Operations Strategies' Dynamic Rationale of the Pharmaceutical Industry in Puerto Rico from 1962 until 2011

Abstract

This empirical research examined the dynamic structure of Puerto Rico's pharmaceutical industry and archetypal operations strategies used by companies during the periods 1962-1995 and 1998-2011. A system dynamics approach was used as a theoretical framework and for analytical purposes, while performances were measured using SCOR Model's performance metrics. The research examines the operations strategies' changes most companies, as a strategic group, undertook on the periods considered and their implications. A possibility for further research regards the level of sustainability of other operations strategies configurations in the industry.

Keywords: Operations strategy, industry analysis, system dynamics.

Introduction

This empirical research examined the dynamic structure of Puerto Rico's pharmaceutical industry and archetypal operations strategies used by companies during the periods 1962-1995 and 1998-2011. Based on the competitive actions of individual companies in each period, the sampled companies [as a collective] encompassed many taxonomic attributes suggested in the academic literature to characterize a strategic group: For instance, competing with similar strategies, levels of integration, learning speed, breadth of the knowledge base (Dess, 1984; Hans-Dieter & Solvay-Gerke, 2010), and performance metrics (Breskin, 1995; Rozek, 2011; Vega-Rosado, 2006). Due to these similarities, instead of examining the performance of individual companies' operations strategies, the prevailing archetypal operations strategies in each period were examined. A system dynamics (SD) approach was used as a theoretical framework, relating the feedback structure of U.S. and Puerto Rico's government policies, human resources availability, accumulated capital, number of facilities, and operations' strategic capability, among other factors and industry constraints.

Performance measurement relies on the identification of those measures that drive operations strategy success. Because most operations strategies performances in the industry were related to supply chain activities, they were measured using SCOR Model's performance metrics (Ashton, 2011; Bourne, Mills, & Faull, 2003; Supply Chain Council, 2012). This model provides a standard way to measure supply chain performance and prevalent metrics to benchmark against other competitors.

During each period, companies used their operational resources and competences to support their parent's business strategies in restricted ways. Until 1963, Puerto Rico had a period of significant economic expansion, with a 6.3 percent average annual growth. At the beginning of the first period, Puerto Rico's economy started experiencing a slowdown in its real average growth, as shown in Figure 1 (Office of the Governor Planning Board and Estudios Técnicos, 2010). There were

continual widening gaps on several important economic indicators between Puerto Rico and the U.S. Under this tattered economic condition, the role that pharmaceutical companies played in supporting their respective parent business's strategies drove most operations' capabilities development efforts. Predominantly, companies were strategically regarded as cost centers by their parent companies. A cost center seeks stability, serving markets through a continuous and high-volume flow of products: Operations' efficiency was their main concern. The rationale for this decision was based on prevailing governments' economic development policies aimed at attracting companies seeking inexpensive upstream production locations.

< Insert Figure 1 here>

Throughout the second period, governments' incentives to the industry changed, natural phenomena worsen, and the effect of some international issues encouraged modifications on a number of industry dynamic parameters and archetypical operations strategies, even though the fundamental industry structure remains [mostly] the same. The phasing out of Section 936 of the U.S. Internal Revenue Code, persuaded parent companies to require companies in the island to be commercially proactive, behaving more as profit centers: Companies were required to undertake limited research and development and marketing ventures, and were accountable for generating targeted levels of gross revenues.

In this study, the researcher developed an SD model characterizing a theory on how the pharmaceutical industry worked, allowing the development of a robust conceptual representation to understand its structural dynamics and behavior, and assess archetypical operations strategies performances (Muhammad, 2009; Angerhofer & Angelides, 2000; Wolstenhome, 1990). Although the structural relations of the industry elements were virtually the same in both periods, differences were reflected on parameter values and other constructs: For example, competitive priorities, market demand, and government regulations (Harland, Lamming, & Cousins, 1999; Guptaa, Pawara, & Smart, 2007).

There is little research on the assessment of implemented operations strategies in the pharmaceutical industry in Puerto Rico. Furthermore, they assess operations strategies from an internal-resource-view instead of a system perspective. The goal of this study is to fill this gap. The underlying principle of using a system perspective was to be able to reveal empirically the structural relations of key industry elements and assess the effectiveness of both archetypical operations strategies in this dynamic.

