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## Entrepreneurial Venturing in a Consortium: A Case of Advanced Biotech R&D in Japan

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This research has focused on studying a form of entrepreneurial and corporate venturing in consortium. This paper bases its conceptual stand in the role of resource competencies as an object of commercializing and strategizing knowledge and expertise. We conducted a case study of a few dedicated biotech firms or DBFs, which operates stem cells and regenerative medicine-related business. Using descriptive statistical analysis, our results indicate that this type of firms have managed to perform well in terms of enterprise value and the number of employees. Our key findings on the underlying statistics for innovation productivity further indicates that the DBFs have shown a positive output trend in terms of the average number of patent production per scientists who have close ties with both research institutions and other firms. Furthermore, these firms have more experienced management teams with a variety of industrial experiences. Basing on these findings, we conclude that a consortium-based entrepreneurial and corporate venturing is a more promising approach to commercialize advanced technology in emerging biotech field.

#### 1. Introduction

This study reviews the techniques for the commercialization of knowledge for new biotech firms in Japan. The bio-ventures carry out business for the discovery, applications and production of drugs in cell therapy and regenerative medicine, a process that requires resource competency to manage innovation for value creation.

Since late 1990's, biotechnology in Japan has been one of the top knowledge creating fields prioritized in science and technology policies hence promoting an increase in the number of biotech start-ups from mere 102 in 1994 to 569 in 2008. These efforts reflects the fact that the ability to innovate and make significant inventions that would lead to successful ventures while creating employment opportunities to many is important to both entrepreneurs and governments.

Despite it's clear importance to economic development, there are various issues related to resource competency that pose a challenge to commercializing biotechnology. Newly established dedicated biotech firms (DBFs) are perhaps facing more challenges in raising and managing resource competency to flourish in the business. We use the term DBFs referring to those firms whose predominant activity involves the application of biotechnology techniques to produce goods or services and/or to perform biotechnology R&D [1].

Central to DBFs competencies in today's competitive environment are open innovation approaches to foster technical competencies [2].

Meaning DBFs need to utilize social capital in the form of networks and alliances [3-5] to license and commercialize patents in order to survive the brutal world of knowledge management which has competent players like large pharmaceutical companies and national universities and research institutions which are so often supported by government funding.

#### 2. Theoretical background

According to the resource-based view (RBV) of the firm, firms become competitive out of having resources, which are unique to them [6,7]. Wernerfelt [7] defines resources as tangible and intangible assets such as skilled personnel, capital and technology tied semi permanently to a firm. Accordingly, a firm will become more competitive when it owns a more unique and embedded resource [6].

Literature has covered the field of commercializing biotechnology from various angles. For instance, it has commonly being pointed out that lack of capital funding and entrepreneurial skills can be setbacks and sources of deaths for biotech ventures [8]; look into the role and transfer of technological capabilities [9] in the form of strategic alliances [10]; absorptive capacity [11] and networking [12]. In this study we argue that a consortium-based approach capable of addressing strategic issues, financial stability, credibility and operational capabilities to support commercialization of the new technologies can work best to support resource competencies in DBFs.

We define the term consortium-based

approach in the commercialization of biotech technologies association as an of multiple organizations which include private firms, public institutions, research institutions, medical institutions and research hospitals, governmental affiliates, and others such as non-profit organizations (NPOs), or any combination of these entities, which share a common innovative goal but not necessarily a pool of resources. The approach has a role not only in raising capital to fund projects but also supports IP through creating patent pool, cell banks, skills and branding which subsequently results to achieving competitive advantage for those involved in the consortium.

#### 3. Result of a Statistical Case Study

In this study, we focused on the stem cells and regenerative medicine (SC&RM) technology field as an example of advanced biotech R&D an area that Japan has vielded international competitiveness [13]. To investigate the characteristics of these DBFs and the environment, we enrolled a case study approach. First, as reported in our other work [14], we studied six companies using data supplemented from the Japan biotech database (JaBit). Selected variables were analysed to measure firm performance using firms' enterprise value and firm size using the total number of employments for the ten years the DBFs had been in business. Furthermore, we tested for technical productivity by measuring the amount of patents and projects for each firm; and the influence of entrepreneurial skills based on the length and type of experiences of the top managers. Our cases included three DBFs engaging in the SC&RM field and three operating conventional drug discovery others technologies [14].

Statistical analysis of the data indicated that the SC&RM DBFs managed to perform better in terms of total number of patents production per scientist due to forming collaboration and alliances with consortium members, an approach that provided an effective business model in a competitive business environment (Figure 1).

### 4. Result of a Descriptive Case Study

We further conducted an in-depth observatory study on one of the DBF, CellSeed Inc., to focus on the application of a consortium-based approach in commercializing biotechnology. This has been done based on a project called Cell Sheet-Based Tissue and Organ Factory (CSTOF).

CellSeed Inc. was founded by Prof. Teruo Okano and Dr. Yukio Hasegawa in May 2001 as a spinout firm from Amersham Pharmacia Biotech, Inc. (APB) and was listed to the JASDAQ in 2010.

CellSeed's business model is based on conducting basic research on various regenerative medical products that utilize cell sheets from various body tissues and organs. The cell sheets are the applied for the regeneration of corneal epithelial, myocardial, oesophageal epithelium, periodontal and cartilage tissues. Using CellSeed's UpCell® temperature-responsive cell culture ware, cells that have been grown to confluency can be detached from the surface of the culture ware as a single sheet known as 'cell-sheets'. With conventional techniques however, they are dissociated into their constituent cells because of the proteolytic enzyme used. To resolve this, Professor Teruo Okano of Tokyo Women's Medical University, TWMU (and a director for CellSeed) developed a more innovative alternative method for temperature-responsive cell culture ware.

