Intellectual Property Management of Biotechnology Start-ups and Companies in Japan

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Abstract— *Intellectual Property (IP) management is crucial for biotechnology start-ups or companies (hereinafter biotech start-ups) which have as their foundation specific proprietary technologies. Furthermore, patentable inventions have become more various with the rapid progress of biotechnology. Through the administering of a questionnaire, the present study investigates the IP management of biotech start-ups in Japan and attempts to show how biotech start-ups manage and exploit their IP. The survey shows that the 'new-drug' group of start-ups put more of an emphasis on IP management including patent protection of inventions by filing applications than the 'non-new-drug' group, and that large companies play an important role in licensing activity of biotech start-ups. Additionally, it is shown that networking seems to play an important role in their IP information management, from an interview study.*
In short, the Japanese 'new-drug' biotech start-ups file patent applications for protection of their technologies as other new-drug companies generally do and it is important for them to develop networks and form beneficial alliances with large companies according to their IP strategies.

Index Terms—*Intellectual Property Management, Biotechnology start-ups in Japan*

1. Introduction

This study attempts to analyze Intellectual Property (IP) management including IP information management of biotechnology start-ups or companies (hereinafter, biotech start-ups) in Japan. There is little evidence from research to indicate how biotech start-ups, with little labor and financial capital, manage their IP, including patent protection of their inventions.

This paper considers the idea that biotech start-ups, especially those involved in the production of new-drugs, do manage IP and they could do so by effectively making use of external expertise and by forming alliances with large companies.

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2. Background

2.1 Management of Intellectual Property in Biotechnology

IP, especially in the form of patents, is very important for companies producing new drugs in the pharmaceutical industry, because a substance patent for pharmaceuticals provides extensive coverage for property rights, a small number of patents can cover one new drug and each patent is extremely valuable.

Patentable inventions have become more various with the rapid progress made in biotechnology and, as a result, the number of patent applications in biotechnology fields has increased. In some cases, traditional rules or practices for the granting of patents do not adequately correspond to recent biotechnology inventions.

Therefore, biotech start-ups, especially 'new-drug' start-ups have to file patent applications to protect their technologies with patents, in proper accordance with such changes in the industry and in patents.

2.2 Biotechnology start-ups in Japan

The number of biotech start-ups in Japan has increased because of government support through policies for the promotion of start-ups, especially since 1999. The Japan Bioindustry Association (JBA) reported that the number of biotech start-ups in Japan in 2006 was 586 including 157 'new-drug' start-ups[1].

2.3 Management of Intellectual Property for Biotechnology start-ups

Biotech start-ups have to cope with the changes in patents for biotechnology inventions, which is a burden for them. Start-ups generally have a small number of employees and it is difficult for them to assign their employees to IP management like patent protection. In Japan, although there are more than 500 biotech start-ups, many of them are in preliminary stages with a small number of employees.

Therefore, it can be said that it is difficult for

Japanese biotech start-ups to manage IP.

There are papers which have reported results from case studies of biotech start-ups' business strategies in the US [2]-[6]; there has been a comparative study of Japanese biotech start-ups' business with those of Europe and/or the US [7]-[8] and there has been a study of strategic alliances of entrepreneurial biotechnology firms in the US [9]. There is also a report regarding IP management of biotech start-ups in the US, in which IP management techniques are classified into both an offensive strategy (filing many patent applications) and a defensive strategy(filing a selected number of patent applications)[10]. Thumm[11] reported on the management of IP rights in European biotechnology firms. He demonstrated that patents are an important incentive for research and development in the European biotechnology industry and patents are used strategically, in different ways.

Tsutsumi[12] reported on the patent strategy of one biotech start-up in Japan in relation with its business strategy. She pointed out that the biotech start-up filed many patent applications as a large company generally would, even though the fees to file patent applications are very expensive for small and medium size companies.

It is necessary to file patent applications to protect inventions and 'new-drug' biotech start-ups have to file as many patent applications as possible for inventions necessary and important for their business.

Biotech start-ups should make effective use of external resources, including existing expertise in IP management, because start-ups are more restrained by their economic and human resources.

3. METHODOLOGY

3.1 Questionnaire Survey

Questionnaire was delivered by mail to 277 biotech start-ups. The 277 samples were drawn from "The Whole of Bioventures (BIOBENTYA TAIZEN)" (2005) (Nikkei BP Inc.) [13] from February to March of 2007. 47 usable responses were obtained(the response rate of the postal questionnaire survey was 17%).

The questionnaire included inquiries about the following topics:

(1) The number of patent and utility model applications and registrations in Japan and other countries
(2) IP licensing activities and alliances with other companies
(3) Information resources for alliance partners
(4) Utilization of external services relating to IP
(5) IP strategy

3.2 Characteristics of Biotech start-ups respondents (N=47)

Tables 1a-1c demonstrate the characteristics of respondents (Tables 1a-1c).

