Understanding the innovation pattern of medium and large size brazilian pharmaceutical companies

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Abstract: Product innovation or business innovation? What should companies follow? Based on products and business innovation concepts and Concurrent Engineering (CE), Integrated Product Development (IPD), Stage Gates and Product Based Business (PBB), this paper presents an innovation reference model developed for Brazilian pharmaceutical companies. Qualitative research was conducted in six pharmaceutical companies in order to better understand their scenario and to compare their reality of innovation processes. The focus of this paper is to understand how these companies identify innovation opportunities (in the pre-development phase) and what constraints they face to implement them. Some comparisons are made among them and some recommendations concerning the innovation process are presented.
Keywords: pharmaceutical product development, innovation patterns, reference model

1. Introduction

PAULA (2004) has developed a reference model for pharmaceutical product (innovation process) based on recognized Integrated Product Development (IPD) methods as Concurrent Engineering (CE), Stage Gates and Product Based Business (PBB). The reference model was developed using: i) literature about product development; ii) pharmaceutical product development literature and legislation; and iii) interviews with professionals, which work in Brazilian medium and large size pharmaceutical companies. The developed model presents three macro stages and seven phases, embracing from business opportunity recognition to product market launching, and reflects the Brazilian pharmaceutical companies' product development reality. The innovation reference model also presents six stage gates to which are associated checklists and development process control documents. The pre-development macro stage, which is not frequently described in the pharmaceutical literature, is well detailed in the model. The innovation pattern suggested in the pre-development macro stage is based on the best innovation practices of pharmaceutical literature and also in Brazilian pharmaceutical companies' experience.

The purpose of this article is to explain the innovation pattern from the reference model for the pharmaceutical product development, compare it with the best innovation practices from literature, and, simultaneously, consider the actual constraints faced by medium and large sizes pharmaceutical companies in performing the innovation activities.

The literature that supported this analysis will be presented in this paper as described: initially it will be presented the innovation process theoretical reference accordingly to different authors; then the reference model of innovation and other models from large and medium Brazilian pharmaceutical companies and, at last an analysis of the constraints and the opportunities faced by these companies.

2. The innovation process

The expression "innovation" has been distinguished from "invention" by several authors. SCHUMPETER (1971) affirms that innovation is a new combination of ways of production and it is the key element of the economy; and invention, on the other hand, if not developed turns out to be economically irrelevant. DRUCKER (1998) establishes that innovation it is not an invention, nor a discovery. It can involve both, and most of the time it does, but focus in economical performance. Recently, BARBIERI (2003) describes invention as a technical action and innovation as a combination of technical, economical and organizational facts. Innovation can be understood as an invention with added value to client and economically viable.

GARCIA & CALANTONE (2002) reviewed 21 researcher's opinion to finally define innovation as "an

iterative process, which begins with the perception of a market opportunity for a technologically supported product and/or service, that leads to development, production and marketing activities, in order to achieve product's commercial success" and innovativeness as "an indicator that is used to reveal the product and/or service degree of innovation." Innovation can be new to the company, to the clients or to the market. The authors also affirm that innovation may be described in two ways, incremental or radical, the first one happens in about 90% of the cases and the second one, more uncommon, happens only in 10% of the cases.

Moreover, innovation is related either to "product improvement", increasing the company product's family or to "business innovation", what means the search for new business opportunities. The latest one is about to incorporate more strategic diversity in a specific business or competitive domain (HAMEL, 2000). In this sense, LOEWE et al. (2001) consider the "strategic innovation" in five possible types of innovation management in companies, depending on their behavioral pattern.

Summarizing, the innovation may be related to processes, product/technology or business. PARASURAMAN & COLBY (2002) explain that an innovation may involve technology, but it must not be taken as a synonym of it. These authors affirm that exist inhibitors and stimulators factors that may influence the client's acceptance of new products with technology associated. The factors that stimulate the acceptance are optimism and innovator style" and the ones that inhibit are discomfort and uncertainty.

Nowadays, innovation is considered to be the most important competitive force in companies, beside costs, quality, time and flexibility. BARBIERI (2003) presents the company' maturity in five levels of competencies, as they present a sum of these forces. The first level of maturity aggregate only cost's competence, the second aggregates "costs + quality", and so forth, towards the highest maturity level aggregates "costs + quality + time + flexibility + innovation" competences. The author also declares that any improvement in costs, quality, time or flexibility is considered innovation and, therefore, might occur at any step of evolution.

