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Myth of market needs and technology seeds as a source of product innovation — an analysis of pharmaceutical new product development in an anti-hypertensive product innovation

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Abstract

We generally believe that product innovation frequently occurs by a strong actor who knows the market and technology. For this reason, the market leader has a stronger position to make an innovative product because of its marketing and technological competence to know market needs and technology seeds.

This paper studies what kind of product inhibits product innovation. For this purpose, very recent pharmaceutical product changes are studied. In pharmaceutical products, we have selected an anti-hypertensive product to focus on the mature stage of market needs and technology seeds for product innovation. In this mature stage, all the companies recognize the research target for the existing innovative product since market needs and technology seeds are commonly shared among all firms.

By analyzing the characteristics of the behavior of the pharmaceutical companies for product change in an anti-hypertensive market, it is demonstrated how strongly an existing product inhibits product change when a new product has a differentiated point and will create a new market.

In conclusion, product innovation to create a new market by differentiation is inhibited by strongly existing products and the market knowledge that is acquired to gain or accumulate the expertise through marketing the existing product. We have shown the existence of a paradox between product strength in a market and product innovation by new technology.

Keywords: Pharmaceuticals; New product development; Anti-hypertensive product; Market needs

1. Introduction

In the case of product change, it is well known that incremental product innovation is well managed by the cooperation between marketing knowledge and technology knowledge (von Hippel, 1988; Clerk and Fujimoto, 1991). If knowing marketing needs and technology seeds is enough to develop the new product, the market leader with research capability could hold the best position to become a successor in the field. The reality is different from this assumption; the successor is very often replaced (Christensen, 1997).

There is a lot of discussion on success factors in product innovation: which is the determinant for success in product innovation, technology-push or market-pull? According to technology-driven theory, the importance of technological innovation is highlighted for product innovation (Rosenberg, 1976; Freeman, 1982; Dosi 1982, 1984; OECD, 1984). In contrast, market-driven product innovation has highlighted the importance of market needs or customer needs (Rothwell et al., 1974; von Hippel 1979, 1980). These discussions have not led to any sufficient conclusion (for reviews, see Dosi et al., 1988; von Hippel, 1988). With respect to new product development (NPD), the aforementioned opposing theories have highlighted the importance of technology knowledge and market knowledge. Although the applicability of the theory depends on the respective product, it is absolutely obvious that the product is an embodiment of market knowledge and technology knowledge.

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In the case of novel technology emerging, technology seemed to serve as a major driving factor to introduce the relevant new product into a market. It is also well recognized that market knowledge can stimulate successful NPD. It seems to be obvious that market knowledge assists the accumulation of technology knowledge. Apparently, both technology knowledge and market knowledge are able to serve as the key factors that enhance successful NPD. If so, the market leader can keep its leading position in the market for the next generation of new products and hence the market leader cannot be easily taken over by the newcomer, even if the new product creates a new market.

For continuous NPD, this assumption is true. The concurrent engineering system is thought to be the best way to launch the next product into the market (Hammer and Champy, 1993). For the automobile industry and the electricity industry, many authors have demonstrated the advantage of the collaboration between technology and the market (Ohno, 1988; von Hippel, 1988).

The opposite of this finding is true. There are many examples of major players losing their strong position in the market when new products emerged. Why can't leading companies maintain the best position in the market? It seems to be related to the characteristics of the product. This problem has not yet been solved by the current discussions on NPD.

In this paper, a recent change to a product in a pharmaceutical market is studied. We focused on the antihypertensive market since its market is mature and its final products have just been launched. By surveying the behavior of the market winner and the newcomer, this paper demonstrates that a strong product inhibits the NPD of a newly emerging product that will replace the existing product. In order to demonstrate the behavior of the companies, R&D and market analysis have been carried out.

Section 2 identifies the characteristics of product change in the pharmaceutical industry. Section 3 analyzes the behavior of the pharmaceutical company in the case of product change. Section 4 describes the case study of product change at a mature stage of the pharmaceutical market. Section 5 presents conclusions and implications.

