

**Strategic Shift in Japanese Corporations: The Case of the
Pharmaceutical Industry.**

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Abstract

The Japanese pharmaceutical industry has traditionally been among the most closed and domestically orientated of all Japanese business sectors. However, in recent years, the number of foreign firms that have established distribution systems within Japan has increased and foreign companies have gradually been increasing their market share. At the same time, the industry topography amongst domestic players has changed, since the new top ten performers in this market are no longer made up only of Japanese companies. The competitive environment in which traditional companies are competing has been radically changed as the traditional barriers to entry have been eroded by deregulation.

Despite the large ageing population, and the fact that Japan continues to be the world's second largest market, price reform, patent loss, consolidation and the presence of new entrants have forced traditional companies to re-think their attitudes towards internationalisation and to re-evaluate their domestic market strategy

In this paper, the pharmaceutical industry is used to illustrate how markets are opening and the new tactics that are being deployed by Japanese corporations as they rethink/re-engineer some of Japan's traditional business practices in order to facilitate the implementation of new strategies. We describe how pharmaceutical wholesaler consolidation is a key strategy being deployed by companies who wish to retain domestic market dominance and we discuss why co-marketing and co-development strategies are being used by Japan's largest domestic companies as "catch-up" strategies for making inroads into international markets.

1.0 Introduction

The global pharmaceutical industry is a dynamic, non-static market, which is heavily influenced by global forces. The structural framework, which determines the way the industry operates, has traditionally provided little opportunity for success outside of the elite top global Western players, unlike some manufacturing industries where Japan has become dominant. The triad rule of “America”, “Europe” and “Japan” does not reflect the topography of this industry because it is driven and dominated by European and American MNC’s.

The reason for Japan’s restricted international presence in pharmaceuticals is largely historic. The vision for Japan’s international expansion was driven by the country’s need to develop a manufacturing base following the devastating impact of the Second World War. Manufacturing became a key factor in building Japan’s international reputation and transformed this once broken country into a developed nation which has aspired to and gained, in a relatively short period of time, both transnationality and global success. If we examine the transnationality status of the world’s largest TNC’s, Japan’s presence is apparent with companies such as Mitsubishi, and Toyota, etc., ranking among the top ten corporate players (UNCTAD, 1998). In contrast, no Japanese pharmaceutical company ranks in the top 100 TNC’s (UNCTAD, 2000) and despite the vigorous consolidations which have characterised the industry in recent years no Japanese company ranks among the industry global top ten (Ishibashi, 2002). The clinical trial process is inflexible and provides little opportunity for late starters to achieve overnight success. In Japan, pharmaceutical growth has derived historically from strategies of domestic market penetration, (Reich, 1990) nurtured by traditional management practices and philosophies. (Abegglen, 1985. Gerlach, 1992. Chen, 1995). Until relatively recently, only a handful of Japanese pharmaceutical companies have really focused on the strategies that need to be implemented for international success. The Japanese pharmaceutical industry has long lagged behind western companies both in terms of its R&D output and its ability to transplant its pharmaceutical business into international markets (Reich, 1990. Thomas, 2001).

1.1 Historic Overhang.

There are a number of reasons for why Japan’s international progress in this industry has been so slow. First, in the aftermath of the Second World War the Japanese government needed to implement strategies, which focused on industry recovery and maximum growth. Industries needed to be segmented into prioritised growth categories based on the country’s-

specific needs and the value that each industry could offer, given Japan's reliance on imported raw materials. In this paper, we suggest that two types of core strategy emerged namely "internationalisation" through exporting and "domestic" growth stimulated by import restriction. In the pharmaceutical example, the strategic position was "domestic focus" (Reich, 1990) and for this reason pharmaceuticals was not one of the industries targeted by government for export growth. Therefore, unlike Japan's manufacturing industry, (Dicken, 1992) pharmaceuticals did not benefit from direct financial and government support, but rather only from various forms of protectionist regulation (Yoshikawa, 1989. Reich, 1990). This domestic orientation was reinforced by an environment in which pharmaceutical imports were low (UNCTAD 2004) and the treatment opportunities available between Japan and the other triad countries lacked parity. The Japanese government's insistence on special clinical trials for products released on the Japanese market was partly responsible. For example, in 1988 out of the 130 global products which had received priority reviews by the FDA, only a very small proportion of these had been developed by Japanese pharmaceutical companies (Thomas, 2001). The closed nature of the market has meant that until relatively recently Japanese patients were unable to receive some of the more standard medicines that characterised western treatments.

