COMPETIVTIVE ADVANTAGE OF BRAND GENERIC PRODUCTS THROUGH ENTRY STRATEGIES ADOPTED BY MULTINATIONAL PHARMACEUTICAL COMPANIES IN KENYA

MAINA CATHERINE MWENDWA

A RESEARCH PROJECT SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMNETS FOR THE AWARD OF DEGREE OF MASTER OF BUSINESS ADMINSTRATION, SCHOOL OF BUSINESS,

UNIVERSITY OF NAIROBI

OCTOBER, 2015

DECLARATION

I declare that this is my original work and has no	ot been presented in any other
University or College for Examination or Academic p	ourposes.
Signature:	Date
MAINA CATHERINE MWENDWA	
D61/60207/2013	
This project has been submitted for examination wit	h my approval as the university
supervisor.	
Signature:	Date
Supervisor: Dr. JOHN YABS	
Lecturer,	
School Of Business Administration,	
University Of Nairobi	

ACKNOWLEDGMENT

I would wish to acknowledge the University of Nairobi for the opportunity to study my master's degree. It has been an exciting study period and I feel privileged to have been part as a student.

My gratitude to God Almighty, for the blessings of seeing me through my studies at the university; I am deeply obliged to my supervisor, Dr. John Yabs, his exemplary guidance and support without whose help; this project would not have been a success.

I also extend my gratitude to my loving family and friends who are a constant source of motivation and for their never ending support and encouragement during this project. God bless you all mightily.

DEDICATION

I dedicate this project to my beloved family for their support and prayers. They have been a source of strength to me. May God bless you.

TABLE OF CONTENTS

DECLARATIONii
ACKNOWLEDGMENTiii
DEDICATIONiv
TABLE OF CONTENTSv
LIST OF TABLESix
LIST OF FIGURESx
ABSTRACTxi
ABBREVIATIONS AND ACRONYMS xii
CHAPTER ONE1
INTRODUCTION1
1.1 Background
1.1.1 Theories of Entry Strategies of International Business
1.1.2 Competitive Advantage of MNC7
1.1.3 Entry Strategies in International Business of Brand generic products and
their Competitive advantage9
1.1.4 Pharmaceutical Multinational Corporation in Kenya
1.2 Research Problem
1.3 Research Objectives
1.4 Value of the study17

CHAPTER TWO	19
LITERATURE REVIEW	19
2.1 Introduction	19
2.2 Theoretical Foundation	19
2.3 Drugs going off- patent and the effect on Pharmaceutical MNCs	21
2.4 Pharmaceutical MNC and Government	24
2.5 Pharmaceutical MNCs emerging markets and the research gap	24
2.6 Empirical Studies and Research Gaps	26
2.7 Chapter Summary	27
CHAPTER THREE	28
RESEARCH METHODOLOGY	28
3.1 Introduction	28
3.2 Research Design	28
3.3 Population of the study	28
3.4 Sample design	29
3.5 Data collection	29
3.6 Data analysis	30
3.7 Chapter Summary	30
CHAPTER FOUR	31
DATA ANALYSIS, RESULTS AND DISCUSSION	31
4.1 Introduction	31

4.2 Demographic Information	31
4.2.1 Designation of the respondents	31
4.2.2 Duration worked in the company	31
4.2.3 Registered Name of the company	32
4.2.4 Business operations in Kenyan market	32
4.3 Medicines in the Portfolio Going Off Patent	32
4.3.1 Pharmaceuticals drugs in the Kenyan Market	32
4.3.2 Drugs that have lost patent protection	33
4.3.4 Loss of exclusivity strategy in place	33
4.3.5 Therapeutic Area expected to have high growth rate	34
4.3.6 Over the counter medicine versus prescription only medicine	34
4.4 Adoptions of Future Strategies in Emerging Markets	37
4.4.1 Planning, formulation, implementation and control of business strate	egies.37
4.4.2 Importance of emerging markets to company growth	38
4.4.3 Revenue contribution of emerging markets in the company	38
4.4.4 Challenges to further growth in emerging markets	40
4.4.5 Constrains to market access	42
4.4.6 Biggest mistake in emerging markets	43
4.4.7 Entry strategies in emerging markets	43
4.5 Attitudes toward Prevailing Trend of Patent Cliff	45
4.6 Summary discussion	46

CHAPTER FIVE47
SUMMARY, CONCLUSION AND RECOMMENADTION47
5.1 Introduction
5.2 Summary of Findings
5.3 Conclusions49
5.4 Limitations of the study50
5.5 Recommendations
REFERENCES52
Appendix I: Questionnaire for International Business Management M.B.A Research
project57
Appendix II: Pharmaceutical MNCs with Local Representative Office62

LIST OF TABLES

Table 4.1: Constrains to market access	.42
Table 4.2: Entry strategies in emerging markets	.44
Table 4.3: Entry Strategies in Africa	.45

LIST OF FIGURES

Figure 4.1: Loss of exclusivity strategy in place Error! Bookmark not defined.

Figure 4.2: Importance of emerging markets to company growth Error! Bookmark not defined.

ABSTRACT

The main purpose of the study was to determine if entry strategies influence competitive advantage of Pharmaceutical MNC in Kenya in light of the patent cliff. The study adopted cross-sectional study focusing on the Pharmaceutical MNC industry with brand products in the market. The population of interest is the big pharmaceutical multinational companies in Kenya with block-buster medicines going off patent. The Kenyan Pharmaceutical sector has about 30 licensed units of pharmaceutical manufacturing companies. Out of which, there were pharmaceutical MNC with a local technical representative office (LTRO) whose main aim was to ensure brand presence in the region. The Pharmaceutical MNC in Nairobi form a population of 15 companies selected. The target respondents were the Country manager, Regional Business Development manager and the Marketing Director or Manager in the Company. The study used primary and secondary data collection through open ended and structured questionnaires. Data collected was coded and entered into the Statistical Package for Social Sciences for analysis (SPSS). The findings were presented in pie charts, frequency tables, bar graphs were used to present the data collected for ease of understanding. The study established that Competitive strategies are critical factors on entry strategies adopted by pharmaceutical firms. The study shows that in companies where product advantages provide very strong competition there was increased marketing. With competitive advantage in place, entry strategies ensure that the pharmaceutical firms are able to give quality output, increased quantity production, customers' satisfaction and amount of sales brought. The findings on the strategies used by pharmaceutical to enter into the Kenyan market established that most of the pharmaceutical companies allow other companies to use their brands in marketing their products through licensing arrangement, followed by the pharmaceutical companies are using technology to manufacture products to ensure that they are of high quality to match customer specifications, the products are easily available, and the products are affordable. The least utilized marketing strategy included the distribution of pharmaceutical products handled by an agent or distributor. The key challenges faced by pharmaceutical companies included poor infrastructural development driving up operational costs, rules on taxation were not fair, customers still relied on traditional medicine practices and there is a poor legal infrastructure. The least challenge was on the instability of the local currency leading to losses or uncompetitive pricing, huge investment outlay in buying state of the art technology for manufacturing pharmaceutical products, strong customer loyalty from multinational pharmaceutical companies and the government is reluctant to develop and enforce laws protecting intellectual property rights. The study recommends that pharmaceutical MNCs should engage with emerging markets more closely and that planning of loss of exclusivity should be an ongoing product lifecycle strategy initiated at the launch of the product up until loss of exclusivity.

