Paper to be presented at the

DRUID Society Conference 2014, CBS, Copenhagen, June 16-18

Business model characteristics and evolution: A qualitative case study from biopharmaceuticals, 2002-2012, extending the Amit & Zott approach

Terje Grønning
University of Oslo
Department of education
terje.gronning@iped.uio.no

Abstract

Recently a ?business model?-focused literature highlighting the value creation and capture processes of organizations has attracted attention. Much of this literature is still conceptual in its orientation, and the matter of how to apply this focus to empirical research is largely unresolved. This paper aspires to contribute to this emerging body of literature on business models by way of selecting nine dimensions which may be used for characterizing the way a particular business model is composed, as well as measuring to what extent any change or evolution of a business model has occurred. The dimensions are created as an operationalization of the three-part conceptualization proposed by Zott and Amit distinguishing between three design elements of a business model, i.e. content, structure and governance. These nine dimensions are subsequently tested in a case study of the Japanese biopharmaceutical company AnGes MG 2002-2012.

Jelcodes:M10,L21

Business model characteristics and evolution: A qualitative case study from biopharmaceuticals, 2002-2012, extending the Amit & Zott approach.

1. Introduction

During recent decades a vast literature has accumulated regarding how organizational forms emerge and evolve (Cravens, Piercy, & Shipp, 1996; Dijksterhuis, Van den Bosch, & Volberda, 1999), and how one may understand the dynamics of strategic dispositions (Teece, Pisano, & Shuen, 1997). A recent addition to this discourse is a “business model”-focused literature highlighting the value creation and capture processes of organizations (Klang, Wallnöfer, & Hacklin, 2014; Zott, Amit, & Massa, 2010). Much of this recent literature is still, however, mainly conceptual in its orientation, and although there is a great deal of consensus regarding the theoretical focus on value creation and capture processes, another matter is how to apply this focus to empirical research. This paper aspires to contribute to this emerging body of literature on business models by way of selecting nine dimensions which may be used for characterizing the way a particular business model is composed, as well as measuring to what extent any change or evolution of a business model has occurred. The dimensions are created as an operationalization of the three-part conceptualization proposed by Zott and Amit (Amit & Zott, 2001; Zott & Amit, 2013), which consists of distinguishing between three design elements of a business model, i.e. content, structure and governance, after having defined a business model as “a bundle of specific activities – an activity system - conducted to satisfy the perceived needs of the market, along with the specification of which parties (a company or its partners) conduct which activities, and how these activities are linked" (Amit & Zott, 2012). Furthermore, any change (or innovation) of a business model is defined as a change in either or all of the content, structure or governance elements of the business model, it can consist of i.e. “adding new activities, linking activities in a novel ways or changing which party performs an activity” (Amit & Zott, 2012).

However, although the main authors within this sub-field Amit and Zott have published some empirical substantiation (Zott & Amit, 2007, 2008), the majority of the works concern the theoretical and conceptual challenges in connection with developing this approach (Amit & Zott, 2012; Zott & Amit, 2010; Zott & Amit, 2013; Zott, Amit, & Massa, 2011). The connections between the conceptual framework and empirical analysis thus remain largely unresolved. But which actual “activities” are to be included, and why? How may one describe business model change in a more accurate way? In what sense is it a system? How can one determine that the activities are interdependent? In this paper I do not aspire to provide answers to all of these questions. Rather the attempt is to address the first two questions listed above through a methodological and empirical study, and thereby strengthen the ongoing foundational work which may open up further empirical and conceptual work within this new approach.

Thus, since this way of conceptualizing a business model may be seen as remaining at a relatively abstract level of precision, the notions of content, structure and governance are in this paper translated into nine measurable dimensions: products, products in development, R&D intensity, and securing and developing workforce when it comes to "content", internal organization of work, its relations with its wholly or partially owned subsidiaries, and its relations with external partners when it comes to "structure", and revenue model when it comes to "governance".[1]

These nine dimensions are subsequently tested in a case study. The case is based on the biopharmaceutical company AnGes MG as the business model's "focal firm". The case study focal firm itself has got an espoused and largely unchanged business model throughout the period of investigation 2002-2012, however, the analysis shows how there are incremental, though significant, changes in "content", "structure" as well as "governance". Thus, the approach may serve as an extension of the Amit and Zott-approach into more precise assessments of business model characteristics as well as of how and to what degree business model evolution may occur.

I first provide a literature review and an overview of methodological issues, before moving on to an overall examination of content, structure and governance of the particular business model. Secondly, I provide further contextual information as for observed changes based on historical corporate information regarding "Issues which should be addressed", as the focal firm saw it, at any time throughout the period. Finally I conclude with summing up the main findings at these two levels, as well as provide some reflections regarding the contributions and limitations of the paper at hand.

