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## Rebuilding oCollective Categories AS The Diffusion of Innovation

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### ABSTRACT

**Background:** The background about this paper is sociology of organization and category in market. **Objective:** The main objective for this paper is to discuss types of category trajectory in markets furthermore. **Results:** The main results for my paper is that there are four types category in market. **Conclusion:** The main conclusion for my paper is there is a category change related category drastically.

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## INTRODUCTION

This study considers rebuilding of collective categories as the diffusion of innovation process, and it proposes to achieve diffusion of innovation by triggering the reinterpretation and defection of labels of category (Negro, Hannan and Rao, 2011). As another case example of this, generics in pharmaceutical industry in Japan are cited. We present a hypothesis that by replacing the label called “me-too drug” in Japanese with generics, not only diffusion of the category called generic has become more widespread, but by also affecting new drugs, it has rebuilt the collective categories of all drugs and it has contributed to the diffusion of innovation by generics.

### Literature Review:

Categories are created in order to lump together similar elements. Furthermore, by attaching a label to the respective categories, differentiation between other similar categories is made possible.

In addition, meaning is given to each category label. Therefore, according to the category label, the audience is able to discern which members with what meaning belong to that category. In the study of categories in the market, an example of movie genre such as action, adventure and animation, is given.

Concerning the meaning of category labels, as the audience gives social consent to the meaning of the label, the category becomes widely accepted. Categories may be rephrased as social consent with regard to labels. Thus, to the extent that the meaning of the label receives social consent, that category becomes widely accepted, clearly defining the boundary of the category. Conversely, if the meaning of the category has only partial social consent, that category is made difficult to accept, making the category boundary indistinct.

If a product indicates the meaning of the label clearly, the audience will accept that product as a member of the category, and the product may be evaluated based on the label. In addition, the audience will be able to reconfirm the existence of the category itself based on the product.

Conversely, if a product does not correspond to the meaning of a widely-accepted category label, or if the meaning of a category label is obscure, or if a product whose category meaning spans several categories more than other products, the likelihood of the audience not accepting the product becomes higher. Hence, existing studies indicate that in the market, the audience is more likely to overlook the product or corporate evaluation, or to penalize the product or company by giving it a low rating. The reason for the aforementioned is, if a product with an indistinct category label is accepted as a member of that category, the meaning of the label of the category itself is made obscure, causing the category boundary to become indistinct.

With consideration to the above argument, in this study, the trajectory of categories in the market is classified into 4 types as shown in Figure 1. The horizontal axis shows whether the company, which is the category producer, changes the meaning of the label without changing the category label, or changes both the

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category label and its meaning. The vertical axis shows whether the company changing the label or both the label and its meaning is an insider of the market (existing enterprise) or an outsider (newcomer enterprise).

	Existing labels	New labels
Insiders	<b>A</b>	<b>B</b>
Outsiders	<b>C</b>	<b>D</b>

**Fig. 1:** Category trajectory in market

First of all, type A is an existing enterprise which breaks away from other existing enterprises over the meaning of a label, seeking to change the meaning of the label while leaving the category label as is.

Type B is an existing enterprise which breaks away from other existing enterprises with regard not only to the meaning of a label but also with regard to the label itself, giving new meaning to the label under a new category, being in competition with the existing label.

Type C is a newcomer enterprise which leaves the category label as is, while being in rivalry with other existing companies over the meaning of the label, and seeks to change the meaning of the label.

Type D is a newcomer enterprise which is in rivalry with other existing companies regarding not only the meaning of the label but also the label itself, and seeks to create a new category and meaning to the label.

In this study, attention will be given to Type B with regard to the path of categories. The reason thereof is that Type B most resembles the target of this study which focuses on breaking away from a widely accepted category to create a new category, and what repercussions this has on collective entity of the existing category.

#### **Research Method and Data Collection:**

The aim of this study is to develop a hypothesis by means of quantitative research based on article search and qualitative research based on interview surveys and semi-structural questionnaires.

