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The linkage between institutional transitions and intellectual property (IP) strategies of pharmaceuticals: Japanese pharmaceutical industry, 1970-2017

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Abstract

The purpose of this article is to reveal the impact of external factors on intellectual property (IP) strategy by focusing on how institutional transitions matter for IP strategy from historical perspective. The paper will challenge to analyze the issue of how institutional transitions matter for strategic choices in the Japanese pharmaceutical industry during the period of 1970-2017. Highlighting the changes in foreign investment regulation and patent system, it reveals the facts of how institutional transitions impact the corporate ownership and subsequent strategies.

This study shows that changes in foreign investment regulation and patent system progress the globalization in the Japanese pharmaceutical industry, thus triggering the transitions of IP strategy. Institutional transitions lead the IP strategy from imitative to innovative for improving international competitiveness. In addition, this innovative IP strategy was developed from scale advantage perspective to resource-based perspective because of increasing R&D cost year after year under institutional pressures.

Keyword: institutional transitions, external factors, research and development (R&D), pharmaceutical, ownership, patent system, innovation

1. Introduction

The purpose of this paper is to reveal the impact of external factors on the intellectual property (IP) strategy of pharmaceuticals, and particularly, to focus on the changes in institutions from a historical perspective.

What determines the IP strategy of pharmaceuticals? IP strategy is defined here as the way through which companies create or obtain IP and what role this plays in the enrichment of drug discovery pipelines. The pharmaceutical industry requires to remain the level and productivity of R&D (Research and Development) spending. Such activity requires sufficiently high profits, and the ability to secure external financing. However, a challenge that pharmaceutical companies have been exposed to since the mid-1990s is a decline in R&D productivity, despite sustained increases in R&D expenditure. The continued increase in the cost of R&D is considered to be one of the driving forces behind the industry's trend towards consolidation to retain competitive advantage. The pharmaceutical industry probably sees more merger and acquisition (M&A) activity than any other industry, both in the number of deals and the amount of money spent on M&A. M&A is seen as an effective way to resolve the issues causing the decline in R&D productivity that impact on its future competitiveness.

In reviewing representative literature on R&D profitability, economy theory, which focuses on scale and scope advantages (e.g., Langowitz and Graves, 1992; Henderson & Cockburn, 1996; Anagnostopoulou & Levis, 2008), may first become most relevant. Those studies have indicated that the greater the R&D expenditure, the greater the number of R&D products (e.g., Langowitz and Graves, 1992; Henderson & Cockburn, 1996; Anagnostopoulou & Levis, 2008). Henderson & Cockburn (1996), for example, suggested that with larger R&D scale and scope, a higher return will be generated due to the spillover advantage and internal spillover of knowledge. They found a positive association between the returns and R&D intensity; that is, because of the economies of scope and scale achieved by R&D, greater R&D efforts were more productive and less uncertain.

And then, later on, resource-based theory (e.g., Danzon et al., 2005; Mait & Raghavendra, 2007; Lowman et al., 2012; Rafols et al., 2014; Paul et al., 2010), which centres on firm-specific capabilities, is likely to be more relevant. Some research has proposed that the utilisation of external resources, and the rationalisation of portfolios will improve profitability from the

cost reduction perspective, since the way of utilising external resources has the following strengths: cost reduction, reduction of the time-to-market, and risk distribution (e.g., Danzon et al., 2005; Mait & Raghavendra, 2007; Lowman et al., 2012; Rafols et al., 2014; Paul et al., 2010). Utilising external resources, however, can not only reduce R&D costs and spread risk, but can help a company concentrate its resources on developing core yields. In order to access the external resources, pharmaceutical companies conduct M&A, as well as form strategic alliances with other companies that have high technologies in the specific field through licensing-in, collaborative research, and out-sourcing the clinical development process (Danzon et al., 2005; Mait & Raghavendra, 2007; Kneller, 2010; Howells et al., 2008; Howells et al., 2012; Lin et al., 2012).

As mentioned before, previous studies consider the IP strategy from the scale advantage perspective, and the resource-based perspective, but have not paid adequate attention to the institutions transition.