Pharmaceutical Industry in Puerto Rico

The first pharmaceutical plant in Puerto Rico began operations in 1957 under "Puerto Rico's Operation Bootstrap" and the support of several vital Internal Revenue Code provisions (Section 931 and, later, Section 936). By the end of the 50s, many international pharmaceutical companies that manufacture prescription and over-the-counter drugs (e.g. Johnson & Johnson, Abbott, and Pfizer), looking for reducing their system-wide operational costs, transfer a sizeable fraction of their operations

to Puerto Rico. These tax break's incentives allowed corporations to take a tax credit on profits earned from manufactured products made in Puerto Rico, which in some cases accounted to as much as 87 percent of their profit (Bhana, 1975; Frosch & Gallopoulos, 1989). The tax incentives provided by Section 936 served as a major operational buffer for the pharmaceutical industry, characterized by restrictive patent regulations, unsuccessful commercial products, and redundant marketing procedures. Questioning the effectiveness of Section 936 to sustainable stimulate the island's economy and concerns that the incentive could be used as a tax hedging process, in 1993 the U.S. Congress determined to phase-out and ultimate terminate Section 936.

With the fading of Section 936, parent's companies (also known as Possessions Corporations) were faced with decisions regarding the restructuring within-and-across their organizations. In some cases, these restructuring became part of broader reorganizations of international operations, which took place over a period of several years (Ramcharran, 2011). Most companies were required to integrate further back and lateral on their operations, i.e., engage in research & development, marketing, and other initiatives entrusted to other business units outside Puerto Rico. An entrepreneurship mind-set became a requirement. By 1998, those companies still operating in Puerto Rico were transformed into revenue centers with diversified operations scopes, leaving behind the conventional stance of cost center manufacturing operations.

As of 2011, the global pharmaceutical market was growing an average of 5.3%, exceeding $832.85 billion, and was expected to grow at an average of 5.6% compound annual growth rate through 2012. By 2005, the island had a $60 billion in pharmaceutical industry infrastructure, including 89 FDA-approved pharmaceutical and biopharmaceutical plants (Richards, 2006). Puerto Rico was the world's 5th largest pharmaceutical manufacturing territory in the world, after the United States, the United Kingdom, Japan and France. The government made the biotechnology industry (where most pharmaceutical companies prepared to reap its advantages) a priority, creating a range of new tax incentives for research and development, process development, and scale-up manufacturing. The industry was driven by a shaky growth in the U.S. market, altering combinations of innovative and mature products, and unstable sources of public and private funding. Also, many manufacturing operations were transferred to other countries, scattering companies and resources in several world regions (Figure 2 shows statistics on the number of companies and employment in the pharmaceutical industry in Puerto Rico from 1999-2011.) This tendency seems to be more pronounced, owing the lack of supplies at home, requiring manufacturing operations to depend heavily on imported raw materials.

< Insert Figure 2 here>

Methodology and Data

The process of developing the SD model was based on the renowned works of Sterman (2001) and Lyneis (1998). Following is a summary of the steps taken in its development. First, the researcher worked on understanding, analyzing, and structuring

the flow of information, interconnectedness, and feedback loops of the industry. The data was obtained using primary and secondary sources from the following organizations: Pharmaceutical Industry Association of Puerto Rico (PIAPR), Puerto Rico Industrial Development Company (PRIDCO), Government Development Bank of Puerto Rico (GDBPR), and Planning Board of Puerto Rico (PBPR.) PRIDCO and PBPR databases consist of longitudinal data from 1959 until 2011. Second, information was collected and analyzed regarding the operations strategies elements used by the sampled pharmaceutical companies. The researcher performed several interviews with companies' representative to improve the understanding of predominant operations strategies elements. Third, a quantitative SD models with stocks, flows, and causal feedback loops was developed, including key SCOR Model performance metrics. The understanding of the cause and effect relationships among the system elements refined the issues of complexity. Fourth, the model was validated through historical data fitting and robustness assessments were confronted with critical exogenous conditions (Deschenes & Chertow, 2001; Kroes & Ghosh, 2010).

Table 1 shows the main characteristics of the sampled pharmaceutical companies. The availability of data is a reflection of their systematic data collection and storage procedures. The information compares favorably with primary data collected from interviews. The information available at these sources allows the examination of almost five decades of industry development and companies' performances, allowing an opportunity for the assessment of the industry's competency and profitability, public and private technology transfer, and other issues, on both periods.

< Insert Table 1 here>

Development of Models

Modeling the pharmaceutical industry's dynamics was based on available and analyzed information from various industry and companies' sources: For example, Puerto Rico and United States tax incentives' policies, the accumulation configuration of human resources and capital used by the sampled companies, interactions with local and global factors, and related restrictions. Morecroft (1998) stressed that good SD modeling practice begins with the development of causal loops and evolves to rate and level flow diagrams with their corresponding equations, capturing the system structure, dynamic interactions, and non-linear relationships of the variables in the system. Consequently, the soundness of the SD model lies in the researcher's confidence in the model, which can be evaluated from model structure, model behavior, and policy implications (Forrester & Senge, 1980; Lewis, Brandon-Jones, Slack, & Howard, 2010).