HAMEL (2000, p. 71) declares that the concept of the business is made of four components i) core strategy (including mission, market and differentiation); ii) strategic resources (considering core competences, strategic assets and core processes - methods and routines to transform raw materials); iii) interface with clients - communication' channels, information and product solutions); and iv) value chain (including suppliers partnerships and coalitions). The pillars of these four components of the model are: efficiency, singularity, compatibility to business and profit driven. These four pillars are aligned to the SCV (Sustainable Competitive Advantage) concept (PORTER, 1996).

COOPER (1993), ROOZENBURG & EEKELS (1995), PATTERSON & FENOGLIO (1999); CRAWFORD & BENEDETTO (2000) and BAXTER (2000) suggested similar procedures in product development methods. The methods known as Integrated Product Development (IPD) and the philosophy of Product Based Business (PBB) emphasize the change from "product development supported by engineering" to an innovation vision of "business supported by product development". In this sense, the corporate strategic planning is generally at the top of the models and should drive the decisions along the development course. The "pre-development" stage, described in the model discussed in this paper, is similar to Hamel's model components because has the same logic to enhance product development' chances of market success. This success is attributed to product planning based on client or market demand (need-pull or market-pull development) as extensively postulated by other authors (DESHPANDÉ & FARLEY, 1998; KOHLI & JAWORSKI, 1990; BAKER & SINKULA, 2002; KOTLER, 2002; McDONALD, 2003). PATTERSON & FENOGLIO (1999: 414) discuss another relevant aspect in these models. They affirm that product innovation is an "enterprisewide system that not only involves coordinated effort among the members of each product innovation team, but also promotes a vertical teamwork linking business leaders to the effort of individual product innovators". This reinforces the importance of multifunction working teams, information management and high-level involvement.

The pharmaceutical innovation process reference model mentioned in this paper was structured based on the former methods and philosophy, in addition of Concurrent Engineering methods and Stage Gates. The innovation best practices of large and medium sizes Brazilian pharmaceutical companies also contributed to the reference model. Part of the reference model and the companies practices, accessed via interviews, will be presented in the sequence.

3. Pharmaceutical innovation process reference model

The pharmaceutical innovation process reference model, developed by PAULA (2004) shown in Figure 1 presents three macro stages (pre-development, development and post-development) and seven phases, embracing from business opportunity recognition to product market launching. Nevertheless, only the macro stage entitled pre-development and its first phase named "identification and selection of business opportunity" will be focused in this paper. The objective is to compare the opportunity identification' best practices, published in specialized literature, with those which are really practiced by Brazilian's pharmaceutical