However, the issue of how organisations (firms) make strategic choices during fundamental institutional transitions, what lead IP strategies changes in the pharmaceutical remain largely unknown. This paper will attempt to analyse the issue of how institutional transition matters for strategic choices in the four leading Japanese pharmaceutical companies, during the period of 1970-2017. This paper addresses the following two issues. The first is to examine the factors that influence four companies' IP strategies. The second is to reveal the IP strategies employed across time.

The paper is organised in four parts. Section 2 provides an overview of the institutional transition and how it impacts the strategic choice, then develops a conceptual framework for analysing four leading Japanese pharmaceutical companies, which include: Takeda Pharmaceutical Company Limited, Eisai Co. Ltd., Daiichi Sankyo Company Limited, Astellas Pharma Inc. during the period of 1970-2017. Section 3 examines how the external environment impacts on IP strategy decisions by those four companies. This section also discusses the nature of the opportunities they exploit and the modes of operation they employ in each period. Finally, the final section concludes.

2. Literature Review- Institutional changes and strategic choices

Institutions are typically conceptualised as "the rules of game in a society" (North, 1990; Scott, 1995), and institutional transitions can be defined as fundamental and comprehensive

changes introduced to the formal and informal rules of the game that affect organisations as players (North, 1990; Peng, 2003). North (1990) defines institutions as the "the humanly devised constraints", which include formal rules (law, regulations) and informal constraints (customs, norms, cultures).

In response, organisations acquiesce to a variety of institutional pressures by making strategic choices (Child, 1972, 1997; Oliver, 1991, 1992). This strategic choice extends to the context within which the organization is operating, to the standards of performance against which the pressure of economic constraints has to be evaluated, and to the design of the organization's structure itself as Child (1972: 2) points out.

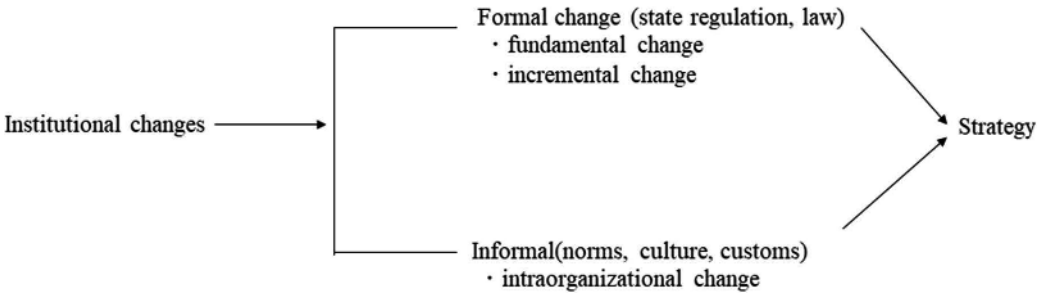
The role of institutions is to reduce uncertainty by establishing a stable (but not necessarily efficient) structure (North, 1990: 5-6). Therefore, an institutional transition can be conceptualised as a move from one primary mode of exchange to another mode (Peng, 2003: 278). In other words, organisations may be required to reject old rules, learn new routines, and develop new capabilities, since conformity is useful to organisations in terms of enhancing organisations' likelihood of survival (Oliver, 1991:150).

According to advanced research by D' Aunno et al. (2000) and Newman (2000), the impacts of institutional transitions can be classified into two phenomenon, namely incremental and fundamental change. The first kind of change is also considered as divergent organisational change that occurs in a brief period (DiMaggio, 1983; Oliver, 1992; D' Aunno et al., 2000, Newman, 2000). D' Aunno et al. (2000) and Newman (2000) focus on fundamental change (or radical change), in which organisations abandon an institutional template for arranging their core activities, suggesting that fundamental change depends on both market forces (proximity to competitors) and institutional forces (state regulation, ownership and governance norms. The second change occurs when institutions evolve through a relatively long period of stability (Gersick, 1991; Peng, 2003).

