Organizational Capability and Competitive Advantage in Pharmaceutical Product Development

Kenichi KUWASHIMA

Graduate School of Business Sciences, University of Tsukuba

E-mail: kuwa@gssm.otsuka.tsukuba.ac.jp

Abstract: Most existing researches treated pharmaceutical product development process as a sort of "black box." This paper, however, will focus on the product development process to explore the organizational capabilities and effective development patterns. Interviews and statistical analyses with leading companies in Japanese pharmaceutical industry indicated that "go or no-go decision" is the significant organizational capability, in fact differing among companies, which effects performances in pharmaceutical product development process. This organizational capability is accumulated through experiences in pharmaceutical product development projects.

Keyword: product development, organizational capability, pharmaceutical industry

1. Introduction

What are the organizational capabilities that influence performances in pharmaceutical product development? In the last decade, studies in fields of innovation management and technology management focused on organizational capabilities and the origin of competitive advantage in product development process of automobile, main frame computers, and software industries (Clark & Fujimoto, 1991: Cusumano & Selby, 1995; Eisenhardt & Tabrizi, 1995; Iansiti, 1998). However, in pharmaceutical industry studies, product development process has been deemed rather as a "black box." There were company level studies on management and organizational capabilities, nevertheless, few investigated management and

organizational capabilities of product development process (Bierly & Chakrabarti, 1996; Gambardella, 1995; Graves & Langowitz, 1993; Henderson & Cockburn, 1994; Omta, Bouter, & van Engelen, 1994).

In pharmaceutical product development, likelihood of success is extremely low; one in few thousands to 10 thousand (JPMA, 2002). Where possibility of success is so extremely low and owes rather to mere chance or luck, it has been considered that pharmaceutical product development is like treasure hunting and impossible to manage. However, when we take a closer look, some parts of the product development process do not coincide with popular theory while some parts do. Pharmaceutical product development process consists of discovery stage, in which chemical compounds potential of becoming new medicines are found, and development stage, in which discovered chemical compounds are developed into new products. In the discovery stage, management is possible on theme decision and resource allocation yet, discovery of new chemical entity is affected by chance or luck. Additionally, research activities are operated on individual researchers' level, therefore, organizational management at this stage is restricted and performance relies largely on talents of researchers. Thus, it is popularly believed that this stage is impossible to manage.

However, development stage differs from discovery stage where development activities are organized and little owes to chance or luck. Here, some sort of management mechanism, organizational factor, or organizational capabilities influence performance directly. Development stage consists of pre-clinical test and clinical test. We focus mainly on the latter test stage to reveal organizational capabilities in pharmaceutical product development process, which so far has not been revealed. Moreover, we present that organizational capabilities differ among companies in fact.

2. Competitive Advantage in Clinical Development Stage

We interviewed in total 20 personnel in charge of clinical development, R & D planning, corporate licensing, and other, in six major Japanese pharmaceutical companies to explain factors which influence product development performance in clinical development stage. Each interview lasted about two to three hours, and additional follow-up questions were asked over telephone and e-mail. The interviewees listed "decision of go or no-go," "protocol of clinical test," "selection of clinical development theme," and "know-how on filling in new drug application form" as factors which influence product development stage performance. Among these, "decision of go or no-go" was the most frequently named factor, which nearly all interviewees regarded significant.

"Decision of go or no-go" refers to the decision making of whether to adopt candidates of new drugs for clinical testing and to carry forward the clinical testing phase. This decision is critical for the whole

pharmaceutical product development process, however, its weight becomes greater from clinical development stage onward. This results from the fact that clinical development requires billions of yen, yet once decided in this stage, chemical compounds structure cannot be changed or corrected in later stages, that is, design modification as in general product development become impossible. In other words, the sole problem solving measure from this stage is the "decision to go or no-go." Most products as automobiles allow "problem-solving by design modification" throughout the whole product development process. On the other hand, pharmaceuticals allow design modification, that is, correction of chemical compounds structure, in the early stages, nevertheless, from clinical development process onward, problem-solving can only be managed by deciding "go or no-go." This is the most distinctive feature of pharmaceutical products.

Table 1. Data Set

	samples
Chugai	23
Daiichi	36
Eisai	42
Fujisawa	62
Ono	24
Sankyo	28
Shionogi	32
Takeda	41
Tanabe	30
Yamanouchi	41

Thus, pharmaceutical product development is forced to make the decision to terminate once a defect is reported in clinical development stage of a certain chemical compound. Basically, investments on the project sink when the decision to terminate is made. Therefore, in clinical development stage, the most influential factor on product development performance, that is efficiency of product development, is the capability to decide "go or no-go" correctly on chemical compounds without prospect.

3. The Decision Pattern of Japanese Pharmaceutical Companies

We conducted statistical analysis using data of 10 major Japanese pharmaceutical companies; namely, Chugai, Daiichi, Eisai, Fujisawa, Ono, Sankyo, Shionogi, Takeda, Tanabe, and Yamanouchi, to verify any difference between companies in decision patterns at clinical development stage. Precisely, we compared the ratio which clinical development theme in each company progress from Phase I to Phase II and to Phase III by survival analysis method. Table 1 shows sample numbers of each company.

From the analysis, χ^2 was 20.64 in log-rank test, and 18.38 in Wilcoxon test, both of which were significant at 5%. This implies that patterns of survival distribution function among firms show statistically significant difference.

