An Empirical Study Comparing Industry Segments as Regards Organisation Management in Open Innovation - Based on a Questionnaire of the Pharmaceutical Industry and IT Component Industry Segment

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Abstract—The aim of this research is to clarify the difference by industry segment or product characteristics as regards organisation management for an open innovation to raise R&D performance. In particular, the trait of the pharmaceutical industry is defined in comparison with IT component industry segment. In considering open innovation, both inter-organisational relation and the management in an organisation are important issues. As methodology, a questionnaire was conducted. In conclusion, suitable organisation management according to the difference in industry segment or product characteristics became clear.

Keywords—Empirical study, industry segment, open innovation, product-development organisation pattern.

I. INTRODUCTION

THE objective of this research is to compare industry segments empirically as regards the influence of organisation management on the success or failure of an open innovation. In particular, the trait of the pharmaceutical industry is defined in comparison with IT component industry segment. In addition, in the pharmaceutical industry, drug development and dosage form development are classified and the difference in a suitable organisation management is clarified.

Nowadays, there is increasing difficulty creating new medicines in the pharmaceutical industry. In addition, the efficiency of research and development (R&D) in pharmaceutical companies is falling [1]. Major pharmaceutical companies have merged others over and over, in order to increase the efficiency of pharmaceutical products development, and the expenses of R&D grow every year. However, the number of new medicines launched every year is decreasing. The focus of drug development has shifted as one background factor. Primary markets, such as infection, circulatory organ disease, etc., in developed countries, constitute core profits. At present, specific areas are, for example, cancer with a low success percentage, and high development difficulty, and Alzheimer's disease. Furthermore, the environment of pharmaceutical products development in a pharmaceuticals company is increasingly challenged by global competition, the promotion of the use of generic medicines, tightening of regulation, etc. [2].

As a result, there is more and more debate about open innovation in pharmaceutical companies, venture businesses, etc. Development is increased by introducing techniques and products from the outside. An open innovation is the notional framework that an external idea should be used in a company, or the channel which continues to a market exceeds the boundary of a company, when it utilises a possession technique [3]. In IT industry segment, particularly, many companies have converted from the so-called vertical integration style that sets up a subject matter in a company and performs research, development and commercial production. Prompt innovation is required in order to respond to the rapid changes in external environments, such as consumer needs and global technological progress or competition. The number of companies which adopt open innovation utilising an external company, a university, etc., is increasing; for example, installation of a special section for open innovation, subcontracting and strategic external cooperation of each process from research to industrialisation, a social cross-industrial consortium, an open innovation from overseas (especially an emerging country), etc. [4].

European and American pharmaceutical companies are leaders in open innovation in the pharmaceutical industry. According to [5], more than half of the 252 items of a new medicine which the United States Food and Drug Administration approved from 1998 to 2007 were created at a drug-development venture or a university. In comparison, in Japan, the ratio of new medicines created in drug-development ventures was very low. However, open innovation activity between pharmaceutical companies, universities, governmental agencies, intellectual property-related companies, etc. has increased recently [6]. For example, there was much funding to make a life science business an investment outlet [7].

On the other hand, if the inter-organisational relation of an existing enterprise and a venture business is observed, an interesting difference exists between IT industry segment and the pharmaceutical industry. In IT industry segment, there are many cases where a venture business successfully expands scale rapidly, eliminates the existing large-scale corporation and becomes a hugely dominant company. However, in the relationship between organisations in the pharmaceutical industry, there are not many venture businesses which grow

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significantly as in IT industry segment. Thus, it is argued, the optimal inter-organisational relation in an open innovation may change with industry segments.