[1] The "content" element and "governance" elements should ideally include three additional dimensions (securing capital in one way or the other, operationalized as equity and share prices; ownership structure; and board composition), however, in the context of this preliminary version of the paper these dimensions have not been included.

2. Theoretical background

The business model research literature can be grossly divided into various strands according to variations of conceptual foundation and the scope of issues being addressed (Klang et al., 2014; Lambert & Davidson, 2013; Zott et al., 2011).[2] This paper is positioned within the strand of literature associating the concept of business models to activities at a "network" level, where a business model is defined as "the system of *interdependent* activities that are performed by the firm and by its partners and the mechanisms that link these activities to each other" (Zott & Amit, 2013, p. 404; my italics):

> "A business model is thus a template that depicts the way the firm conducts its business … crafted by a focal firm's managers in order to best meet the perceived needs of its customers. … [T]he focal firm's business model often spans across the firm and its industry boundaries" (Zott & Amit, 2013, p. 404).

Elsewhere the same authors elaborate by specifying that the three main elements constituting a particular business model are content, structure and governance respectively. Content refers to "the selection of activities that are performed", i.e. to the goods or information that are being exchanged, and to the resources and capabilities that are required to enable the exchange" (Amit & Zott, 2001). There are in addition second order activities which must be selected, such as e.g. training activities, which may be necessary in order to carry out the primary activities (ibid.). Structure refers to "how the activities are linked", i.e. the distribution as well as sequencing of the activities transactions (Amit & Zott, 2001; Zott & Amit, 2010). In addition, structure concerns the importance of particular activities to the business model and the mechanisms for enabling transactions (ibid.). In short, structure "refers to the parties that participate in the exchange and the ways in which these parties are linked" (Amit & Zott, 2001). Finally, governance refers to "the ways in which flows of information, resources, and goods are controlled … the legal form of organization, and to the incentives for the participants in transactions" (Amit & Zott, 2001). Whereas a business model is constituted by these three "elements", a case of business model change (i.e. "business model innovation") is in turn constituted by a change in either one of the three elements (Amit & Zott, 2012). There indeed exist alternative approaches and conceptualizations. However, this paper is positioned within the content-structure-governance oriented category of research literature, since this way of conceptualizing and delimiting appears to provide one of the most promising gateways towards relating the emergent

[2] In this preliminary version of the paper I present exclusively on the selected strand of literature, whereas a revised version will obviously include a brief review of alternative strands.

business model literature to mainstream organization theory. This promise is due to paying simultaneous attention to current practice (i.e. "activities") as well as future strategy, in contrast to the strategy emphasis within most alternative approaches.

3. Methodology

The study is an "instrumental" (Stake, 1994) case study, in the sense that it is selective rather than comprehensive when it comes to presenting aspects of the case. The case study's function is to illustrate, rather than being descriptive in its own right. This aim and form of presentation is in correspondence with what Siggelkow (2007) states as one crucial ambition with case study research, namely that the conceptual contribution may be illustrated with empirical, case-based examples, in order to develop conceptual or methodological arguments.

The firm was visited in connection with field research in October-November, 2012, and is within a larger sample of firms visited at that occasion. The firm presented and discussed within this paper is a "convenience sample" (Lunneborg, 2007), due to the fact it was based on an initital impression assumed to constitute some form or another of incremental changes of a business model. The empirical material is based on an analysis of information available in the annual report to the Japanese taxation office (AnGes MG, Annual). This source is ca. 100 pages each year. Although major parts are detailed financial information the report also provides information about how the focal firm itself views its business model, the type and number of collaboration partners, the volumes of investments in R&D, etc. The focal firm presents in an overall representation of its business model that it has remained virtually unchanged during 2012-1012 (Fig. 1), with the exception that starting in 2007 the term "etc." has been added to the term "sales rights". Nevertheless, several incremental changes may be revealed through an examination of the source. Worthy of special mention are the sections entitled "Issues which should be addressed" and "Perceived risks",[3] albeit the latter section is not included in reports preceding 2004. These sections illuminate both the rationale behind past and current activities, as well as the rationality and feasibility of new activities.

< Fig. 1 about here>

I also conducted a group interview with three middle managers and an individual interview with the focal firm's CEO during visits to the firm in 2008 and 2012 respectively. The

[3] Translations into English of these and all other terms and material originally in Japanese are by the author.

information from these various sources has subsequently been analyzed according to whether it was deemed as relent to content, structure and governance elements respectively.

4. Content, structure and governance of the business model

4.1 Content

Content refers, as mentioned, to the selection of activities or "the goods or information that are being exchanged, and to the resources and capabilities that are required to enable the exchange" (Amit & Zott, 2001). In more concrete terms the study delimits itself to the following content dimensions: products, products in development, R&D effort, and securing and development of workforce.

