Exploring the Characteristics of Pharmaceutical Product Development: A Cross-industry Perspective

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Abstract: The development of pharmaceuticals is an extraordinarily unique process. However, the aspects that are unique in comparison with other industries have never been clearly explained, either academically or practically. Clinical trials are an emblem of the uniqueness of pharmaceutical development; however, using industry-specific ideas and vocabulary do not enable cross-industry comparisons. This paper analyzes the product development process of pharmaceuticals using a problem-solving model that can be applied to comparisons across industries, and organizes the characteristics as well as effective management techniques. From the problem-solving perspective, the pharmaceutical development is unique because it requires the generation of numerous alternative solutions and complex testing. There exist products or industries that share one of these two characteristics, but only a few products or industries share both the characteristics. These characteristics closely relate to product development management of pharmaceuticals. In other words, considering the cost of product development, it is difficult to
simultaneously create many alternatives and conduct complicated tests. Therefore, pharmaceutical companies focus on creating many alternatives in the upstream development process, and then testing in the downstream process, responding to this problem by balancing between the two characteristics and switching at the appropriate time. Determining the timing of this switch is one of the most important management techniques that impacts the performance of pharmaceutical development.

Keywords: product development, problem solving, pharmaceutical industry, cross-industry analysis

Introduction

Pharmaceutical product development is considered to be unique. However, the uniqueness of drug development in comparison with other industries has never been clearly explained, either academically or practically. Numerous studies have focused on product development management in the fields of technology and innovation management from the 1960s to today. Previous studies adopted the approach of identifying universal success factors common to all products and industries. However, beginning in the 1990s, more emphasis began to be placed on the product development process, and a more detailed analyses resulted in the discovery that effective product development patterns differed depending on product and industry (e.g., Eisenhardt & Tabrizi, 1995; Iansiti, 1998; Kuwashima, 2003; Pisano, 1997; Tomita, 2009; Wi, 2008; Yasumoto & Shiu, 2007; Yoshimoto, 2009). However, having hundred effective development patterns for hundred products and industries is too complex; a framework is required for cross-industry

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1 See Kuwashima (2012, 2013) for more information on the history of product development research.
analysis that more simply organizes relationships between product and industry characteristics and development patterns.

A cross-industry analysis requires a generic perspective that can be applied to product development in all types of industries. For example, clinical trials are one trait unique to drug development; however, using industry-specific ideas and vocabulary do not enable a comparative analysis across industries. Thus, this paper employs a framework based on a highly generic problem-solving model to organize the characteristics of drug development and effective management from the perspective of inter-industry comparisons.

Characteristics of Pharmaceutical Product Development from a Problem-solving Perspective

(1) What is a problem-solving model?

Problem-solving models were not originally developed as an analytical framework for technology management or innovation management. Rather, they were used in the fields of organization and statistical decision theories, and were then applied to other fields including technology management and innovation management (Barnett & Clark, 1998; Lynn, 1982; Simon, 1969; Thomke, von Hippel, & Franke, 1998; Wheelwright & Clark, 1992). As can be seen from the fact that organization and statistical decision theories were the sources of this approach, problem-solving models are extraordinarily generic and can be applied to all types of products and industries, making them suitable for cross-industry analyses.

In general, problem-solving models are formulated in the following

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2 Viewing the product development process from the problem-solving perspective has been long used in the field of research into technology management (e.g., Allen, 1966; Frischmuth & Allen, 1969; Myers & Marquis, 1969). However, Clark and Fujimoto (1991) were the first to explicitly use problem-solving models as an analytical framework for product development processes.
Applying this model to pharmaceutical product development provides the following steps:

1. Determination of target therapeutic areas
2. Synthesis of and/or search for chemical compounds
3. Non-clinical and clinical trials of chemical compounds
4. Evaluation of chemical compounds
5. Selection of chemical compounds

In general, the core activities of problem solving include the generation of alternatives and testing (Simon, 1969). Thus, the following two points can be derived by focusing on these two activities and organizing the characteristics of pharmaceutical development from the perspective of a cross-industry comparison.