Table 1a. Overview of Respondents (years of business)

years of business		ratio (%)
-5	Sample	20
	Respondent	11
5-9	Sample	52
	Respondent	64
10-14	Sample	11
	Respondent	11
15-19	Sample	6
	Respondent	4
20-	Sample	11
	Respondent	11

Samples:N=273, Respondents:N=47

Table 1b. Overview of Respondents (number of employees)

Number of employees		ratio (%)
1-4	Sample	13
	Respondent	6
5-9	Sample	23
	Respondent	13
10-19	Sample	26
	Respondent	23
20-49	Sample	25
	Respondent	43
50-99	Sample	9
	Respondent	18
100-	Sample	5
	Respondent	2

Samples:N=247, Repondents:N=47

Table 1c. Overview of Respondents (Capital Scale)

Capital Scale (million yen)		ratio (%)
less than 50	Sample	35
	Respondent	26
from 50 to less than 100	Sample	14
	Respondent	13
from 100 to less than 500	Sample	28
	Respondent	23
from 500 to less than 1000	Sample	9.4
	Respondent	15
from 1000 to less than 5000	Sample	9.8
	Respondent	19
5000 or more	Sample	4.1
	Respondent	4.3

Samples:N=266, Repondents:N=47

Samples are drawn from "The Whole of Bioventures (BIOBENTYA TAIZEN)"(2005)(Nikkei BP Inc.)[13]. The number of Samples are different among the three items, because the data with no answers are excluded.

Respondents contained few biotech start-ups in preliminary stages and few of a very small-size with respect to employees and capital than Samples.

The group of respondents contained few biotech start-ups in preliminary stages and few of a very small size with respect to employees and capital.

The data of this survey should, then, be interpreted as reflecting a view of biotech

start-ups other than those in the beginning stages of business and of a very small size.

The respondents are divided into 2 groups: the 'new-drug' group and the 'non-new-drug' group, based on their type of business.

The 'new-drug' group (N=19) includes respondents whose business scopes include the production of new drugs or the search for seeds of new drugs.

The 'non-new-drug' group (N=28) includes all respondents other than the 'new-drug' group, whose business scopes are research tools, supporting services for new drugs and other such things.

3.3 Interview study

2 biotech start-ups were interviewed.

Both of them are 'new-drug' biotech start-ups in roughly their eighth year of business.

4. RESULTS

4.1. The number of patent or utility model applications and registrations

From the questionnaire, it was found that more than 90% of biotech start-ups (N=47) have filed more than one Japanese patent or utility model application and more than 70% of them have filed more than one US patent applications, even though the number of patent or utility model registrations is low. One reason for the small number of patent or utility model registrations would be that it takes several years for processing from the filing date of applications for registration and their applications have not yet been completed and therefore the patents are not registered yet.

The biotech start-ups which filed no patent or utility model applications both in Japan and in the US are 'non-new-drug' companies. The biotech start-ups that filed more than 10 US patent applications are 'new-drug' companies.

Therefore, IP is more important to 'new-drug' companies than it is to 'non-new-drug' companies and it can be said that 'new-drug' biotech start-ups are more aggressive in filing patent applications.

4.2. Utilization of External services relating to IP

There are many resources providing IP information or services in Japan, including various websites, seminars, and so on provided by the Japan Patent Office (JPO), the Small and Medium Enterprises Agency, and the Municipal Intellectual Property Right centers.

The results from the questionnaire relating to the utilization of external resources providing IP information or services are as follows:

(1) More than 50% of biotech start-ups used the JPO's website, seminars and other resources (79%) and also used IP experts like lawyers and patent attorneys (61%). Other external resources were used by only a small number of biotech start-ups (9-38%).

(2) The 'new-drug' group has a policy for more actively making use of IP experts like lawyers and patent attorneys in the future than the 'non-new-drug' group (Table 2).

Table 2. Utilization of external resources

resource	*Priority to use in the future*[1]				
	New-drug		*Non-new-drug*		*t value (p value)*
	Mean	*SD*	*Mean*	*SD*	
Japan Patent Office (website, seminars etc.)	*4.1*	*1.5*	*4.1*	*1.6*	*0.16(0.44)*
IP Experts like lawyers and patent attorneys	*4.3*	*1.5*	*3.5*	*1.6*	*2.06(0.02)**

*: $p < 0.05$

[1]Five-level Likert Scale(very important 5 -not important at all 1)

The 'new-drug' group has a policy for more actively making use of IP experts like lawyers and patent attorneys in the future than the 'non-new-drug' group.

The JPO is a government authority and patent attorneys are authorized experts specialized in IP. It can be said that biotech start-ups, especially those of the 'new-drug' group, rely on specialized IP resources when choosing among many external resources.

4.3. IP strategy

Table 3 demonstrates that the 'new-drug' group gives greater priority to exploiting the rights exclusively, hindering others' entry in the market or product imitation, and using the rights for earning license income than the 'non-new-drug' group.

Table 3 also demonstrates that the 'new-drug' group gives priority to forming beneficial alliances, presenting their own technology to potential investors, and giving incentives to employees.