ABBREVIATIONS AND ACRONYMS

MNE : Multinational Enterprise

MNC : Multination Corporation

OPP : Out of Pocket

LOE : Loss of Exclusivity

IMS : Intercontinental Marketing Service

CHAPTER ONE

INTRODUCTION

1.1 Background

A multinational enterprise (MNE) is a company that has a worldwide approach to markets and production or one with operations in several countries. The focus of the operations of multinational corporations is on the coordination of the allocation of resources in its international operations in order to minimize production cost and maximize revenue. Areas of study in International Business include legal systems, political systems, economic policy, language, accounting standards, labor standards, living standards, environmental standards, local culture, corporate culture, foreign-exchange market, tariffs, import and export regulations, trade agreements, climate, education and many more. Each of these factors may require changes in how individual business units operate from one country to the next.

The entry strategy chosen by a corporation will greatly determine the success in the new environment. There is a current wave of mergers, acquisitions and strategic alliances of which technology has played a big part in blurring the boundaries of trade. Strategic variables impact the choice of entry mode for multinational corporation (MNC) expansion beyond their domestic markets. These variables are global concentration, global synergies, and global strategic motivations of MNC. The relevant theories of entry strategy include export, manufacturing and distribution licensing agreements, alliances and mergers, partnerships, off-shoring and financial agreements as Foreign Direct investment, turnkey operations, wholly owned subsidiaries as green field investments.

The motivation to carry out this study is to enhance the understanding of how entry strategies impact on the competitive advantage of Pharmaceutical products in a very dynamic and competitive market environment. Especially in light of the patent cliff of major block buster drugs for Big Pharmaceutical Multinational Corporations. Using the Kenyan context, most of the Population pays for drugs out of pocket. Therefore it is of interest to see how the Big Pharmaceuticals will ensure that they do not lose market share with the increasing competition from generic pharmaceutical manufacturers. The combination of growing generic manufacturing and patent expirations will be a definite force to contend with for the brand drug manufacturers.

A patent is a form of intellectual property rights similar to copyright and trade mark. A patent certificate is issued to attest that the object of the patent is novelty, inventive, usable and there is complete disclosure of the invention. Patents are limited by time most going for 20 years from date of filing and by space/jurisdiction of the patent office granting the patent. The "patent cliff" describes the end of patent protection rights for innovator drugs for a number of major pharmaceutical manufacturers. The patent cliff is also described as roughly a five year period for majority blockbuster drug-products to go off patent; it emerged in 2009 and is still in progress.

The Pharmaceutical industry is a trillion dollar international market dominated by few major companies. The top 15 companies consist of nearly half the total revenue in the industry in 2008. (www.triplehelixblog, 2014) The patent cliff has resulted in loss of billions of dollars in revenue for multinational corporations that include the likes of Pfizer, Novartis and Merck. The gains by generic manufacturers like Teva and Mr. Reddy are surmountable. This rapid dynamic environment will result in changes in consumer perspective, back end research & development and business development standpoint in major pharmaceutical companies in years to come.

Patent holders try to mitigate losses by authorizing generic entry prior to patent expiry. More recently Teva Pharmaceuticals Industries Ltd. agreed to buy Allergan PLC's generic unit for \$40.5 billion, both of these companies are generic manufacturers. This deal will now rank Teva Pharmaceuticals in the global drug makers market at a very competitive and strategic position. (WSJ, Business, 2015).

1.1.1 Theories of Entry Strategies of International Business

The strategic variables used by MNC in deciding to enter a new market include concentration, synergy and motivation. Global concentration is when many MNC share and overlap markets with a limited number of other corporations in the same industry. Global synergy is the reuse or sharing of resources by a corporation and may include marketing departments or other inputs that can be used in multiple markets. Global strategic motivation factors go beyond entry mode they are the basic reasons for corporate expansion into an additional market. These strategic reasons may include establishing a foreign outpost for expansion, developing and sourcing for cheaper manufacturing cost.

Once the decision to go into foreign markets is affirmed, the strategists in the MNC make a series of decisions bases on location, timing and mode of entry (2W1H). (Global strategic Management, Peng, 2009 2nd edition) Expansion being the main reason for the existence of multinational firms, the entry strategy used is critical for the success in the foreign market. The mode of entry chosen is influenced by cost like -transport, manufacture, marketing, and revenue-through quality, adaptation to local demand conditions, risk that affect after sale performance and control implications and attitudes of government for each option. The host country regulations especially in developing countries may restrict entry method.

Many MNCs have shied away from emerging markets when they should have engaged with them more closely. Since the early 1990s, developing countries have been the fastest-growing market in the world for most products and services. MNCs can lower costs by setting up manufacturing facilities and service centers in those areas, where skilled labor and trained managers are relatively inexpensive. Successful companies develop strategies for doing business in emerging markets that are different from those they use at home and often find novel ways of implementing them. (Harvard Business Review, 2005, Strategies That Fit Emerging Markets)

The main entry strategies in penetrating new markets are zero-base because the assumption is that there is no existing business in the market, limited market knowledge and low managerial competence. The three main considerations used when deciding on the mode of entry are Industry based, resource based and Institution based. Industry based depends on rivalry among firms, entry scale economies, bargaining power of suppliers and buyers as well as substitute product. In resource based consideration the factors involved are rarity, imitability and organization strength. Institution based strategies focus on regulatory risks, trade barriers, currency risk, cultural distance and institutional norms.

Export is the least risky method of international entry methods. A firm is either a direct or indirect exporter. Indirect exporting is when a firms' product are sold in foreign markets without any special activity for this purpose being undertaken within the company. The export operations are carried out by other firms; export house or trading company and the manufacturer may not have the knowledge. These include documentation, physical movement of goods and channels of distribution for sale.

Licensing is the relationship between the parent company (licensor) and licensee, in that the licensee is required to generate its own brand awareness and does not receive a lot of support from the parent company. A licensing agreement occurs when a person/company approaches the developer of a product or service and seeks permission to sell or produce the product within a specific area. With a licensed product one can access experience and know-how of the Innovator Company and break into a new market with the new product; also less costs and risk are involved.

Turnkey contracts happen when a business already has a proven, successful business model and merely requires investment capital and labour. Franchises are typically turnkey business, but any existing business that's already up and running successfully or a new business whose doors are ready to be opened could be considered a turnkey business. Franchising is an agreement with a lengthy commitment and involves training and support in the effort to establish company presence. The franchise location is a mirror image of the parent company and overlooks culture and operations of the home base. It involves the creator of a product or service allowing others the right to use the name and method of delivery of that product or service at a fee. The companies with a strong brand recognition, solid market technique and easy transferability of operating system have better chances with franchising.