First Period SD Model

During the first-period Puerto Rico's manufacturing industry enjoyed several U.S. Internal Revenue Code provisions (primarily Section 936) allowing the island to offer competitive cost incentives. The main objective of the government was to offer a cost-effective fiscal infrastructure to those international companies seeking to reduce total supply chain (including

manufacturing operations) costs. It wasn't aimed at excelling in research and development projects, as can be inferred by the data in Table 1. Those few research and development initiatives were undertaken to support small in-house or overseas projects, which were delivered worldwide to the private sector though technology transfer or spin-offs.

Human resources were the main production factor of the industry and in a lesser degree, process technology. The compensation in most companies exceeded those on the same [or similar] industries in Latin America, but it was two third of similar jobs in companies operating in continental U.S. Most human resource professionals came from (1) local academic institutions, particularly the island's public higher education system, (2) many expatriated managers, and (3) company training programs and apprenticeships intended for youth that didn't have a university degree. Going abroad to pursue an education in engineering, business administration or science was uncommon.

On the relationship of companies in Puerto Rico with their parent companies, accumulated data suggested that they had similar operations strategies to support their parent companies' business strategies. There are a number of possible types of operations strategies proposed by the academic literature, although it is agreed that there may be others (Lowson, 2002; Jacobs, 2009). Table 2 shows the final construct of the operations strategies used by pharmaceutical companies in Puerto Rico during this period. An evaluation of the data concluded that only two (low-cost and mix-and-volume flexibility) of five identified operations strategies, were considered significant and customary. The SCOR Model's performance metrics (version 10) was used for assessing each operations strategy performance (Georgise, Thoben, & Seifert, 2012).

< Insert Table 2 here>

In order to outline all dynamic feedback aspects, many elements pertaining to the industry, strategic external forces, government policies, and operations strategy decisions were framed within the SD Model. Figure 3 shows the archetypical structure causal loop relating the first three aspects, representing a dynamic snapshot of key elements in the industry. The causal loop shows that U.S. and Puerto Rico government actions were aimed at guaranteeing that the industry had a competitive stance to attract companies interested in establishing a relatively long-term presence in the island. However, it was expected that once these companies gained a certain level of maturity, certain policies would become redundant. For example, the U.S. government gradually would reduce tariff duties' exemptions and opens up to the possibility of diversification into other markets through what it was described as industry-mobility-policies, outlining the positive causal feedback loop. Data analysis and interviews suggested that besides (i) public and private technology transfer, (ii) human resources availability and (iii) government support were important in maintaining industry profitability. The ability to control and manage the latter was "organized" through industry competency.

An expected outcome was that pharmaceutical companies with numerous experienced personnel were more likely to be more profitable. However, expanded production capacity depended on private funds, indirectly generating more vacancies

that needed to be occupied by new employees, forcing changes in the industry mobility policies. Furthermore, data shows that a potential drop on capacity expansion could diminish average management effectiveness and therefore, industry competency. The causal loop shows how capacity expansion increases as the quantity of private funds and industry profitability increases. Ultimately, the two reinforcing feedback loops describe the positive effect that public and private technology transfer, Puerto Rico government's support, and human resources availability had on industry competency.

< Insert Figure 3 here>

Figure 4 shows the relationship of strategic manufacturing capabilities derived from an empirical examination of the operations strategies used by the sampled companies, as described by Größler & Grübne (2006). The path model yielded results consistent with the model's expectations. The operations capabilities were tested applying a structural equation model. Path coefficients as well as t-values for significance of coefficients are given. From these results, a hierarchical relationship between operations strategies capabilities, as defined in the SCOR Model (refer to Table 2), can be deduced: manufacturing agility is fundamental for the success of low cost operations and quick response strategies. An alternative interpretation is that mix-and-volume flexibility is fundamental for the success of a low cost operations strategy.

< Insert Figure 4 here>

A partial stock-and-flow model is shown in Figure 5. The model includes four-level variables: accumulated capital, number of facilities, human resources availability, and operations strategic capability. These variables influence and were influenced by archetypical strategic elements through feedback interactions and corresponding mathematical functions. As expected, the greater the sources, availability and amount of private funds, the greater the opportunities for capacity expansion in the industry, improving its competency status. Since most companies were treated as cost centers, the accumulated capital was in the form of the accumulated transfer-price of products sent to different units of the organization.

The number of manufacturing facilities could be regulated through accumulated capital, industry profitability, industry mobility policies, and other variables. Mix and volume flexibility strategies depend on the number of facilities: Some companies had cooperation agreements for providing added capacity if needed. Therefore, an increase in the number of facilities increases the likelihood that these strategies were successful (an observed trait of business clusters.)