2. Characteristics of pharmaceutical product change

Although pharmaceutical products are usually classified into types of material, due to their influence on human health, any pharmaceutical product innovation is not immediately embodied into the product. Table 1 shows the R&D expenditure per product. The average development cost is US$300–400 million for one product and is increasing rapidly. According to statistical analysis by the Japanese Pharmaceutical Manufacturers' Association (JPMA, 1999a), the success ratio of NPD was approximately 1/6000 between 1992 and 1996, as shown in Table 2. This means that the research target for NPD is not easily selected. Furthermore, it was found that the development period takes approximately 10 years from the discovery stage to the launch into the market. This means that sufficient discussion is required to complete NPD from both the standpoints of technology and marketing before selecting the research target and the development target for NPD. This feature of the pharmaceutical industry characterizes the process of NPD.

Fig. 1 shows the factors of the decision making process for NPD in the pharmaceutical industry. According to the flow diagram in Fig. 1, the strong position of the market leader in NPD is described as follows.

2.1. Selection by marketing knowledge

Before initiating clinical development, the product candidate is selected according to the marketing function. If the sales estimation is enough to recover the huge investment, the clinical candidate enters into the development stage from the discovery research stage. For these reasons, all clinical candidates are filtered and selected by the market knowledge of each company.

2.2. The necessity of the superior or differentiated points for NPD

We propose that there are two types of new products that change the existing market. As summarized in Table 3, one is a new product with a superior point and another is a new product with a differentiated point. According to Ansoff's product-market matrix (Ansoff 1966, 1988; Ansoff et al., 1993), a superior product corresponds to a new product with the same mission. A differentiated product corresponds to a product with a new mission that develops or creates the new market.

Once a new product with a superior point is marketed, the existing product will immediately lose its market share. In the case where a new product with a differentiated point is marketed, a new market will be created. Table 3 also summarizes the positioning in the market of a new product with a differentiated point and a new product with a superior point.

If a new product with a superior point meets the market needs, the market share of existing products will rapidly depreciate. In fact, the new product with a superior point replaces the existing product if the superior new product is continuously developed (Christensen, 1997).

In contrast, a new product with a differentiated point produces an additional market. Due to the rapid replacement of the existing product by the differentiated product, the characteristics of the pharmaceutical market are

Table 1
R&D expenditure/product (unit: million US$)[a]

	1991	1994	2000[b]
USA	230	400	1000
Europe	150	300	700
Japan: large-sized companies	128	300	600
Japan: medium-sized companies	80	160	300

[a] USA: estimated by survey of Purdue University; Europe, Japan and R&D expenditure/product in 2000: estimated by survey of Inter Pharma Consulting.
[b] Estimation by Japanese Licensing Association.

Table 2
Success ratio of new pharmaceutical product[a]

Stage	Number of compound	Ratio to become the next stage	Accumulated success ratio
Synthesized compounds in discovery research stage	320,832		
Pre-clinical study	280	1:1.146	1:1.146
Clinical studies	167	1:1.68	1:1.921
Submission for new drug approval (NDA)	106	1:1.158	1:3.027
NDA approval	(88)	(1:1.120)	(1:3.646)
Self-made compounds from discovery research phase	53		1:6,053
Introduced compounds from the other company	(35)		

[a] Calculated from data on 17 member companies of JPMA over 5 years from 1992 to 1996.