Management contract is an agreement between investor of a project and a management company hired for coordinating and overseeing a contract. It spells out the conditions and duration of the agreement and the method of computing management fees. A Joint venture happens when two independently owned organization that agrees to enter a market, expand, grow and promote synergy especially when core competencies unite to form a more robust company. The domestic firm expands operations abroad, learns and teaches new skills while gaining

a new business partner. This is the main avenue for local organizations to gain entry to foreign markets and overcome political barriers of foreign direct investment.

There has been a sharp decline in the importance of wholly owned subsidiaries in developing countries in favor of joint ventures and non-equity arrangements. In developed countries, entry or diversification through acquisitions and mergers has been growing and the expansion of strategic alliances has become a major new issue. International Business is a term used to describe all commercial transactions that take place between two or more regions, countries and nations beyond their political boundaries. Private companies undertake such transactions for profit; governments undertake them for profit and for political reasons.

The term "international business" also refers to all those business activities which involve cross-border transactions of goods, services, resources between two or more nations. The host-home country Governments regulates these businesses through policies of International trade. The difference between domestic and international business is the influence of macro and micro factor since both are influenced by transactions that use economic resources including capital, skills, people for production of physical goods and services such as finance, banking, insurance, construction.

International business management is defined as a process of accomplishing the global objectives of a firm by (1) effectively coordinating the procurement, allocation, and utilization of the human, financial, intellectual, and physical resources of the firm within and across national boundaries and (2) effectively charting the path toward the desired organizational goals by navigating the firm through a global environment that is not only dynamic but often very hostile to the firm's very survival.

International business participant must have an understanding of economics, finance, marketing and strategy, a social understanding of culture and managing across culture. International negotiations have been increasing through trade relationships, politico economy integrations and progress to globalization. Leaders who possess a global mindset are able to interpret and decode situations from multiple, even competing, points of view. They have an insatiable interest to learn about other cultures, nurturing relationships with associates and friends transcending cultural barrier to create trust. They care to understand other people's perspectives and suspend their judgment, are knowledgeable about economic and political issues around the world and can grasp the inherent complexity of international affairs from multiple national perspectives. Finally, international leaders nurture relationships with associates and friends around the world and have a unique ability to transcend cultural barriers and cultivate trust. (Harvard Business Review, April 2012, What Being Global Really Means)

1.1.2 Competitive Advantage of MNC

The big Pharmaceutical MNC usually develops defensive strategic plans to combat generic competition. They tend to use multiple strategies to compete and maintain their market share. The strategic planning team often develops plans to maintain and grow the brand in the market. These include ever greening, authorized generics and moving prescription only drug to over the counter statues. The PMNCs will implement these strategies as early as possible to defend their market share. Most brand manufacturers have thorough legal departments for patent cases, they train develop skilled marketing/sales force and have extensive manufacturing capability.

To ensure they have a competitive advantage, PMNC adopt ever greening approach that means developing line and franchise extension to maintain market share. In

franchise extension the brand manufacturer switches patients to the newly patented drug before the patent of the original drug expires. Therefore, the generic drug maker finds a depleted patient population which is a less attractive market to enter, while the brand manufacturer minimizes market share loss. This is a high risk strategy to gain competitive advantage. Since, the R & D of the next generation will cost money in the tens- hundreds of millions of dollars, it may lack efficacy in a larger population, can be proven unsafe or fail to get regulatory approval. The brand drug manufacturers must plan and launch next generation line extensions with precision and advice from physicians and patients. Line extension ideally starts when the product is launched into the market. This allows the brand manufacturer time to market the drug, through altering the form of delivery, modifying formulation through extended release drugs or changing dose forms. At what point is a line extension not feasible? This happens when the brand drug being marketed competes with generics in the market and fails to yield positive return on investment; it could go as far as boosting sales of the generic competitor. A decrease of more than 80 per cent of market share usually forces brand drug manufactures to slash advertising especially in the first year of launch of generic formulation.

Another route to ensure the PMNC maintain a competitive advantage is entering into the generic market through own subsidiary generic units or manufacturing and distributing their own version of the generic brand. This strategy only works if the brand generic enters the market early. Strategic partnerships usually function as out of court agreements to resolve patent infringement rights. Partnering with generic manufacturers is a win-win situation; a portion of the brand generic drug is manufactured at the same facility under a generic label to be distributed by a generic MNC in exchange for royalties. This mitigates other generic manufacturers from

entering into the markets, since there will already be an established generic brand, it also encourages existence of only one generic preventing farther loss of market share from multiple generics.

1.1.3 Entry Strategies in International Business of Brand generic products and their Competitive advantage

What is in a name? There are brand and generic products for most health conditions from Cardiovascular, Central nervous system, Gastrointestinal, Respiratory system, Oncology, Anti-infective and hormone regulators.

Branded product or brand name drug is a medicine that is discovered, developed and marketed by a pharmaceutical company. The company files for a patent to protect against other companies producing the drug up to 20years exclusivity. The name makes the drug stand out in the market place. It takes several years of research and development through to clinical studies to have a drug molecule approves. The cost of research, development and marketing is born by the manufacturer, explaining the high prices for most brand name drugs. The phases involved to bring a molecule from discovery to manufacturing include three developmental phases of clinical tests, filing a New Drug Application, approval by government authorities to conduct phase IV clinical trials on the larger population (WHO, ASEAN TRIPS report, 2006).

Generic Product or generic name is a drug's common scientific name. Also, international non-proprietary name (INN). The generic product will have the same active ingredient as brand product but is only available after the patent expires. Generic medicines may now be produced by manufacturers other than the innovator company. They are usually 20% - 90% cheaper than the originator equivalent.

According to the World Health Organization (WHO) a generic pharmaceutical means a product that can be interchanged with an innovator product, manufactured without a license from the innovator company and marketed after the expiry date of the patent. Commodity generics are those drugs that enjoy approval of 1st time generic with 180 days of exclusive competition with the innovator but which later surfer reduction in price as other generics now enter the same market.

Branded generic product or "value-added generic" is available when the innovator pharmaceutical manufacturer also produces the generic version or enters into agreement with another company to produce the drug. A good example in the market is Sandoz Ltd. the generic division of Norvatis Pharmaceuticals Ltd. which recently opened up a national office in Nairobi. Many Pharmaceutical manufacturers are using this opportunity to find new ways to formulate drugs that have lost patent protection. Branded generic as defined by Intercontinental Marketing Services (IMS) is a novel dosage form of a drug that has lost patent protection and is produced by a manufacturer that is not the originator of the molecule, or a molecule copy of an offpatent product with a trade name. It is also taken to mean a different salt of an approved brand name drug.

There are a number of brand and generic drug manufacturers who are entering into agreements and forming alliances, establishing partnerships, co-licensing agreements in manufacturing and distribution. This ensures that costly legal battles due to patent infringement are avoided. The brand company ensures it maintains a competitive edge and keeps the manufacturing facility operational, retains market share and still captures a share of the generic market through royalty payments from the generic company sales.