The focal firm specializes in genetic medicine, and had at the outstart three distinct projects (Table 1): A genetic therapy for critical limb ischemia; a treatment for inflammatory diseases based on the so called "NF-κ B decoy oligo"; and finally, the "hemagglutinating virus of Japan Envelope vector (HVJ-E)", which is said to have a potential for drug delivery or cancer immunity (*Zipangu Magazine*, 2013). The rationale behind such a relatively widespread strategy was that: "Setting up a new company with a single research theme would obviously mean an excessive concentration of risk… [The founder] Morishita deliberately chose three themes as a risk hedge" (AnGes MG CEO Yamada, as cited in *Zipangu Magazine*, 2013). The HVJ-E business was from an early stage organized as a separate subsidiary, GenomIdea, and was in 2013 spun out through the sales of all the AnGes shares in the company. On the other hand, there are as of 2012 several additional side products within the development portfolio, including two within the segment medical devices. Incidentally, the only product on the market (and hence not included within Table 1) is a product licenced-in from a foreign collaboration partner, and AnGes is the representative in Japan for this drug (Nagalazyme, for the treatment of a rare disease causing dwarfism, thickened skin, progressive joint stiffness and respiratory infections). Another product (line) which is not included in Table 1, is the anticipated products emerging from a "healthcare science" subsidiary established in 2011.

<Table 1 about here>

R&D expenditure has shown a steep increase until ca. 2005 (Fig. 2). One may interpret a flattening out and subsequent decline of such expenditures as reflecting the maturing of the existing projects, at the same as new major projects have not been initiated in recent years. In addition, revenues in the form of payment at contract etc. (see below) follow more or less a parallel curve, and this situation may also have had an impact. From an early stage AnGes strived towards differentiation of the client base, whereas Daiichi Sankyo for a long time held a dominating position. Starting in ca. 2005, however, additional clients were secured at the same time as the overall level of revenues nevertheless for the time being declined since one major part of the revenue model (see below) is payment of royalties only after products are on the market. Employment during 2002-2012 (Fig. 3) has varied between high 50s and low 90s (Fig. 3), with an additional decline reported for 2013.

<Fig.2 about here>

<Fig. 3 about here>

Summarizing these main "content" element dimensions, we see that there has been some turbulence during 2002-2012 where some of the changes may be interpreted as being within the frame of the original business model. There is, however, also evidence of fundamental changes, such as gradual increased diversification of the client base, the introduction of the new activity of in-licensing of an externally developed product and subsequent serving of the end market, and diversification of the product base in the form of medical devices and healthcare products being included in the portfolio.

4.2 Structure

"Structure" concerns the focal firm AnGes' internal organization of work, its relations with its wholly or partially owned subsidiaries, and its relations with external partners. Regarding the first, the initial impression when comparing 2002 and 2012 is increased complexity (Fig. 4). From the perspective of business model analysis, however, it is also noteworthy that research reagents have diminished in role, whereas healthcare (AnGes Healthcare Science) as well as the product area medical devices have been added since the start.

<Fig. 4 about here>

<Fig. 5 about here>

Regarding the relationship to and with external partners, there is increased complexity (Fig. 5) as well as increased volume over time, although some alliances are eventually discontinued after a while. The 1999 major contracts both concern individuals and their patents, and are part of the firm's foundation. In the subsequent years we see that there are two peaks when it comes to the number of new contracts, 2005 and 2011. There are, however, few major contracts amongst these (only two in 2005). On tte other hand there are several major contracts during the firm's early years 2000-2002, including the basic sales contracts (see below) with the first major Japanese pharmaceutical firms Daiichi Sankyo (in 2000 and 2001) and Mitsubishi Tanabe (2002). The years 2005-2006 signify imortant changes in the firm's orientation in that there were two major contracts every of these two years with foreign orgnizations: Vical Inc. in 2005 and 2006; St. Elizabeth Medical Center in 2005 and BioMarin Pharmaceutical, Inc. in 2006. An examination of the actual contracts shows that there is some variance as for the mechanisms used (Table 2).

<Table 2 about here>

4.3 Governance

The focal firm's self-representation of its revenue model is rendered as Fig. 6. The revenue model is built upon transactional mechanisms such as payment at contract, milestones and royalties, in line with industry practices when it comes to governing relations between drug discovery firms on the one hand and fully integrated pharmaceutical companies on the other hand (Rothman & Kraft, 2006). This AnGes visual representation is not included in the annual report after 2007, but the explanatory text suggests that the same line of reasoning continues towards 2012.

<Fig. 6 about here>

From the perspective of business model analysis, it is interesting to contemplate that the entrance into healthcare from 2011 as well as inclusion of the product area medical devices could entail other types of revenue mechanisms, as well as relationship to other types of customers (e.g. sales to end customers), compared to the mechanisms prevalent within pharmaceuticals. Indeed, during the early phase of the focal firm's history one part of the business was sales of reagents (AnGes MG, Annual). Thus, as for the characteristics of actual revenue model (differing slightly from the visual representation as rendered in AnGes MG, Annual) it had a dual character divided between drug development service and drug discovery during the early stages, another type of dual character consisting of drug discovery supplemented with in-licensed drug sale during mid-stage, and a complex character divided between healthcare and medical device on the one hand and drug discovery as well as in-licensed drug sale on the other hand in late stages.