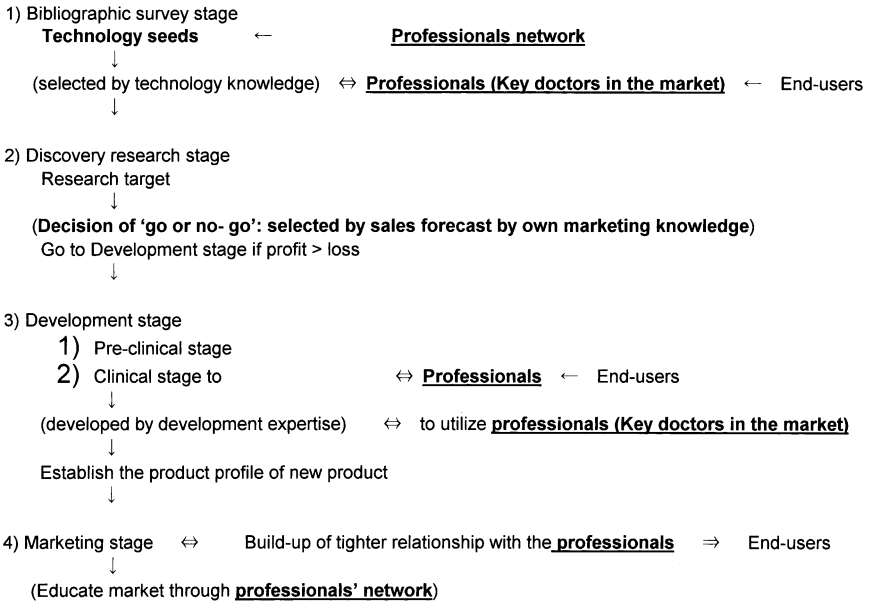

Fig. 1. Factors for the decision making of NPD in the pharmaceutical industry.

completely different from those of ordinary commodities. These characteristics are explained by the nature of the pharmaceutical products, in that the market waits for a new product to meet its unmet needs.

2.3. Professional as sales target

Due to the professional characteristics of the product, the marketing target is not end-users but professionals.

Table 3
Two types of new product

Type of new product	Superior point	Differentiated point
Competition with existing product	Direct competing	Indirect competition or neutral
Mode of market penetration	Replace old product	Create new market
Influence to NPD	Enhancing	Inhibitory

Pharmaceuticals are selected and prescribed by professionals such as physicians and hence the market needs are incorporated not from the end-user but from the physician. Professionals have maintained the position that they obtain information on technology trends and market needs through the professionals' network.

Sales representatives have kept frequent contact with physicians through distribution activities. Patients who need medication consult professionals concerning illness and treatment. The market leader can maintain the strongest contact with the market through the professional and therefore can incorporate market needs and technology trends.

According to recent research on the product innovation system of 3M, the importance of the utility of the leading user is obvious (for review, see von Hippel et al., 1999). The pharmaceutical industry originally utilized this leading user system (Pisano, 1997).

2.4. The strong position of the market leader

The market leader has the best position to collect technology seeds and market needs through the network of professionals. Owing to strong contact with the professionals, market leaders can often utilize their superior position to collect market and technological information. This kind of strong relationship with professionals contributes to them maintaining a good position through incorporating market needs and technology seeds into their market and technology knowledge. To identify the next research target for the next new product, the market leader is in the best position to collect sufficient information on the next product.

In opposition to this assumption, this paper demonstrates that market leaders often lose the opportunity to develop the next product to obtain a good market position, even in the case when they can easily succeed in the development of the next new product. If market leaders have lost the timing of the start of NPD, their followers will soon start development since technology sources tend to be commonly shared between competitors.

3. The behavior of the pharmaceutical company in the case of product change

Due to the foregoing characteristics of pharmaceutical product change, the behavior of the pharmaceutical product is generally subject to the following factors.

3.1. Market segmentation of pharmaceutical market

The pharmaceutical market is segmented into several major therapeutic fields, for example, cardiovascular, diabetes, central nervous system and gastrointestinal. The market size of the cardiovascular field is US$44,571 million and the market share is 17.64% of the total market, the largest in the pharmaceutical market. In the cardiovascular field, the anti-hypertensive market accounts for 56.02%.

Pharmaceutical companies tend to act to keep their positions in the market segment since they have a lot of infrastructure for marketing their products in the market segment. In fact, companies that have existing products (first-generation products) very often develop the second-generation products.

In the case when the idea for a new product is brought in via new technology, the positioning of the new product in the market is influenced by the marketing knowledge of each company, although this kind of product is usually recognized as a technology-push product,

3.2. Important role of marketing competence

Since the development cost has been increasing over the last 10 years, as shown in Table 1, market estimation is a key for the decision of "go or no-go" for NPD. Even if a new product is found, NPD is rejected from entering into the development stage when market estimation is negative or small. From this aspect, the core competence of NPD is characterized as a mixture of technology competence and marketing competence. Therefore, the factors for successful NPD are divided into a technology factor and a marketing factor.

Pharmaceutical product innovation can be divided into two categories: technology-push and market-pull. In the pharmaceutical industry, the former may sometimes become a breakthrough product and the latter is often a mimic or an improved product. The breakthrough product basically originates from technology-pull and is checked by market knowledge, as shown in Fig. 1.