Pharmaceutical MNC switch a prescription only drug to over the counter statues to maintain a competitive edge over generic manufacturers. How does this work? The brand drug about to loss patent protection will move to over the counter statues and loss sales revenue making the market unattractive. This strategy is used together with other defense strategies to be successful. The switch offers a public relations advantage by offering lower-priced drug to the public, though it is really voluntary.

1.1.4 Pharmaceutical Multinational Corporation in Kenya

The Kenyan prescription pharmaceutical market industry was worth \$423.2 million in 2013 and set to increase at compound annual growth rate of 11.8% to 2019 (Frost & Sullivan, 2013) with a high generic product penetration.

There is a Kenya National Pharmaceutical Policy (KNPP) that serves as the official National Medicines Policy document. Currently the National Pharmaceutical Strategy is being developed that give access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution. The Department of Pharmacy, Division of Pharmaceutical Policies is responsible for Pharmaceutical policy monitoring and evaluation. The market for pharmaceutical products in Kenya is estimated at Shs 8 billion per annum. The government, through Kenya Medical Supplies Agency (KEMSA) is the largest purchaser of drugs manufactured both locally and imported, in the country. It buys about 30% of the drugs in the Kenyan market through an open tender system and distributes them to government medical institutions. (Barasa, 2013)

In the Kenyan law there is an Intellectual Property Act that is the national patent law, and contains the following TRIPS flexibilities and safeguards, in line with the TRIPS agreement: Compulsory licensing provisions that can be applied for reasons of public health. Bolar exceptions-which allows researchers to use patented inventions in order to better understand the inventions, allow manufacturers of generic drugs to use the patented invention to obtain marketing approval without the patent owner's permission and before the patent protection expires, as soon as the patent expires, the generic producers can market there version and parallel importing provisions

Currently in Kenya, there are 45 licensed pharmaceutical manufactures with the capacity for production of formulations from pharmaceutical starting material to finished dosage forms. There is no capacity for Research and Development for discovery of new active substances or Production of pharmaceutical starting materials. In 2010, the market share (value) of pharmaceuticals produced by domestic manufactures was 28%. (Kenya Pharmaceutical Profile 2010) The Regulatory Framework in Kenya under the Medicines Regulatory Authority, Pharmacy and Poisons Board (PPB) which operates as a department in the Ministry of Medical services has the mandate to legally proved pharmaceutical products marketing authorization (registration) and licensing after inspection of the manufacturing facilities. The approval process for medicines in Kenya is that they are registered at a fee by their INN (International Non-proprietary Names) or Brand name.

In Kenya, there are no legal requirements affecting the pricing of medicines or mandating that retail medicines price information be publicly accessible. The government only monitors retail prices in the public, faith-based and private facilities. In 2004, WHO conducted a pricing and availability survey in Kenya.

The findings were that the Median Price Ration in the public sector was 3.6 for originator and 1.99 for generic, while in the private sector it was 18.1 for originator and 3.33 for generics. There is no value-added tax, but an Import Declaration Fee levied amounts to indirect tax on Pharmaceuticals.

The competitive environment faced by domestic pharmaceutical producers in Kenya is on two main fronts: within the industry and from imports. The factors that have resulted in the flooding of imports are; Foreign drugs are easy to register at the PPB, there is severe price completion from imports, Kenya has no import tariffs, the PPB has limited capacity to monitor Good Manufacturing Practice(GMP) status of foreign Pharmaceutical facilities that import into Kenya, quality testing of incoming imported drugs is uneven and irregular, penalties on substandard imports are low, most local Pharmaceutical producers lack WHO prequalification thus excluded from donor-funded procurement, financial strains by delayed reimbursements from governments of duties and VAT paid and the size of small firms in Kenya does not allow them to participate in large volume tenders.

1.2 Research Problem

A successful market entry strategy takes time, money and commitment. Brand products undergo large investments in promotional campaigns before they become success stories. Transaction costs are a barrier to international trade in terms of researching the markets, language barriers, logistics cost, enforcing contracts through weak legal systems and risk limit factors. Some of the factors are too high such that only government engages in the transaction (Mutambah, 2012).

Currently there is a shortage of new medical innovations while the block buster drugs are losing patent exclusivity. The current trend of patent expirations has resulted in decrease in R&D output; billions of dollars in patent expirations and increasing generic competition has contributed to this output. The innovators are forced to reevaluate traditional business model while generic manufacturers are facing increasing competition and stringent regulatory guidelines. There is pressure across the industry to adapt and transform strategies to maintain income and develop new revenues streams.

Government main purpose is to seek growth and distribution of resources internally and externally. Using the Affordable Care Act (ACA) 2010 in the United States of America as a reference, which states that federal government, offers subsidized health coverage to millions of citizens who cannot pay or are underinsured. This legislation is aimed at reducing the government health care expenditure. What does this mean for big Pharma and their brands products? The impact of branded products depends on: formulary coverage, therapeutic class and commercial plans. For example in the Contraceptives as a precedence, federal regulations require that all commercial insurance plans to implement zero co-pays, but the implementation was that some followed the legislation others the spirit of the legislation. Meaning, some insurers put only one generic oral contraceptive available at zero co-pay while others put all branded contraceptive at zero patient out of pocket. The first half of 2013 showed a year over year decline in all branded volumes, due to an inexorable shift to generics despite improvements in patient cost sharing.

In Kenya majority of the population pay for drugs out of pocket (OOP). The Healthcare Businesses have divided the Kenyan market into three groups of consumers: those at the top who can pay those who can pay less and those who cannot pay. There is a limited percentage that has insurance and can therefore access private healthcare service. Research data from PSP4H/UKaid shows that of 5 percent insured/can pay, 50 percent uninsured/can payless and 45 percent cannot pay and live below the poverty line. (PSP4H, 2014) Therefore, the Kenyan population will greatly benefit from the "patent cliff" as most generic manufacturers will be able to access the Kenyan market and compete effectively with the innovator companies. Taking a population of forty-four million, the can pay less segment is at twenty-two million citizens who are underserved and therefore the healthcare business simply cannot ignore this segment. Many Pharmaceutical manufacturers plan for the loss of exclusivity late and end up with silo type of strategies, brand, division or country. There is therefore, an urgent need to review the National Health Insurance Fund (NHIF) and the public sector healthcare access system following the rapid changed in Healthcare and Pharmaceutical markets. The informal sector workforce represents 83.3 percent of total Kenyan workforce and few opt for NHIF, while in the formal sector 2 percent of workers have formal employment. (PSP4H)

David R. and Micael W. (2005) research paper indicates that generic drug prices are high when brand generic are in small niche markets, but less profitable in larger markets. The discussion paper done by Silvia Appelt (2010-2013) generated empirical evidence on the impact of early entry of generic drugs to the innovator drugs in the German market, the second largest generic drug market in the world, experiencing the largest number of early entries of all European generic drug markets between 2000 and 2007 (EUC, 2009). 75 pharmaceutical products lost exclusivity between

2002 and 2007. By the end of 2007, 87 generic firms entered in the markets, resulting in a total of 724 market entries by independent generic firms. Early entry occurred on average four months prior to loss of exclusivity. This shows that regardless of the market, generic will still penetrate and compete with brand manufacturers.

