

UGSM-Monarch Business School Doctoral Dissertation Proposal

**In-Licensing as a Business Strategy for Pharmaceutical Companies:
A Framework for the Nigerian Industry**

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1.0 INTRODUCTION

The Nigerian pharmaceutical manufacturing industry is believed to be underdeveloped (Erhun, Babalola & Erhun, 2001; Olugbade 2005). Its total output accounts for approximately 30% of the local pharmaceutical market (Okhamefe, 2006). The main challenges in the industry include non-affordability of medicines (Erhun et al., 2001), drug counterfeiting (Erhun et al., 2001), poor dispensing ethics associated with a chaotic distribution network (Akunyili, 2007), the absence of Good Manufacturing Practice (GMP)¹ and a virtual absence of an effective research and development (R&D) base (Ogunyemi, Ibiwoye & Oyatoye, 2011).

The World Health Organization (WHO) has reported that Nigeria has the highest drug prices in the world, and the only country where its citizens spend up to 23% of their income on medicines (Magaji, 2010; Mourik et al., 2010). Citing the same WHO report Ogundipe (2010) observes that the average drug price in Nigeria is 82% higher than the next country in a group of eight nations with the highest drug prices in the world. Ammon (2008) points out that until recently, Nigeria was one of the few countries in the world with a high prevalence of fake drugs. Further, an overriding challenge in the industry is a severe lack of capital (Garuba, Kohler & Huisman, 2009). Such weak capital structure undermines the capacity of firms in the industry to engage in R&D (Okhamefe, 2006), acquire the requisite infrastructure to

¹ For example Obinna 2010 reports that no Nigerian pharmaceutical company is certified by the WHO as conforming to the rules of Good Manufacturing Practice (GMP).

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manufacture in line with basic WHO standards (Erhun et al., 2001), distribute and market efficiently (Akunyili, 2007), and generally operate with reasonable profits.

Various scholarly works have been completed on the industry with the objective of providing a viable path for real and steady growth while in turn addressing many of the above-mentioned issues. For instance, scholars such as Eaton (2008) have argued that the industry needs a huge intervention fund to be able to function optimally. However, such a proposal is vague and does not recommend how such funds can be efficiently applied. Erhun, Demehin and Erhun (2005) call for mergers and acquisitions. This would however cause many firms to lose their corporate identities; an idea that would be difficult to sell to Nigerian businessmen who have a business culture of passion for their own corporate identities (Onugu, 2005)².

Other scholars such as Osemene (2007) have examined strategic alliances as a possible solution, as this would make it possible for firms to pull resources together to meet individual objectives. On alliances Ogunkola, Bankole and Adewuyi (2008) for instance have recommended Joint Ventures (JVs) between Nigerian firms and others in advanced and emerging markets. Apart from JVs producing an entirely new identity which may not be widely accepted³, such vertical linkages with foreign firms,

² Various accounts detail what is described as the highly individualistic character of Nigeria's business culture. Onugu's (2005) doctoral thesis for example sees the tendency for investors in Nigeria to hold on firmly to what they have even when such concerns are not viable, as a major retardant to growth in the industrial sector. Nweke (2011) calls it the sit-tight syndrome. Other accounts include Akande (2009) and Obinna (2010).

³ Ibid.

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most often undermine the interest of one party in the alliance (Villa, Compagni & Reich, 2008). This is particularly so where research is needed for remedies to diseases peculiar to the weaker of the two economies where the firms in a JV arrangement are located⁴. Osemene, Ilori and Erhun (2012) call for horizontally constituted JVs. While this could help, it falls short of the “corporate identity” test (Onugu, 2005) earlier mentioned.

Another form of strategic alliance that has been suggested for Nigerian firms is franchising⁵. This form of alliance involves a firm’s contractual arrangement with another on an already established product to be marketed under the franchisor firm's trade name, in exchange for a fee or royalty. In effect, as noted by Sherman (2011) franchising is restrictive and tailors the franchisee to the rules of the franchisor. This means that franchising has no place for research toward the creation of a new product. In this form of alliance however, all parties maintain their corporate identities without forming a third organization.

Outsourcing as a variant of strategic alliance has also been considered for pharmaceutical firms in Nigeria (Osemene et al., 2012). This refers to an

⁴ Villa, Compagni and Reich’s (2008) account for instance argues that big pharmaceutical companies of the developed economies have little interest in tropical diseases given the fact that economies of tropical countries are too weak to support the huge capital demands of R&D.