To recover big investments from the market, breakthrough product innovation is targeted by many large pharmaceutical companies. For this purpose, marketing estimation and sales estimation are very important in selecting the next NPD. Marketing knowledge is a critical factor for deciding "go or no-go" for new products entering the clinical stage. If the breakthrough product

is approved by marketing evaluation, it can enter into the clinical development stage.

4. Case study of product change in the mature stage of the pharmaceutical market

4.1. Stage of anti-hypertensive market

The cardiovascular market has recently become the top therapeutic category in the pharmaceutical industry (Scrip Magazine, 2000). The market share is much higher and the positioning is more important in leading countries such as the USA, Europe and Japan, although in developing countries the market share of essential drugs for life, such as antibiotics, is the largest. In the cardiovascular market, anti-hypertensive medication is the largest sector both in leading countries and all over the world (IMS, 1999).

The anti-hypertensive market is almost mature, because the existing products treat almost 90% of patients. According to interviews conducted by the authors, only three companies in the top 20 pharmaceutical companies in the world maintained research activity for hypertensive drugs in 1999 and the others have been winding down this activity, although all companies reinforced research activity on anti-hypertensive drugs at least 10 years ago. Last product innovation was emergent, although the anti-hypertensive market is in the mature stage. The final products, ATIIs (angiotensine II antagonists), were made based on the same new technology and have been launched country by country. In Japan, the first product was launched in August 1998.

4.2. Major products in the anti-hypertensive market in the USA and Europe

In hypertensive medication, there are two major products, Ca blocker (Ca) and Angiotensine Converting Enzyme Inhibitor (ACE). Since Ca shows rapid onset and sharp efficacy, it is used as the first choice for the treatment of hypertensive patients who do not have organ malfunction, such as diabetics. Although the efficacy of ACE is less than Ca and ACE has the side effect of a cough, ACE is used for older patients who are at risk from organ damage.

Fig. 2 illustrates the market share of major product segments in the American and European anti-hypertensive market in 1998. For pharmaceutical market analysis, all estimations are made based on the IMS database, since it is commonly used as a source of pharmaceutical market analysis. Major products in the USA and Europe are ACE and Ca. Although in the USA the market share of Ca is almost the same as ACE, in Europe the share of Ca is less than ACE.

4.3. The strongest product in the Japanese anti-hypertensive market

The Japanese market is different from that of the USA and Europe. Compared to the USA and Europe, Ca had the biggest share in the Japanese anti-hypertensive market in 1998, as shown in Fig. 3. Fig. 4 shows the transition in the number of prescriptions of each product segment of anti-hypertensive drugs in Japan. The number of prescriptions represents the number of patients being treated by each product segment. Only Ca is expanding the market share in anti-hypertensive drugs in Japan.

According to the authors' interview with senior management of the top 20 Japanese companies in 1998, no company doubted the strength of existing Ca drugs and cared for the threat to Ca by the launch of new products such as ATII in the future market. Fig. 5 demonstrates the real situation of the marketing competition of the existing drugs of Ca. Only one product, Pfizer's Amlodipine, which was launched in 1993 by Pfizer and its co-marketing partner, Sumitomo, under different brand names, has increasing sales. Although the other products are losing market share, the sales have been maintained because of the increase in the total market.

Ca is principally recognized as the first choice for new patients due to the rapid onset of the treatment (Kokusai Iyakuhin Jouhou, 1997; JPMA, 1999a). ACE is recognized as the second choice product due to its mild efficacy, although ACE has an organ protection function. Compared to Japan, American and European consumers are concerned about the risk of organ damage due to the difference in life style. Disease trends are changing in Japan because of the increase in "life style diseases". The organ protection function of ATII will also become more important in Japan in the near future, as in the USA and Europe (Monthly Mix, September 1999).

According to the authors' interview of the top 20 pharmaceutical companies in Japan, all companies without exception believed the myth that Ca will keep the largest share in the future, even after the launch of new products such as ATII. The same opinions were observed in Japanese journals of drug marketing (Kokusai Iyakuhin Jouhou, 1997).

