years of strong business growth. As a consequence of this series of US-Japan Structural Talks, Japan reformed its industrial structure on its own initiative. However, the medical devices industry, which had plunged into the international competition without building enough basic corporate stamina, ended up becoming an import channel for US products. If the Japanese Government, as its national strategy, had provided advice and assistance to the medical devices industry, such as recommending corporate mergers and other tactics to compete with US products while continuing to open up its market, the situation may not have become what it is today. It cannot be denied that, in the medical device sector, there

were no strategies to speak of for the country as a whole. These developments are believed to have subsequently relegated medical devices to the fixed status of an industry dependent on imported products, where SMEs are the predominant players. These circumstances have become a factor for hampering chemical companies from entering the sector.

2. FACTORS THAT MAKE UP AMERICA'S COMPETITIVE-EDGE

What sort of policies did the US use to maintain its international competitive edge? The US has traditionally invested huge sums of development money in products used for military purposes, giving rise to huge industries [6]. For example, a product which Hewlett-Packard, a pioneer in venture business, developed in the early stages was an oscilloscope for military use. It is a well-known fact that the Internet was also developed by the Pentagon as military networking systems. Additionally, in the chemical sector, development of chemical weapons was carried out, and enlargement of the scale of operations was stepped up so that a variety of technologies that the companies had owned could be combined to commercialize such items. After the end of the Cold War, these technologies were allowed to be turned over to the civil supplies. Therefore, a growing number of entrepreneurs spun out, along with the developers.

In the US, the medical devices sector is overseen by the Food and Drug Administration (FDA). This Agency belongs to the United States Department of Health and Human Services (DHHS), which coincides with Japan's Ministry of Health, Labor and Welfare. In enforcing the Federal Food, Drug and Cosmetics Act, the FDA is given the authority pertaining to regulations on quality, hygiene management, and advertisement/ publicity from the consumer protection perspective. Its history began in 1848 when it first tested imported drugs. At present, the agency regulates over $1 trillion-worth of products, provides information to ensure that medical devices and radiation-related products are used properly, and monitors adequate labeling. Over 9,000 staff members work in 167 cities throughout the US, and the Center for Devices and Radiological Health (CDRH) guarantees the safety and efficacy of medical devices.

The FDA's approval review process is based on Title 21 Code of Federal Regulations (21 CFR) of the Federal Food, Drug and Cosmetics Act (FDC Act), and the agency examines the applications to see if Section 201(h) of the Act applies to a particular product or not. Part 812.1, entitled "Scope" of Title 21, stipulates the following: "The purpose of this part is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use, and to that end, to maintain optimum freedom for scientific investigators in their pursuit of this purpose." As seen, the FDA allows scientists to maintain optimal freedom for the purpose of promoting the development of medical devices.

First, medical devices are classified into classes I through IV. In selling products ranked Class II or above in the US, a declaration prior to marketing (Premarket Notification or 510k) is required. In this case, sellers must verify that their products have features and safety that are the same as, or better than, those of similar products that are already being distributed in the US market. These procedures usually take from 6 to 12 months.

Meanwhile, Premarket Approval, or PMA, is used for products classified as Class III. The product makers are required to verify the product's functions and efficacy through clinical tests, so the process takes at least one year (1 to 3 years) from submission of application.

However, submitting an Investigational Device Exemption (IDE), makes it possible to use not-yet approved medical devices in clinical research. Before submitting an IDE, one can contact FDA prior to clinical trials and avoid paying needless costs. One must submit a clinical protocol plan and its results, a clinical trial plan, a risk analyses plan, and a patient consent form which indicates that the patients are to be fully informed, so they have a choice to participate in the clinical trial or not. The FDA must answer these plans with documents within 60 days and hold meetings. Only one clinical physician can execute IDE feasibility clinical tests. The process for approving the submission of an IDE is carried out in this fashion. Although it might appear that contacting the FDA in advance would be a bad move, inducing mutual collusion, it appears that the Agency places more value on issuing speedy approvals, and ultimately, on encouraging the smooth development of innovative medical devices.