The sheer size of the market and the fact that it has been highly regulated and closed has meant that domestic companies have not needed to transnationalise their pharmaceutical business. Prior to deregulation the strategic strength of Japan's domestic companies lay in the network affiliations that characterised traditional management practices (Abegglen, 1985. Chen, 1995) and the integrated procedural networks that had been shaped into the legal and regulatory system (Reich, 1990) as part of Japan's import restriction strategy.

1.2 Deregulation

In recent years and in response to deregulation, macro-forces, and the globalisation of markets the structure of the global pharmaceutical industry has begun to change. A number of key influences have been fundamental to the change. Consolidatory activity has increased significantly (Pilling, 15/3/99) in response to the high need to offset R&D costs, failure rates of product innovation and to a genuine need to avoid product launch gaps when patents expire and innovation fails. (Pilling, 1999) In addition, the regulatory protocols under which products have traditionally entered and have progressed through the R&D development life

cycle have been subject to regulatory review and reform (The Ministry of Foreign Affairs Japan, 2000. Trade Compliance Center, 2002), the impact of which has had positive and negative implications for the industry. Ageing populations, (UK Trade & Investment, 2004) and longevity issues coupled with the increase in healthcare expenditure around the world have meant that the global pharmaceutical industry has attracted a great deal of government attention. Worldwide, governments have combined forces to implement policies and practices that enable the industry to harmonise regulatory protocol. (McGregor, 1999, Pilling, 1999, The Ministry of Foreign Affairs Japan, 2000. Trade Compliance Center, 2002. Michaels, 2002, The Japan Times, 2002).

1.3 Price Reform

The constant attempt by governments to review and reduce prices has had a severe impact on pharmaceutical revenue and on pricing strategies. In Japan, the Ministry of Health, Labor and Welfare has implemented a number of pharmaceutical reform policies. A key factor is rising health expenditure, as increasing numbers reach retirement age. 22% of the country's 127 million population will be of retirement age in 2010 (UK Trade & Investment, 2002). This figure is expected to continue to increase until at least 2020 (UK Trade & Investment, 2002). Consequently, the development cost versus final price debate has intensified. In the Japanese market, the established policy of "price down" (The Financial Times, 2001, JETRO, 1998. Scrip, 25/10/2001) and the newly proposed reform pricing protocol have had a significant effect on business performance and have succeeded in dampening the revenue growth that pharmaceutical companies can achieve from their domestic products (Datamonitor, 2002, 2003, November 2004). The lack of growth that appears to characterise Japan's pharmaceutical market post-2000 can be explained in part by the "price down" effect and the implications that this type of pricing method has for overall business performance. This is because in Japan the reimbursement prices for products defined as "long time listed pharmaceuticals" are reviewed regularly (JETRO, 1998) and are usually subject to a mark down in price every few years. So, whilst the overall volume of patients receiving treatment from a particular product may increase year on year, sales revenue from that product may decrease in response to the impact of "price-down" (JETRO, 1998, Japanese Company Annual Reports, 2004).

1.4 The Harmonisation of Regulatory Protocol

The industry has recently been affected by the introduction and acceptance of “bridging trials” which have made international markets more accessible for all countries but in particular for Japan (Furata, 2000, The Ministry of Foreign Affairs, Japan. 2000. Trade Compliance Center, 2002 U.S. Department on Commerce, 2004). This has, however, also made the Japanese market more accessible to foreign companies. Bridging trials have enabled trial data to be linked across the different countries. This pooling of trial data has functioned to make the clinical trial process shorter for a number of products (Pilling, 5/7/2001. The Ministry of Foreign Affairs, Japan. 2000. Trade Compliance Center, 2002).