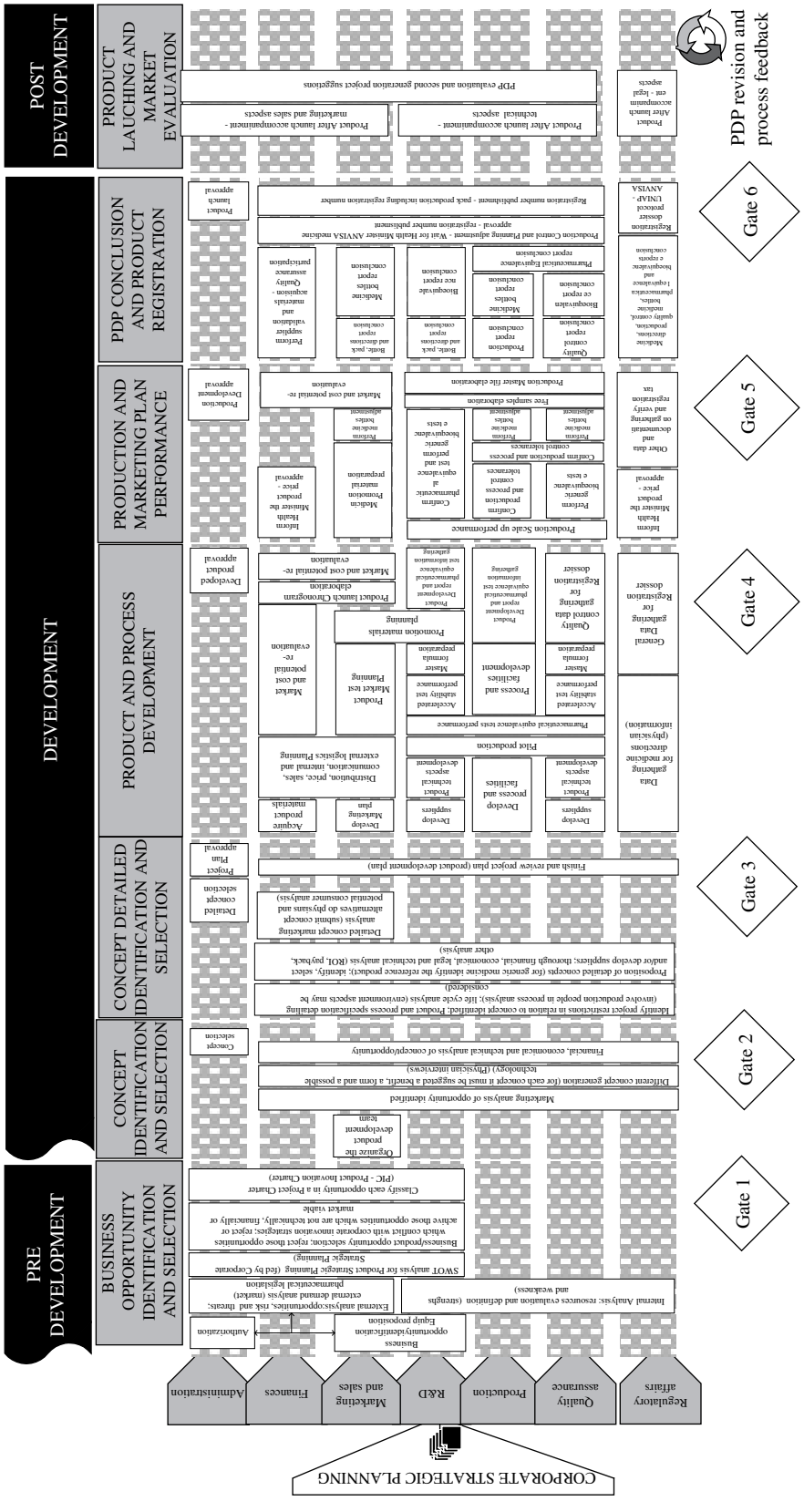

Figure 1. Reference model for Pharmaceutical Development Process - macro vision. Emphasis in general aspects: three macro stages (black blocks); seven phases (grey blocks); team (horizontal dashed stripes under the white blocks which represent work packages); and six gates between phases. Work packages are not emphasized in this figure. (Source: adapted from PAULA, 2004).

companies. This is justified by the importance of the opportunity identification in the innovation process and the literature absence of details on "how to do" this opportunity identification.

Before presenting the Brazilian pharmaceutical companies' practices, it will be described the best product development procedures incorporated in the reference model, as described in item 2. The best practices will be stressed in bold letters.

The competitive scenario faced by companies obligates them to thoroughly plan the development of new products and/or services in order to reduce the market uncertainties and chances. In this sense, the Corporate Strategic Planning (CSP) defines the business strategies (Figure 1). The decision team (high-level management) needs to be concerned in **defining adequate innovation policies**, for example, going through new markets or to move towards radical, instead incremental innovation. This definition may mean the success or the failure of the business. In such case this decision must be supported by **information thoroughly gathered by the multifunctional innovation team**. Figure 2 summarizes the team work packages at this phase (team represented in gray columns).

It is important to pay attention to every group of work packages presented in Figure 2, especially to the group concerning the '**resources evaluation and definition'**.