Biotechnology makes use of a living organism's biological reactions and responses. R&D on cutting-edge medical devices entails a high level of uncertainty. If product liability were to be applied in this case, therefore, it might hamper the progress of said technology. Therefore, providers of biomaterials are exempt from product liability due to the enactment of the Biomaterial Access Assurance Act. The IDE system, moreover, eases the burden of submitting safety-related documents and materials under the premise that patients have received thorough explanations on the fact that unapproved medical devices will be used and said patients have freely consented to such use. It is true that protecting human life is important; however, it must be good news to the patients to know that if they must rely on new medical devices for treatment, they have the option to use them, even when such medical devices have not yet been approved.

In Japan, on the other hand, submission of application for approval of medical devices is regulated by the March 1997 Ordinance No. 28 of the Ministry of Health and Welfare concerning Good Clinical Practice (GCP), which is the criterion for implementing clinical tests. This ministerial ordinance was stipulated to protect the human rights and safety of the test subjects, and to guarantee the reliability of clinical test data. The objective is that a clinical test be carried out in a "scientific" manner under "ethical" considerations. In case of violations, legal punishments are imposed. The IDE attempts to eliminate technological stagnation by means such as mandating a quick response within a short time of the receipt of an application. In contrast, the system in Japan gives no choice to the patients, device lag occurs, so it may be said to be impeding development.

3. JAPAN AND THE US AS SEEN IN A CASE EXAMPLE

Japan's optical technology suffered a devastating blow with the defeat in WWII. However, it integrated Japan's outstanding technologies into camera lenses and built a global competitive edge in optics machinery and tools. As one application of this technology, fiberscope-style endoscopes are medical devices whose market is dominated by

Japanese products, in particular those of Olympus Corporation. There are two types of medical endoscopes: the rigid endoscope, which is in the form of a hard cylinder, and the flexible endoscope, which is a tube that bends at will. The former type is used in laparoscopic surgery, while a gastro camera is an example of a flexible endoscope. At present, a long, black tube is inserted via the mouth or the nose for diagnostic purposes to observe the inside of the digestive tract such as the esophagus and stomach. Development of this device can be traced back to the 1950s, when an ultra-compact silver halide film camera was attached to the tip and used to take photos. With the advancement of electronic technologies, it has become possible to use glass fiber for the tube and to observe the inside of the digestive tract in real time. However, the basic structure has remained unchanged for over half a century.

A gastro camera, which is inserted via the mouth or nose, causes patients a certain degree of pain. Colonoscopes as well as endoscopes for the small intestine, that are inserted from the anus, are even more stressful and uncomfortable for the patients, since the intestines are very convoluted, demanding high-level skills on the part of laboratory technicians. Anyone who has undergone this test has no doubt felt that their discomfort could be considerably alleviated if the procedure could be performed using a camera within a capsule that could simply be swallowed. It was a capsule endoscope produced by Given Imaging, an Israel-based venture company, that helped realize enhanced QOL for these patients.

Dr. Gavriel Iddan, a senior engineer in the R&D group of the Israeli Ministry of Defense, was conducting research into attaching a small camera to the tip of a missile to take pictures right up until target impact and send those images back to the military base. In 1981, an idea flashed into his mind as he spotted one of his colleagues swallowing a capsule containing vitamins, and he began developing a capsule-type camera for the digestive organs. While visiting Boston on vacation, he met an internist who specialized in digestive organs, and things then began to move dramatically forward. Dr. Iddan first integrated various technologies to create a device, conducted repeated animal experiments, and obtained US patents in 1997. To transfer the outcome of his research to a private-sector company for commercialization, Given Imaging Inc. was established to carry out the development, production and sale of swallowable capsule endoscopes.

The capsule endoscope is easy to operate. Numerous wireless sensors are attached to a belt that patients wrap around their waists; they then swallow the capsule endoscope. Patients can move around while having the pictures taken. The capsule reaches the small intestine by way of the esophagus and the stomach and takes photos inside the winding digestive tract. The number of pictures taken while the endoscope passes through the small intestine is dependent only on the capacity of the battery. Initially, the device succeeded in taking two photos per second, revealing even tiny abnormalities of less than 0.1 mm in diameter. Photographing ends after about eight hours, and the endoscope is subsequently excreted in the toilet. The images taken are transmitted by radio frequency to various sensors on the waist-belt worn by the subjects and stored on a recorder. The capsule contains a microchip camera, as well as an LED for flash illumination, a silver oxide battery, and the latest power-saving wireless technology (a radio frequency transmitter). In 2001, it was approved by the FDA and released to markets all over the world as the M2A disposable

capsule-type endoscope. In response, moves to develop a domestic capsule endoscope finally got under way in Japan. In November 2004, Olympus Medical Systems, which commands about 70% of Japan's digestive endoscope market, embarked on developing capsule-type endoscopes after announcing that they had succeeded in developing the necessary peripheral technologies. The transmitter they first adopted was made in Canada. It would have been very easy for them to develop this device just by combining different domestic technologies; however, the entrepreneurial spirit of trying to develop such innovative equipment was previously absent in Japan.