Differences in pattern of survival distribution function among firms can be taken as the differences in decision making capabilities. As we have

Table 2. Comparison of Survival Rate

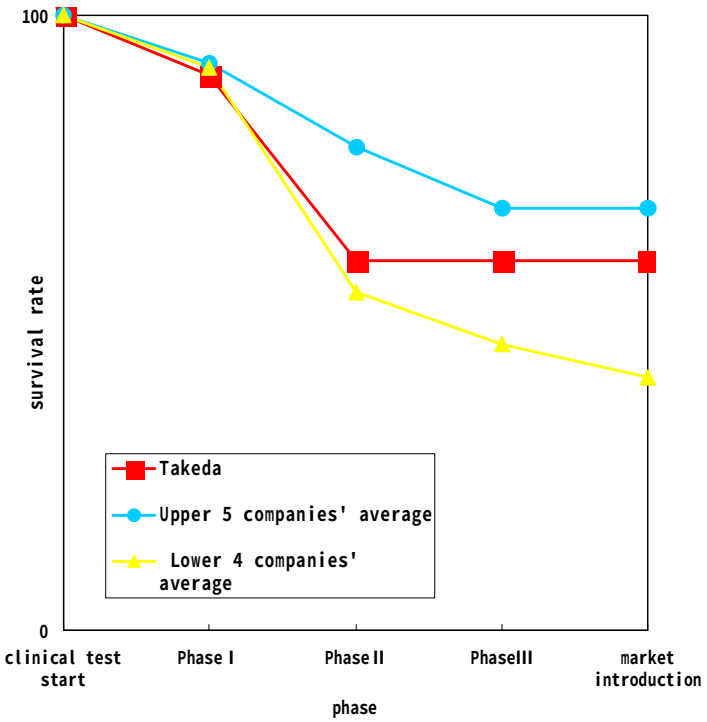
	Order in Survival Rate	
	In Total	After Phase II
Chugai	7	8
Daiichi	5	6
Eisai	9	9
Fujisawa	8	4
Ono	10	7
Sankyo	1	2
Shionogi	4	10
Takeda	6	1
Tanabe	3	5
Yamanouchi	2	3

mentioned, clinical testing is extremely costly. Therefore, superficially, companies showing higher success rates at clinical development stage would possess higher decision making capabilities. However, pharmaceutical companies must minimize clinical development cost while minimizing opportunity cost as well. Which is to say, if the company aims to minimize clinical development cost alone, they should run clinical tests on only auspicious compounds. Nevertheless, by doing so opportunity cost occurs that compounds with potentials of market introduction may be dropped. In order to minimize opportunity cost, the company may take an antithetical approach: to run clinical tests on every compound with slightest possibility of market introduction. Yet, this requires enormous amount of money. Thus, how to manage this trade-off is the most critical issue for pharmaceutical companies.

As we have seen, clinical test consists of Phase I, Phase IIa, IIb, and Phase III. Cost increases drastically from Phase IIb, and Phase III cost even more. Considering above makeup of development costs, an effective approach to overcome the problem is to; carry forward test to clinical stage with compounds which are presumably safe and effective on human body, terminate test on unpromising compounds before Phase IIb, that is, when they pass Phase IIa. We shall call this pattern "spread catch net wide, pull at once at the right moment." In fact, they say among pharmaceutical manufacturers that the best pattern of compound selection is to determine the potential by Phase IIa so that there is no dropout in Phase IIb, which makes success rate after Phase IIb a 100%.

Consequently, what reflects capabilities of pharmaceutical manufacturers is assumably not "success rate in clinical development," but "decision pattern of go or no-go." In an interview of major Japanese pharmaceutical companies, most named Takeda Chemical Industries, Ltd. as having great clinical development capability (Kuwashima, 1999). However, we can see in our analysis that Takeda is sixth among 10 in clinical development stage success rate (Table 2). On the contrary, when we look at survival distribution function, that is decision pattern of go or no-go, Takeda draws an almost ideal pattern (See Figure 1). Figure 1 compares the

Figure 1. Survival Distribution Functions



Note: Upper 5 companies; Daiichi, Sankyo, Shionogi, Tanabe, and Yamanouchi.
Lower 4 companies; Chugai, Eisai, Fujisawa, and Ono.

survival distribution function between Takeda and other nine pharmaceutical companies dealt in our analysis. We divided the other nine companies in two groups with higher clinical development success rate and lower clinical development success rate. There is a difference between higher and lower group in success rates, however, both groups draw a downward slope after Phase II. In contrast, Takeda draws a horizontal survival distribution function after Phase II. Clinical development success rate of Takeda after Phase II is 100%, which is best among 10; though success rate through all phases is sixth among ten. Therefore, the reason that Takeda is highly evaluated among pharmaceutical industry lies not in its clinical development success rate but in survival distribution function pattern: especially in the pattern after Phase II (Table 2).

4. Conclusion

We focused on product development process, which have been regarded as a "black box" in pharmaceutical industry in order to examine effective product development pattern and organizational capabilities on the firm's performance.

From interviews and statistical analyses, we revealed that the effective compound selection pattern is to "spread catch net wide, pull at once at the right moment" at clinical development stage, whereby "go or no-go" decision is the critical organizational capability. Moreover, we showed that there is actually difference among firms concerning this ability.

How do firms build such organizational capability? Knowledge and know-how in pharmaceutical product development could not be easily acquired but accumulated within the firm through learning by doing multiple numbers of product development projects. As a matter of fact, Takeda, which proved to possess higher organizational capability in our research, experiences more clinical development projects than other major pharmaceutical companies according to data from 1977 to 1996 (Kuwashima, 1999).

However, mere experience in numbers of projects would not build organizational capability. In order to reflect project experiences in organizational capabilities, the quality of the experience is substantial as well as retention of acquired knowledge. Future research should try to analyze the formation process of organizational capabilities in consideration of these respects.

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