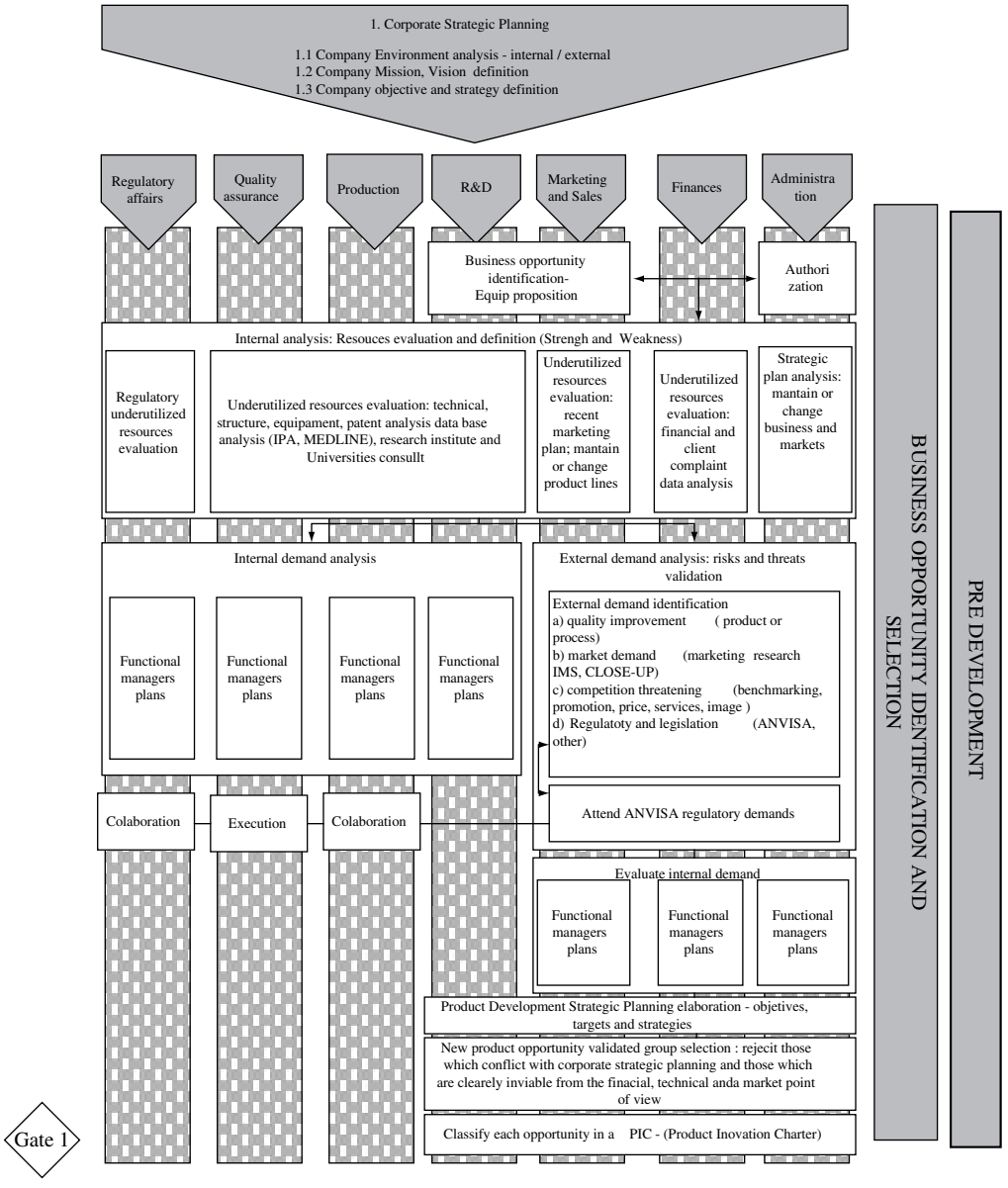

Figure 2. Business opportunities identification and selection phase – detailed vision. Adapted from: PAULA (2004).

The evaluation activities have two focuses. The first one based on measurement of the **underused resources as financial; legal level; structural, technical, equipments, patents, data bases, research institutes and universities**. The second focus includes the **analysis of the current marketing, product portfolio and corporate planning**. The objective at this phase is to optimize resource uses in order to better plan the innovation.

Other activities into the opportunity identification phase should receive special attention. They are the **internal and external evaluation of demands**, implementation of the **SWOT analysis and the prioritization of opportunities in the Innovation Charter**. These activities complement the comprehension of the company scenario.

Evaluation of internal demands means that every professional, in each functional department, may express ideas and collect observed demands in current or past projects. The historical data may be important aiming to avoid past project failures. It must be also considered the opinion of high-level management, which ultimately will align the ideas with the strategic direction of the business. The evaluation of external demands can be worked out by the application of SWOT Analysis. In this case, **internal and external benchmarking** is helpful to examine company's strengths and weakness. The analysis of competitors emerge their marketing strategies, technological strengths and weakness, facilitating the detection of new opportunities. The analysis of its own products life cycle (**portfolio analysis**) and the competing products analysis, leads to the identification of new market shares; a **contracted market research** (from institutes as IMS Health or Close Up International) is also an efficient tool for market share identification. In this same direction the **client demands analysis** or ideas of new products, services or business must be considered. Some tools are recommended to better accomplish this activity. BAXTER (2000) suggests the adoption of **consumer panel tool**, reminding that in case of medicine and cosmetics investigation of hospitals and drugstores environments are relevant, as the **opinion of physicians and patients evaluation**. Regarding the risks, the frequent **analysis of ANVISA (Governmental Regulatory Agency) databases** is actually important, in searching potential constraints or new rules. The **cost of human pharmaceutical essays** as bioequivalence, toxicity and pharmacological investigations may represent a limitation and must be considered in broader decisions as "to start the development of reference medicines (breakthrough innovation, radical innovation)", for example.