⁵ Ogbera, Chinenye and Akinlade’s (2008) study for example, examines the role of franchising in the marketing of insulin in Nigeria. In fact franchising was the strategy adopted by investors who bought over interests in divesting foreign pharmaceutical companies in Nigeria in the 80s, culminating in the establishment of a group of franchise holders called NIROPHARM – Nigerian Representatives of Overseas Pharmaceutical Manufacturers (see www.niropharm.org).

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arrangement where either a part or a complete process in the value chain is contracted to a vendor, with the principal firm maintaining its corporate identity just like franchising. Unlike franchising however, outsourcing can be applied at any point in the value chain (Drake & Davies, 2006). Outsourcing however, is a very broad terminology that covers both termed and spot or ad hoc contracts (Drake & Davies, 2006). Therefore, the contemplated research will have to first determine the most applicable form of outsourcing before considering its ramification for the industry.

Licensing which is essentially a form of outsourcing, involves the termed transfer of intellectual property of one firm to the other or others for a fee (Reepmeyer, 2006). However, unlike generic outsourcing, licensing is never contracted on an ad hoc basis. There are two variants of licensing namely in-licensing and out-licensing. Where there is an agreement such that the expertise of one is used to develop or process the products of others, it is in-licensing. On the other hand, where a firm transfers or licenses its intellectual property to another to develop for the licensee's own use at a fee, the firm is out-licensing such property (Reepmeyer 2006). Reepmeyer (2006, p.21) describes the licensing variants in context as follows: "In-Licensing refers to acquiring intellectual assets whereas out-licensing refers to selling them".

In the context of the contemplated research which assumes a Nigerian industry centered approach, in-licensing is the area of interest. Table 1 shows a comparison

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of the features of types of possible strategic combinations discussed. The four methods highlighted in grey have been proposed by scholars for the Nigerian pharmaceutical industry.

TABLE 1						
Comparison Of Features Of Type Of Alliances And Mergers & Acquisitions						
Features	In-licensing	Out-licensing	Outsourcing	Franchising	J. Vs.	M&As
Applicability	Any point of the value chain	Between product discovery and manufacturing	Any point of the value chain	Only finished products	All points of value chain are managed by a new entity	All points of the value chain managed by one party or a new entity
Corporate Identity	Remains the same	Remains the same	Remains the same	Remains the same	New identity created	Loss of identity to one or all parties or new identity created
Flexibility	Parties can disengage at any time on agreed terms*	Parties can disengage at any time on agreed terms	Parties can disengage at any time on agreed terms. Can be applied on ad hoc or spot basis	Parties can disengage at any time on agreed terms	Process of disengagement more cumbersome	Process of disengagement more cumbersome
Creativity	Open to innovation and creativity	Open to innovation and creativity	Open to innovation and creativity	Franchisee is tied to the terms of franchisor	Parties are tied to agreed terms in a new entity	One party or all parties tied to agreed terms in another or a new entity
Product ownership and Management	By licensor	By licensee for the period of contract	By licensor or principal	By franchisor	By a new entity	By one party or a new entity
<p><i>*Rogers, Gupta & Maranas (2002) for instance suggest how dynamic or flexible in-licensing can be by showing that parties can engage or disengage from in-licensing contracts at any point in the value chain.</i></p> <p><i>Source: Chuba Keshi, 2012</i></p>						

The features of in-licensing and outsourcing as shown in Table 1 are almost the same and show that the two types of alliances are more advantageous than the other forms of strategic combinations. This is because they are the only forms of

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combinations that have the advantage of applicability at any point in the value chain without loss of corporate identity. In addition and unlike the others, there is relative ease of disengagement and a window for innovativeness at any stage of the value chain for these two forms of strategic collaborations. The main difference between the two is that while basic outsourcing can be applied on an ad hoc basis, in-licensing cannot. In-licensing contracts are always termed and therefore more enduring; a necessary condition for sustained growth. This, among other features listed in the table, is why this type of strategic alliance is believed to be more relevant than any other within the context of the contemplated research.