Who are the players in the progress of transition? Peng (2003: 283) notes that as the transitions progress, more new entrants join the game and organisational diversity increases, resulting in three major organisational forms, which are (1) incumbent firms, (2) entrepreneurial start-ups, and (3) foreign entrants. Scott (1995) states that during the transitions, different organisational forms are likely to confront different institutional pressures, thus leading to various strategic choices. Therefore, I highlight here the strategic choices of incumbent firms during the phases of transition in the Japanese pharmaceutical

industry. Incumbent firms used to be the central players prior to the transition, and their practices define institutional norms; however, the better the fit they have with the pretransition institutional context, the more difficult it is for them to successfully transform themselves (Peng, 2003: 285).

Figure 1 Conceptual Framework



Therefore, this paper will attempt to analyse the issue of institutional changes including formal and informal institutional change in the four companies. Special emphasis will be placed on how institutional changes (fundamental or incremental) impact on players in the progress of transition. Furthermore, the paper will analyse the issue on the basis of the following factors proposed by Oliver (1991). These are causes, constituents, control, and context. These will determine the choice of strategy, depending on why these pressures are being exerted, who is exerting them, what these pressures are, how or by what means they are exerted, and where they occur Oliver (1991: 159).

3. Institutional transitions in the Japanese pharmaceutical industry

Some of the leading pharmaceutical companies have long histories of about 200 years. Most Japanese pharmaceutical companies started their business in Doshomachi[1], which is located in Osaka, as wholesalers of traditional herbal medicine, and they did not undertake innovative activities (Yamashita, 2010)[2]. Japanese pharmaceutical companies, although

1 Doshomachi was a center for lapan's pharmaceutica industry comprised 124 drugs brokerage companions that were recognised officially as fellow traders of stocks (thing which wholesale dealers gather, and put money paid to the authorities in the Shogunate, and monopolise authority of buying and selling) in the times of General Yashiro Yoshimune Tokugawa in 1722 by the Shogunate.

2 Innovative activities are those which develop new chemical entities (NCEs) through extensive R&D programmes and market them as patented preparations.

historically not as innovative as those in the United States and Western Europe, became strong competitors within decades primarily as a result of expanding globally. The pace and source of these transitions have varied dramatically since the late 1970s. What were the triggers for those changes? This paper examines the dramatic transformation of four leading Japanese R&D-driven pharmaceutical companies which mentioned above during the period of 1970-2017. While the Japanese pharmaceutical industry as a whole remained globally uncompetitive, the period of the 1970s saw divergent change for Japanese firms that shifted from being manufacturing-based to research-based for survival. The paper shows how firms respond to institutional changes, including fundamental and incremental institutional changes, and does so mainly through analysing the secondary data (industry reports, annual reports, newspapers, news releases).

3.1 Fundamental change

Two fundamental changes will be considered here. One is the Amendment of Patent Act of 1976, the other is the 100% capital liberalisation of the Japanese pharmaceutical industry that occurred in 1975. The patent system has had a significant effect on the development of pharmaceuticals; most importantly, it allows firms a period of market exclusivity in which they can partially recoup R&D expenditures. The Japanese Patent system[3], however, had remained the weakest of the pharmaceutical industry before 1976. Prior to 1976, patents on pharmaceuticals had focused on the process, enabling pharmaceutical companies to produce new drugs that could be developed by foreign companies in different ways. Japanese firms were likely to depend on obtaining licences from foreign firms rather than developing their own products through innovation, as drug drug discovery and development is time-consuming, expensive and unpredictable[4].

1976 marked the beginning of a new era that shifted the focus from process patents to

3　Japanese Patent System (not only pharmaceutical but all sectors) was weak before 1960s. Because during this period, Japanese companies had focused on learning and imitating the technologies that discovered by American and European companies, paying little attention to intellectual property right (Tanaka, 2011: 1150).

4　Especially in the pharmaceutical industry which requires huge R&D expenditures to develop one new drug, and the huge cost always decreases the firm's profit. It takes an average of 10-15 years to develop a new medicine, from the earliest stages of discovery to the time it is available for treating patients. The average cost to develop a drug increased from $179 million in 1970s, to 2.6 billion in 2010s (http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf Accessed Nov 18th 2019).

ingredient patents[5] on pharmaceuticals. The Japanese Patent Act was amended in 1976 and this had a fundamental impact on Japanese firms. The amendment of the Patent Act resulted in the fact that Japanese firms had to make a considerable commitment to R&D, both in terms of the size of their R&D budget and R&D staff to remain sales. The patent amendment in 1976 was also divergent change that decided firms' future directions: operating as manufacturing-based or research-based.