Research by Jon Hess (U.S.A, 2005) concluded that the differences between brand and generic manufacturers are overlapping and meshing together. Generic companies are building their R & D capacity while brand manufacturers are entering into the generic markets through deal-making strategies. He gave the example of Norvatis' generic company rebranding in 2003 to Sandoz, which makes and markets more than 200 generic drugs in different therapeutic classes. Defense strategies employed include partnerships, alliances, licensing agreements between brand and generic manufactures.

The research gap found is that most of the studies on effects of brand and generic drug manufacturers are in the developed countries. These countries seem to have a thorough developed pharmaceutical regulatory frame work in place. There are few studies in Nigeria, South Africa and India on the impact of generic drugs leading to reforms in the health sector. In emerging markets like Kenya, I found limited studies, mainly on procurement and supply chain of raw material in manufacturing, distribution of pharmaceutical drugs as well as Doctors perception of generic drug. Therefore, this study is focus on the big PMNC in Kenya, and how they will maintain market share as their molecules continue to loss patent protection globally. What then will be the impact on the Pharmaceutical MNC in Kenya following the progressive patent cliff and how will this influence the entry strategies employed to maintain a competitive advantage.

1.3 Research Objectives

The aim of the study is to determine if entry strategies influence competitive advantage of Pharmaceutical MNC in Kenya in light of the patent cliff.

1.4 Value of the study

In so doing, it will assess variable used by MNCs in selecting product strategy and underlying reasons behind that choice of how to maximize revenue once the patent protection has lapsed. This study will be of value to the Pharmaceutical sector reforms, because it is focused on a current issue that seems not to receive much attention especially in the areas of price control of prescription medication. It will also be of value to see how the expiration of patented molecules will affect the pricing of branded products and branded generic products in the Kenyan market, due to the highly competitive nature of the Kenyan pharmaceutical industry. This will add to the body of knowledge regarding product strategy decisions around patent expiry by considering what decisions were previously taken by companies as product lost patent protection. Will there be possibility of upgrading the manufacturing level in Kenya? Change in the business models being used currently? The research scope is limited to a sample of MNC's with offices in Kenya and has specific products that have lost patent protection in the global Pharmaceutical industry. The patent protection must have lapsed and the corporation set up a defined strategy. The time frame is from 2010-2015.

Scholars will be able to use the outcome of the study to understand the effects of the patent cliff in emerging markets. The scope will focus on decisions pertaining specifically to those products that have lost patent and will include company level decisions, especially where this acquisition is aimed at increasing revenue of the product and extending patent protection through license to manufacture type of

agreements. Academically the study will contribute to the body of knowledge in International business and stimulate research in entry strategies in emerging markets, especially for MNCs undergoing serious and expensive market challenges.

Government as the national policy maker will be able to use the findings as a guideline on how to negotiate with MNC that have numerous products going off patent. They will be able to reduce the health care expenditure and still provide safe, efficacious and affordable drugs to the public. Policy makers will also use the information in revision of the Kenya National Pharmaceutical Policy especially in areas of product selection and pricing. Will there be a consideration in ensuring that the manufacturer and distributers quote the price of the product in the originator Country. This will cap the price at which drugs are sold, more so when the patent of the innovator drug expires and competition from generic manufacturers increases. The study will be useful to Pharmaceutical stake holders who will either benefit from or undergo straining periods. Especially for the MNCs whose brand products are going off patent and generic versions are available at highly competitive prices.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This chapter is structured based on the research objectives. It will review past relevant literature available on the concept of entry strategies for MNCs and focus on off-patent molecules in emerging markets like Kenya.

2.2 Theoretical Foundation

The process of developing a new pharmaceutical product is long and expensive with estimates ranging between \$800 million to \$1.2 billion for a successful molecule to be brought to market. (Scott et al, 2012) A common practice for "Big Pharma" is to produce generic versions of the original drug prior to loss of exclusivity through subsidiaries or licensees. The fast movers to the market enjoy sustained competitive advantage over subsequent entrants, (Caves et al., 1991; Hollis, 2002) and reduce incentives for generic entry. A study by Berndt et al (2007) suggests that authorized generic entry prior to patent expiry may reduce incentives to generic firms.

Caves et al., (1991) examined 30 products that lost patent protection between 1976 and 1987 in the Unites States of America market. Their main concern is to explain price movements, market shares, and quantities sold of both generic and branded drugs. The results showed that a greater number of generic entrants depressed the generic price and lowered the quantity share of the brand, but they do not model the entry decision directly. The second result of Caves et al was that brand advertising started declining two years before patent expiration and then fell substantially with generic entry. The interpretation of the result is that brand advertising does not limit generic competition post-patent; otherwise it would continue after patent expiration.

The Pharmaceutical industry has had a long period of growth and profits due to novel products and innovations in medicines. This industry is now facing uncertainty and transition challenges due to reduced spending in Research and development, price controls and government control over the market. There are three environmental issues that have thoroughly pressurized this sector. First, microeconomic conditions and slow down of western markets but strong growth in emerging markets, secondly raising pressure by governments to reduce health care costs and third aggressive, very aggressive generic competition and increasing cost in pharmaceutical innovation. The products demanded are in two categories, over the counter and prescription only medicines. The prescription only medicines are most important in terms of regulations and market structure, either hospital or domestic. (Craig and Malek, 1995)

The pharmaceutical sector is a high-technology and knowledge-intensive industry. The structure of the industry is a two-tier structure. The largest companies account for the majority of the R&D investment in the industry holding the majority of patents. The second tier is formed by a large number of smaller firms manufacture off-patent products or under license to a patent-holder. The pharmaceutical industry is deeply regulated. Few aspects of the industry are unaffected by regulatory controls (OECD Regulatory in the Pharmaceutical industry, 2000).

A Product Loss of Exclusivity (PLE) strategy falls in three categories: Compete via differentiation, meaning either launch line extension and shift patient volume away from LOE product or continue brand promotion based on product characteristics. Reduce incentives for generics by moving the product to Over the Counter status and the use of intellectual property activity to delay generic launches. Compete via price, through the launch of a generic line and price management of branded product.

2.3 Drugs going off- patent and the effect on Pharmaceutical MNCs

The phenomenon of a drug going off-patent has always been there, but the present feature of a "patent cliff" has made many MNCs rethink their entry strategies and operational structures. Patent cliff is a massive expiration of exclusivity rights for a range of products owned by top 20 big pharmaceutical companies (<\$3 billion annual sales) that make up more than half the industry and profit and losses against generic competitor. With the ever present threat of competition from generic manufacturers there is a need to focus on the growth and innovation of pharmaceutical products going forward. Patent holders mitigate loss of monopoly by authorizing generic entry prior to patent expiry. The competition adversely affects market attractiveness due to the low cost of generic products. The Research and Development model has to evolve to cope with the environmental changes, it will have to focus on cost reduction and delve into areas of sustainable returns or a mix of both strategies.