2.0 THE RESEARCH QUESTION

The primary aim of the proposed research is to develop an appropriate framework of in-licensing alliances for the Nigerian pharmaceutical industry so as to produce an operational model for growth that may lead toward global competitiveness. Thus, the main research question is:

Main Research Question:

"What are the characteristics of a new strategic model for the Nigerian pharmaceutical industry that makes use of in-licensing in an effort to drive optimal efficiency and further develop the market to a level of global competitiveness?"

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3.0 THE RESEARCH RELEVANCE

In recent years in-licensing has grown in significance in the global pharmaceutical industry. In 2006, approximately 33.3% of the world's pharmaceutical products were licensed (Alcacer, Cantwell and Giltelman's, 2008), while in 2007 in-licensing was estimated to have accounted for 40% of the revenue of the top 20 pharmaceutical firms in the world⁶. The importance of this type of alliance in the industry is shown in such works as Rasmussen (2007); Nathan (2007) and Enyinda, Briggs and Hawkins (2009). The authors demonstrate that rising complexities in creating value in the industry have made partnerships a strategic imperative. This view is perhaps best captured by the following quote:

“The most successful pharma companies will be those that recognize the underlying value locked in their supply chain and can leverage it as a value and brand differentiator rather than just a cost,” Steve Arlington (2011) cited in Taylor (2011).

The underlying goal of the contemplated research therefore, is to explore how this value can best be leveraged in the Nigerian pharmaceutical industry, within the

⁶ JSP Intelligence (n.d.) records this in their intelligence report. The report quotes Lam (2004): “... 20 (world's) biggest pharmaceutical firms formed nearly 1,500 alliances with biotech companies between 1997 and 2002.” See: <http://www.pharmexec.com/pharmexec/article/articleDetail.jsp?id=95090>.

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context of in-licensing. The significance of the research is therefore, to respond to the following objectives:

1. To explore contemporary theories of in-licensing as a form of strategic alliance;
2. To relate them to the present forms of in-licensing in the global pharmaceutical value chain;
3. To explore these forms in terms of their workability, within the context of the Nigerian business environment, and
4. To develop an in-licensing framework for Nigeria.

Essentially, the research will not only explore existing theories and models of in-licensing and situate them in Nigeria's environment; it will look at the strategy within the context of the value chain and construct as well as develop a framework accordingly.

4.0 CONTRIBUTION TO EXISTING KNOWLEDGE

Existing knowledge on strategy initiatives in the Nigerian pharmaceutical industry is mostly drawn from baseline survey reports by global multilateral bodies and rating institutions whose conclusions are largely anecdotal⁷. Although in-licensing is a

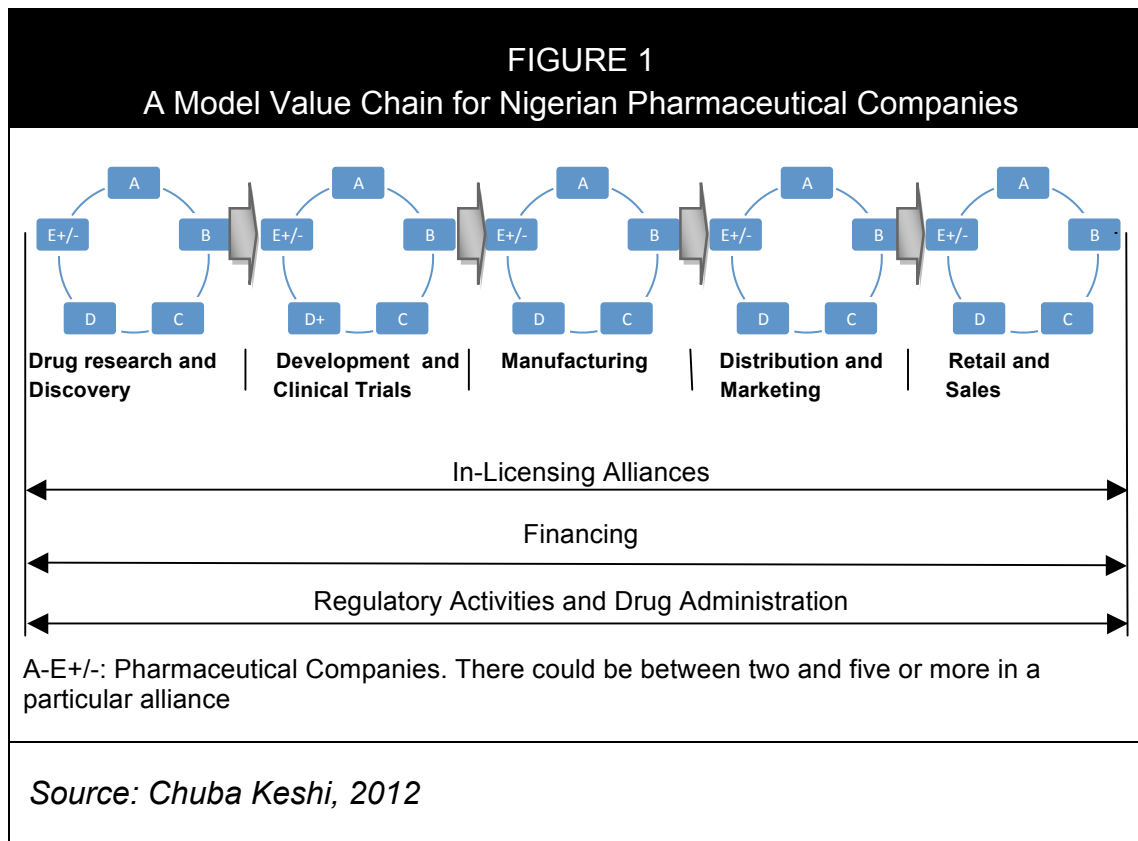
⁷ Various studies have noted this as a major gap in available analyses on the Nigerian pharmaceutical industry. Examples include Erhun et al. (2001), Okhamefe (2006), Echebiri & Edaba (2008).