4.4. Final product in the anti-hypertensive market

The merit of Ca is the rapid onset of the effect to reduce blood pressure. The demerit of Ca is that it cannot be used to treat patients at risk from organ malfunction, such as in diabetes and hyper-lipidemia. ACE is no threat for diabetes patients due to its mild efficacy, but it can produce the side effect of a cough.

Recently, another category of anti-hypertensive product, ATII antagonist, has been marketed in the USA, Europe and Japan. It is a technology-push new product discovered by finding its effect on elevating blood press-

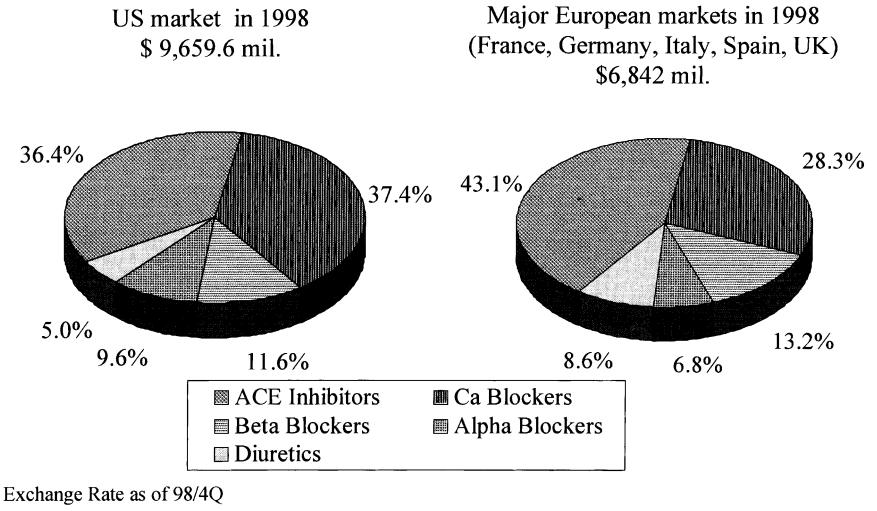

Fig. 2. Anti-hypertensive markets in the USA and Europe.

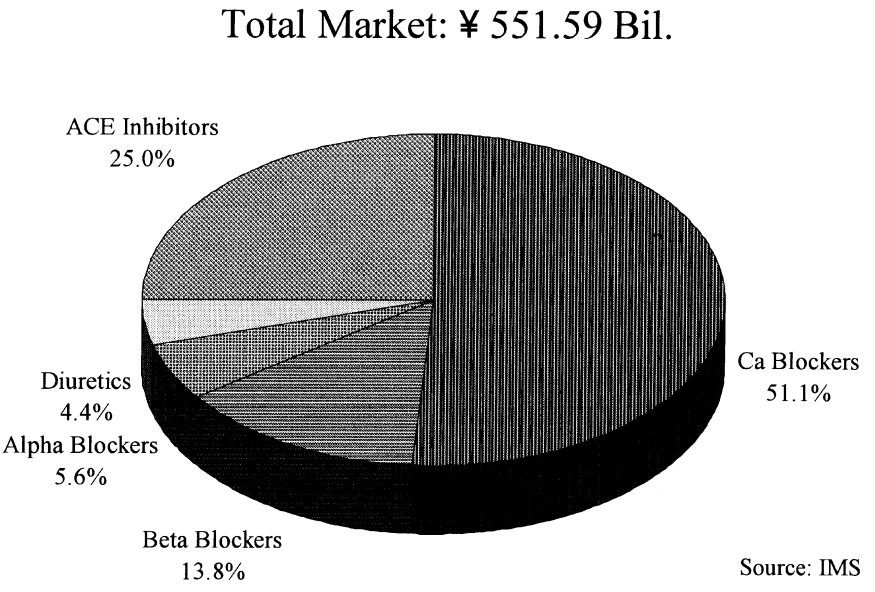

Fig. 3. The Japanese anti-hypertensive market in 1998.