< Insert Figure 5 here>

Second Period SD Model

In the second period, two main themes emerged. First, the shift from a cost center to a vertical managed entrepreneur model became the *de-facto* business model implemented by most manufacturing companies in Puerto Rico. The business model calls for fewer employees, improve infrastructures (hard and soft), and new management competencies considered essential for success in this new role. Companies outsourced more processes, and some suppliers performed key

product and process developments. From the standpoint of the parent companies' operations strategy, companies had to sustain low cost and mix-and-volume flexibility as key strategies.

During the first period, pharmaceutical companies were more integrated to their parent companies and considered overseas operations as supply chain extensions. Parent companies considered most overseas plants as complementing assets of their global operations making return on supply chain fixed assets an important metric performance. Throughout the second period, companies became more independent and priorities shifted to manage more efficiently their internal operations and financial transactions, particularly cash-to-cash cycle time. As previously done, the set of operations capabilities were tested and manufacturing agility still proved statistical fundamental to the other strategies (as required by the parent companies) with significant strong path coefficients, even with the added efficient-consumer-response's SCOR strategy. Sampled pharmaceutical companies implemented the operations strategies presented in Table 3.

< Insert Table 3 here>

The new business model adopted by companies in the industry attempted to compensate for the decrease in tax incentives and support, as well as some global issues that had a negative impact on the industry. For example, the delivery of products required supply-chain integrators, which could maintain product coherence from concept to customer across often numerous company boundaries. This shift made some internal processes redundant. Companies needed to assess the financial and technical implications of a supplier's product with respect to other product's subsystems, sometimes from other suppliers. Interviews with companies' employees suggested that there may be additional critical skills needed to manage these new collaborative developments. Once the researcher re-examined the industry parameter values, mathematical equations, and feedback interactions, a revised archetypical dynamics was developed.

Before experimenting with the models, three validity tests were performed: stability, time phase, and pattern of oscillation. Stability aims at identify the extent to which the model represents the real system; time phase at finding if the variables behavior has time phase relationship; and pattern of oscillation to verify whether the oscillation pattern fits the real system's pattern. Results validated the both models.

Results and Discussion

Figure 6 shows simulation results of the model for both periods, according to the procedure described. Both graphics illustrate the time-phase evolution of supply chain management total cost, return on supply chain fixed assets (or cash to cash cycle time), upside deliver adaptability performances, and order fulfillment cycle time, the latter for the second period archetypical model. During the first period, according to the initial values and the strength of supporting parameters, supply chain management total cost rises more than return on supply chain fixed assets. Therefore, it is reasonable to conclude that supply chain management total cost has a stronger supportive relationship with upside deliver adaptability elements than with

returned on supply fixed assets. This result was confirmed by Größler & Grübne' path model methodology (0.51 versus 0.32). The inhibiting trade-off relationship between upside deliver adaptability and returned on supply fixed assets was maintained on various simulation runs. Considering that during the first-period companies were treated as cost centers, it could be argued that the steady increase of supply-chain-management-cost was one of the more pressing issues for the industry. Thus, management focused on efficiency issues in order to decrease those costs, weakening service levels, for instance; upside deliver adaptability. These conclusions were confirmed by the interviewed managers.

Until the 70's energy crisis, supply chain management total cost and upside delivery adaptability initiatives were highly correlated. Parent companies aimed at increasing service levels that require management's attention to upside delivery adaptability. In turn better capacity expansion management increased supply chain costs. After the energy crisis, total supply chain cost increases, requiring more financial resources to keep the same level of upside delivery adaptability. Therefore, as time moved on, higher costs were needed to sustain the same service level implemented by initiatives related to upside deliver adaptability. Later that period, companies began to look at different approaches to be more resilient due to an increase in the number of hurricanes in the region and the possibility of cost increases in outsourced material and components. Due to these conditions, even that Low-Cost strategy was the most important from the system perspective; it was also the most difficult to implement and control.

< Insert Figure 6 here>

Throughout the second-period, considerably effort was placed in increasing customer levels, as expected in a profit center model. Due that most strategies depend on the execution of supply chain management cost that was difficult to manage due to external hurdles, most performances didn't change. The only performance that showed certain improvement was cash-to-cash cycle, since most companies modified their capital management policies; through several incentive and inventory improvement projects, companies reduced receivable days and inventory days, and increase payable days, renegotiating terms with customers. Furthermore, changes in capital management policies, positively influenced an otherwise overdeveloped industry capacity. The expanded production capacity that took place during the first-period created added vacancies that required to be filled by new employees, which in turn diluted the proportion of experienced personnel, reducing average management effectiveness and manufacturing competency.