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major strategic tool for pharmaceutical firms that are making significant impact in global business (Lam, 2004) there is no evidence in the available literature of the presence of Nigerian manufacturing companies either within the global network of in-licensing, or the presence of in-licensing within the enclave of the Nigerian industry. The only group participating in the global network is importers whose products are wholly in-licensed to foreign firms in the area of manufacturing (Erhun et al., 2001). There are also no recommendations presented on how the situation can be corrected or ameliorated.

The illustration below is a broad representation of possible in-licensing alliances at each point of the value chain. The number of firms and terms of each contract arrangement will depend on the individual and collective strategic needs of firms (Roger & Maranas, 2005) in the industry. Details of how these alliances can be structured to suit the Nigerian industry would constitute the contribution of new knowledge within the field of strategic business studies in Nigeria for the pharmaceutical industry.

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In summary, an in-licensing framework for the Nigerian pharmaceutical industry should contribute to new knowledge through the development of the following elements:

1. The construction of a new in-licensing model that recognizes the unique characteristics of Nigeria's pharmaceutical industry;
2. The clear identification of the value structure obtainable in each aspect of the value chain, if the models for collaboration to be recommended by the research are adopted;

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3. The identification of behavioral patterns in Nigeria's business culture that are central to the workability of any business model or models, such as those to be recommended;
4. The development of methods for approaching business problems common to firms in any particular industry in Nigeria, and
5. The identification of avenues for further research on strategic alliances in the Nigerian pharmaceutical industry.

5.0 RESEARCH METHODOLOGY

Research methodology refers to the scientific or philosophical principles that guide the process of a research (White, 2000 p. 20; Zikmund, 2003). It intrinsically comprises the methods employed in these processes including data generation, collection and analyses. Methodology also guides the logic of a research's literature that leads to inferences, deductions and extrapolations, ultimately leading to the thesis of the research.

The contemplated research will employ a qualitative methodology and a combined theoretical framework of the Theory of Phenomenography and Strategic Group Theory, respectively. Although Saglam (2006, p. 13) notes that Johansson, Marton and Svensson (1985), originally used the Theory of Phenomenography to qualitatively measure the values of variation in a group of persons' understanding of

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a physical phenomenon, scholars such as Eltantawy (2005) have successfully applied this theory toward understanding and explaining the variations in persons' dispositions and competencies in value chain management. Faray (2011) has applied it to social pharmacy research, while Lin (2011) has also applied it in examining consumers' different conceptions of marketing.