The last activity in this phase is to Classify the opportunities identified in the innovation chart and the result from a meticulous data analysis and selection of opportunities, which are aligned with the corporate strategic planning and high-level management' interests. Certainly not all the opportunities will be promptly explored and, therefore they are allocated in the innovation chart. The decision team communicates the chosen opportunities to be worked out to the innovation group, which will start the next phase "Product or service concept generation". The former phase is not the scope of this paper.

After presenting the ideal innovation model, accordingly to the literature, it is time to elucidate and analyze the Brazilian pharmaceutical companies' practices.

3.1. Innovation models in large and medium size Brazilian pharmaceutical companies

The objective of this investigation was to identify the innovation practices of Brazilian pharmaceutical companies, medicines and cosmetics producers. A qualitative research was carried out with professionals of two large size companies and three of medium size ones. Data from another large company, from the cosmetic area, was collected from specialized literature. The professionals interviewed were responsible for the areas of production, R&D, quality control and/or assurance, marketing, sales, regulatory affairs, financial management and high administration.

The interviews were accomplished from July to October 2003 and the questionnaires were divided in three groups of questions: i) general information (companies' characteristics); ii) existence of innovation or product development models; and iii) model stages and their main difficulties or constraints. The interviews were recorded for future transcription and analysis.

The general information items allowed to extract information about aspects, which reveal the companies´ way of conducing their innovation processes, including corporate strategic planning (when formalized), social economic influences (governmental rules, standards), type of organizational system (project oriented, hybrid, not project oriented) and organizational structure depending on the corporate size (functional, cross functional, staff). This information is summarized in Table 1.

Incremental innovation is predominant in Brazilian pharmaceutical companies. Most of medicines and cosmetics products are not totally innovative, but similar to the competitors. The regulatory copy of a reference medicine, previously launched by a pioneer industry is called a "generic medicine", and can be interchanged with a reference medicine without the physician authorization. This type of product is endorsed by government regulatory agencies via the presentation of *in vivo* (human) tests called bioequivalence assays. All the interviewed companies develop generic and similar medicines. The similar product is a copy from a reference medicine, but not bioequivalent to it and, therefore, may not be interchanged with the reference product. Similar and generic products

Table 1. Main characteristics of brazilian pharmaceutical companies interviewed.

Company product (size)	Strategic planning /organizational structure	Source of innovation ideas	Project team (Departments)	Project leader
Company 1 Medicine (medium)	Not formalized /functional structure	Ideas from financial management and R&D List of drugs/medicines which dispense bioequivalence studies (human research)	Multifunctional (Production, R&D, quality control, marketing, sales, regulatory affairs, financial management)	Financial management and R&D
Company 2 Medicine (medium)	Not formalized /functional structure	Ideas from sales and marketing department/ ideas from high administration /ideas from clients	Multifunctional (Production, R&D, quality control, marketing, sales, regulatory affairs, financial management and high administration)	Distributed by the team
Company 3 Medicine (medium)	Not formalized /functional structure	Ideas from sales department/ ideas from clients (physicians and patients)/ high administration and list of products previously authorized by the Brazilian Regulatory Agency (ANVISA)	Functional – sequential (Production, R&D, quality control, marketing, sales, regulatory affairs, financial management and high administration)	Distributed by the team
Company 4 Cosmetics (large)	Yes, formalized/matrix structure	Ideas from marketing department, from market research, from research institutes and Universities, tendencies in the area, analysis of concurrent products (benchmarking)	Multifunctional (Production, R&D, quality control, marketing, sales, regulatory affairs, financial management and high administration)	Marketing department
Company 5 Medicine (large)	Yes, formalized/matrix structure and Business Strategic Units (BSU)	Ideas from marketing, sales, patents, market research, from research institutes and Universities	Multifunctional (New product committee: Product management, sales, R&D, regulatory affairs)	Product management – marketing
Company 6 Cosmetics (large)	Yes, formalized/matrix structure and BSU	Ideas from market researches, patents, consumer habits, from research institutes and Universities, tendencies in the area	Multifunctional (Innovation Vice Presidency: segment manager (marketing); process and packing engineer, logistics control and planning technicians, R&D, business committee, advanced concept technology, Commercial Vice Presidency)	Segment management - marketing