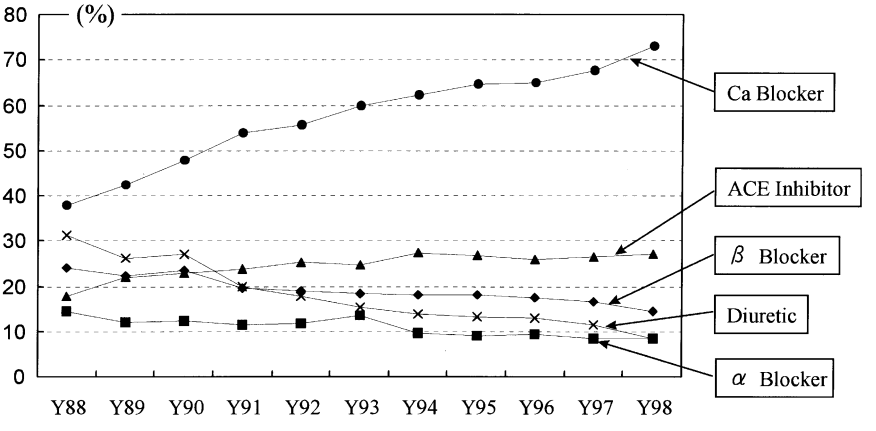

Fig. 4. Transition in the prescription of anti-hypertensives in Japan.

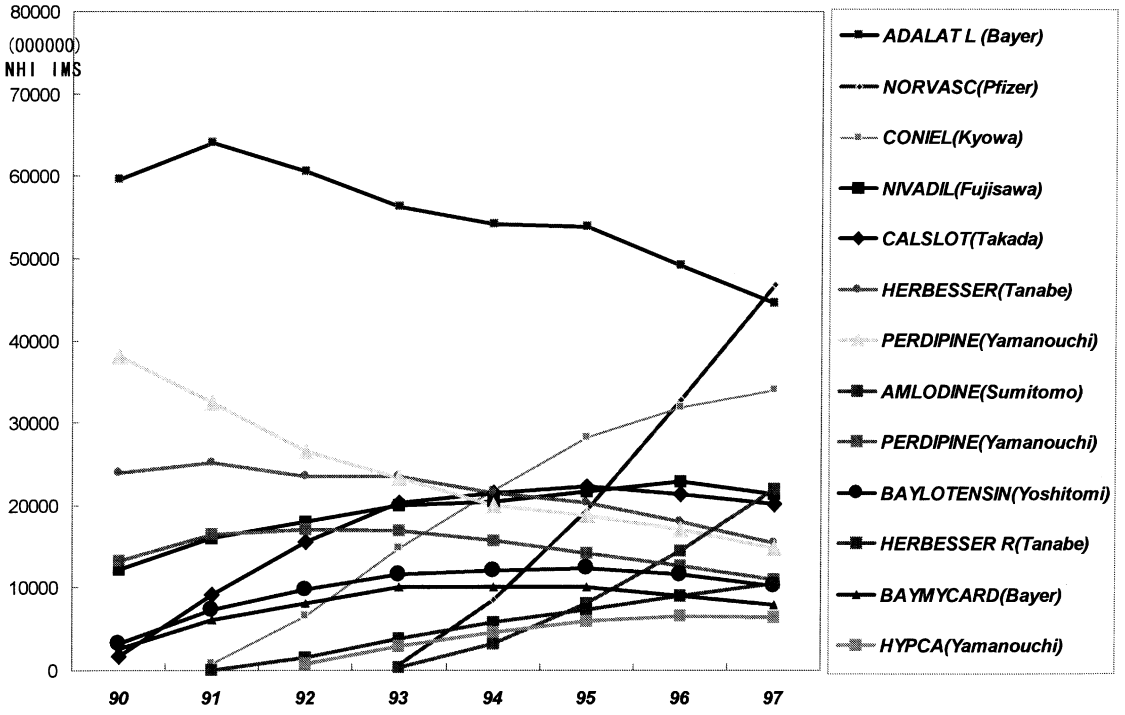

Fig. 5. Sales trend of Ca blockers in Japan.

ure. It decreases blood pressure by inhibiting the binding of ATII to the ATII receptor.