As suggested by works such as Arias and Patterson (2009); Babatunde and Biala (2010), opinions on business and policy issues in the Nigerian pharmaceutical industry are group-driven. Thus, while the Theory of Phenomenography will help observe particular individual understanding of issues and their interpretative patterns that result in forms of group cognition (Stahl, 2006; Richard et al., 2007; Conein, 2007), Strategic Group theory will help establish the substance of the research from the group perspective.

Both primary and secondary data will be employed in the research. Secondary data will be obtained from books, periodicals, journals, research papers, doctoral research theses, archives, gazettes such as policy documents, electronic and scholarly internet sources. Primary data collection will be in the forms of telephone interviews, in-depth personal interviews, emails, text messages and questionnaire(s).

6.0 THE LITERATURE REVIEW

The review of literature will examine extant works on in-licensing in a manner that will first elaborate on the concept as a form of licensing, separate it from the other licensing variant, namely out-licensing (Sanchez, 2004; Reepmeyer, 2006) and identify, as well as describe the different variables inherent in the topic. It will also examine the different scholarly perspectives on the subject, its different paradigms and relate them to the Nigerian context.

6.1 LICENSING THEORIES

There are no specific in-licensing theories; rather organizational behavior theories propounded by scholars to explain strategic alliances, explain the concept of in-licensing. The different views of these scholars will be identified and the benefits and pitfalls of each of these views will be analyzed. The relevance of these theories to this research work is in the exploration of the extent of their applicability to the Nigerian situation. The theories are briefly described below.

6.1.1. Resource-Dependency Theory

This theory is based on the economic axiom that resources are scarce. Grant (2001) and Bretherton and Chaston (2005) have argued that firms recognize comparative advantages others have regarding certain resources particularly intellectual resources, such that they find it more rewarding to ally with such firms in order to take advantage of such resources.

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6.1.2. Transaction Cost Theory

Scholars such as Sanchez (2004); Huang, Tzeng and Ong (2005) and Judge and Dooley (2006) have looked at strategic alliances as a means for firms to benefit from the economics of large scale production. By pooling resources together transaction costs are scaled down through the dynamics of large scale production.

6.1.3. Organizational Learning Theory

This theory looks at unique organizational cultures and how they shape cognition traits within the corporation. Scholars such as Grant and Barden-Fuller (2004); Njuguna (2009) and Liu, Ghauri and Sinkovis (2010) have noted that such organizational learning confers on firms certain knowledge that could become specialized and sometimes exclusive, such that others in the industry would find allying with them strategic.

6.1.4. Relationship Marketing Theory

In-licensing agreements on product marketing between or among companies are often predicated upon marketing pedigrees of firms within specific markets. Morgan and Hunt (1994); Hunt, Arnett and Madhavaram (2006) and Ismail and Alsadi (2010) suggest that over time and with deliberate efforts, firms become established in specific markets in ways that make them masters of such markets. It thus becomes strategic for another firm to market its own product(s) through the established firm especially when considering cost of entry into a new market.

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6.1.5. Strategic Behavior Theory

Proponents of this theory see alliances as products of proactive management actions of organizations. In this regard, firms enter into alliances to hedge against what may be perceived as future risks usually following market intelligence reports. The sum of this approach is that strategic alliances are proactive collaborations of firms in the same industry. Scholars including Szyliowicz, Kennedy and Nelson (2004), Chen and Fan (2006) and Loke, Sambasivan and Nelson (2009) have given accounts of how firms collaborate among themselves using this approach. Such behavioral patterns are interesting to explore as they may assist in understanding the extent to which group cognition (Stahl, 2006) applies to firms within the same industry in Nigeria.

6.2 IN-LICENSING PARADIGMS AND FRAMEWORKS

Scholars have identified different paradigms or models that firms have adopted toward applying this type of strategic alliance. The research will examine these models and consider them as reference points or benchmarks for the purpose of constructing a new model for the Nigerian pharmaceutical industry. These models or paradigms are briefly described below.

6.2.1. Specialty Pharmaceutical Model

Within the framework of this model of in-licensing, firms capitalize on the therapeutic-marketing or drug-development pedigree of other firms (Schafer, 2002; Levine,

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2007). This model will be discussed in detail to determine if Nigerian firms have the potential to acquire the capacity for a niche position in any given therapy.