The results of endoscopic research were first announced in 2000 at a meeting of the American Gastroenterological Association. At the exhibition booth there, Given Imaging exhibited a large-scale demonstration site. The first Japanese to take note of this accomplishment was Akira Terano, President of Dokkyo Medical University at that time. He predicted a new phase of endoscope era: that the notion of conventional endoscopy would be radically changed. In May 2002, the Business Incubation Department of Marubeni Corporation established a sole agency in Japan for marketing Given Imaging's capsule-type endoscopes in collaboration with Suzuken Co., Ltd., a trading house engaged in importing medical devices. The new company's investment ratios were 34% for Marubeni, 15% for Suzuken, and 51% for Given Imaging. In the meantime, Dr. Terano agreed to look after the clinical aspects, and clinical tests were initiated in 2003 at Dokkyo Medical University Hospital and Social Insurance Central General Hospital. As opportunities for the media to cover capsule endoscopes grew, hospitals became flooded with inquiries from patients suspected of having diseases of the small intestine, insisting that they undergo tests using the endoscope. By 2004, physicians at ten medical institutions set up a Capsule Endoscope Study Group, led by the director of the Endoscope Department of Dokkyo Medical University's Optic Medical Center. Vigorous activities are now being carried out at healthcare sites, such as trying to enhance the diagnostic capabilities of the unique images taken by capsule endoscopes by formulating image atlases (images for reference purposes) by diseases that are often seen to develop in the small intestine. This capsule endoscope not only causes minimal pain or discomfort in the patients, it also alleviates the risk of medical accidents such as a fiberscope breaking through the intestinal wall. Therefore, beginning in 2003, the US FDA has recommended prioritizing capsule endoscopy over the double contrast technique if a disease of the small intestine is suspected. Similarly, in 2004, the European Society of Gastroenterological Endoscopy (ESGE) recommended patients suffering intestinal tract hemorrhaging of unknown cause to undergo capsule endoscopy as a first step. Of course, if the capsule ends up remaining inside the blocked intestines, it must be removed by surgery. The method therefore has been practiced with the acceptance of such small risks by the patients. As of September 2007, the device has been used by 500,000 people in 60 countries.

In Japan, application for the approval of capsule-type endoscopes as medical devices was filed in March 2004. At that point, the equipment had a track record of being used by 350,000 people in 50 countries. The endoscope market has been expanding tremendously throughout the world. However, the device was finally approved in Japan after almost three years, on February 19, 2007. Clearly "device lag" was an issue in Japan. In brief, Japan lagged behind the radical innovation market in endoscopes, and the government is further

contributing to this delay. The US, on the other hand, adopts a policy of not hampering R&D, which may be due to the IDE regulation system as mentioned in this paper. From the standpoint of protecting patients, it might initially have been thought that the Japanese system would be better; however, in this particular case, if we take into account the fact that many people in the world were already using the device, we could say that the Japanese Government might be depriving patients of opportunities to use cutting-edge medical devices.

4. CONCLUSION

The case example cited in Chapter 3 shows that, although Japanese companies operate on a small business scale, their corporate culture prevents them from freely carrying out dynamic inter-company partnerships and alliances. If we look back to Table 1, the root of the problem can be the corporate attitude of avoiding any risk of failure.

Given Imaging was established as a venture by an Israeli weapons developer. Its seed was from application of military high technology. As a NASDAQ listed venture, it has been posting dramatic growth. In Japan, technology developers inside corporations tend not to move from the company they are employed with after graduating from college, since there is no employment mobility. A military engineer challenged the capsule endoscope development with a flexible mind and pushed forward development with a partner doctor in Boston, Canadian technologies. As seen, the spirit of entrepreneurship is well esteemed in the US, and this becomes the driving force that brings about venture businesses. It may be said to be due to differences in values and more specifically, differences in industrial cultures.