CellSeed has an agreement with TWMU that grants the company a patent protection for cell sheet tissue engineering for myocardial tissue. CellSeed transferred from TWMU a number of important resources including machinery (cell sorter, cell culturing system, etc.); cell/material banks/ patient data (human cell lines) and GMP lab facility. CellSeed also received from TWMU and APB patents and non-patentable research skills for the polymerisation from specific monomers and conjugation of synthesized polymers to matrices..

Figure 2 shows the overview of the CSTOF Project. In this project, there are two development groups: the Tissue Factory and the Organ Factory. The Tissue Factory develops the integrated and automated tissue fabrication system, aimed at achieving consistent quality and lowering the cost of cellular products. This group also develops the interface for linking processes, as well as software for controlling quality, so that the systems comprising each process work coherently in the overall tissue manufacturing. The automated system called 'T-FACTORY,' adopted modular architecture and is being developed with a design that installs modules in a cluster.

The Organ Factory is a more advanced system that enables mass production of cell sheets through the development of a technology that induces stem cells to differentiate and sort into target cells. At the same time, the group is developing a technology for in vivo tissue placement—adding the vascular network in particular—under an in vitro environment. By doing so, the group aims to make it easier to layer the cell sheets and to establish the base technology for higher functionality as well as organ regeneration.

To achieve all these, the CSTOF project gathered multiple external collaborators including seven private firms, three research institutions and two other support institutions that established a consortium of players to manage the project. CellSeed played the central role to lead the consortium by pioneering the application of the advanced technology using networks, entrepreneurial and technical skills of their top managers, to motivate academic researchers, and other players through business alignment and securing funding from banks and VCs.

#### 5. Conclusion, Study Limitations and Outputs

Conclusively, the study acknowledge that commercializing biotechnology in an open innovation approach means inventions are being commercialized to create wealth through a technological dynamism that involves various actors in the field ranging from venture capitalists to universities and other small and large firms seeking to making profit or expanding to new niches. The process is challenging and offers variable disadvantages to new DBFs who need to compete to create value and become successful.

Concisely, the study showed that a consortium-based entrepreneurial and corporate venturing is a more promising approach to commercialize advanced technology in emerging biotech field and that it has supported the Japanese DBFs in the new field of SC&RM to build up their resource competency. The approach is a win-win to the players because it enables small and new companies to gain resources needed to innovate or compete in the market while large corporates are able to fund projects externally as a means of spreading costs and risks of innovation [5]. Similarly, the Japanese government through strategizing policies and funding scientific projects have helped to create wealth for the nation's economic development.

The consortium-based approach is however challenged by the need to have a functional unified organization structure in place so it can connect the actors efficiently. Organizational support for a consortium is essential because the focus of the individual companies involved may be limited to the objective to maximize profits and not necessarily match the objectives of the consortium as a whole.

The study a case study approach basing on most data available from public sources and is thus lacking more elaborative field data that could be supplied through personal interviews or more quantitative manipulation of variables. We hope to extend the study further on the subject of a consortium approach by interviewing the players in the field and make long-term observations and apply quantitative approaches to learn the necessary condition for supporting this approach.

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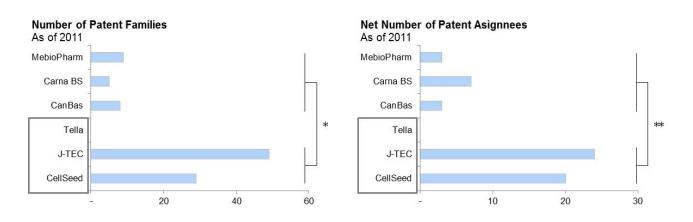
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#### Figure 1. The Comparison of Selected Performance Indicators using JaBit

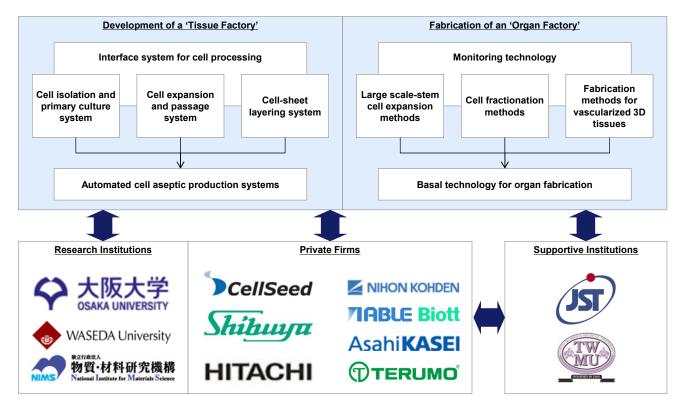
Source: Reference [14].

As of FY2011, individual firm's intellectual property base in terms of the number of patent families are presented by the figure to the left and the number of patent assignees by the figure to the right. Results shows some significant differences in both indicators \*\*: p<0.05, \*: p<0.1. for the two sets of DBFs.



## Figure 2. The Overview of the CSTOF Project Organization

Source: Public exposure<sup>1</sup>; Modified by the authors.



 $<sup>^1\</sup> http://twins.twmu.ac.jp/first/en/index.html$