The big Pharmaceutical companies have responded to this event through partnerships, mergers and acquisitions, consolidation, diversification, licensing agreements and downsizing human and capital resources. The information concerning authorized generic entry as an incentive to generic firms is evidenced in the United States, were the first generic manufacturer to file for market approval with a successful certification will get 180-day exclusivity period where no other generic version of the same drugs is entitled to market. This 180-day exclusivity period is an institutional feature in the U.S pharmaceutical market. The innovator drug producers seem to make case-by-case decisions in which agreements to have more so in the year before loss of exclusivity. (EUC, 2009)

A product losing exclusivity has three options. First, to complete via differentiation, second reduce incentives for generic and thirdly competing through price wars. Competing through differentiation could take the shape of product line extension. This means new indications for the drug, new formulations or route of administration. Line extension increases the product life cycle and value proposition of the branded product without engaging in price competitions with generics. Depending on the level of differentiation, the product may require price parity strategy to ease the patients to the newly differentiated line. Depending on the disease areas and the product characteristics it could fall in a niche therapy that may not attract much generic competing, also the brand image and awareness may be strong with the doctors and patients until a time when managed care is dominant.

How does reducing incentives for generics work? Moving a prescription-only product to over-the-counter (OTC) statues, especially if it has strong safety profile and minimal risk of abuse extends the lifecycle. The decision maker is the patients, especially OOP financing, since OTC prices are lower. Therefore, the brand manufacturer launches advertising and marketing to ensure success of the strategy. Intellectual property information works best for products with synthetic pathways and formulations that give it unique characteristics. This restricts generic manufacturers because they might produce a formulation that negatively differentiates it from the brand product. Also, patent term restoration of more than 5 years is used to make up for time lost in clinical tests and orphan drug status where no other drug will be approved for same indication for more than 7 years.

Competing through price is achieved by launching own generic line and price management of the brand product. This is the last resort before patent expiration and loss of exclusivity occurs. Launching own generic can effectively compete in lower

price markets while maintain the price of the brand to compete with other generics in the markets. Options to launch include; authored generic where the manufacture of the generic has an advantage and the third party has marketing and distribution advantage. Licensing a third party manufacturer who can produce at cheaper cost, can promote and distribute at lowers cost while remit royalty payments to the innovator. Branded generic where the manufacturer promotes and distributes the product under a generic name. In this case the manufacturer has a marketing, distribution and manufacturing advantage to launch own generic than licensing. Maintaining or decreasing price is a last supporting strategic approach to end-of-life option of a brand product. Maintaining price and losing market share is seen as more profitable option than reducing price, because the outcome will be determined by competitors. (Slovic, 2011)

"The generics issue is here to stay and will absolutely change the operating structure of business in this industry", Barbara Ryan, Deutsche Bank "The value of Africa's pharmaceutical industry rose from \$4.7 billion in 2003 to \$20.8 billion in 2013. These totals include patented and generics prescription drugs and over-the-counter medicines. That's good news for MNC and local pharmaceutical companies seeking new sources of growth as developed markets stagnate and good news for patients, who have gained access to medicines previously unavailable on the continent. But knowing where to find the next growth engine isn't enough for the industry. Leaders must also understand where growth is concentrated, what challenges they are likely to face, and how to work collaboratively with health systems to overcome the barriers to fulfill Africa's full potential." McKinsey & Co. 2015

2.4 Pharmaceutical MNC and Government

Empirical studies done (Hollis, 2003; Reiffen and Ward, 2007; Berndt et al., 2007) investigating the impact of early entry on generic product arrived at different conclusions. Berndt et al. (2007a) concede that authorized generic entry prior to patent expiry may reduce incentives to generic manufactures, yet they emphasize that there is no comprehensive empirical evidence based on recent data that would show early entry to have had a delaying or deterring effect on generic entry. Except for the study by Berndtet al. (2007), peer-reviewed analyses rely on data from the late 80s, early and mid-90s.

Therefore, if early entry occurs in markets that are more attractive than given market characteristics unauthentic correlation between early entry and generic entry decisions are made. The early entry decision is motivated by innovator financial distress on loss of exclusivity. Thomson report (2011) indicated that products with weight in their portfolio in terms of sales will be heavily affected and ignite changes in the dynamics of the industry shifting perspective from patents and R&D efficiency. The MNCs main changes will be in R&D pipeline noting more mergers and acquisitions taking place in the markets, alliances developing, finding new revenue segments in developing markets, and sharing of resources and knowledge.

2.5 Pharmaceutical MNCs emerging markets and the research gap

The "Big pharma" industry is at risk of losing \$259 billion in sales by 2020. Several block buster drugs are losing patent protection and the low priced generics will quickly reduce revenue for each drug by approximately 90%. Planning of Loss of exclusivity should be an ongoing product lifecycle strategy initiated at the launch of the product up until loss of exclusivity. Currently a primary managed care strategy is to tier pharmaceutical co-pays and create economic incentives for patients to choose

the less expensive option. This is observed in the Germany were generics are found at the top tier co-pay and brand products are second to third tier. Step therapy is another strategy that health care organizations are using, where by "generic first" policy is established. Access to brand agents is after treatment failure with the generic option. This is an incentive on physicians to use the less expensive treatment option before moving to the brand product.

The option that government and insurance companies are using to lower the cost of their health budgets has made business life for global pharmaceutical executives very difficult. The big pharma therefore have to look at emerging markets with fresh eyes. The traditional models defined by fully integrated operations, significant investment in Research and Development hubs as well as manufacturing sites will now pave way for new entry strategies, that show emerging markets as potential areas for developing and manufacturing medication not just consumer markets.

Emerging markets are expected to amount to nearly a third of the global pharmaceutical market by 2016, and it is anticipated that they will play a vital role in sustainable growth in the industry. Market attraction is due to increasing populations, increasing prosperity, and improving longevity However, although these regions offer huge untapped potential, they display a wide diversity in their stages of development, particularly with regard to their healthcare infrastructure. For this reason, there can be no "one-size-fits-all" approach to emerging markets. Even among the three main clusters of markets — the BRICMT economies (those of Brazil, Russia, India, China, Mexico, and Turkey); second-tier countries such as those of Southeast Asia; and finally Africa It is vital to distinguish between those markets in which pharmaceutical companies want to expand their presence in the short term, and those that are "on the back burner" for the time being.

"We're thinking hard about what happens when those emerging markets start to slow because they are not going to continue growing at the rate that they're growing forever and a place where we're putting a lot of our attention is Africa," Joseph Jimenez, chief executive officer of Novartis, Reuters.

2.6 Empirical Studies and Research Gaps

Empirical evidence confirming that the profits of pharmaceutical firms producing the branded drugs substantial reduces due to entry of generic versions are widely available in the published media. A good example is of the effect of patent cliff is a drug like "Lipitor" by Pfizer; it was released in 1998 and by 2011, had generated \$115 Billion in revenue, in 2005 Lipitor made about 40% of total profits for Pfizer. When the patent expired, Pfizer global sales of Lipitor fell by 40% and total profit declined by 19%. This drop in revenue was quite steep, even after the company completed a licensing agreement with Indian firm Ranbaxy to have exclusive rights of production for 180 days, of the generic for Lipitor.