The quantitative aspect of this study is based on newspaper article search. In order to gauge the communication of the category audience in the market, a chronological record is made of the number of keyword hits that a category label receives based on the article search database of various newspapers. Newspapers are, in effect, an audience who serve as a critic communicating with the category producer, and an intermediary enabling the category to be widely accepted by society. Therefore, this indicates that the more hits a label receives, the more frequent the communication between the newspaper, as an audience, and the category producer. By extension, it means that the category producer is communicating on a wide scale to society, as an audience, by means of the newspaper.

The qualitative aspect of this study is based on interview surveys. The subjects of the interview surveys were 3 major specialized generic manufacturers and 8 major new drug manufacturers. The term of the survey was from December, 2012 to December, 2013. The semi-structural questionnaires regarding generic labels were given to the public relations department of major specialized generic manufacturers, generic drug trade associations, and societies for the promotion of generics. The term of the survey was from December, 2013 to June, 2014.

#### **Case Study of Generics In The Ethical Drug Industry:**

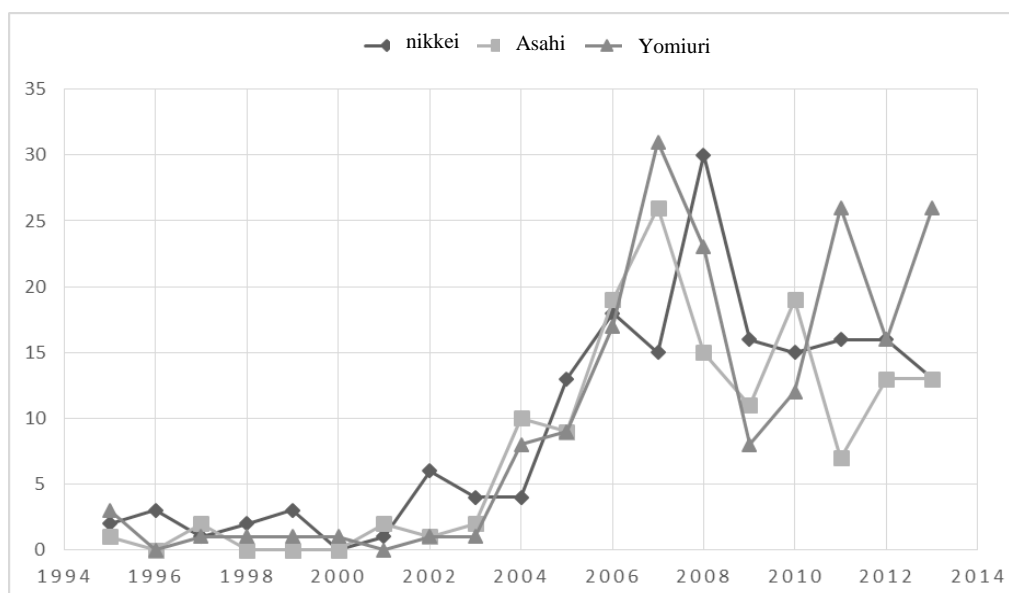
As an example of revolutionary categories, generics in the ethical drug industry will be taken up. Drugs may be categorized into ethical drugs which require a doctor's prescription, and non-prescription drugs which may be obtained at a general pharmacy without a prescription. Furthermore, ethical drugs may be categorized into original drugs (so-called new drugs) in which the pharmaceutical company developing the drug may patent it for exclusive production and sales, and generic drugs which other pharmaceutical companies may sell along

with original drugs after the expiry of the patent term (in general, this term is said to be 10 to 15 years after the acquisition of the patent).

To be more precise, generic drugs are drugs which have been approved for production and sales by the Ministry of Health, Labor and Welfare based on the Pharmaceutical Affairs Law as having the same quality, efficacy and safety as the original drugs after the patent expiry of the original drugs. Because the development costs for these generic drugs are extremely low in comparison to the original drugs, the drug pricing is set at a low rate. Therefore, not only is the out-of-pocket expense for the patients reduced, but because it also contributes to the reduction of the national health care expenditure, the administration such as the Ministry of Health, Labor and Welfare endorses the usage of generic drugs. Presently, the market share for generic drugs as ethical drugs is 22.8% in volume terms, and 8.8% in value terms, and a larger segment of the market is forecasted to be occupied in the future (Ministry of Health, Labor and Welfare website, 2012a).