First is the necessity of generating an extremely high number of alternatives. In pharmaceutical development, it is very difficult to specify in advance the chemical compound structures that will achieve the goals. Accordingly, several thousand to more than ten thousand compounds must be generated or searched to find an effective compound.

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3 The definition of the “problem” in problem solving differs by researcher, but generally, when a person has a goal, that person is said to have a “problem” (Johnson, 1955; Newell & Simon, 1972). More specifically, the gap between an existing situation and a desired state is a “problem” (Kaufmann, 1988; Pounds, 1969). The methods used to fill that gap, or achieve a goal are undetermined, thus the need for problem-solving activities (Kaufmann, 1984).
Second is the necessity of highly detailed tests. Pharmaceuticals affect humans, and thus companies must carefully confirm both the efficacy and safety of compounds. Therefore, highly detailed and complex tests called clinical trials are used, and these cost from tens of millions of dollars to hundreds of millions of dollars.

From the perspective of a problem-solving model, the requirement for both the “generation of many alternatives” and “complex testing” are marked characteristics of pharmaceutical development compared with other industries.

(2) Problem-solving framework

Figure 1 is a plot of several products, including pharmaceuticals, in a matrix comprising two axes, the number of alternatives generated and level of test complexity. This figure plainly indicates the uniqueness of pharmaceuticals. For instance, beer is a product that, similar to pharmaceuticals, requires the creation of many alternatives. Many factors affect the taste of beer, including the types of barley and hops, the type of fermenting agent, and the temperatures in the fermenting process. The possible permutations of these factors are practically infinite. Discovering the combination that achieves the desired taste requires numerous alternatives. However, in the case of beer, testing is very simple, and is conducted by a sensory inspector. On this point, beer differs from pharmaceuticals, which require complex, high-cost testing such as clinical trials.

On the other hand, automobile requires complex testing much like pharmaceuticals. Automobiles are complex products, having to meet various customer needs for safety, ride, fuel efficiency, and so forth. Accordingly, automakers must conduct various tests in all conditions (driving tests, crash tests, and so on) to determine whether a

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4 Figure 1 is based on the framework of Fujimoto and Yasumoto (2000).
particular product design provides the expected functionality (ride, safety, fuel efficiency, etc.). As automobiles are assembled products and their technology is mature, automakers need few alternatives to generate a design that provides the desired functionality. Thus, automobiles differ from pharmaceuticals.

**Management of Problem Solving in Pharmaceutical Product Development Process**

Both characteristics of pharmaceutical development identified by an analysis based on the above problem-solving model closely relate to product development management. In other words, the
development process for pharmaceuticals requires both the
generation of several thousands, if not several tens of thousands, of
alternatives, as well as complex testing in the form of clinical trials.
However, considering the cost of development, it is impossible for
companies to conduct detailed tests on all alternatives.

Pharmaceutical manufacturers respond to this problem by
switching between the generation of alternatives and testing in the
upstream and downstream product development process. In other
words, they balance the two characteristics by switching as follows:

In the upstream phase, companies focus on the generation of
alternatives, conducting simple tests using cell fragments.

As development moves into subsequent phases, alternatives are
filtered, and the focus shifts to testing on animals.

Finally, the alternatives are used in humans as the process moves
to clinical trials, which is the most detailed and complex form of
testing.

Switching between the generation of alternatives and testing can be
considered as a “narrowing down” pattern of alternative chemical
compounds in the development process. Empirical studies in the
technology management domain have shown that the management of
narrowing down pattern of compounds affects the pharmaceutical
product development performance.

For example, Kuwashima (2003) performed survival analysis using
data from ten major Japanese pharmaceutical manufacturers to
statistically analyze patterns for narrowing down chemical
compounds from each company in the clinical development stage.
Based on the results of the analysis, it was found that Takeda
Pharmaceutical Company, which had maintained a high level of
competitiveness over a long period of time in Japan’s pharmaceutical
industry, exhibited a pattern of “casting a wide net and narrowing
down candidates all at once and at the right time.” This contributed
to Takeda’s efficiency in product development.
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