Not only does the ATII antagonist (ATII) have no side effect of a cough, but also it has the organ protection function that overcomes Ca. Owing to the organ protection function, ATII can be used to treat diabetic patients, kidney malfunction patients, heart disease patients etc., but the efficacy is between that of ACE and Ca. In conclusion, ATII is superior to ACE and differentiated from Ca. It took a long time in Japan to believe that ATII will expand in the anti-hypertensive market and will replace some of the old products, including Ca (Monthly Mix, September 1999). This was proved by the fact that ATII became the top in the anti-hypertensive drugs market, obtaining 67.5% of the prescription rate for new patients (Monthly Mix, September 1999). All companies believed that ATII would compete only with ACE and not with Ca, and the market share of Ca would not be deprived by ATII. In fact, the Japanese Pharmaceutical Manufacturers' Association recognized that ATII only has the advantage over ACE with respect to the cough side effect and higher efficacy (JPMA, 1999b).

The top Japanese pharmaceutical company (Takeda) made the first ATII product in the world and its potency is the strongest. Takeda licensed this product to a European company and discontinued the development of ATII since it believed Ca was more important (authors' interview). Takeda initiated the development in 1988 to be stimulated by overseas development by foreign companies (Yomiuri Newspaper, 10 October 1999). The second founder of ATII was Sankyo. Takeda's ATII was launched in Europe by Astra in November 1997 and launched in Japan in June 1999. Sankyo behaved similarly to Takeda, licensing their product to a European company outside of Japan and deferring the start of clinical development in Japan. The overseas' clinical stage of Sankyo's ATII is PIII, which is several years ahead of the Japanese clinical stage (Pharma Projects, 1999).

Table 4 shows the competition of the development of ATII in Japan. Although Japanese companies lost the

Table 4
AT-II competition in Japan (source: Asu-no Shin-yaku, August 1999)

Compound	Company	Stage[a]	Expected year of launch[b]
Losartan	Merck	Approved	1998
Candesartan	Takeda	NDA	1999[c]
Valsartan	Novartis	NDA	2000
Irbesartan	BMS	P-III	2001[d]
Telmisartan	Boehtinger Ingelheim	P-III	2002
CS-866	Sankyo	P-II	2004
Tasosartan	Wyeth	P-II	2004
KRH-594	Kissei/Wakunaga	P-II	2004
KD-3-671	Kotobuki/Daiichi	P-II	2004
YM-358	Yamanouchi	P-II	2005
GA-0113	Yoshitomi/Asahi Glass	P-I	2005
TA-606	Tanabe	P-I	2005

[a] Stage of clinical development.
[b] Year of commercialization.
[c] Launched in August 1999.
[d] NDA filing scheduled in fourth quarter 1999.

Table 5
World leading top 10 companies of Ca antagonist in 1998 and the development of ATII (source of ranking table: IMS (1999))

Leading corporations	Market share (%)	Development status of ATII in USA and/or Europe
Pfizer	33.9	No
Bayer	12.8	No
Hoechst	9.0	3rd (license-in from SmithKline Beecham)
Astra	3.7	5th (license-in from Takeda)
Basf	2.7	No
Monsanto (Searle)	2.4	No
Kyowa Hakko Kogyo	2.2	No
Yamanouchi Seiyaku	2.0	No
Takeda	2.0	9th license-out to Recordati
Novartis	2.0	Originally no (2nd)

easy chance to get the leading position in the newly emerging market, American or European companies took the prevailing position in Japan.

Table 5 summarizes the development status of ATII by the top 10 companies in the world Ca market. Of the top 10 companies, six have no ATII product. Although two companies, Takeda and Novartis, have ATII products, Takeda does not market Ca outside of Japan, and Sandoz Co. and Ciba-Geigy Co. (who merged) brought ATII in 1997. Two companies, Hoechst and Astra, are developing license-in ATII products. Ten out of the top 10 companies have no self-made products.

The behavior of ACE leaders is different. Table 6 demonstrates the positive behavior of leading companies for developing ATII and ACE/NEP. ACE/NEP is a superior product to ACE, like ATII, because it has higher potency than ACE and reduces the cough side effect of ACE by adding NEP inhibitor activity. Seven out of the top 10 companies are developing their own products and one company is developing a license-in product. This fact demonstrates the positive attitude of the ACE leader for developing ATII or ACE/NEP. The remaining two companies do not develop ATII. This is because of their strong position as first and second in the Ca market, since their total market share is approximately 47%.