4.4. Three stages of firm evolution

One invaluable additional source which supplements the information rendered in the previous sections is AnGes management's annual assessment of issues which needed to be addressed each year (Fig. 7). The need for "strengthening current operations" topped the list every year until 2010, followed by "implementing new projects" and "developing development structure overseas" more or less during the same time period. "Achieving capital accumulation" has been another issue both during this time period, as well as thereafter. Starting in 2005, several other issues entered the list if issues, with "constructing domestic sales structure" as number four on the priority list in 2005. The following year, "policy for avoiding takeover" was formulated as an additional issue, and starting in 2010 "securing alliances" was added. Incidentally, 2011 was evidently marked by a reorientation when formulating these issues and possible countermeasures since a majority of the issues which had regularly had been included more or less throughout the 2002-2010 period were excluded, and a new practice formulating a select few issues was initiated: four in 2011 and only three in 2012 compared to 6-7 throughout 2006-2009. I interpret this not necessarily as evidence for the previously issues having totally vanished, but rater as a new practice prioritizing in a stricter way the most urgent issues. Thus, we see in 2011 that "securing alliances" takes the top spot, followed by "constructing domestic sales structure" and "achieving capital accumulation" in both 2011 and 2012.

<Fig 7 about here>

Combing the information from the preceding sections with management annual assessments the main traits of the focal firm's evolution can thus (with the exception of the focal firm's pre-IPO stage (1999-2002)) be divided into three distinct stages (Table 3). The first stage 2002-2005 constitutes a start-up stage, where the focal firm was heavily dependent on a select few external relations, i.e. one particular pharmaceutical corporation Daiichi Sankyo. This relation did, however, allow for a high level of R&D expenditures and a relatively high number of staff. The second stage 2006-2010 constitutes a consolidation stage, exemplified by the implementation of a “Policy for avoiding takeover” (2006), “Constructing domestic sales structure” policy (2005), and the first alliances with overseas partners. The third stage 2011-2012 is recent and most probably ongoing, and therefore more difficult to articulate. However, the stage constitutes most possibly a reorientation of the focal firms’ activities as exemplified with a “healthcare science” subsidiary established in 2011, “securing [new] alliances” as a new policy in 2011, and spinning out one of the three original pharmaceutical (the subsidiary GenomIdea (in 2012-2013). Another symbolic indication for the start-up of this new and third stage lies within the way the “issues” formulation practice itself changes starting in 2011. While the original and overall pharmaceutical revenue model based on milestones and licensing is grossly intact, the inclusion of non-pharmaceutical potential revenues points towards a rather different business model in 2012 when compared to 2002. Referring to the content-structure-governance framework the de facto implementation of a more nuanced revenue model entails changes to “governance”, and these changes are accompanied by changes in “content” (diversification of product portfolio, simultaneously with slimming of pharmaceutical project portfolio from three to two), and “structure” (establishment of a separate subsidiary for healthcare and spinning out part of the pharmaceutical business) as well. All these changes did not, however, occur suddenly in 2011-2012. Some changes occurred already during the consolidation phase 2005-2010, such as “structure” changes regarding the character and number of external partners.

<Table 3 about here>

5. Conclusions

The case study shows that there appear to have been incremental changes and adjustments of the business model which actually is in use, in spite of the focal firm’s rendering of its business model as being virtually unchanged during an 11 year period. In order to reveal these changes the paper took at its starting point the overall and abstract subdivision of a business model into the three elements content, structure and governance, but operationalized each of the three elements into more articulated dimensions: products, products in development, R&D intensity, and securing and developing workforce when it comes to “content”; internal organization of work, its relations with its wholly or partially owned subsidiaries, and its relations with external partners when it comes to “structure”; and revenue model when it comes to “governance”. The advantage of this more detailed approach is that it becomes easier to perform qualitative assessment of the character of a business model at a given point in time, as well as assessing any changes to the business model over time. This aspect of the study was most clearly illustrated by showing that the business model as espoused by the focal firm remained virtually unchanged, whereas the assessment performed according to the analytical dimensions shows that incremental changes have nevertheless occurred. Another advantage is that the accumulation of studies of this or a similar type would provide better case based data for theorizing business model characteristics and evolution than the currently available studies, since, according to Lambert and Davidson (2013), a majority of these are based on exceptionally few variables or dimensions. A possible disadvantage of the proposed approach could eventually be that it is relatively resource intensive when it comes to research effort and data intensive regarding the data required for analysis. Concerning the latter issue, the relevant data for the entire relevant time period are available for the type of firms used within the current case study, however, this may not always be so.