are expected to be cheaper than reference medicines, consequently with larger market competitiveness. They are the most challenging type of product developed in Brazilian pharmaceutical companies, since the technology demanded for radical innovative product development is not available since the costs of it are extremely high (approximately U$ 800 million).

The six companies innovation practices comparison is presented in Table 2. The Table 2 informs if the business opportunity identification and selection activity is performed or not by the company. The activities presented in Table 2 are derived from de reference model from Figure 2, as an ideal reference from the literature. Tables 1 and 2 show clearly that medium size companies do not perform formally the corporate strategic plan, and present a similar profile. They execute part of the internal and external investigations. On the other hand, large companies, carry out most of the activities suggested in literature.

The innovation behavior of each company will be presented as follow. **Company 1** – The corporate strategic planning did not support the company innovation process, by the time of the interview, so there were no established innovation policies. The guidelines were determined by some "aisle talk" between the high-level management and R&D responsible, based on a list of possible products (which do not demand expensive pharmacological assays). After this, actions are triggered in all functional departments. The R&D professional interviewed declared the existence of a "multifunctional" innovation team, but also informed that they were the same people who performed routine activities. In that case, they just shared their time in different tasks. This reality is frequent in medium size Brazilian companies,

Table 2. Comparison of innovation activities observed in Brazilian pharmaceutical companies. Legend: Y (yes); N (no); P (in part); and - (unknown).

			Company 1	Company 2	Company 3	Company 4	Company 5	Company 6
Formal and Systematic Corporate Strategic Planning performance			N	N	N	Y	Y	Y
Macro Stage	**Phase**	**Activities**						
Pre Development	Business opportunity identification and selection	Select the innovation team	N	N	N	Y	Y	Y
		Resources evaluation and definition						
		At the legal level	P	P	P	Y	Y	Y
		Technical, equipment, patent database, research institutes	P	P	P	Y	Y	Y
		Marketing plan/portfolio analysis	N	N	Y	Y	Y	Y
		Financial resources	P	P	Y	Y	Y	Y
		Internal demand analysis (functional sector demands) Department directors' plans	P	P	P	P	P	-
		External demand analysis: risks and threats validation						
		Political, Technological, Social, Economical information	P	P	P	Y	Y	Y
		Market information, competitors information	P	P	P	Y	Y	Y
		Classify each opportunity in a PIC - (Product Inovation Charter)	N	N	N	Y	Y	Y

since the scarce of financial resource is responsible for a downsizing reflecting in work overloading. The extremely succinct pre-development stage gives rise to failures in the next steps, as commented by the interviewed professionals, leading to frequent product abortion and money loss (there is not a financial plan for innovation). The delay in product approval by ANVISA was mentioned as an important constraint. However the company presented an unfavorable innovation scenario, at the time of the interviews, it was investing in generic medicines, considered as a great business opportunity by most medium and large Brazilian pharmaceutical industries at that time.

Company 2 – This company presents an innovation behavior very similar to company 1, about professional board and responsibility overloading. However, concerning this they use information from clients accessed by the marketing department. It may not be considered a market research, since it captures only the most immediate client's demand. Another peculiarity is that, although reduced investigation, the professional group involved with the development job have periodical meetings, when they may exchange information and take decisions, what is more similar to the behavior expected of a team. Nevertheless, some product aborts were mentioned due to innovation process failures and, despite the money loss, a higher organizational degree was observed in this company, which was investing in infrastructure and equipment at the time of the interview. The interviewed professionals (production, R&D, quality assurance) recognized the necessity of a formalized procedure and the need of more investigation in the earlier innovation phases. A major complaint was the reduced investment in human resources by the company high level management, besides the delay at product registration by ANVISA.