In addition, while the drug development of a pharmaceutical manufacturer becomes difficult, the dosage form development attracts attention as a lifecycle management (LCM) strategy. The lifecycle of pharmaceutical products is roughly divided into four stages: an introductory period, a growth phase, a mature phase and a decline period [8]. If an LCM dosage form development is strategically marketed according to each stage; the market extension of new products and a protraction of product lifecycle can be performed efficiently [9]. For example, in a growth phase, this includes administration reform (miniaturisation of a tablet or a capsule), change in packaging (small-quantity packaging, individual packaging and weekly sheet), etc. In a mature phase, there are dosage form additions (a granule, liquid medicine, etc.), modification of administration route (injection, taking orally or external application), launch of a high-value-added tablet, etc. (rapidly disintegrating tablet, a sustained release product, etc.). In a decline period, there is renewal combination pharmaceutical products, a high-value-added medicament (market creation oriented tablet which combines a new packaging container and tablet), etc.

Although there are many case studies of an individual firm or individual product developments ([10], [11], etc.) as regards the open innovation of a dosage form development, there is little quantitative research. Therefore, it is important to study the difference in drug development quantitatively in terms of dosage form development. A dosage form development requires wide-ranging technological knowledge and experience. For example, the innovative tablet technique using Drug Delivery System (DDS) is needed. DDS is a medicinal substances transfer system which controls the distribution of medicinal substances in the living body quantitatively, spatially and in time. Additionally, the research style suitable for a dosage form development differs from a drug development considerably. For example, the research style of a drug development pursues intently the molecular structure which acts on the cause of a sickness in a laboratory. However, the research style of a dosage form development is not only a pure technical development in a laboratory. An understanding of each patient's various conditions is required. It is also necessary to understand and resolve the problems of a user, the physicians and nurses, in an actual use site, such as a hospital. Therefore, the organisation management which is required in the open innovation of a dosage form development differs from that of a drug development. For example, the desired responsibility and scope of authority for a project leader who manages R&D for an open innovation may differ between drug development and dosage form development.

As methodology for this research, a questionnaire was conducted in the companies belonging to the pharmaceutical industry and IT industry segment, in order to compare organisation management for open innovation between industry segments. In particular, it was observed both the relationship between organisations, and the management inside

an organisation. Moreover, in the pharmaceutical industry, not only drug development but also the persons involved in dosage form development were investigated. In IT industry segment, as various business categories were included, such as product, service and infrastructure, the focus was on components for comparison with pharmaceutical products. Most customers of pharmaceutical products are professionals, such as hospital physicians, nurses and pharmacists. Therefore, the part of industry where customers are professional is considered more suitable for comparing inter-organisational relations.

II. PRECEDENCE RESEARCH

A. Product-Development Organisation Pattern and R&D Performance

International empirical quantitative analysis was conducted by [12] as regards the relationship between the pattern of product development organisation and performance in the motor vehicle industry. According to [12], product integrity, which points out the overall harmonisation and integrity of various product attributions in the product development of a motorcar, is important for competition. In addition, it was shown that a Heavy Weight Product Manager (HWPM) system was effective as one of the organisation patterns, and as regards which product integrity was important. HWPM is here a powerful leader which has two functions – a coordination between sections (internal integration), and a product-concept furtherance (external integration) – in order to raise the integrity of a product. Though product-concept is the creation of a responsible person, the influence of HWPM on production, sales and design is strong. In relation to the project, it has strong influence rather than the department head of each function, and generalises the whole project powerfully, thus exceeding a mere coordination person.

Furthermore, [13] analysed effective product development in the computer industry, compared with the motor vehicle industry. In the motor vehicle industry, the internal integration of overlap style problem-solving between design and production was effective. However, in the product development of the computer industry, an internal integration was unrelated to the product development performance. Instead, technology integration, which unifies effectively the upper stream (a precedence development or basic research) and the lower stream (individual product development) of a product-development process, affected the performance in the computer industry.