One limitation of the paper is that there may still be still further dimensions that could have been included in analyses, in addition to the nine dimensions which were included within this study. Or ,there could conversely be arguments for reducing the number of dimensions and still conduct adequate analyses of business model characteristics and change. As for this issue, additional research along the same vein should be able to contribute to the task of eventually specifying in more generic terms what kind of dimensions and activities one should actually include within empirical analyses of business models and business model evolution. Acknowledging its present limitations, the paper aims nevertheless at being one first contribution towards such future efforts.

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Tables and Figures

Table 1: Product development portfolio, 2002 & 2012.

	Seg-ment	Product name / Project	Target indications	Development stage	
				2002	2012
Subsidiary product	Medicine	GEN0101	All Diseases	-	Clinical trials
Alliance product		Allovectine® genetic medicine	Metastatic Melanoma	-	Phase Ⅲ (US/Europe)
Self-developed product		Collate-gene® (HGF Plasmid)	Peripheral Arterial Disease (PAD)		Preparing for phase Ⅲ
			Parkinson's Disease	Pre-clinical	Pre-clinical
			Ischemic Heart Disease (IHD)	Preparing for clinical trials	Preparing for clinical trials (Jpn) & Phase Ⅰ(US)
			Lymphedema	-	Preparing for phase Ⅰ/Ⅱ(Jpn)
		NF-κB Decoy Oligo	Atopic Dermatitis	-	Phase Ⅱ (Jpn) &Pre-clinical (global)
	Medical Device	Drug-eluting PTA balloon catheter	Prevention of Vascular Restenosis	Preparing for Clinical trials	Clinical trials (Jpn)
		Functional Peptides (Cure Peptin®)	Wounds	-	Applied research

Source: Author's analysis based on information derived from AnGes MG. (Annual).

Table 2: Actual AnGes practice regarding revenue model in the case of 14 major contracts 2002-2012.

	Payment at contract	Fixed rate royalty	Milestone	Development costs support	Revenue sharing
Technology import (8)	6	7	3	0	0
Sales contracts (3)	3	3	3	2	0
Coll. development (3)	1	2	3	2	1

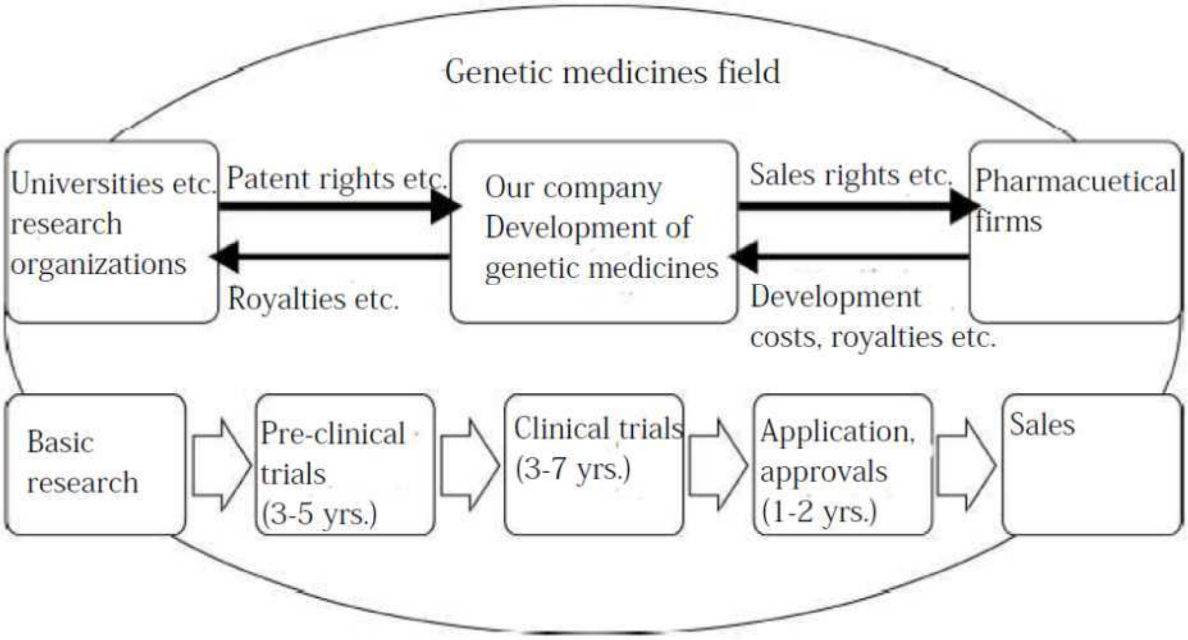
Source: Author's analysis based on information derived from AnGes MG. (Annual).