4.5. The reason for the failure of NPD of ATII

Following the discussion in Section 2.2, ATII is superior to ACE and differentiated from Ca. From a market viewpoint, ATII competes with ACE directly and replaces the ACE market. The leaders in the ACE market need to develop ATII to keep the current market position because it is obvious that ACE will be replaced once ATII is marketed. In contrast, Ca does not compete with ATII but creates a new market. The leaders in the Ca market do not need to develop ATII to keep their market position in the Ca market, as described above. Surprisingly, the leaders in the Ca market, including Japanese companies, were prohibited from the development of ATII.

This finding demonstrates that a strong existing product inhibits NPD when the product creates a new market, as summarized in Table 3. The most critical reason for the failure of NPD of ATII was the underestimation of the sales forecast, since the sales forecast is basically calculated based on product strength. The company acts to increase the strength of its own product as a market winner in Ca, insisting on the strength of its own product (Monthly Mix, April 1999). This reduces the market value of the new product, creating a new market.

Table 6
World leading top 15 companies of ACE inhibitor in 1998 and the development of ATII (source of ranking table: IMS (1999))

Leading corporations	Market share (%)	Development status of ATII in USA and/or Europe
Merck Co.	31.0	1st
Zeneca	13.4	5th (license-in from Takeda)
Bristol-Meyers Squibb	10.7	4th and 1st of ACE/NEP inhibitor
Warner-Lambert	6.4	No
Novartis	5.3	2nd
Hoechst	3.8	3rd
Servier	3.7	2nd of ACE/NEP inhibitor
Tanabe Seiyaku	1.9	No
Banyu Seiyaku	1.8	1st (Merck's Japanese affiliate)
Sankyo	1.7	8th (license-out to an European company)

As shown by the analysis of the behavior of pharmaceutical companies, even if NPD could be achieved by the technology-push method, the new product is often not successfully developed. Referring to Fig. 1, the decision of "go or no-go" of NPD is made by the sales forecast on the basis of the companies' own marketing knowledge. As a result of this analysis, it is demonstrated that successful completion of NPD is critically influenced by market knowledge. Marketing knowledge is sometimes a failure factor for successful NPD if a new product creates a new market. Our research results are summarized as follows:

1. A new product is one of two types: a superior product or a differentiated product.
2. The existing product acts in direct opposition to NPD, enhancing or inhibiting.
3. For a new product with a superior point, the existing product enhances its position.
4. For a new product with a differentiated point, the existing product inhibits its position.
5. A strong existing product greatly inhibits the development of new products with differentiated points but enhances the development of new products with superior points.

5. Concluding remarks and implications

As demonstrated by this survey, the necessity of product development is recognized at the final stage of the product development since at this stage it is easy to understand the marketing positioning of the new product.

Our question was why are strong market players unable to keep a strong position in the market in the case of product change, even though they have the expertise to collect the relevant market information? In order to address this question we surveyed the behavior of pharmaceutical companies in the current anti-hypertensive market, which is recognized as almost at the mature stage after launching the latest anti-hypertensive product, ATII.

Many authors emphasize the necessity of technology and market knowledge, and furthermore types of knowledge are critically important in making NPD successful. Surprisingly, our conclusion is contrary to this position. We demonstrated that market knowledge serves as a failure factor.

Technology knowledge, on the other hand, was demonstrated to contribute to NPD, even if the new product competes with an in-house existing product.

There are disputes over product innovation between the technology-push and the market-pull theories. Our findings support the existence of technology-push product innovation and market knowledge serves as an inhibitory factor for NPD. Considering these findings, technology knowledge has no effect on NPD.

Regarding the importance of knowledge, technology knowledge promotes NPD. In contrast, market knowledge sometimes inhibits NPD. This finding suggests that successful NPD is not only due to knowledge creation. For differentiated product innovation, the crucial point is the marketing position of the new product. From a marketing point of view, NPD is categorized as either "market substitution type" or "market change type". Our findings suggest that in the case of the latter, successful NPD is not derived from market knowledge creation but initiated by technology knowledge, while freezing market knowledge.

Therefore, in challenging the "market change type" innovation, an important point would be how market knowledge freezing or releasing systems could be incorporated in a firm's decision making system. Thus, future work should be focused on the elucidation of these institutional factors by a comparative analysis between success and failure cases of NPD.

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