1.5 New Product Development

Despite the year on year growth patterns (Datamonitor 2002, 2003, 2004) that characterise the global pharmaceutical market, the industry has been paralysed by the fact that the success rate of new products has dramatically decreased (Pilling 22/4/1999. Dyer, 2002). Also, there is an increasing presence of generics in response to the high number of products, which have lost their patent protection (Dyer, 2002). The severity of the problem is highlighted by the fact that in the global pharmaceutical market the loss of patent protection between 2000 and 2005 is expected to cost pharmaceutical companies approximately \$40 billion (Dyer, 2002). In 2002, the number of new medical entities (NME's) being put forward for FDA approval declined significantly (Dyer, 2002). The lack of new products entering the market is clearly a global problem. However, one could argue that this is even more fundamental in the case of Japan because of the combined impact effect of all the other macro-forces and the consequences of deregulation. Traditional companies are, therefore, having to deal with the combined impact of greater market openness and domestic market change (Tsukagoshi, 2000. Ishibashi, 2002). Traditional Japanese companies have not only been affected by the increase in foreign companies that are gaining access to the Japanese market, but also by the mass of patent expirations and the increasing supply of generics, despite the fact that, historically, generics have not been viewed as acceptable to patients. The Japanese business environment is little different from the global one in one important respect: the majority of a company's profits tend to be generated by a small number of products: “blockbusters” in the overall product portfolio. For example, Sankyo is highly dependent on the cholesterol agent “Mevalotin”. This product is believed to account for 55% of the company's total operating profits and 35% of its domestic sales revenue (Abrahams, 1999). Not surprisingly, when the product came under threat of product for product substitution by the competing product

“Lipitor” the company became vulnerable. Thus, the threat of patent expirations in the domestic market has severe implications for one of the largest pharmaceutical companies in Japan.

1.6 Technology

Advancements in technology have enabled less developed countries (LDC's) to build their pharmaceutical businesses. The rapid pace of technology has also reduced the length of the development path in the product life cycle and the profit that can be obtained from new products. Internet usage has resulted in the consumer/patient becoming more educated and therefore consumer choice is becoming more selective as patients pursue the more global, documented, products through the Internet.

The literature describes how macro-forces influence the decision making process and how these forces can hinder or drive the internationalisation process generally (Fahey, 1986. Johnson & Scholes, 1997. Yip, 1996). In pharmaceuticals, the impact of a number of forces has been instrumental in shaping Japan's recent pharmaceutical strategy. These macro-forces have changed the competitive environment in which pharmaceutical businesses compete and these market dynamics have had significant consequences for Japan.

1.7 In Summary

Deregulation and regulatory reform have changed the macro-environment (Fahey, 1986) in which pharmaceutical companies compete and have provided an opportunity for pharmaceutical conglomerates to re-think their global expansion strategies. This is significant because unlike other industries, the uniqueness of the clinical trial procedure, in terms of the success/failure ratio, and the length of and disparity between trial processes had erected barriers to the transplanting of pharmaceutical products into new markets.

These changes in the macro-environment are increasing the competitive nature in which pharmaceutical corporations compete and are actively driving the globalisation process. In theory this should mean greater market penetration by western conglomerates and the rapid expansion of Japanese corporations into international markets. This is significant given the

low degree of transnational success that characterises Japan's pharmaceutical industry (UNCTAD, 2000). From this the following research questions emerge:

- 1) Is there any evidence to suggest that the once very domestically driven and closed Japanese pharmaceutical market is opening?
- 2) Given the "late start" of Japan's pharmaceutical industry how are Japanese corporations internationalising their product portfolios and what are the strategies open for organisations who do not wish to pursue the international option?
- 3) If more foreign companies are successfully accessing the Japanese market. How are Japanese pharmaceutical manufacturers and distributors responding?