Table 3: Three stages of the focal firm's evolution

Elements	Activities	2002	2006-2011	2011-2012
Content	Products on market	Reagents None	One licensed-in product (orphan drug) since 2006	One licensed-in product (orphan drug) since 2006;
	Products in development	Three pharmaceutical products	Three pharmaceutical products Medical device Healthcare products	Reducing from three to two pharmaceutical products starting in 2013 Medical device Healthcare products
	R&D effort	High levels of R&D expenditure	Peak (in 2006) regarding R&D expenditure followed by decrease (2007 and onwards)	Continued decrease of R&D expenditure
	Securing and developing workforce	Between 70-80 employees	Peak (in 2006) regarding number of employees followed by decrease (2007 and onwards)	Lowest number of employees ever
Structure	Internal organization of work	Reagents and pharmaceuticals	Pharmaceuticals Medical device	Pharmaceuticals Medical device
	Relations with its wholly or partially owned subsidiaries	One pharmaceutical	One pharmaceutical	One pharmaceutical (to be spun out from 2013) Healthcare products
	Relations (main) with external partners	Major development and sales contract with few select firms (in essence, one)	First overseas contract (licensed-in orphan drug in 2006)	Huge increase in number of lesser contracts (form 2011) and two additional major development and sales contracts with new firms Continued licensed-in product (orphan drug) since 2006
Governance	Revenue model	Strict milestone-etc. based revenue model, and sales of reagents	Strict milestone-etc. based revenue model, and fees for selling licensed-in drug	Milestone-etc. based revenue model, fees for selling licensed-in drug, medical devices, and healthcare products sales to end customers

Note: The tree dimensions securing capital, ownership structure and board composition not included in this version of the Table.

Fig. 1: AnGes MG's business model as of 2012.



Source: AnGes MG. (Annual, 2012 edition).

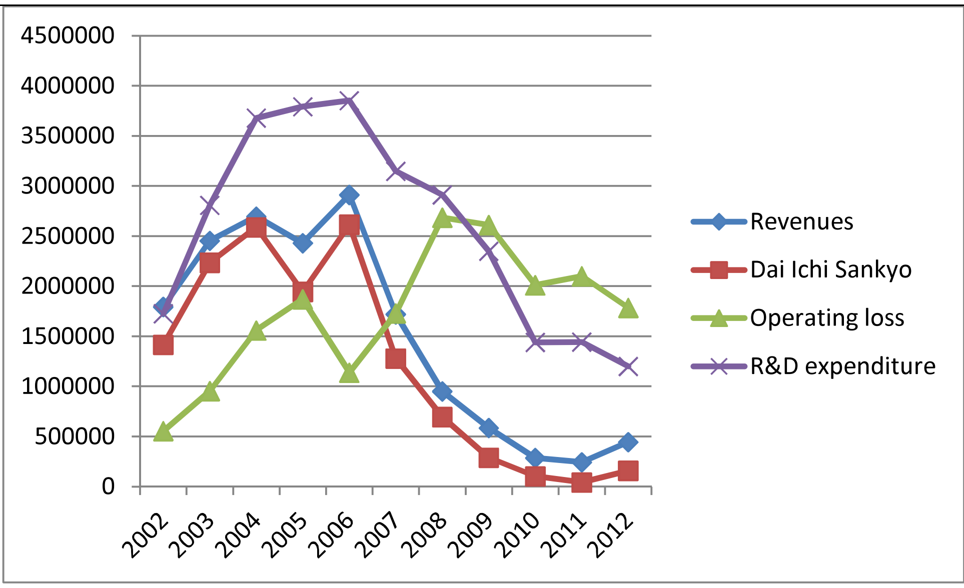


Fig. 2: Revenues, Dai Ichi Sankyo Pharm's share within revenues, operating loss (minus), and R&D expenditures, 2002-2012

Source: Author's analysis based on information derived from AnGes MG. (Annual).