In the early 1990's pharmaceutical MNCs focused on innovator drugs and owned subsidiaries to produce generic versions of the drug whose patent is held by the patent company. In 1993, Merck established a division to markets generic version of Merck products in 2003, Norvatis established Sandoz its generic subsidiary. Though acquisition of a generic drug company is not necessary for an innovator firm to bring a generic version into the market it is an effective strategy. Also, management contracts have been successful, where by patent holder manufacturers the generic version of its drug which is marketed by another firm and carriers the marketers label, Lilly used this for it antibiotic "Ceclor", Sanofi Aventis uses this for its Hepatitis B vaccine "Shanthan" and P&G authorized Watson lab to produce a generic version of anti-infective "Macrodantin" (David R. and Michael W, 2005)

Schering-Plough in 2002 tried to introduce "Clarinex" as a next-generation of "Claritine" through the franchise extension strategy and failed due to delays in the USA-FDA approval of "Clarinex". Claritin patients were therefore not able to switch to "Clarinex" in time, to maintain adequate market share for Schering-Plough. The sales of "Claritine" fell from \$3 billion to \$ 300 million by 2004. Astra Zeneca has a success story, when Prilosec sales declined and Nexium sales increases using the same strategy in 2001-2004. GlaxoSmithKline (GSK) used the line extension strategy to maintain competitive advantage and it worked well for "Zyban" a line extension of "Wellbutrin" effective in smoking cessation. (Jon Hess, 2005)

2.7 Chapter Summary

The literature reviewed shows that loss of patent exclusivity greatly affects the revenue generated from sale of blockbuster drugs. Though fast mover generic makers enjoy a competitive advantage it is not sustained over time with more generic maker entering the market. The loss of exclusivity strategies in place also do not work in silo, but are effective when combined with entry strategies like mergers, acquisitions, partnership deals and generic subsidiary/division as recently observed in the Pharmaceutical market. Emerging markets like Africa are gaining more attention from Big Pharmaceuticals who would be better advised to use tailor made strategies for the environment the choose to move into and not use a one size fits all approach.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Introduction

This chapter outlines the steps taken in the execution of the study to achieve the set objective. These steps include: research design, population of interest, sample data collection instruments and procedures and, data analysis.

3.2 Research Design

This was a descriptive research design, targeting a cross-sectional of the Pharmaceutical MNCs. It gathered information concerning the current statues of the industry with respect to present variables; asking individuals there perception, attitudes and behavior toward a phenomenon. A competent description challenges the accepted assumption of how things are and provokes action. The research respondents were chosen within the Pharmaceutical industry, focusing mainly on MNC with brand products in the market. The Information was collected through questionnaires; data was analyzed and interpreted.

3.3 Population of the study

The population of interest was the big pharmaceutical multinational companies in Kenya with block-buster medicines going off patent. The Kenyan Pharmaceutical sector has about 30 licensed units of pharmaceutical manufacturing companies. Out of which, there were pharmaceutical MNC with a local technical representative office (LTRO) whose main aim was to ensure brand presence in the region. The Pharmaceutical MNC in Nairobi form a population of 15 companies selected from the Pharmaceutical directory as at 31st July 2015.

3.4 Sample design

The sample design was a census due to the small number of Pharmaceutical MNC (PMNC) with Local Technical Representative Office. Therefore, all PMNC originators in Kenya were subject to the study. The target respondents were the Country manager, Regional Business Development manager and the Marketing Director or Manager in the Company.

3.5 Data collection

The study used primary and secondary data collection through open ended and structured questionnaires. The questionnaires were personally administered to the respondents and picked up during or after they have been filled in, depending on availability and willingness of respondents. The researcher was present to clarify any issues the respondent might have in the questionnaire. The questionnaires were in four parts, the first part carrying general information of the company and the respondent, the second part detailed the drugs going off patent and current strategies in place, the third part contained future entry strategies to adopt and finally attitude toward prevailing trend of patent expiry. A five-point Likert scale was used to determine the strength of opinion from the respondent to facilitate data classification for analysis.

Secondary data was collected using desk search technique; it includes current information from business and pharmaceutical publications, reports, journals and research papers.

3.6 Data analysis

In order to make sense of the data collected, analysis of the information gathered through questionnaires were done. Data analysis involves the interpretation of findings against the research questions. Data collected was coded and entered into the Statistical Package for Social Sciences for analysis (SPSS). SPSS helps in organizing and summarizing the data by the use of descriptive statistics such as measures of central tendency (i.e. mean, mode and median) and measures of dispersion. Pie charts, frequency tables, bar graphs were used to present the data collected for ease of understanding.

3.7 Chapter Summary

This section outlines the type study and research tool used to carry out the study. Descriptive research is useful and the most sponsored research in census, collection of social and economic indicators that eventually provoke explanatory research into a given phenomena.

CHAPTER FOUR

DATA ANALYSIS, RESULTS AND DISCUSSION

4.1 Introduction

This chapter presents results on competitive advantage of brand generic products through entry strategies adopted by multinational pharmaceutical companies in Kenya. The data was analyzed using descriptive statistics and presented in mean; standard deviation; pie charts; frequency tables and bar graphs.

4.2 Demographic Information

The study sought to determine the current designation of the respondents; how long they have worked in the current position; registered name of company and how long the business operations have been in the Kenyan market.

4.2.1 Designation of the respondents

The study sought to determine the current designation of the respondents in the company. The respondents selected for the study were the Country manager for the company, the Regional Business Development manager and the Marketing sales director of the companies. There are 15 companies that participated in the study hence; three of each manager was obtained from the companies forming respondents of 45 managers.

4.2.2 Duration worked in the company

The study sought to determine how long the respondents have worked in the current position. The respondents indicated as follows: the Country managers had worked in the companies between 8 to 12 years. The Regional Business Development managers indicated that they had worked in the current position in the company between 5 to 10

years. The Marketing directors indicated that they had worked in the current position in the company between 2 to 12 years.

4.2.3 Registered Name of the company

The study sought to determine the registered name of the company. The respondents indicated the registered name of the company See Appendix II: Pharmaceutical MNCs with Local Representative Office.

4.2.4 Business operations in Kenyan market

The study sought to determine how long the respondents have had business operations in the Kenyan market. The respondents from different companies indicated that the Pharmaceuticals opened a regional hub in Kenya for over 20 years.

4.3 Medicines in the Portfolio Going Off Patent

The study sought to determine the medicines in the portfolio going off patent that were in the Kenyan market. The interviewees indicated that there were several drugs in their portfolio that were in the Kenyan Market; those that have lost patent protection have loss of exclusivity strategy in place; time period to loss of patent protection; therapeutic area expecting high growth rate in Kenya in the next five years; generation of revenue by over the counter medicine versus prescription only medicine; revenue before generic version of products entered in the market and revenue after loss of exclusivity and competition from generic version of drug in Kenya.