6.2.2. Blockbuster Model

Some firms that are brand owners of blockbuster drugs, use in-licensing to limit the opportunistic behavior of generic hawks at the back end of a patent life. According to Gilbert, Henske and Singh (2003) firms do this by fashioning partnerships with other firms whereby the licensor uses the cheap labor costs of the licensee to lower production costs and thus contain generic competition after a product goes off patent.

6.2.3. Open Innovation Model

Rasmussen (2007) citing Chesbrough (2003) and Chesbrough et al. (2006), discuss the Open Innovation model whereby firms pull together resources and ideas to develop new products, leveraging on one another's strength. Through the exploration of the Open Innovation theory we can have a richer understanding of how firms could strategize collectively. Such group understanding will be related to the unique Nigerian business environment in such a way that will enable the construction of a realistic framework.

6.2.4. Clinical Phase Model

Schafer (2002) notes that there are instances where firms discontinue products at different points in the clinical trial stage only for other firms with superior market

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intelligence information to pick up such products. The author argues that some firms deliberately adopt a strategy of sourcing such products and subsequently seek collaboration with the originators in in-licensing arrangements, or get the products fully out-licensed to them. Other scholars supporting this view include Robbins and Monro (1951) and Rogers et al. (2005). The contemplated research will explore this theory and if desirable, suggest how it can be modified and applied within a new R&D structure.

6.3 EXISTING FRAMEWORKS WITHIN THE NIGERIAN CONTEXT

This section will reiterate the basics of in-licensing and its models, against the pharmaceutical business environment in Nigeria. The Nigerian pharmaceutical business environment will be observed from the perspectives of biotechnology, capital, infrastructure and culture. In this way we can have a broad understanding of the extent to which Nigeria's local content of these factors conform to global trends. This will essentially provide a basis for recommendations toward how increased value may be obtained through a restructuring of the value chain by way of an increased and more efficient use of in-licensing agreements.

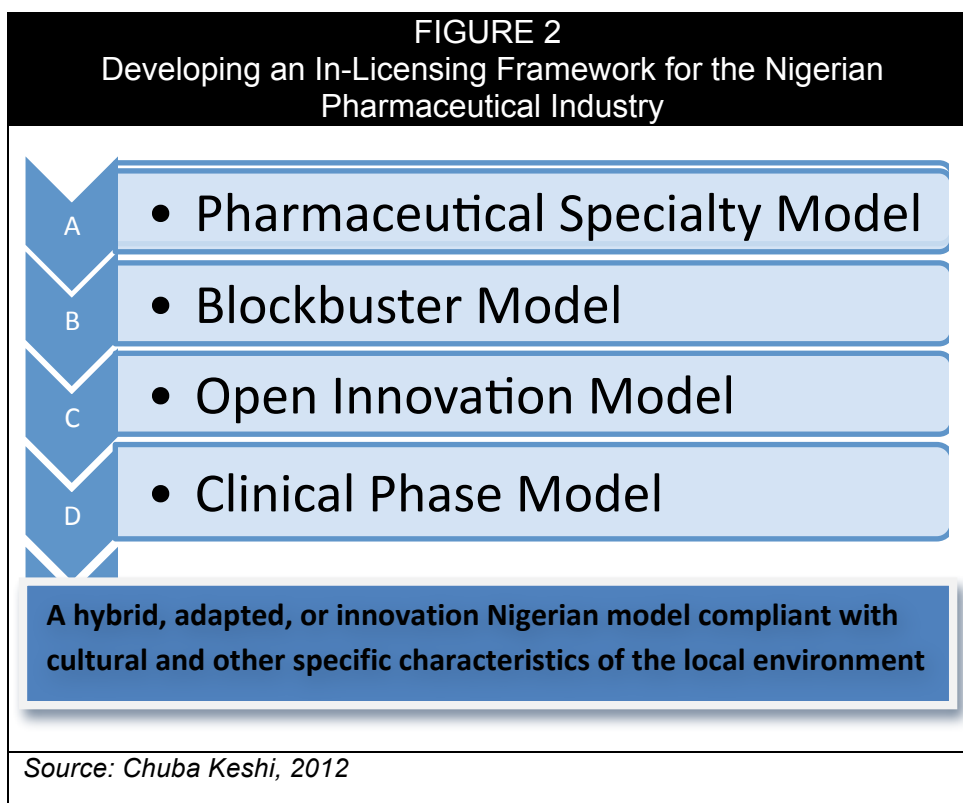
6.4 THE NEED FOR A NEW FRAMEWORK FOR NIGERIA

There are several scholarly accounts on Nigeria's business environment and factors that make the application of globally acclaimed investment models difficult in Nigeria. For example, Ayanwale (2007) suggests that the capacity of environmental

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infrastructure in Nigeria is grossly inadequate to support vertical alliances as operated globally. Ajayi (2007) in a similar vein observes that the same low capacity of infrastructure makes horizontal alliances either unworkable, or suffer stifled growth where they are contracted.