As long as the nature and the value of the inhibiting links between the industry elements persisted, it seems that the most effective action to improve all three operations strategies were through increasing public and private technology transfer rate, decreasing technology and incentive erosion rate, and improving process technology. The latter can be enhanced through research and development investments or technology transfer (causing a positive feedback loop.) Although managers stated

that this rate of investment was difficult to sustain, given the present business environment characterized by increasing drug development costs and dependence on a few successful products, they agreed that improvements could be achieved.

Due to the speed of technological advancement, process technology required more research and development efforts to achieve and sustain higher competency levels. This could be implemented increasing the government support and establishing relevant collaborations with academic institutions and private research organizations. Interesting enough, scenario analysis showed that an increase of 1% of government support (in dollar incentives) would yield a 5.2% increase in upside deliver adaptability performance, a counterintuitive relation that could be recognized through a SD model.

Finally, PIAPR developed a position paper on measures to enhance the competitiveness of the industry in the island. Most recommendations were related to the suggestions cited, from the perspective of general guidelines. Some suggestions that may help strength the industry are; strengthen elements of the infrastructure, improve cost of manufacturing, offset high-cost service items with joint government-industry capital investments, and identify mechanisms to improve the investment funds system to free up companies' cash flow.

Conclusion

This empirical research proposed a conceptual model that provides a rationale to understand the dynamics of the pharmaceutical industry in Puerto Rico from 1962 until 2011, divided into two periods. The periods' threshold was defined by the year that U.S. and local tax incentives in the manufacturing sector started to phase out. The premise of the study was that dynamic properties of an operations strategy should not be ignored when examining its potential performance. The conceptual model explained the dynamics between industry elements and archetypical operations strategy decisions, and was translated into a SD model, which allowed for explaining those interactions that account for strategies' performances differences on both periods. Starting from a literature-based discussion of the existence and relevance of operations strategic capabilities of the pharmaceutical companies in Puerto Rico, the study shows that the dynamic nature of the interactions among components in the industry is best described using a system perspective. The model reflects the mechanism of capability accumulation and other system's levels, and implicitly the issue of trade-offs. A possibility for further research regards the level of sustainability of operations strategies configurations in the industry.