Table 3. IP strategy of Biotech start-ups in Japan

Item of IP strategy	Priority level[2]				t-value (p-value)
	New-drug group		Non-new-drug group		
	Mean	SD	Mean	SD	
Exploiting the rights exclusively in order to rise up own share in the market	4.8	0.3	4.4	0.8	2.1(0.02)*
Hindering others' entry in the market or product imitation	4.7	0.3	4.3	0.6	2.1(0.02)*
Open to others for earning as a license income	4.5	0.6	3.5	0.9	3.9(0.00)**
Taking advantage in cross-licensing	3.6	1.3	3.3	0.7	1.0(0.16)
Enjoying priority in alliances	4.2	0.7	3.8	0.5	1.8(0.04)*

Free open and growing up own company together with a market growth	1.6	0.6	2.5	1.1	-3.5(0.02)*
Permitting others to use patents widely in order to make own technology as the Standard in its field	2.4	2.1	2.5	0.9	-0.3(0.40)
Presenting to customers different points of own products from others'	4.3	1.2	3.8	1.0	1.5(0.07)
Presenting own technology to potential investors	4.4	0.9	3.7	1.1	2.5(0.01)**
Funding by IP on mortgage	3.2	1.8	2.9	0.8	0.9(0.20)
Giving Incentives to employees	3.6	1.0	2.9	0.9	2.4(0.01)**

*:$p<0.05$, **:$p<0.01$

[2]Five level Likert scale(Very important 5 – not important at all 1)

The important purposes to file applications and to obtain rights of IP for new-drug group are to use as exclusive rights and to gain income by licensing.

This demonstrates that the most important reasons behind the 'new-drug' start-ups' filing applications and obtaining IP rights are to obtain exclusive rights to their products or processes, to gain income through licensing, or both.

Therefore, it can be said that the purpose to obtain IP rights for 'new-drug' biotech start-ups is to be able to exploit these.

4.4. Licensing Activities and Information resources for alliance partners

Table 4 shows the main partners for out-licensing are companies other than start-ups and small or medium enterprises (SMEs), while the main partners for in-licensing are companies other than start-ups and SMEs and universities. The number of start-ups which did cross-licensing is few in number.

This demonstrates that companies other than start-ups and SMEs, that is, large companies play an important role in licensing activity.

Table 4. Licensing Activity

Alliance		Out-licensing	In-licensing	Cross-licensing
Partner	Total number of start-ups	17	22	2
Start-ups		18(%)	18(%)	0(%)
SMEs		18	23	0
Companies other than start-ups and SMEs		82	45	50
Universities		0.6	50	0
Government Research Organizations		0	23	50
Others		0.6	18	0

The main partners for out-licensing are companies other than start-ups and SMEs and the main partners for in-licensing are companies other than start-ups and SMEs and Universities. The number of start-ups which did cross-licensing is few in number.

4.5. Information resources for alliance partners

As a channel for biotech start-ups to find partners for licenses, referring to the customer companies (43% of respondents) and networking such as getting acquainted at academic societies (70% of the same), are found to be the most commonly used methods. Other channels like Technology transfer and Licensing Organizations (TLOs), business or university websites, patent market, patent search, patent distributer and trading companies are found to be used by only 0-26% of respondents.

Differences in information resources for alliance partners between start-ups with licenses and those with no licenses are found to be few.

4.6. Interview study

The following information was found through the interviews of two 'new-drug' biotech start-ups (A and B):

(1) They both actively file patent applications and are selective in their choice of patent applications because of economic restraints.

A selects the number of patent applications by dividing into inventions for which to file applications and specific know-how to keep as a secret.

B files patent applications first and then selectively abandons certain applications.

(2) They both make use of patent firms (lawyers or patent attorneys) as external services.

A and B rely on networking to obtain the persons or companies, who or which will support their business.

A obtains information relating to IP from the JPO's website and filters the information through networking, when too much information is provided.

B obtains information regarding inventions or patent applications from universities through networking developed anywhere.

This demonstrates that 'new-drug' biotech start-ups should selectively file patent applications and networking is a useful IP information management tool. IP information obtained through networking leads these companies to manage IP effectively.

5. CONCLUSION

'New-drug' biotech start-ups in Japan file patent applications and their purpose for obtaining IP rights is focused on eventual exploitation of these. As well, 'new-drug' biotech start-ups in Japan file patent applications for the protection of their technologies as other new-drug companies generally do.

From many external resources, biotech start-ups select resources with expertise in IP.

This is one strategic IP management method for start-ups with a small number of employees.

Large companies play an important role in the licensing activity of biotech start-ups. Customer

companies and networking are used the most as channels for finding licensing partners.

Therefore, it can be said that biotech start-ups should develop networks and form close ties with large companies, especially as customer companies.

The results of this study are based on a small sample of biotechnology companies, which affects the relevance of the findings.

Adding more companies to the sample is necessary for determining whether the results of this study can be generalized for biotech start-ups in preliminary stages.

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