The computer industry has been compared with the motor industry [14], and the influence on development lead time by two contrastive product development strategies – experiential strategy and compression strategy – has been analysed. The variables of powerful leader, a cross functional team, etc. belonging to experiential strategy contribute to shortening lead time [12]. However, the result of the overlap of a development phase or participation of a supplier was not the same. The cause of this inconsistency has been explained by the difference in industrial trait [14]. That is, while the management environment is comparatively stable in the motor industry, in

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the computer industry, transition is rapid and forecasting is difficult.

B. Cause Uncertainty and Result Uncertainty

A problem-solving model is formulised in five phases: (1) definition in question, (2) search for alternatives, (3) experiment (simulation), (4) assessment and (5) selection [15]. According to [16], generally, the central activity in problem-solving is (2) search for and (3) experiment (simulation) with alternatives. It has been shown the cause uncertainty (width of a search) and result uncertainty (depth of a simulation) for every industry and product on the basis of a case study [17]. The trait of product development of drug development and dosage form development can be classified according to two scales as compared with other products and industries. For example, in the beer industry, since there are many design parameters about a taste and combination is countless, a wide-ranging search is required. On the other hand, the test is simpler only when examined by a sensory test person. Additionally, in a new medicine development, in order to discover an effective compound, the researcher has to search thousands of alternatives. Also, as regards simulation, since it is difficult to predict the effect of a medicine and the toxicity of a compound, detailed trials, such as preclinical animal testing and a clinical human trial are required [15].

Furthermore, in a dosage form development, although the relevance of a compound and an additive agent, application of a drug delivery system, etc. need to be searched, a wide-ranging drug development search is not required. In addition, it is rare that the effect of a medicine and the toxicity of a new tablet cannot be forecast, and simulation is limited to a soundness test, a biological equivalence test, etc.

C. Market-Needs Ambiguity and Product Structure Complexity

Each industrial trait has been evaluated [17] by the scales of the ambiguity of market needs, and the complexity of a product structure. The ambiguity of market needs can specify a market and customer needs uniquely. A motorcar is a typical example of a product with high ambiguity. Since the criteria for choosing a pharmaceutical product concern whether it is effective, ambiguity is low. The complexity of a product structure is related to the numerousness of the components which constitute a product, and the interdependence between each component. As a general trend, if the complexity of a product structure is high, the scale of a development organisation will become large and its necessity for the coordination between organisations will also increase. As a result, the necessity for an internal integration will also increase. A typical example of a product with high product structure complexity is a motorcar. Furthermore, the structure ingredients of pharmaceutical products are several including a principal component and an additive agent. For this reason, there is not much engagement with R&D and the team is small. In such a small-scale team, since a mutual coordination is easy, the necessity for an internal integration is low [15].

Furthermore, the user needs of a dosage form development are not only effect like pharmaceutical products. The convenience which increases the adherence of medication, such as the ease of taking in by a patient and the ease of treatment by the physician, the nurse, the pharmacist and a patient household, is evaluated. The ambiguity of a dosage form development is higher than the usual pharmaceutical products. In addition, the latest dosage form of pharmaceutical products has added various functions (orally-disintegrating tablet, a sustained release product, prefilled syringe, transdermal systems, etc.). Therefore, the complexity of the product structure is higher than the usual pharmaceutical products.

D. Open Innovation and an Organisation

In order to take in external knowledge and to connect to revenue, absorptive capacity in a company is important [18]. Absorptive capacities are the capability, knowledge and information which are required to carry out a series of activities, such as perception of new knowledge and information, assessment, intake, assimilation and utilisation. An absorptive capacity is a by-product of a fundamental R&D activity, the capability to be borne by continuous and gradual accumulation of knowledge in an organisation. A company needs to be conscious of the optimal degree of an external dependence as regards the balance of exploration and creation capability, and absorptive and exploitation capability. The degree of an external dependence is defined as the ratio of the cost which has been invested externally by an alliance etc. from the whole R&D cost. If the degree of an external dependence is too low, the information on the new knowledge produced outside of the company cannot be acquired quickly and efficiently. On the other hand, if a company is too dependent on the outside, the absorptive capacity of new knowledge will decrease [18]. The knowledge which the company acquires cannot be utilised for commercial production sufficiently, and acquisition cost is no longer harnessed to the utmost.