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Figures and Tables

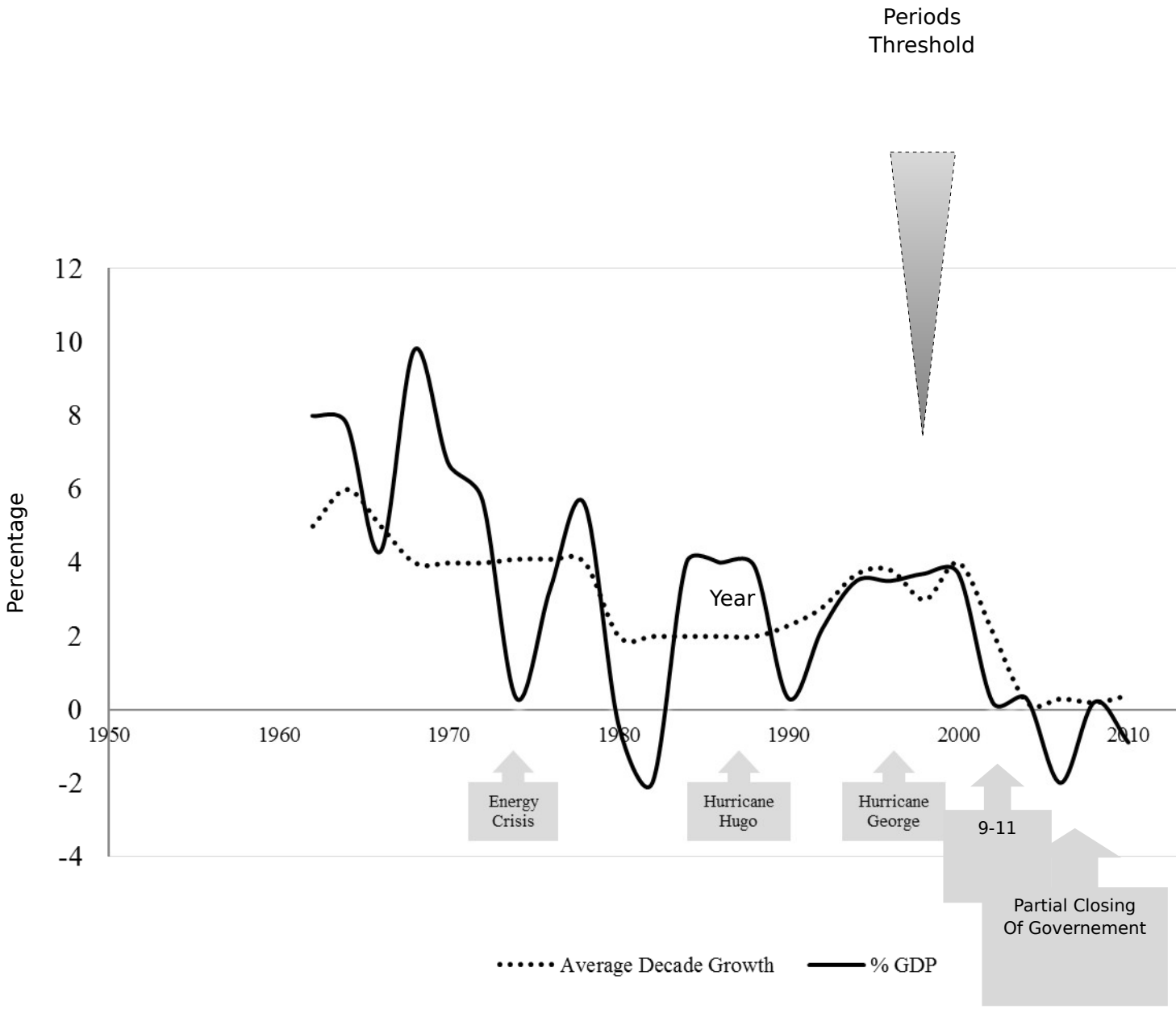

Figure 1. Puerto Rico's GDP Historical Performance

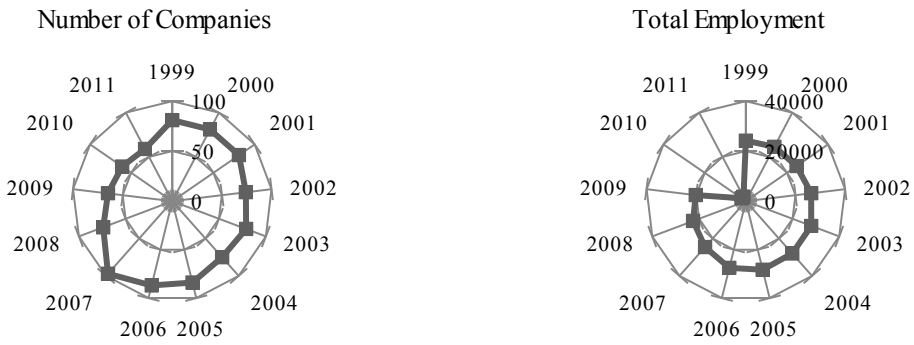

Figure 2. Number of pharmaceutical companies and total employment (1999-2011)
Source: Custodio Collazo, M. "En lucha por la Supervivencia." *El Nuevo Día* [San Juan, PR] 10 July 2012: Print

Table 1. Main characteristics of the sample

Characteristics	Mean	Median	Mode
Total employment	334.5	243	21
Export as a percentage of total sales	89.3	85.0	0
Research spending as a percentage of total sales	6.4	5.3	5
Company age	59.3	54.2	52
Number of products introduced over the five last years	2.3	2.1	0
New products at a percentage of current output	9.1	7.2	0

Table 2: Operations Strategy Elements (1962-1995)

Strategy		Key Metric Performance	Operational Definition
Literature Definition	SCOR Model Definition		
Low Cost	Low cost operations	Supply chain management total cost	Average Total Cost = Cost to Plan+Cost to Source+Cost to Make+Cost to Deliver
Mix and Volume Flexibility	Manufacturing agility	Return on Supply Chain fixed assets	$\frac{Supply\ Chain\ Revenue - COGS - Supply\ Chain\ Managemen}{¿}$
	Quick response (QR)	Upside Deliver Adaptability	The maximum sustainable percentage increase in quantities delivered that can be achieved in 30 days with the assumption of unconstrained finished good availability.