An “entrepreneur” is the person who can connect a new idea and various elements. Joseph A. Schumpeter (1883 – 1950) was an Austrian-American economist and political scientist. He called a person who implements a new combination in a new business or system an entrepreneur. He popularized the term "creative destruction" in economics and paid attention to entrepreneurs’ roles as driving forces of the economic development [7]. He might have watched US economic development from the European continent after WWI. Afterwards, entrepreneurs have been regarded as having an important position for economical expansion. Schumpeter was the first economist who paid attention to the functions of entrepreneurs. It well explains US economic expansion.

In Japan, however, there seems to be very few entrepreneurs. As Dr. Yoshimi Ito describes, Japanese enterprises employ engineers to be generalists [8]. Their attentions are loyal to their company; they have never considered spinning off from their company nor quitting their career. If they are ordered to transfer to the other sister company, engineers may feel they are deviating from their main career-path. They would not assess new venturing technologies. Therefore, the new combinations that Schumpeter speaks of seldom happen.

The Japanese government established the Technology Licensing Offices (TLO) in the late 1990s to learn from the US technology development style aiming at establishing stream from licensed sleeping technologies in universities to private companies. This policy has almost failed, as the staff there were former executive engineers in large companies, and

they would not and cannot assess university technologies. They should have carefully scrutinized the technologies that small innovative companies are working to develop; even seeds that were assessed as unprofitable have potential for radical innovation. We can recall the Given Imaging Case which changed competition of endoscope development phase dramatically. Olympus Medical Systems (now Olympus Corporation), the dominant company in endoscope area, would suffer a crushing defeat in the global market, even if it could still survive in a Japanese market that emphasizes safety under a universal healthcare system.

It should be noted, however, that Given Imaging's product aroused a tremendous response, even among the Japanese public, each time it was covered in the media, and it is said to be the subject of numerous inquiries. Now that it has obtained pharmaceutical approval, the product is expected to be in higher patient demand. Olympus will inevitably compete on equal footing with its overseas counterparts and is currently in the process of developing a similar product. There is also a product called Sayaka, made by RF System Labs in Japan, which claims that its product had a head start over those of Given Imaging and Olympus. As seen, competition at the new level has already begun [9].

5. DISCUSSION

To begin with, an industrial competitive-edge is the power to create innovations. Japan once had the world's preeminent competitive edge, and its key industries had made it an economic superpower. At that time Japanese success was due to process and incremental innovation. However, Japan has entered an era in which we can no longer maintain our international competitive edge by this type of innovation alone. Entities that constantly seize opportunities at this juncture, take risks, and boldly take on challenges without dwelling nostalgically on past glories. Japanese leading companies or stable companies that have involved medical development engineers must conscientiously carry out their development work. They can carve out their elemental technologies into medical device development. Small enterprises with accumulated workmanship are also in an advantageous position in entering into the new industrial area such as medical device development.

Before Japan had suffered from the devastating natural disaster in March 2011, the author envisioned a model where the large companies would support small venture enterprises and help nurture 'good seeds'. However, now held is a view that such a monolithic model alone might not have enough resilience or adaptability in reconstructing the devastated economy, as the paradigm has been shattered and will need to be rebuilt from scratch. The sense of security and safety Japan used to live with were abruptly replaced by uncertainty, and more people are now feeling the need of self-protection and preparation against disasters. In the sphere of the economy, relying on the large corporations has turned out to be less secure than before. This situation, in turn, paved the way for those corporations that have superior technology to utilize it and compete in the international market, regardless of their size. The medical device sector is a prime example of such technology being utilized, for it allows developing new products by combining a wide range of existing technologies. It is important that government provide the environment that

encourages companies to develop new technologies by amending the Pharmaceutical Affairs Law and introducing systems such as IDE which enable companies to partially recover the cost spent on developing the product in earlier stages.

The above-mentioned case of the Israeli military engineer who developed the capsule endoscope exemplifies what ‘venture entrepreneurship’ is. In the preceding study, the case was introduced in a context of ‘entrepreneur risk taking.’ What more the author can derive from this case is the importance of making an effort to find business chances in a variety of situations. The era of relying on the large corporation seems to be coming to an end; replacing it would be the one where entrepreneurs play an important role with their strong initiatives in developing new products based on their highly sophisticated technologies and skills.