Research-and-development capability was classified by [19] into component competence and architectural competence. Component competence is the fundamental individual capability and the knowledge for everyday problem-solving. Architectural competence is the capability to use component competence, and to unify component competence effectively or to make new component competence. The relevance of organisational ability was explored by [19] as well as the results of pharmaceutical-products research on medicament for circulatory organs of pharmaceutical-products companies in the United States and Europe. From the analysis, it was explained that both component competence and architectural competence related to the productivity of a drug development.

III. Survey Hypothesis

The aim of this research is to clarify the difference by industry segment or product characteristics as regards organisation management for an open innovation to raise R&D performance, following the results of precedence research.

In considering open innovation, both inter-organisational relation and the management in an organisation are important issues. The former concerns the kind of information and

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knowledge to absorb from an external organisation through an open innovation. The latter concerns the information and knowledge which are absorbed connected to the outcome of R&D.

According to precedence research on inter-organisational relation, an important issue is the integration between organisations which perform open innovation; that is, the relationship with a parts supplier, a finished-product maker and a user. For example, in the pharmaceutical industry, it is the relationship with a pharmaceutical company, the physician, nurse and pharmacist of a hospital or bio-venture, Contract Research Organisation, etc. As a pattern of integration, a comparison of broad shallow relationship and narrow deep relationship can be considered. According to precedence research, a search of alternatives (width of a search) and the ambiguity of market needs influence the selection of an integration pattern. If the value acquired through open innovation is the contingent encounter with technical information and market needs useful for a company, the width of a search by broad shallow and ad hoc relationship is important. In comparison, when market needs are equivocal and a tacit knowledge factor is strong, external information is not understood easily. It is necessary to understand and absorb precious information, while associating over many hours, and to make it unite carefully with the product development of its company. In such a case, deep long inter-organisational relation is needed.

As a hypothesis, since the cause uncertainty of a drug development is high, the breadth of the search as regards the technique and intellectual property information in an open innovation raises the performance of R&D. Moreover, the cause uncertainty of a dosage form development is not high compared with a drug development. In addition, since the solution proposal according to the various conditions of a therapy site or a patient is required, the ambiguity of the market needs in a dosage form development is high. A deep relationship with a customer is searched for in a dosage form development. Since, for an information technology product, a market environment changes markedly and the technique evolves rapidly, a cause uncertainty is high. It becomes a competition to discover the combination of new needs and seeds to readiness, and to continue changing it. Therefore, in the open innovation of an information technology product, the breadth of a search of a market and technical information raises the performance of R&D. Therefore, the following hypotheses are proposed:

H1. As regards the inter-organisational relation in the open innovation of a drug development, broad relationship (width of a search) is effective.

H2. As regards the inter-organisational relation in the open innovation of a dosage form development, deep relationship is effective.

H3. As regards the inter-organisational relation in the open innovation of an information technology product, broad relationship (width of a search) is effective.

The next issue is the management inside an organisation. According to precedence research, the important issues of the internal management in an open innovation are the absorptive and architectural capability of an organisation. Absorptive and architectural capability is considered that the result uncertainty and the product structure complexity of a product and an industry segment are related.

If the result uncertainty is high, the deep simulation in R&D of a product is needed. Therefore, it is difficult to connect the knowledge and information acquired from the outside to the knowledge and information of its company organisation, and a long-term process management is required. A drug development is considered a typical example, and since the result uncertainty is high, a long-term process management is required.