2.0 Methodology

Case study methods have been used for the purpose of this research (Yin, 1994. Stake, 1995. Gillham, 2000). The data in this paper utilises a variety of secondary sources to produce pictorial maps of pharmaceutical industry activity in Japan. Corporate behaviour was clustered into two groups, namely:

- 1) Companies that have a heavy domestic focus but have recently started to think about transplanted strategies;
- 2) Companies that are pursuing internationalisation as a corporate strategy and are beginning to make headway in global markets.

Within these two core groups modes of entry patterns and competitive strategy were mapped. The analysis was conducted in a variety of stages. As a first step, we investigated if there was any evidence to suggest that Western companies were expanding their geographic coverage into Japan.

In stage two, the international activity patterns of Japan's top domestic companies were analysed to investigate if there was any evidence to suggest that the Japanese were changing both their business strategy and attitude to international pharmaceutical investment. We used

secondary sources such as annual reports, data monitoring reports and UNCTAD data to evaluate the extent of international activity that had been taking place between traditional Japanese firms. In particular, we wanted to know if there was any particular type of entry strategy that appeared to be favoured by the Japanese, e.g., Licensing, co-marketing, co-developing, consolidation, etc., or, alternatively, were multiple modes of entry characteristic of Japan's international expansion strategy?

In stage three, we investigated the activity patterns of traditional Japanese pharmaceutical companies who have been slow to internationalise or have not internationalised their business operations. The aim of this was to investigate the survival tactics and strategies that these companies are pursuing in response to deregulation. If Japanese pharmaceutical companies are choosing not to internationalise, what strategies are they pursuing?

3.0 Findings & Discussion.

The findings suggest that this once very domestically driven and closed Japanese pharmaceutical market is now opening. Foreign companies are increasing their presence in Japan's pharmaceutical market in a number of ways: Sales are increasing, larger sales forces are being recruited and new products are entering the market at an unprecedented rate in response to regulatory reform.

3.1 Increased Sales

The successful penetration of Western MNC's into the Japanese pharmaceutical market has changed the topographical landscape of Japan's top twenty pharmaceutical players. These companies have increased their sales revenue in Japan and are increasing their market share. The spate of M&A activity that is currently occurring between Western and Japanese companies continues to reconfigure the ranking positions of Japan's pharmaceutical corporations.

3.2 Expanding Sales and Promotion Teams

A number of foreign companies have established self distribution systems in Japan (JETRO 1994) and are actively expanding their field force size in the Japanese market (Hosaka, 2001). For example, in the Japanese market the more traditional companies have tended to have large numbers of medical representatives for selling and promoting pharmaceutical products. In 2001, the number of medical representatives of Takeda Chemical Ltd, one of Japan's largest pharmaceutical companies was reported to be 1,350 (Hosaka, 2001). In contrast the number of sales representatives in Japan for the western company Pfizer were reported to be 1,700. Other western pharmaceutical companies operating in Japan are also increasing the size of their field force: Merck 1,200 (Hosaka, 2001) medical representatives, Aventis, 980 (Hosaka, 2001) medical representatives, etc and have comparable field force sizes to those of their Japanese rivals. This is significant since historically it has been difficult for western firms to recruit Japanese employees given the difference in culture and management practices and the "jobs for life" policies that have characterised the employment systems of Japanese firms. (Chen, 1995).

3.3 Speed to Market – New Product Development

Foreign companies have been capitalising on the fact that Japan is now willing to accept foreign data that has been collected as part of "bridging trials" in response to the new ICH E5 guidelines. For example, AstraZeneca have used bridging data (AstraZeneca, 2000) for products approval in Japan and have consequently succeeded in bringing new products to market at an unprecedented rate.

3.4 Strategic Shifts in Japanese Corporations

In response to the opening up of the domestic market Japanese companies are rethinking their attitudes towards internationalisation. The degree of internationalisation and the stage of internationalisation varies significantly among Japanese companies. We have observed the following:

The preferred mode of entry varies between companies. Firms that appear to be pursuing an international strategy are predominantly the traditional top ten pharmaceutical companies within Japan. These firms appear to be pursuing both domestic market share and international

market expansion strategies. A number of types of entry strategy characterise the behaviour of the sector: namely, licensing, co-marketing, co-developing and consolidation. Some companies are also establishing subsidiaries abroad.