Adeyemo and Salami (2008) suggest that the constant intervention of government either through direct investment or through policy instability or both makes potential alliance opportunities not viable. Other factors to be considered include the dynamics of Nigeria's business culture environment (Hofstede, 1980; 2001) and other social factors.



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In effect the research will attempt to construct an alliance framework that will recognize the unique or specific characteristics of the Nigerian business environment (Omoleke & Adeopo, 2005) as shown in Figure 2.

6.5 SUMMARY AND AVENUE FOR FUTURE RESEARCH

The Nigerian business environment has some characteristics with which any holistic business strategy has to contend. These include poor infrastructures, unstable government policies, poor capital base, cultural nuances, absence of reliable quantitative data (Ammani, Sani & Alamu, 2010), among others. Any approach toward addressing these factors must therefore have a close and in-depth understanding of the cultural, economic and social objects that shape the Nigerian business environment. Although the contemplated research is in this direction, there is need for further research on the unique factors that shape businesses in Nigeria from the point of conception of an idea to that of sustaining a product in the market for a considerably long life time.

7.0 RESEARCH PLAN

In-depth review of literature will take place within a twelve month period, during which the questionnaire will be structured, pre-tested and finalized. This will be followed by the administration of the questionnaire which will be through a five-month period. Personal and telephone interviews will be done in the four geopolitical zones

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of Nigeria where pharmaceutical production is concentrated. These are the South-West, South-East, North-Central and the South-South regions. This will be done during the same period of administering the questionnaire. Collation of collected data will be followed by data analyses, writing of the manuscript and completion of the work.

8.0 RESEARCH TIMELINE

Time estimates that cover the entire research work, showing milestones and allotted time periods are presented below.

Date	Stage
July 2011 – May 2012	Choice and development of topic; development of research proposal
May 2012 – December 2012	Literature review and identification of scope of research study
December 2012 – April 2013	Development of questionnaire, interview design and scheduling; questionnaire pretesting and finalization
April 2013 – August 2013	Questionnaire administration / interview administration
August 2013 – October 2013	Follow-up interviews resulting from response issues
November 2013 – February 2014	Analysis of collected data
February 2014 – May 2014	Writing of the thesis manuscript
May 2014 – June 2014	Review, editing and proofreading of the manuscript
June, 2014	Thesis finalization, submission and defense expectation

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Although this research work is expected to strictly follow the timeline, there may be adjustments in the time estimates due to unforeseen circumstances.

9.0 RESEARCH BUDGET

Some expenses are expected to be incurred in the process of data collection and processing. These include purchase of articles and electronic materials not available in the university's library facilities, questionnaire production and administration, interview administration, among others. Below are the cost estimates.

TABLE 3	
Dissertation Research Budget	
Item	\$
Travel expenses	2, 000
Sourcing secondary research materials	2, 000
Electronic sources and equipment administration	1, 000
Questionnaire production and duplication	625
Interview and questionnaire administration	2, 000
Hotel accommodation	2, 100
Four regional questionnaire collators' fees	1, 250
Sundry expenses	650
Total	\$11, 650

The research will be fully funded by the researcher. No grants or scholarships will be requested of outside agencies. No financial assistance is required or being

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requested of UGSM-Monarch Business School Switzerland. The contemplated research is presently funded and research may begin.

10.0 RESEARCH PROPOSAL APPROVAL

The contemplated research proposed herein has been approved by the University and the student may commence the research immediately. The student is not to deviate from the proposed research unless expressly confirmed by both the Supervisor and the University in written form.

Approved By The University
On 19-May-2012 in Zug-Switzerland
By: Dr. Jeffrey Henderson, D.Phil., Ph.D

Mr. Chuba Keshi, M.Sc.
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