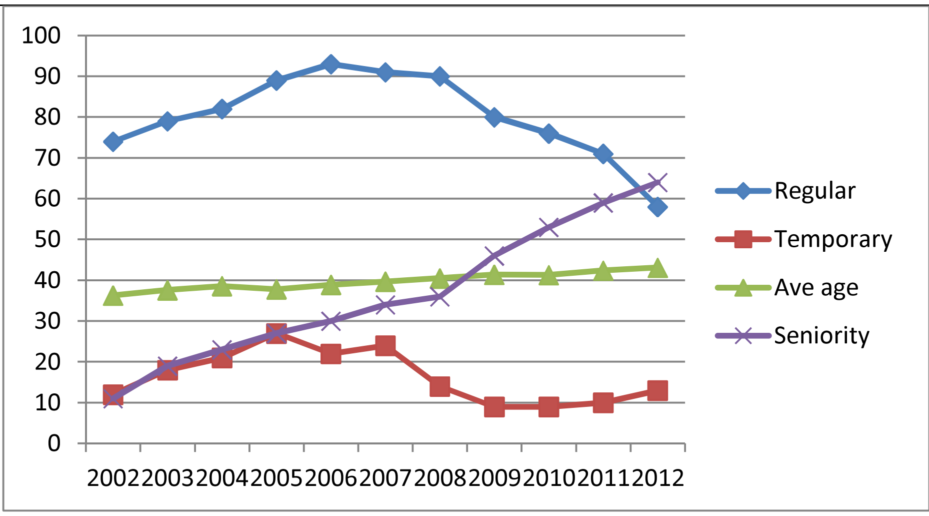
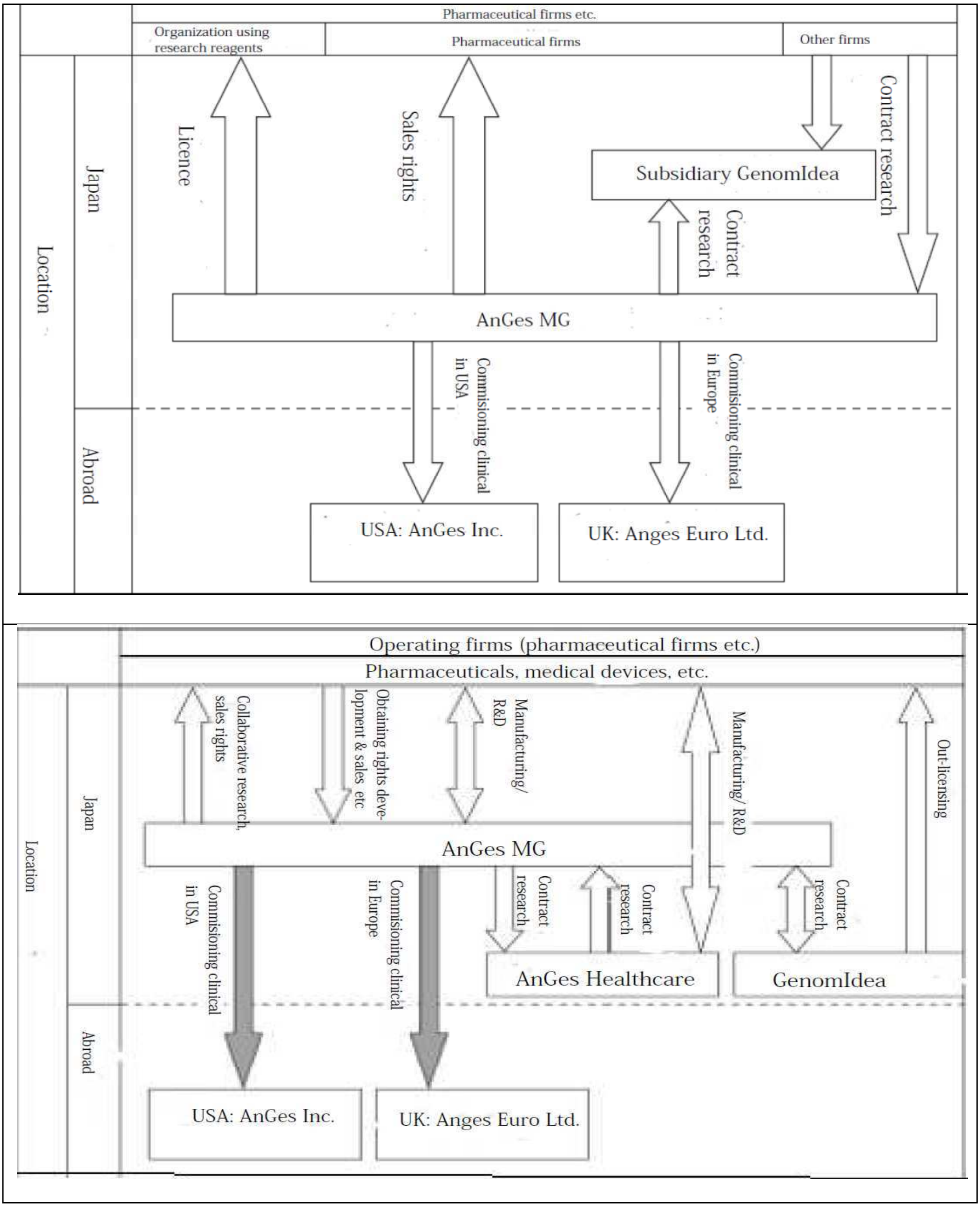


Fig. 3: Employment, 2002-2012

Note: the number of employees refers to both the main firm as well as its subsidiaries

Source: Author's analysis based on information derived from AnGes MG. (Annual).

Fig. 4: AnGes consortium in 2002 (above) and 2012 (below).



Source: Author's analysis based on information derived from AnGes MG. (Annual, 2002 and 2012 editions).