The 100% capital liberalisation in 1975 had two critical influences on Japanese firms. Firstly, it varied the ownership structure and governance. Japanese capitalism has been characterised by the long-term relationships of firms with their employees (lifetime employment), other firms (keiretsu relationships[6]), and the government (state-industry relation). For example, Japanese firms have long maintained keiretsu relationships with other firms through cross-shareholding. The main shareholders are financial institutions and affiliated companies. These relationships, however, have gradually unravelled due to capital liberalisation since 1967[7]. As result, the ownership structure of Japanese firms has also grown more diverse since the 1970s (Torii, 2017). As the ownership structure has an obvious impact on the likelihood of a change in corporate control, ownership composition has a primary influence on the need for such changes (Lichtenberg & Pushner, 1994: 244). The ownership structure constituted by cross-shareholding plays a critical role in deterring external takeovers, and the aim of governance was to pursue stabilisation of management through maintaining traditional long-term and stable business relations（Torii, 2017）. Since unravelled in stock cross-holdings, the ratio of foreign shareholding began to increase in the early 1990s, especially in larger firms[8]. As shown in Figure 2, the ratio of foreign

5 A substance patent for the active ingredient of an approved drug product.

6 Keiretsu with the governance ties of equity ownership, director transfers, and shacho-kai (presidents' council) membership is a structure of major company in Japan. Keiretsu network is composed by manufacturers, supply chain partners, distributers, and financiers who remain financially independent but work together to ensure each other's success. Keiretsu networks can be classified into three types: horizontal keiretsu, which involve cross-holdings among companies centered on a bank; vertical keiretsu, which among a manufacturer and its suppliers; and compound keiretsu that involve features of horizontal and vertical types.

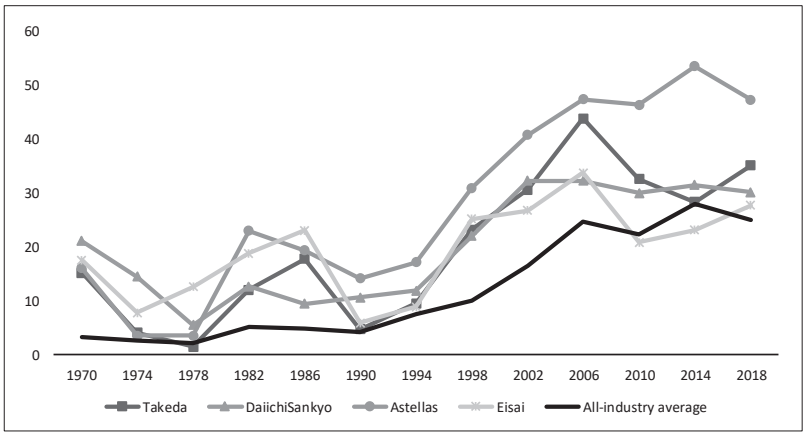
7 According to Aramaki (2004: 57), the first phase of Japan's liberalization was in July 1967, as regards inward direct investment, foreign.

8 In the case of the pharmaceutical industry, the government prohibited resale price maintenance (as apart of distribution reform) in pharmaceuticals in 1991, effectively dissolving the keiretsu relationships between select wholesalers and manufacturers (Inoue, 1990).

shareholding has increased rapidly in four companies after capital liberalisation. Since 1970, the ratio of foreign shareholding in four companies exceeded the average of all industries, except Eisai during the period of 2010-2014.