Company 3 – The proximity of this company with large pharmaceutical companies makes its innovation process a hybrid between medium and large size companies. In one hand, they have a strong marketing department and execute some typical tasks, as the marketing plan and some market investigation, what is superior of its competitors. On the other hand the information gathered is informally transferred to the R&D and to the process professionals without any previous discussion, multifunctional meeting or similar. The company has a strong delivery channel, what guarantee a relative sales success. Similar to the other medium companies interviewed they are interested in the medicine generic market, and were suffering profound high-level management changes at the time the interviews were made. The marketing and sales professionals interviewed recognized the need of innovation process formalization, mainly the creation of a model they could follow. They considered the pre-development phase acceptable.

Company 4 – The culture of corporate strategic planning is present in this company, what makes the innovation process more delineated. There is an innovation team and the development efforts are conduced by guidelines previously established. This company belongs to the cosmetic area in which radical innovation products are more frequent.

However, this company is known to be less challenging than its greatest competitor in Brazilian market, the company 6. A strong marketing effort was evident in the interviews, leading to success market products. Some weaker aspect in their model are the little concern with internal opinion (from department professionals) and a formal registration of historical projects failures, which would be worthy in new projects. Although they are interested in broadening their international market, they have no clear strategies in that direction. It was not observed a tendency for business diversification.

Company 5 – This Brazilian company presents a clear market focus, mainly hospital products, result of the development fidelity to its origins. The culture of planning is strong in this company, which is segmented in Business Strategic Units (BSU), what have boosted the sales and incomes in the last years, accordingly to the interviewed professionals (marketing and R&D). This management option defines the existence of product managers for each BSU who are responsible for the segment innovation, always conduced in agreement with the corporate strategic planning. A peculiarity at this company is the development of products with broader levels of innovativeness, including chemical modifications in drugs, what results in a new or improved pharmacological effect of the drug. These incremental innovation activities make this company an exception in Brazil. Much of this challenging behavior is attributed to the Organization culture. Different from the previous company presented, business diversification is a tendency, what may be reinforced if the product managers provide the appropriate feedback to the corporate strategic planning. A small gap is observed between BSU and corporate strategic planning despite the relative autonomy offered to the product managers.

Company 6 – This company is indeed a well-known cosmetic producer, competing in the same level of important international industries from this area. Its innovation process was described by NASCIMENTO et al. (2001), which is based in WHEELWRIGHT & CLARK's (1992) proposal. The Organization culture is strongly oriented towards business diversification, what appears as a clear competitive strategy. The challenging character of its high managers has given rise to creative forms of competing with international cosmetic industries, using local resources and cheaper investigative alternatives (as an investigative patent department locally), other than expensive investments in developing active substances and pharmacological human tests. This company has been served as inspiration to other Brazilian pharmaceutical producers, from the cosmetic and medicine fields. The qualities mentioned before for company 5 are similar in this Organization.

3.2. General analysis

The qualitative survey research approach used in this investigation proved to be effective in highlighting the PDP processes general understanding and restrictions from medium and large size Brazilian pharmaceutical companies. More information about the rerence model construction methodology may be found in PAULA (2004). Although this theme is of strategic nature the companies' professionals were willing to answer the questions. It was easy to notice that the professionals from company 4 were more reserved in describing the PDP process than were the others.

Companies 1 to 6 may be grouped by different classification criteria. Considering the size, companies 1 to 3 (medium size) present very similar innovation process behavior, mainly characterized by the lack of formalization and corporate strategic planning, different from the reference model which enforces formalization and standardization of internal procedures providing intervention and PDP quality improvement. The large companies, 4 to 6, are concerned with corporate strategic planning execution, which defines the guidelines for innovation, as specialized literature recommend.

Regarding the companies' culture, the medium size companies (1 to 3) present a very conservative management behavior. The local action over specific processes or activities is predominant, contrarily to the open horizons managerial attitude showed by administration of companies 5 and 6 that are aware of market revolutions and act systemically in the business. The entrepreneur attitude is typical from company 5 administrators whose PDP process presents the funnel innovation pattern from WHEELWRIGHT & CLARK (1992) in which data gathering is an important entrance resource. It is a cosmetic company and data from patents are considered valuable by the development team, as well as market information and research information from Brazilian Universities. In fact, this company proves that innovation is an iterative effort of information searching and analyzing that leads to new product ideas. Another important characteristic from this company is its trade mark management. The company identity is easily noticed by clients and consumers since its product development pattern shows a strong alignment between mission-value declarations and product development practice. Company 4, on the other hand, is also from the cosmetic field but shows a conservative behavior if compared to company 6. The sales strategy is completely distinct from its competitor and it presents a smaller market share. Its administration, despite being aware of the business world revolutions, still maintains a reserved attitude, without challenging product changes. The PDP process is not as formally designed as in company 6, what seems do reduce the process overview vision and knowledge of development team. In other words

the PDP pre-development stage is not as emphasized as it is in company 6.