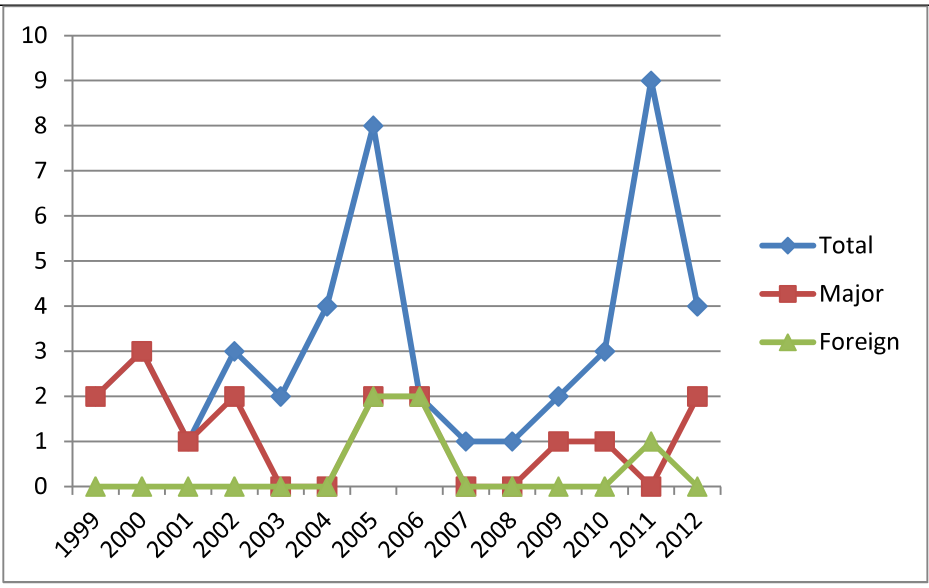
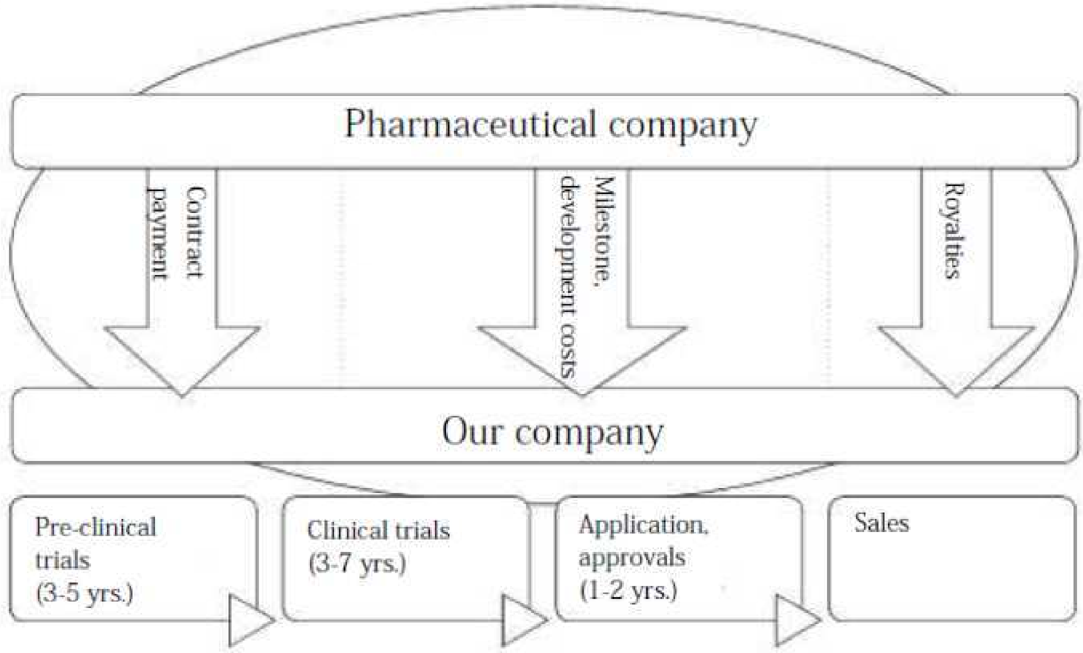


Fig. 5: Contracts

2002-2013

Source: Author's analysis based on information derived from AnGes MG. (Annual).

Fig. 6: AnGes revenue model, 2002-2007



Source: AnGes MG. (Annual)

Fig. 7: Focal firm's "Issues to be addressed", with annual internal ranking of each issue

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Strengthening current operations	1	1	1	1	1	1	1	1	1		
Developing development structure overseas	3	3	3	3	3	3	3	3	4		
Implementing new projects	2	2	2	2	2	2	2	2	2		
Achieving capital accumulation	4	4	4	5	5	5	5	5	6	3	3
Constructing domestic sales structure				4	4	4	4	4	5	2	2
Policy for avoiding takeover					6	6	6	6	7	4	
Securing alliances									3	1	1

Source: Compiled by author based on AnGes (Annual).