The different ownership types lead to different forms of managerial outlook and mentality due to a number of macro and micro foundations giving rise to various managerial cognitions. The "voices" expressed by financial institutions and corporate shareholders differ from foreign institution investors. Financial institutions and corporate shareholders try to expand the long-term transactions[9], while foreign institutional investors are concerned with rising stock prices and maximising shareholder value[10] (Fukao, 1998). Foreign institutional investors pressure managers in order to improve shareholder value by voting (Torii, 2017). Under the pressure from foreign institutional investors, the situation of Japanese domestic markets has driven Japanese pharmaceutical companies to strengthen their operations in American and European markets.

Figure 2 Transition in foreign stockholding ratio, 1970-2018 (%)



Note: The DaiichiSakyo's figures for 1970-2002 based on Daiichi. The Astellas's figures for 1970-2002 based on Yamanouchi.

Source: Japan Exchange Group, Yuka-shoken-hokokusho of each company mentioned above, various years (www.jpx.co.jp/markets/statistics-equities/examination/01.html Accessed Nov 18, 2019)

9 Previous studies show a common fact, that is lower profitability among group-affiliated firms. For example, Nakatani (1984) observed slower output growth and more stable performance among these firms, Caves and Uekusa (1976) found that profits were also negatively related to the share of equity held by group affiliates.

10 Cable and Yasuki (1985) revealed that the concentration of shareholders outside the business group had a significant positive effect on profitability, but that concentration within the group did not matter.

Secondly, the 100% capital liberalisation greatly changed the business model of Japanese firms. Capital liberalisation decreased the level of competition that Japanese firms faced in the domestic market. In the era of deregulation, Japanese firms sold the drugs that produced foreign-discovered drugs under licence. For foreign firms, starting a market alliance with a Japanese firm is the best way to do business in the Japanese market because of foreign investment regulations. At the same time, this change promoted divergent change by increasing market competition. Foreign entrants adopted an entry strategy centred on wholly owned subsidiaries and acquisitions instead of taking market alliances with Japanese firms, due to the more aggressive market liberalisation. Capital liberalisation led to a rapid rise in the number of foreign firms operating in Japanese from 74 in 1970 to 239 by 1980 (Umemura, 2013). This trend meant that Japanese firms were forced to find new sales drivers by themselves, and had to change their business model from imitative to innovative for survival. Between 1975 and 2016, the R&D expenditure in the Japanese pharmaceutical industry grew from 95.2 billion yen to 1,352 billion yen (JPMA, DATABOOK 2018). As a result, the number of drug patents by domestic firms increased from 376 in 1980, to 1,769 by 2016 (JPMA, DATABOOK 2018).

Therefore, capital liberalisation altered both governance norms and the business model of Japanese firms. Japanese firms (incumbents) having some foreign ownership may be more likely to initiate restructuring, because foreign investors may tolerate less inertia and have better access to resources that can facilitate restricting (Peng, 2003: 288). As foreign institutional investors' definitions of effective performance become partially supplanted by corporate governance through voting rights, the institutional investors will increase the degree of control to the investing firm in order to maximise profits by voting. Unsatisfactory performance may push some incumbents to search for new competitive advantages (Filatotchev et al. 2000).

Capital liberalisation was a formal change; however, it also brought informal change which is norm of governance. Norms about governance are critical because they specify which actors, other than owners, will influence strategic decisions, such as those to engage in divergent change (Fligstein, 1996). Governance norms play an important part in promoting divergent organisational change because they specify how firms should be organised, including what roles superordinate authorities, such as boards, should play in decision-making (Fligstein, 1996).

In summary, the amendment of the Patent act and 100% capital liberalisation[11] were crucial determinants that led Japanese firms to alter their strategy from imitative to innovative in order to improve international competitiveness. There were divergent changes for Japanese firms caused by market competition and institutional factors. In other words, those institutional changes accelerated the globalisation of the Japanese pharmaceuticals industry.

3.2 Incremental change

Continued reform of drug price policy and US Food and Drug Administration (FDA)[12] regulations are considered here as incremental changes. In Japan, the prices of pharmaceutical products are set by the government and decline on a biennial basis[13]. The drug price policy of the Ministry of Health and Welfare (MHW), constrain the profits of Japanese firms; however, it is also a policy which can protect sales against the influences of generic after patent expired. At the same time, it was indicated that domestic companies faced pressure to enter foreign markets as a result of national policies to curb expenditure on pharmaceuticals[14].