Considering maturity levels, companies 1 to 3 devise the importance of formal innovation processes and highlight pre-development activities, mainly market-oriented ones. However, this attitude is consequence of an external environment imposition, that is slowly taking part of the administrators reality, different from the more entrepreneur administrators from companies 5 and 6, who have been aware of the competitive driving forces in the last two or three decades. This fact has great consequences, since the former administrators have a barely notion of the background necessary for competition, and, sometimes, underestimate the necessity of investments in human resources, marketing tools and knowledge acquisition. The interviews showed another common situation in medium companies. It was observed the company administrators decided to reinforce pre-development activities and to formalize innovation processes, but lost relation to the corporate strategic planning starting point, risking acting locally, instead of systemically. Most of the time, this scenario was associated to a lack of financial resources, corroborated by the high costs of contracting external expertise.

The Brazilian historical pharmaceutical low technological level allied to the long period of patent not recognition, established condition for the culture of product imitation. As mentioned, the production of generic and similar medicines predominates in the local pharmaceutical industry (even multinational pharmaceutical industries prefer to reserve the innovation to their main base outside Brazil). Worse than this seems to be the lack of experience in conducing the pre-development activities, which generate market intelligence, and the predominant linear way of analyzing the environment. For example, taking into consideration the cases from this paper, a meticulous SWOT analysis would have shown that there was not in Brazil a complete infrastructure for generic approving pharmacological essays, two years ago. Even recently, some companies complain that are stuck in long lines waiting for research institutes to perform their products bioequivalence tests. Furthermore, the high costs of such assays prevent the generic cost reductions, at the level expected by patients-consumers. In fact, some generic medicines may present final prices higher than the reference medicine in drugstores. Most Brazilian pharmaceutical companies imagined, in a first glance, they would have competitive advantage if invested in generic medicines. Nevertheless, the great number of companies competing and ANVISA generic prices regulation has decreased the profit margins. Periodicals of the area have been questioning if generics production are actually an advantage for Brazilian companies.

Someone would question if this recent scenario would not have been predicted and if it would have changed the innovation decisions of some Brazilian companies, conducing them to the way out of the commonplace.

Summarizing it is possible to distinguish from this investigation the following scenarios for **Medium Brazilian pharmaceutical companies:** i) incremental innovation is predominant in Brazilian pharmaceutical companies, instead of radical innovation; ii) medium companies do not have a structured pre-development process and their professionals still believe that market investigation is a very hard expensive task that their companies cannot afford paying; iii) in these medium companies, product development ideas come mainly from technical area or client direct demand and their professionals do not recognize the importance of other information sources, other than the formal market research they do not afford paying; and iv) the absence of formal corporate strategic planning difficult the establishment of a common direction for professionals to drive their efforts, in relation to product development and other internal processes either. For **large Brazilian pharmaceutical companies:** i) large companies' PDP pre-development structure vary in formalization level, but are already performed by multifunctional teams, what brings synergy to the group; and ii) it is observed that the companies' administrators daringly profiles are determinant to company innovation behavior, since companies 5 and 6, whose administrators are more entrepreneurs than those from medium companies, are investing in basic research development or acquisition what is the foundation of radical innovation. Nevertheless incremental innovation still predominates in these companies either.

The main restrictions observed in medium and large size Brazilian pharmaceutical companies, besides the low profits for investment in new product development, are of paradigmatic and managerial natures. Despite the limitations represented by the high investments necessary for radical innovation in pharmaceutical companies and the high competition levels in internal market, even for generic and similar medicines (by the presence of several multinational industries), the Brazilian pharmaceutical companies' administrators should wonder about the following facts in search for opportunities: i) past paradigms rupture is a difficult task but actually compulsory toward radical innovation; ii) non-linear ideas may generate wealth to organizations; iii) business innovation is a more effective competition tool than product/technology innovation since the last ones are easiest imitated; and iv) alliances are relevant to support business concept innovation.

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