3.5 In-licensing, Co-marketing, Co-development & Internationalisation

Co-marketing and co-development strategies appear to be providing Japanese companies with inroads into international markets and at the same time function to reduce both cost and risk. For example, if we examine the activity patterns of the Japanese company Shionogi it becomes apparent that a number of products (Shionogi Annual Reports, 2000, 2002) have been in-licensed for development in Japan, and four of these are being co-developed in Japan with other companies. The strategic rationale is clearly to defend against product launch gaps, and to minimise risk and cost in the home market. The company is also seeking to expand its global market share by actively pursuing international expansion opportunities. For example, until relatively recently four products were being co-developed as part of a joint venture with the western company GlaxoWelcome (Shionogi Annual Report, 2002). In addition, the company is actively developing products in-house for sale outside of Japan (Shionogi Annual Report, 2002). The rationale for market expansion was fundamentally driven by domestic shrinkage in response to price down and greater market penetration by western firms in Japan.

In general, the top ten traditional pharmaceutical companies have been actively pursuing internationalisation as a corporate strategy and the top six of these are definitely beginning to make headway in international markets. In 2002, Takeda, Sankyo, Yamanouchi, Eisai, Shionogi, Fujisawa, Daichi; Taisho; Mitsubishi Pharma and Chugai were considered to be Japan's top ten domestic performers (Hanawa, 2003). The ratio of overseas sales for some companies is 40%.

3.6 Heavy Domestic Focus But Starting To Think About Transplantation Strategies

Despite the impact of deregulation and the opening of the Japanese market, a large proportion of Japanese companies continue to be reliant on domestic market revenue. These companies tend to be in the early phases of internationalisation. The strategic approach used does appear to be different between these players and in some cases the strategic decision and choice is

reflected by the corporate culture of the individual company. Whilst a majority of domestic companies appear to be increasing their R&D investment, companies who are outside the top ten domestic rankings in both sales and market share appear to have mixed views towards the way they should develop their product portfolios. Despite the overall shrinking of the domestic market, the threats of “price down” (Annual Reports, 2004) and generics, some companies continue to pursue growth by implementing strategies which focus on building domestic market share. On the face of it this raises questions about the overall potential survival of firms who continue to follow traditional style management practices and retain Japanese values. If we take the example of Dainippon, some new strategies do appear to be emerging.

Dainippon appears to be channeling its international growth using unconventional methods such as giving its products to other domestic manufacturers who have successfully implemented international strategies. This has been achieved by negotiating deals, which give the overseas marketing and development rights to other domestic companies. In the Dainippon example, Takeda, acquired the international rights for the company’s anti-diabetes agents AJ9677, AS3201 (The Nikkei Weekly, 22/1/2001). Internationally competitive strategy may therefore, be pursued by traditional companies using co-operative strategies based on the strong relationship management (Abegglen, 1985, Chen, 1995) that exists through the alliance network structure (Gerlach, 1992) characteristic of the Japanese market. In the Dainippon example, the company appears to be retaining the rights to develop and market their products in Japan but are out-licensing the marketing and development rights for the U.S. and Europe to Japanese companies who have established an international presence or to the larger global conglomerates (Dainippon Annual Report, 2004). In the home market, the company is defending against product launch gaps by marketing products that have been licensed-in from other pharmaceutical companies. Examples include, Klaricid from Abbot Japan Ltd and QVAR from 3M (Dainippon Annual Report, 2004). Co-marketing and co-development strategies are also been used to maximise both risk and sales revenue. Whilst QVAR was licensed in by Dainippon it is co-promoted by the Japanese company Dainippon and the American firm Schering Plough (Dainippon Annual Report, 2004)