In western countries, when the doctor prescribes a generic drug, he does not write the brand name but rather the generic name (component name) on the prescription. Thus, generic drugs has been called “generics” in western countries. According to the interviews conducted under this study to societies and trade associations, in public documents in Japan, the Japanese term for generic drugs is still used to the present, but in general, the English term “generics” is used in line with western countries.

However, it is only in recent times that the label “generics” has come to be used as a common name for generic drugs and have begun to have communication with a larger audience. As Figure 2 shows, from 1995 onwards, the label “generics” began to be used in major newspaper articles, whereas trade journals began to use the term from 1991 onwards. Thus, the term “generics” can said to have come into use in the early part of the 1990’s.



**Fig. 2:** Word of Generics

Furthermore, the term “generics” came to appear more frequently in newspaper articles from 2006 to 2008. We can presume that during this time, the category of “generics” came to be widely accepted by the audience. In 1997, the specialized generics manufacturer Sawai Pharmaceutical Company put out for the first time a campaign advertisement on a nationwide newspaper with the caption, “Have you heard of generics?” However, the newspaper advertisement by itself did not penetrate into society. As Figure 2 shows, it was only when Sawai Pharmaceutical and Towa Pharmaceutical broadcasted a nationwide television commercial from 2004 onwards that communication gradually came to be established with society through the category of “generics.” In other words, although the term “generics” was already in existence around 1995, it did not spread rapidly as a category label in the ethical drug industry until the 10 years between 2004 and 2014.

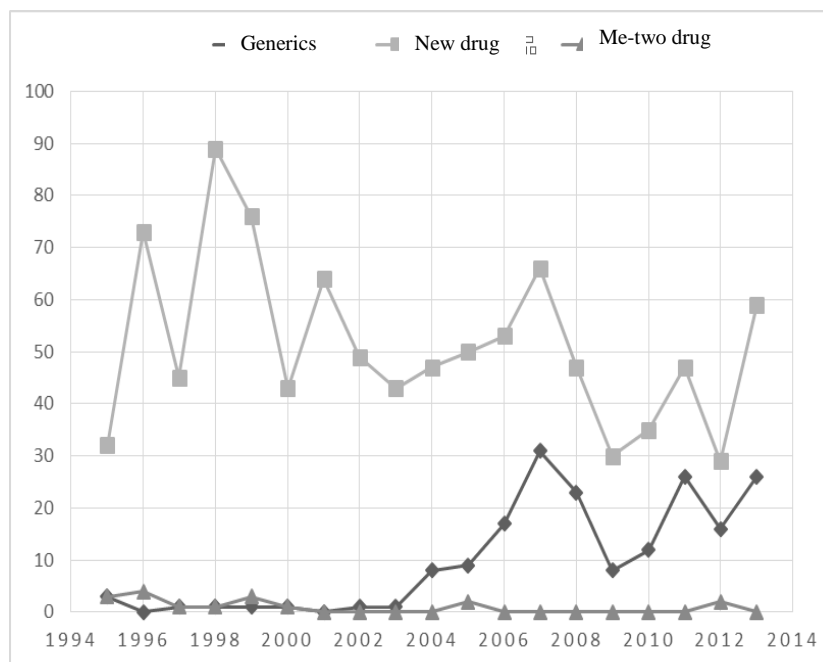
Even before the use of generics as a label, generic drugs which were produced and sold by other companies after the expiry of the original drug patent existed, with names other than “generics.” Because various pharmaceutical companies gradually began to sell such drugs en masse after the expiry of the patent, these drugs came to be called “me-too drugs.” Although there were reservations about using this label openly, the label “me-too drug” came to be used in the early part of the 1980’s, and years before the term “generics” came into existence, it can be presumed that the label “me-too drug” was used as a common name for generic drugs.

The label “me-too drug” has a negative connotation. The “me-too drug” label is the pole opposite of original drugs which are placed on the ethical drug market and are called blockbuster drugs, equipped both with creativity and quality. The term generic drug itself means that it is a drug which comes after the original drug, in a “cheap and nasty” form. In addition, the “en masse” reputation is attached to the “me-too drug” label, eliciting an unspeakable suspicion.