Japan has an unfavorable balance of trade in medical devices. Large Japanese companies hesitate to enter the medical device industry. Japanese companies would not engage in an uncertain area of business, which means they are risk averse. In the US, however, people can take chances aggressively if there seemed to be high potential. Therefore, the propensity for risk in the United States and Japan is different. A system called IDE, Investigational Device Exemption, indicates that US Medical Industries are in a stronger position than their Japanese counterparts. The author has to say that Japan has no policy to foster medical venture, but devices are inspected strictly for the pharmaceutical approval. It is predicted that the Japanese economy will no longer be able to grow in a stable manner just by relying on the large corporation-led export of manufactured goods, whereas those SMEs with the sophisticated technology, by accommodating the needs of the medical institutions, will be highly competitive internationally in a narrow and specialized market.

In May of 2008, Web Newspaper described that “Given Imaging Ltd., an Israel-based manufacturer maker of pill-sized diagnostic cameras, recently reached a patent infringement settlement with Olympus Corp. related to the companies' respective capsule endoscopy products sold in the United States. The companies will sign a formal written agreement to finalize the settlement. Under terms of the agreement, Given Imaging will receive a $2.33 million payment from Olympus.” This settlement is scarcely known in Japan, but Japanese economists or researchers must pay attention to this kind of global competition. The online article goes on to say, “In addition, the settlement calls for all past legal actions to be dropped and a deal to not file lawsuits regarding current products. Each company also will receive a cross license related to future pill-sized cameras.” Of course Olympus would like to keep quiet regarding this news, but no arguments were aroused.

“Given's technology is called the PillCam Platform, incorporating a disposable, miniature video camera contained in a capsule, which is ingested by the patient; a sensor array; data recorder and the company's Rapid software. Given Imaging manufactures the PillCam SB capsule (available in the United States and 60 other countries) to visualize the entire small intestine; the PillCam ESO to visualize the esophagus; and PillCam Colon, which received CE Mark in Europe but is not yet cleared by the FDA in the United States. More than 650,000 patients worldwide have been treated with the PillCam capsule endoscopy procedure, according to the company.” In this platform, every company can enter into with some clear condition, and new area of capsule endoscope has started. However, Japanese professors in commerce research area discuss “platform” or “ba” with

other successful cases. Through this settlement, Olympus Corp. can survive a new stage of endoscope development. Its cross license was very unique, and Given Imaging will be able to secure sale stream which Olympus already established. This is one example of large Japanese companies' survival measures. However, if Olympus would have listened to inside opinions recommending capsule endoscope strongly, they would not have to have paid $2.33 million. Dr. Yoshimi Ito already paid attention to eminent Japanese technologies with global view, and research in the area of commerce must watch failed Japanese cases; otherwise, all Japanese companies will be defeated in completing registration of intellectual property. Japanese manufacturing culture must accept diversity, or at least, Japanese government and industries need to try to do so.

Year	Domestic Production 1.mil.Yen	Export 1.mil. Yen	Import 1.mil.Yen
1996	1456136	229308	709396
1997	1514015	327517	750760
1998	1521376	327328	834509
1999	1487902	365042	834383
2000	1486266	363144	821114
2001	1516989	397453	836268
2002	1503507	376880	840030
2003	1498918	420281	883594
2004	1534365	430147	955296
2005	1572401	473915	1012045
2006	1688344	527526	1097867
2007	1684465	575054	1021974
2008	1692352	559160	1090749
2009	1576198	475155	1074964

data by MHLW

Appendix 1. Japanese medical device Market data by MHLW

Year.	Import value	Year-on-year changes		Index
		Amount of change	Rate	
	\1 mil.	\1 mil.	%	%
'96	709,396	120,696	20.5	100.0
'97	750,760	41,364	5.8	105.8
'98	834,509	83,749	11.2	117.6
'99	834,383	-126	0.0	117.6
'00	821,114	-13,269	-1.6	115.7
'01	836,268	15,154	1.8	117.9
'02	840,030	3,762	0.4	118.4
'03	883,594	43,564	5.2	124.6
'04	955,296	71,702	8.1	134.7
'05	1,012,045	56,749	5.9	142.7
'06	1,097,867	85,822	8.5	154.8
'07	1,021,974	-75,839	-6.9	144.1
'08	1,090,749	68,775	6.7	153.8
'09	1,074,964	-15,785	-1.4	151.5

data by MHLW

Appendix 2 Changes in the import value of medical devices (Index: 1996 = 100)

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