3.7 Consolidation Erodes Traditional Management Practices In Japan

Despite the fact that mergers and acquisitions have not historically typified Japanese corporate strategy (Okumura, 2000) mergers and acquisitions are increasing (Nomura Securities, 2004). In the domestic pharmaceutical market “In-In” activity is becoming a common method used to maintain market share and position. The recent announcement by two of Japan’s largest pharmaceutical companies, namely, Fujisawa and Yamanouchi, (Fujisawa Annual Report, 2004) of their intent to merge from April 1st 2005 demonstrates the market’s willingness to abandon traditional management philosophies (Abegglen, 1985, Gerlach, 1992. Chen, 1995) in search of competitive advantage. The new company will be called “Astellas Pharma Inc”. The combined effort of these two companies will make the new company a major domestic and international player. (Fujisawa, Annual Report, 2004). Astellas Pharma Inc will be active in all key markets. In addition, just like the Dainippon example, the company is strengthening its products portfolio and reducing the potential for launch gaps by in-licensing a variety of therapeutic products into the Japanese market. In-licensing examples include, the osteoporosis product FK481 from Servier and the antipsychotic product from AstraZeneca (Fujisawa, Annual Report, 2004). The company’s “Taisho and Toyama” Chemical offer similar examples of Japanese companies who have combined forces in response to the increased pressure that Japanese companies are experiencing in the home market (Toyama Chemical, Annual Report, 2004). Interestingly, business reconfiguration through the use of consolidation strategies has not been restricted to pure Japanese companies. The recent Chugai-Roche merger offers an example of the increasing significance of the “Out-In” type of merger. (Chugai Annual Report, 2004)

3.8 Wholesaler Consolidation in the Domestic Market

Outside of the production-based companies, Japan’s distributors have also been forced to re-evaluate corporate strategy. In Japan it could be suggested that the opening up of the market through deregulation has had a dramatic impact on the way Japanese domestic companies are able to compete. Japanese pharmaceutical wholesalers are restructuring their business operations in response to increased competition in the domestic market. “In-In” consolidatory activity has taken place between some of Japan’s largest wholesalers. Major wholesaler companies have gone against traditional business practices and pursued consolidatory options in search of business survival (Abrahams, 1999). This is significant because in pharmaceutical distribution the wholesaler is fundamental to the marketing process in Japan

and so behaviour shifts offer insightful information into the way the industry is changing. In the late 1990's, a wave of wholesaler mergers and acquisitions took place in the domestic market. Kuraya, announced its intent to merge, with Sanseido and Tokyo Pharmaceuticals (Abrahams, 1999). Suzuken responded by merging with Akiyama (Abrahams 1999) and the companies Nakagawayasu and Chuokouikai, agreed to merge to produce the company "Azwell". (Nikkan Kugyo and Nihon Keizai, 21/4/2000). Shionogi also merged 11 wholesalers by creating the company Ohmori Co., Ltd in an attempt to remain competitive (Abrahams, 1999. Shionogi Annual Report, 2000).

The inter-corporate links developed by this type of re-alignment coupled with the degree of "In-In type" activity that has characterised the industry in recent years does provide evidence to suggest that some form of "re-grouping strategy" is being undertaken by wholesale distributors in an attempt to regain control and maintain distribution channel strength, in response to changes in the macro-environment. The "group structure cluster" of network affiliates that characterise traditional Japanese business practices, appears to be shifting, from a "broad" spectrum of markets and industries to a more "narrowly" focused group network structure of "inter-related same-industry firms", in search of competitive advantage in domestic performance. The size of these transactions has significantly enhanced the strength and scale of traditional wholesaler distributors.

4.0 Implications.

Deregulation and the impact of macro-forces have changed the competitive structure of the pharmaceutical business, widening the gap between the large and middle size players. Japan's approach to the internationalisation of its pharmaceutical business results in the abandonment of key traditional practices (Gerlach, 1992. Chen, 1995. Okumura, 2000) and a re-evaluation of competitive strategy. A combination of entry strategies are being used to reposition products and corporate profiles in international markets. In response, top domestic players are expanding Japan's international profile. Despite, the "late start" the industrial topography may well be about to change as more and more Japanese companies expand their business portfolios in search of a transnational presence. A combination of co-marketing, co-development and in-licensing strategies are been used by Japan's largest pharmaceutical companies as "catch-up" strategies for making inroads into international markets.

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