The suspicion toward the “me-too drug” label does not merely originate with a mental image. Although generic drugs are defined as having the same efficacy as the original drug, the process method and additives may sometimes differ to those of the original drug. Thus, health care professionals, in particular doctors and other new drug manufacturers have cast doubts on the quality of generic drugs. For example, as a result of severe testing, there were cases in which impurities exceeding the standard have been detected in the generic drugs of antihypertensive drug Renivase.

Moreover, generic drugs have had the problem of reliable supply, which is the most vital requirement for drugs. In fact, according to a survey by a trade association in 1994, a problem arose regarding reliable supply when short intensive sales of generic drugs took place as a result of a sharp price reduction as well as withdrawal from the market due to reduction in drug pricing. Hence, it can be said that the negative connotation attached to the “me-too drug” label held by many including health care professionals for many years, is not mere hearsay but is well-grounded.

As shown in Figure 3, in recent years, however, the “generics” label has come to be used more frequently, as if to cast the “me-too drug” label to the distant past, and has become widely accepted by the audience. In the last 10 years, in the ethical drug-related articles in the popular newspaper Yomiuri Shimbun, articles on generics have increased, relatively speaking.



**Fig. 3:** Word of Generics and Other Words

Needless to say, the increased attention from society toward generics and the acceptance of generics as a label are attributed greatly to the promotion in the use of generic drugs by the administration, such as the Ministry of Health, Labor and Welfare. However, the fact that the administration who uses the Japanese term for generic drugs in public documents and who merely promote the use of generic drugs cannot explain the wide acceptance of the “generics” label. Therefore, through mutual cooperation of specialized generics manufacturers, manufacturers who handle both new drugs and generic drugs, trade associations such as the Japan Generic Medicines Association, societies such as the Japan Society of Generic Medicines, and awareness-raising groups such as Japan Generic Drug Association, changeover from the traditional “me-too drug” label to the “generics” label has been achieved, realizing the positive transition from the negative connotation of the “me-too drug” label.

Amid such endeavors, the effort expended by specialized generics manufacturers includes various aspects, such as the effort to improve quality assurance of generics and to reduce out-of-stock goods through drug inventory control. However, in this report, focus will be given to the following 2 points.

Firstly, specialized generics manufacturers have sought to spread generics advocating less burden on patients. Less burden does not only refer to less burden for the patient because of the low cost of generics in comparison to original drugs. It has also been emphasized that generics are less burdensome for the patient because of the ease of use (pharmaceutical preparation technology, etc.) and the ease of recognition.

However, it cannot necessarily be said that all specialized generics manufacturers are developing technology related to ease of use and recognition in advance of ethical drug manufacturers. Rather, as cases of antihypertensive drugs as shown in Table 1 indicate, in many cases the original drug manufacturers anticipate the patent expiry of the original drug, modify the dosage form and specifications of the drug, thereby competing with generics after patent expiry. For example, due to the expiry of the patent in 2008 of the antihypertensive drug, original drug manufacturers did not wait for 2008, but rather launched sales of the OD tablet (Amlodin tablet) derived from the same product in 2006.

However, capitalizing on such endeavors of the original drug manufacturers, specialized generics manufacturers have launched sales of oral jelly and OD film surpassing the aforementioned. Only 1 company is taken up as representative of all generics, but in actuality, a total of 38 companies including Towa Pharmaceutical has received sales licenses in 2008. Thus, it can be said that there is fierce competition between generics, and differentiation among generic products is indispensable. Therefore, the meaning ease of use is inevitably added to the category label of generics amid fierce competition between generics.

Secondly, specialized generics manufacturers have turned their attention not only to original drug manufacturers and doctors as the target of their sales promotion as they have done in the past, but also to pharmacists and patients (including potential patients). After all, the patient is the one who, at the dispensing pharmacy, decides whether to go with the original drug after patent expiry or the generic drug, not the doctor or the pharmacist. In addition, even among the generics, the patient can, to some extent, select the manufacturer of the drug. Thus, specialized generics manufacturers are obliged to widely disseminate the category of generics to society including patients through television commercials and to make publicly known the names of the companies producing the generics. By so doing, the category of generics will further penetrate into society. In other words, it can be said that as specialized generics manufacturers have shifted the traditional customer target, the category of generics has become widely accepted.