The globalisation of the Japanese pharmaceutical industry was a two-way street. Just as the number of foreign firms in the Japanese market grew, so the number of Japanese firms expanded overseas (Umemura, 2013). Between 1965 and 2016, the number of Japanese pharmaceutical companies expanding overseas grew from 10 to 372 (JPMA, DATABOOK 2018). Hence, in addition to the regulation of the domestic market, Japanese firms have a

11　The Japanese government implemented these changes following Japan's membership of the OECD and the World International Patent Organisation, under strong pressure from the United States, and based on its own desire to encourage technological development among Japanese firms (Umemura, 2013).

12　The FDA is the institution that gathers evidence of the efficacy and safety of US food and drugs. The FDA plays an integral role in the use of pharmaceutical of pharmaceuticals, not only in the United States but worldwide. It has played an important role in shaping the modern, internal pharmaceutical industry by making the scientific approach and the clinical trial process the standard for establishing safety and efficacy.

13　There has the National Health Insurance (NHI) Drug Price List, which is a list of drug prices to be reimbursed to hospitals and pharmacies under the national health insurance programs. Drug prices listed in the NHI Price list are periodically reviewed and revised to reflect actual trade prices based on market survey results. Once the drug which is listed in the NHI price list, this drug's price will not be affected by generic even patent expired.

14　United States International Trade Commission, 1991:11.

duty to conform to the regulations of foreign countries when they advance into overseas markets. The FDA, for example, requires data to demonstrate the safety of the product under consideration, so Japanese firms need to conduct a lot of testing to satisfy the FDA review while expanding into the US market which is the largest market in the world. The Kefauver-Harris amendment in 1962, total testing and FDA review increased, on average, from three to 10 years, given the increased emphasis on safety and efficacy[15]. During this period, the scale of R&D expenditure was considered to be one of the main driving forces[16].

Although the two-system drug price policy and FDA regulation vary in terms of procedures and purposes, the basic effect is to increase the R&D cost of pharmaceutical products.

3.3 Historical transition of IP strategies

How did firms respond to fundamental and incremental institutional changes? Although Oliver (1991) proposes five types of strategic responses, including acquiescence, compromise, avoidance, defiance, and manipulation[17], Japanese firms commonly accede to institutional pressures by acquiescence.

This research focus on IP strategy employed by four companies since 1970s. It should be emphasised that Table 1 is not a representation of the overall but is limited to the period of 1970-2017. Changing IP strategy was stimulated by the loosening of protectionism from the late 1970s. Protectionism, which blocked foreign direct investment, led to stable management. The phenomenon was intensified by the patent system and foreign investment regulation.

Table 1 Historical transition framework

1970~1975	1976-2005	2005~2016	2016-2017
imitative strategy	in-house strategy	open-innovation strategy	co-innovation strategy

Takeda was founded in 1781. In fiscal year 2017, its gross income was JPY1,770,531 million, with an operating income of JPY241,789 million. It invested about JPY 325,441million in R&D

15 United States International Trade Commission, 1991: 8.

16 United States International Trade Commission, 1991 :4.

17 For further details on the five strategic responses, see Oliver (1991:151-158).

in 2017, and in total has 27,230 employees.

Astellas Pharma Inc. was created through a merger of Yamanouchi Pharmaceutical Co., Ltd. and Fujisawa Pharmaceutical Co., Ltd. on 1 April 2005. In fiscal year 2017, its gross income was JPY1,300,316 million, with an operating income of JPY213,258 million. It has invested about JPY213,258 million in R&D in 2017. Astellas employs 16,617 staff worldwide.

Daiichi Sankyo was established through the merger of Sankyo Company, Limited and Daiichi Pharmaceutical Company, Limited in 2005. In 2017, Daiichi Sankyo's gross income was JPY960,195 million, and its operating income was JPY76,282 million. It invested JPY236,046 million in R&D 2017. It has 14,446 employees over 22 countries.

Eisai was established in 1942, had 10,456 employees in 2017, in which year gross income was JPY600,054 million, and its R&D expenditure was JPY 117,213 million.