In addition, if product structure complexity is high, it is easy to manage a series of technology and processes by integrating in a company. Even though a company cooperates with an external organisation, it is desirable to extend its knowledge and capability so that external technology can be understood well. In addition, it is suitable that the integration of inter-organisational relation is high. The motor industry is a typical example, and the inter-organisational relation of a keiretsu and HWPM system, which manages the inside and outside of an integrative organisation, is effective. In a dosage form development, since the complexity of a product structure is larger than a drug development, integrative R&D is required, understanding well the kind and quality of various materials in and outside the company, the various environments in a hospital and others, etc. Even if it is not comparable with a motor industry, a heavyweight product manager system may be necessary to some extent.

In comparison, if product structure complexity is low, the necessity to research and develop everything in a company is low. It is suitable for a company to select R&D in an area with competitive advantage, and to concentrate resources strategically. IT industry segment is considered to be a typical example; it is an industry of the combination style on condition of open and standard interfaces, such as a USB interface and Android OS. With IT components, strategic narrowing down of an R&D area, and a search and combination strategy of a wide-ranging external resource are effective.

The following hypotheses can be drawn:

H4. As regards the management in an organisation in the open innovation of a drug development, a long-term process management is effective.

H5. As regards the management in an organisation in the open innovation of a dosage form development, an integrative process management is effective.

H6. As regards the management in an organisation in the open innovation of IT components, a strategic process management (a selection and concentration) is effective.

IV. Verification Method and Result

A. The Verification Method

The industry segments comparison questionnaire was conducted as the verification method. The questionnaire consisted of question items about the result of the open

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innovation used as the aim variable, and question items in connection to the organisation management of R&D used as an explanatory variable, in order to verify the abovementioned hypotheses.

As a result of an open innovation, improvement in market share and profitability ratio was measured. The question items about organisation management were greatly divided into inter-organisational relation and the management inside an organisation. The question items about inter-organisational relation consisted of question items about the width of a search, and question items about the depth of inter-organisational relation according to the abovementioned hypotheses.

Next, the question items about the management inside an organisation were set up on many sides as follows, in reference to precedence empirical studies which conducted a questionnaire regarding R&D management: strategic factor ([15], [17], [20], [21]), process management factor ([15], [21], [22]) and organisational-ability factor ([4], [15], [17], [21], [23]-[26]).

All question items used the five-point Likert style (strongly agree, agree, undecided, disagree, and strongly disagree).

B. Synopsis of the Results of an Investigation

The questionnaire survey form was distributed at the business study meeting which the author organised. In total, the effective responses of 80 companies (20 drug development companies, 27 dosage form development companies, 33 IT components companies) were collected. The survey period was April to May, 2015. As regards the collected questionnaire results, principal component analysis was conducted after removal of the ceiling and floor effect, and reliability assessment, and regression analysis was applied by stepwise in relation to the principal component score with each hypothesis. SPSS from International Business Machines was used for the statistical procedure.

C. Principal-Component-Analysis Result

The question items in connection to the result of an open innovation were collected by one principal component named the "result."

Two principal components were extracted from the question items in connection to inter-organisational relation. Each was named the "width of search" principal-component and "depth of cooperation" principal component.

Two principal components were extracted from the question items about R&D strategy of the inside management of an organisation. One consisted of question items about the strategic selection of a product or a technical area, policy clarification and differentiation technology, and it was named the "strategic-research resource-allocation" principal component. Another consisted of question items about the extension of a domain identity including related software or service and a multi-lateralisation, named the "value chain extension" principal component.

In addition, two principal components were extracted from the question items regarding process management of the inside management of an organisation. One consisted of question

items about the resource-allocation balance over the whole R&D process, clarification of the assessment criterion for every phase, etc.; this was named "long-term process administration" principal component. Another consisted of question items, such as rearrangement of a research process and the flexibility of technical introduction and diversion, and named the "flexible process administration" principal component.

In addition, two principal components were extracted from the question items regarding organisational ability of the inside management of an organisation. One consisted of question items about personnel transfer between sections, human diversity, sector crossing communication, etc., and it was named "organisation and human mobility." Another consisted of question items about the encouragement of innovative technology, an aggressive climate, the free hand of a researcher, etc., and named the "innovative organisation" principal component.