### ***Discussion:***

The generics example described above was centered on the efforts of specialized generics manufacturers that served as category producers that reformed existing categories such as generic drug and me-too drug and created a new category of “generics” while engaging in dialogue with their audience, which resulted in that category becoming widely accepted among their audience. To shift the meaning from what the me-too drug label signified to health care providers and patients, specialized generics manufacturers and various stakeholders used the new category label of “generics” to signify that they are accessible to patients not only in the sense that they are reasonably priced, but also because they are easy to use and easy to take. Hence, the “generics” label quickly came to be widely accepted, and it can be thought that efforts to further strengthen the “easy-to-use for patients” meaning of the label while working to resolve various issues with stable supply and quality improvement and actively incorporate techniques for manufacturing original drugs into generic drug manufacturing led to the “generics” category becoming widely accepted.

This “generics” category can be said to have a similar path to the Type B path in Figure 1. First, the existing category label of me-too drugs was switched out for the new label of “generics.” Next, the meaning also shifted from the “cheap price” meaning of the me-too drugs label to the “easy to use and easy to take” meaning of the “generics” label.

However, although the category path in the generics example starts out the same as the example given of the Type B model, the generics path has a different course and end point. In the Type B model, existing companies break away from other existing companies with regard to category labels and the meanings of those labels to create new category labels with new meanings, and the existing label and the new label compete in the market.

In contrast, in the generics example, the existing label did not compete with the new label, but rather there was a shift from the existing label of me-too drugs to the new label of “generics.” Therefore, this example differs from the Type B model in that the existing category of me-too drugs was eliminated and the new category of “generics” was created.

These differences between examples arise because in the example from the world of French cuisine, the new category that was created opposed the category from which it broke away, whereas in the generics example, although at first glance it appears that a new category (“generics”) was created in opposition to the category from which it broke away (me-too drugs), the category it opposed was not the category from which it broke away (me-too drugs), but rather categories with the opposite meaning of the category from which it broke away (new drugs and blockbuster drugs). The purpose of this change was not to simply shift to “generics” as a new category (from me-too drugs to “generics”); it was an attempt to reform the category network (the relationship

between innovative new drugs and me-too drugs that lacked in innovation). Therefore, unlike the nouvelle cuisine category, the “generics” category is a revolutionary category that the pharmaceutical industry created as an attempt to rebuild the existing group of categories as a whole.

Furthermore, the generics example in this study showed that the boundaries of the “generics” category grow clearer as companies actively adopt techniques used in new drug manufacturing for use in generic drug manufacturing. That explains why the “generics” category is rebuilding the existing category as a whole while retaining its own boundaries.

Therefore, it is considered that Type B can be further divided into two subtypes. As shown in Figure 4, the first type is when a new label is created but it continues to compete with an existing label (Type Y). The second type is when the existing label shifts to the new label (Type V).

The hypothesis proposed in this study is that Type V-like categories are revolutionary categories that have the potential to not only change the label or meaning of the category, but also to rebuild the category as a whole.

		Existing labels	New labels
Competition	競争 ラブリ	X	Y
Replacement	立替 轉換	Z	V

Fig. 4: Some Types of Type B

#### Conclusion:

In this study, findings from research on categories in the market, which has been a popular topic of study in recent years, were arranged to build the framework for analysis presented herein. Then, it was discovered that the category of “generics” in the pharmaceutical industry had a category path that differed from patterns described in previous studies, and this type of category was named a “revolutionary category.”

In the revolutionary category path, not only does the existing category shift, the category as a whole is incorporated and rebuilt in a network-like fashion in order to shift from the existing category to the new category. In addition, it was noted that to rebuild the category as a whole, the revolutionary category clarifies the boundaries of the category while incorporating elements of opposing categories to rebuild existing categories as a whole.

Categories integrate similar concepts and simplify our thinking. However, categories do more than this; they also oppose existing categories and rebuild existing categories. Furthermore, a category can also change the complete landscape of categories that were previously widely accepted. This means that research on categories in the market could be considered one perspective for studying innovation, which is the main finding of the present study.

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