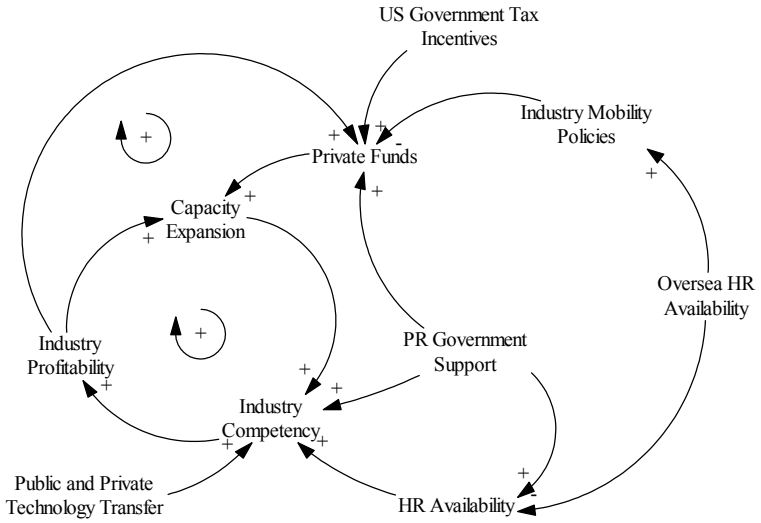

Figure 3. Industry-government-external factors causal loop

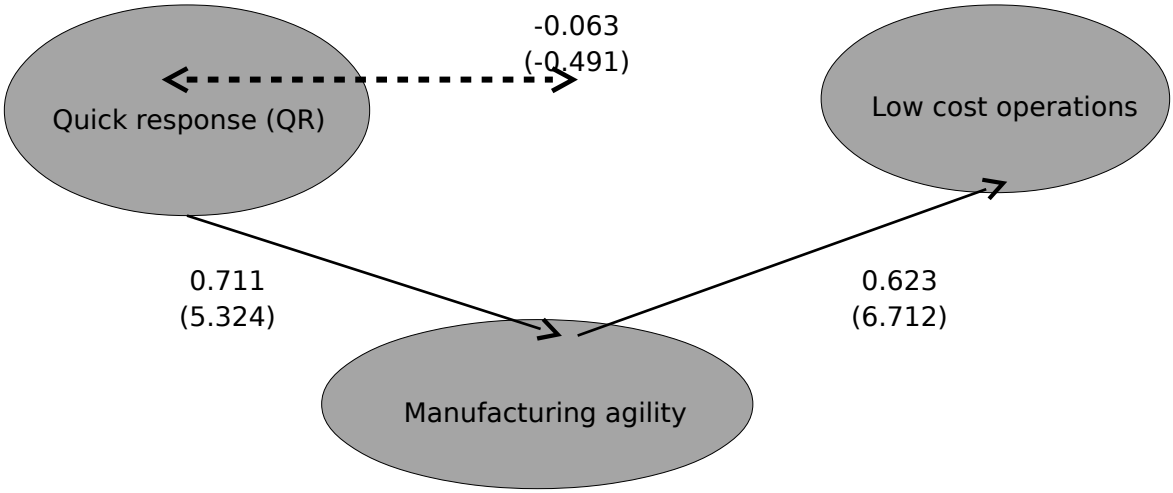

Figure 4. Path model of operations strategic capability hierarchy

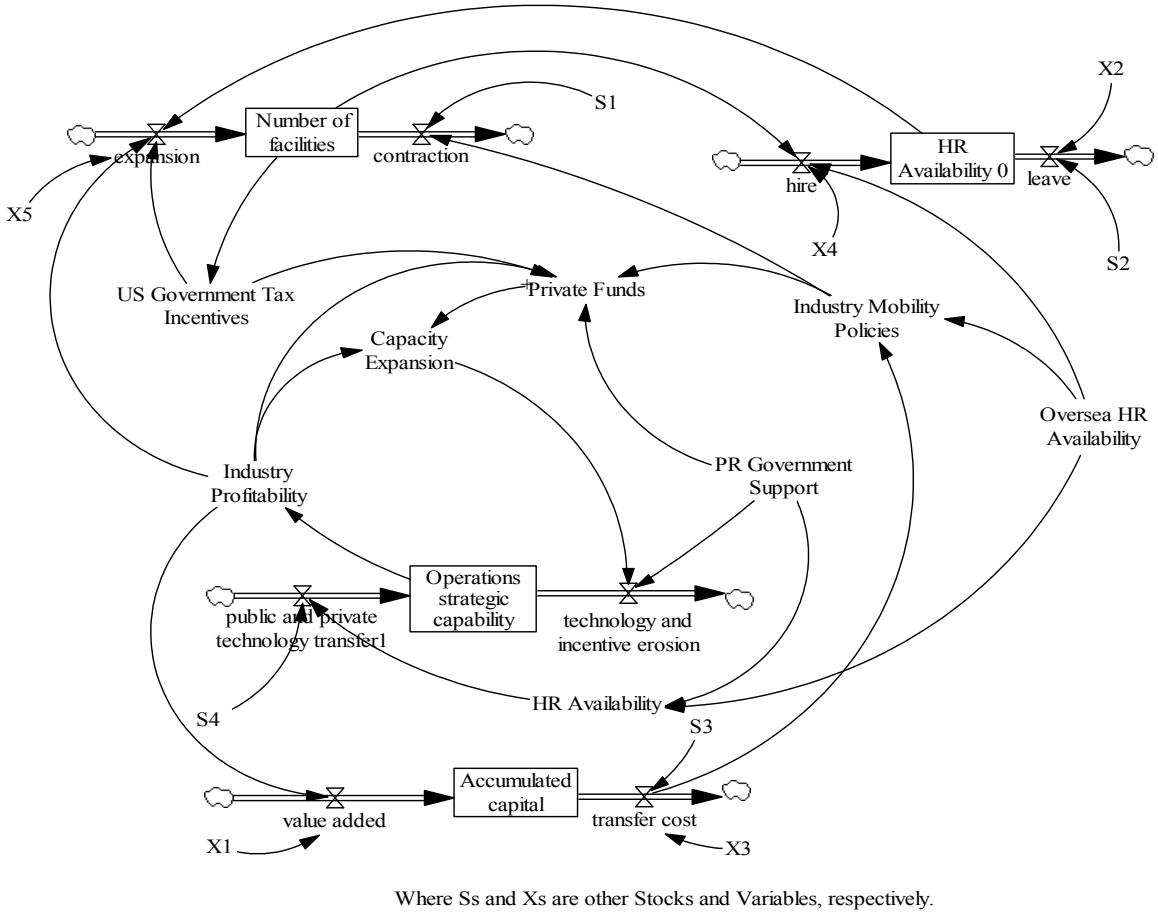

Figure 5. Archetypical operation strategy industry model

Table 3: Operations Strategy Elements (1998-2011)

Strategy		Key Metric Performance	Operational Definition
Literature Definition	SCOR Model Definition		
Low Cost	Low cost operations	Supply chain management total cost	Average Total Cost = Cost to Plan+Cost to Source+Cost to Make+Cost to Deliver