D. Regression-Analysis Result

The "result" principal component of the open innovation was made the aim variable, each principal component of the organisation management was made the explanatory variable and regression analysis was applied by stepwise. Dividing a regression-analysis result into drug development, dosage form development and IT components, the principal components which were the most influential according to inter-organisational relation and the management in an organisation are shown in Table I.

TABLE I
REGRESSION-ANALYSIS RESULT

Industry and product	Inter-organisations	Inside organisation
drug development	width of search (.482**)	long-term process administration (.676**)
dosage form development	depth of cooperation (.343*)	organisation and human mobility (.450**)
IT component	width of search (.482**)	strategic-research resource allocation (.533**)

(**: 1% of significance level, *: 5% of significance level)

V. CONSIDERATION

According to precedence research, when considering the relevance of organisation management and performance of R&D, an industry segment and a product can be classified in terms of the combination of the width of a search, the depth of a simulation and the combination of market-needs ambiguity and product structure complexity. If a drug development, a dosage form development and IT components are applied to each matrix based on the statistics analysis result of the abovementioned questionnaire, it will be as in Figs. 1 and 2.

		depth of simulation	
		low	high
width of search	high	IT component	Drug development
	low	dosage form development	

Fig. 1 Framework of "width of search" – "depth of simulation"

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	market-needs ambiguity	
	low	high
Product structure complexity · high		dosage form development
Product structure complexity · low	Drug development	IT component

Fig. 2 Framework of "market-needs ambiguity" – "product structure complexity"

In a drug development, a wide-ranging relationship with various organisations is effective in terms of the search for external information, including technology, intellectual property, regulation, etc., as a hypothesis. In addition, managing a development process in the long run is effectively connected to a result, narrowing down the information acquired through the open innovation as it is a hypothesis, since a deep simulation is required.

A drug development and a dosage form development are considered to be mapped by the contrastive quadrant, being in the same pharmaceuticals industry segment. In this connection, medical equipment and a dosage form development are assumed to be near positioning. A finding of the equivocal needs of an individual medical site and a patient and the solution proposal which made full use of various materials are effectively connected to a result. For this purpose, as a hypothesis, while a product manager accumulates various experiences, it is important to build a customer, a supplier, etc. and a deep relationship. Unlike a drug development, the project manager in a dosage form development considers that HWPM as in the motor vehicle industry may be suitable.

Finally, since IT components are in the industry segment of rapid transition, the width of a search to find a new technology or a new market is important as a hypothesis. It is suitable to perform an ad hoc and wide-ranging open innovation, specializing resources investment in the advantageous technique of its company, since the industry segment is standardised and made modular.

The environment where various talents are connected easily is suitable for the inter-organisational relation in IT industry segment as, for example, Silicon Valley. If market needs can be imagined, it is possible to create one new company after another and to grow rapidly. On the other hand, the inter-organisational relation in the pharmaceutical industry considering the division of roles, such as a pharmaceutical company which has long-term R&D, and bio-venture which creates knowledge, and the formation of a long-term relationship may be suitable. For example, in the keiretsu organisation in the motor vehicle industry, the finished carmaker raises the industry aggregate by building a long-term relationship through personal exchanges, financial support, etc. with various external component companies. Similar inter-organisational relation may also be suitable for the pharmaceutical industry.

VI. Conclusion

This research verified empirically the difference in organisation management in open innovation by industry segment and product. Suitable organisation management according to the difference in industry segment or product characteristics became clear as a result of the questionnaire. The implication of research findings may be useful for the decision-making of those who promote open innovation. The limitations of this research are the spans of the sample used for the survey. There is a possibility that the special conditions in the management environment of a Japanese firm have influenced the search result. A future subject would further generalise by international comparison research, etc.

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