Our four target companies have some common characteristics and differences. Firstly, they all had conservative IP strategies until the 1970s, although their operations were global. However, as Table 2 indicates, compared to Takeda, Daiichi Sankyo, Astellas, Eisai has been starting basic research earlier than other three companies, as Eisai started up as an innovative maker. Takeda started its business selling traditional Japanese and Chinese medicines in Doshomachi, Osaka. By contrast, the antecedent companies of Astellas and Daiichi Sankyo started its business importing drug. Four company had focused on importing business until 1950, in which year import exchange allocation system was introduced. Under this circumstance, they began to sell the drugs that produced foreign-discovered under license (Yamashita, 2010).

Secondly, they had shifted their IP strategy from in-house strategy, open-innovation strategy, then to co-innovation strategy (see Table 2). They engage in utilizing external resource mainly through M&A, outsourcing, license-in and cooperation. Compared to Takeda, Astellas, Daiichi Sankyo and Eisai, do not engage in M&A due to restriction of financial nature and lack of global management skill. Since 2016, they share the R&D candidate and pipeline with competitors in order to improve the output of R&D.

Table 2 Transition in Strategic choice by four companies

<table>
<tr><th></th><th>1970~1979</th><th>1979-2005</th><th>2005~2016</th><th>2016-2017</th></tr>
<tr><td>Takeda</td><td rowspan="3">・take marketing license with foreign firms
・focused on process patent
・lack of basic research</td><td>・1781 established
・in-house policy
・marketing license with foreign firm
・1993 global operations</td><td rowspan="2">open-innovation policy
・M&A
・outsourcing
・license-in</td><td>co-creation policy
・share resource with competitor
・M&A
・outsourcing
・license-in
・alliance with other</td></tr>
<tr><td>DaiichiSankyo</td><td>・2005 established
・in-house policy
・2000 global operations</td><td rowspan="3">co-creation policy
・share resource with competitor
・outsourcing
・license-in
・alliance with other fields</td></tr>
<tr><td>Astellas</td><td>・2005 established
・in-house policy
・1993 global operations</td><td rowspan="2">open-innovation policy
・outsourcing
・license-in</td></tr>
<tr><td>Esai</td><td>・take marketing license with foreign firms
・focused on process patent and basic research</td><td>・1941 established
・in-house policy
・1997 global operations</td></tr>
</table>

Source: Based on annual reports of each company mentioned above.

In summary, prior to Patent System reform, Japanese companies obtained licences from US and European companies, thereby gaining access to new products. Japanese firms had depended on licensing foreign patented medicines rather than developing their own products through innovation during this period. Since the Japanese domestic pharmaceutical market was protected, they did not sufficient to build a strong R&D capability for competing on a global basis[18]. Consequently, it had not developed an R&D infrastructure that was comparable to that of stronger and more innovative industries such as those in the United States and some Western European countries[19]. By contrast, the US pharmaceutical industry had invested extensively throughout the world. During the 1940-80s, US firms accounted for about 62 percent of the new drugs introduced, Western European firms for about 27 percent, and Japanese firms for about 2 percent[20]. The pharmaceutical industry requires access to a highly developed research base to develop innovative pharmaceutical products and improve R&D productivity.

18 United States International Trade Commission, 1991.

19 United States International Trade Commission, 1991: 3.

20 Pharmaceutical Manufacturers Association 1989:19.

Facing external, international demands, the Japanese investment regulation and patent system initiated major policy reforms. As a result, market competition dramatically intensified. After reform of the patent system and capital liberalisation, foreign companies invested directly instead of by contractual arrangement. Japanese firms faced the pressure to enter foreign markets, and to compete with foreign firms in the domestic market. The report indicates that of the 20 or so US firms that operated in Japan, 13 had wholly owned subsidiaries and eight had majority owned subsidiaries in 1991[21]. The only way for Japanese companies to survive the international competition was to improve their R&D capability. Japanese firms shifted their strategy from imitative to innovative through their in-house policy to catch up with Western firms. However, as Japanese firms lacked the capacity to conform when consistency was low (e.g., inadequate resources such as talent, technology) to introduce innovation activities, they promoted R&D while entering alliances with foreign firms. The number of global New Molecular Entities (NCEs) discovered during 1975-89, was as follows: U.S. firms accounted for 47 NCEs, Western European firms 44 NCEs, and Japanese firms 5 NCEs[22].