Mix and Volume Flexibility	Manufacturing agility	Cash-to-Cash cycle time	The time it takes for an investment made to flow back into a company after it has been spent for raw materials.
	Quick response (QR)	Upside Deliver Adaptability	The maximum sustainable percentage increase in quantities delivered that can be achieved in 30 days with the assumption of unconstrained finished good availability.
Responsiveness	Efficient consumer response (ECR)	Order fulfillment cycle time	The average actual cycle time consistently achieved to fulfill customer orders.

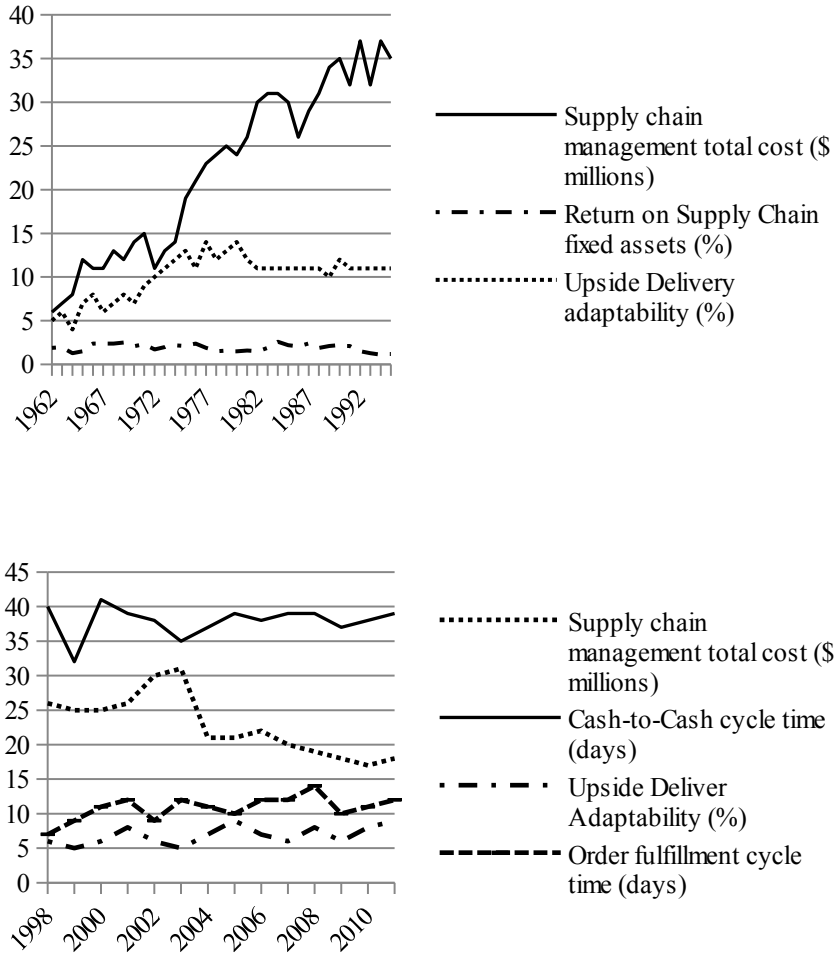

Figure 6: Archetypical Operations Strategies Performances