Under the pressure of the Drug Price Policy and FDA from the 1990s, the R&D expenditure has increased year by year which has been a great burden for pharmaceutical companies[23]. The R&D strategy became open, firms began partnerships with companies, which had the skills they lack, in order to bring together experts and knowledge from different fields, through the methods of M&A, licensing-in, collaborative research, and clinical process out-sourcing. Pharmaceutical companies have therefore utilised external resources outside the company with the aims of modifying processes, shortening the R&D duration, and improving their core capacity. As regards the level of utilisation of external resources, however, there are big differences among Japanese companies, American companies, and European companies. That is, American and European companies utilise the external resources actively, whereas Japanese companies do not utilise them much (Xu, 2018). The Japanese industry did become more R&D intensive, more dynamic and

21　United States International Trade Commission, 1991: 8.

22　United States International Trade Commission, 1991: 9-8.

23　The average time and cost to develop a new drug is an average of 10-15 years and $800 million to $2 billion (Source: Website of PhRMA　http://www.phrma.org/sites/default/files/pdf/2014_PhRMA_PROFILE.pdf Accessed Feb.3 2019).

competitive—particularly with the entry of foreign firms. But whether it was the level of R&D investment or the size of firms, the Japanese scale remained smaller than that of global leaders. By raising the cost of R&D, firms have recently begun to make alliances not only with pharmaceutical companies but also with firm in other fields. Hence, incremental changes have altered the strategy from open-innovation to co-innovation because of financial factors.

4. Conclusion

The paper has tried to reveal the impact of external factors on intellectual property (IP) strategy by focusing on how institutional transitions matter for IP strategy from historical perspective. The paper focused on the case of Takeda, Eisai Co. Ltd., Daiichi Sankyo, Astellas to examine institutional transitions and IP strategies employed by pharmaceutical companies, and how institutions affect IP strategies.

The finding suggests that institution factors have fundamental and incremental impacts on the strategies of pharmaceutical companies. Prior to the era of deregulation, Japan's imitative and inefficient pharmaceutical firms had been sheltered by protectionist policies. Japanese firms were lagging behind in R&D research, due to delays in reforming the legal systems (refers to patent system and foreign investment regulation). Foreign investment regulation had protected domestic firms from overseas competition. Thus, delays in reforming this regulation delayed a firm entry to the global market and negatively affected weaker firms' global competitiveness. Japanese firms attempted a large scale move towards internationally after changes in the patent system and foreign investment regulation. The presence of foreign investors, in particular, can create a motivation to operations. On the other hand, firms can gain competitive advantage by exploitation of strategic options. The changes in the patent system and foreign investment regulation mean that not only is the Japanese pharmaceutical market facing a globalisation wave but also firms are beginning to take a global view of their strategies.

Drug price policy and FDA regulation have increased the cost of R&D year-to-year. In order to respond to Drug price policy and FDA regulation, many strategies have been employed. IP strategy was developed from scale advantage perspective to resource-based perspective because of increasing R&D cost year after year under institutional pressures.

Firms engage in cross-border M&A, cooperating with competitors, which is considered as a strategic investment as well as an internalisation strategy, as it is a way to access external knowledge, finance, and international markets.

Furthermore, the reason why Japanese companies have fallen behind Western companies is that Japanese companies delayed their shift to R&D-driven business model because of patent system and foreign investment regulation. Therefore, the paper proposes that external factors impact corporate operations and strategy, and especially, a protective legal context will lower the motivation to engage in corporate activities.

This finding contributes to a better understanding of the influence of institutions on IP strategies on pharmaceutical industry. However, some limitation remains. Data constraints means this study could not fully analyse the causal relationship between overseas sales ratio, time periods and global operations. Despite these limitations, the finding suggests that fundamental change positively affects their global operation.

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