4.3.1 Pharmaceuticals drugs in the Kenyan Market

The study sought to determine the drugs in the Kenyan market portfolio. The respondents indicated that there are several to many drugs in their portfolio that are in the Kenyan Market.

4.3.2 Drugs that have lost patent protection

The study sought to determine how many drugs have lost patent protection in the Kenyan Market. The respondents indicated that all drugs have lost patent protection while the interviewees indicated that only a few of the drugs have lost patent protection with the majority of the interviewees indicating that they are not sure of the drugs that have lost patent protection.

4.3.4 Loss of exclusivity strategy in place

The study sought to determine the loss of exclusivity strategy in place. The findings were presented in the figure below.

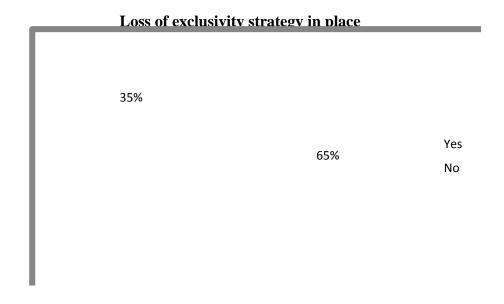


Figure 4.1: Loss of exclusivity strategy in place

The study sought to determine whether the respondents have a loss of exclusivity strategy in place. The majority of the respondents indicated that they do have a loss of exclusivity strategy in place and this accounted for 65% of the respondents. However, 35% of the respondents indicated that they do not have a loss of exclusivity strategy in place. The study also sought to determine the time period to loss of patent

protection. The interviewees indicated that the time period to loss of patent protection is about 5 to 10 years.

4.3.5 Therapeutic Area expected to have high growth rate

The study sought to investigate the therapeutic area expected to have a high growth rate in Kenya in the next five years. The respondents indicated that the therapeutic areas expected to have high growth rate in Kenya are: anti-infective drugs; endocrinology drugs; oncology drugs; respiratory drugs and central nervous system. Under the anti-infective drugs, the interviewees indicated antibiotics and vaccines. The interviewees indicated the endocrinology drugs as anti-diabetics and anti-hypertensive drugs. The interviewees indicated the respiratory drugs as Asthma and CoPD. The central nervous system drugs were identified as Anti-epileptics.

4.3.6 Over the counter medicine versus prescription only medicine

The study sought to determine between over the counter medicine versus prescription only medicine, which generates more revenue for the company in Kenya. The respondents indicated that prescription only medicine generates more revenue for the company in Kenya. However, some of the interviewees indicated that over the counter medicine sometimes generates more revenue for the company in Kenya. The respondents indicated that over the counter medicine (OTC) market, whereby customers can buy drugs or medicines without a prescription is increasing in value and volume across the world, with the potential for growth in emerging markets even more exciting. The respondents indicated that in recent years, the decline in the growth of the prescription-only sector is due to a number of factors such as: Lower value generics dominating large therapy areas (i.e. statins); Demand-constrained payers needing to demonstrate better value for money disappointing growth from emerging markets and Life sciences research and development delivering fewer, high

quality assets. In contrast, the OTC market has experienced higher year-on-year growth as: Payers shift the cost burden of relevant diseases onto patients by promoting self-medication and the use of OTC medicines; Pharmaceutical companies seek to exploit switch opportunities the formal process of switching a prescription-only medicine to an OTC medicine to protect revenues from branded drugs that are about to lose their patent protection; new channels become available e.g. supermarkets and the internet increasing access to OTC medicines and emerging markets add critical mass to the patient population available for self-medication.

Emerging markets are expected to continue to drive healthy growth for the global OTC industry largely as a result of an expansion in the middle classes. There is no doubt that the OTC market, particularly in emerging markets, offers significant potential for the life science industry. But the customer is not the traditional customer of the life sciences industry and shifting focus from physicians and payers to consumers will be an important success factor for those companies wishing to compete effectively. While a number of global life science companies have increased their focus on developing their OTC or consumer arms, and are well-placed to realize the OTC potential offered by emerging markets, there are a number of challenges that all multinational corporations will need to address: emerging economies are typically saturated with local players who are well-embedded in the healthcare system, understand local market dynamics and are more nimble than large western corporations. Large multinationals, wishing to succeed in these markets will need to identify the optimal organizational structure for effectively competing with local players, possess a thorough understanding of local market dynamics and, understand and engage with local stakeholders across the OTC and health value chain.

Intellectual property (IP) regulations are typically weak or poorly enforced in emerging economies. Governments of emerging economies argue that this is driven by the need to provide wide access to basic medicines for large but low income populations. Multinationals seeking to launch branded or original OTC medicines in these markets need to consider the likely level of IP protection that is available and to what extent this will be enforced.

OTC markets have gone through a period of regulatory liberalization, such as: direct-to-consumer advertising, relaxation of advertising regulations, and increased access to OTC medicines through new channels such as supermarkets, convenience stores and online pharmacies. This trend is likely to spread to emerging markets, some are already moving towards a Western structure, with retail channels driving growth.

OTC markets in emerging economies have traditionally been focused on herbal remedies and preventative therapies. Indeed, over 50 per cent of Chinese and Indian consumers take supplements. Medicines which have previously been prescription-only drugs are predominantly for treating diseases not preventative therapies. There is uncertainty around whether the mind-set of OTC consumers in emerging markets can be broadened to accept prescription-only drugs as OTC medication.

There is no doubt that potential exists to generate significant OTC revenues from emerging economies. Evidence suggests that global pharmaceutical companies have struggled to realize the full potential of the prescription-only market in emerging economies due to local dynamics. Given the issues highlighted above, there is a real risk that the OTC market will play out in the same way and prove just as challenging for multinationals.

The interviewees were required to indicate how the revenue before generic version of the product entered the market. They response revealed that the revenue before generic versions of the products entered the market was very high. However, the organizations that benefit most from selling generic products indicated that their revenue was low before generic products entered the market. The study further probed the interviewees to determine how revenue after loss of exclusivity is. The response revealed that the revenue after loss of exclusivity was slightly lower than before. The study also determined how competition from the generic version of the drug in Kenya was. The response revealed that competition is very high and that the competition was as a result of quality products offered in the market.

4.4 Adoptions of Future Strategies in Emerging Markets

The study sought to determine the adoptions of future strategies in emerging markets. The study sought to investigate who is involved in the planning, formulation, implementation and control of business strategies; potential of emerging markets to company growth; revenue contribution of emerging markets in the company; revenue contribution of emerging markets in the company; relevant emerging markets; markets in Africa with growth; rate performance of company since its entry into emerging markets; percentage of growth experienced; constraints to market access; review of market strategies and entry strategies considered a priority in emerging markets over the next 5 years in Kenya.

4.4.1 Planning, formulation, implementation and control of business strategies

The study sought to determine who is involved in the planning, formulation, implementation and control of business strategies. The respondents indicated that the board of management is involved in the planning and formulation of business

strategies in the company. The Chief Executive Officer (CEO) and the directors in charge are involved in the implementation and control of business strategies.

4.4.2 Importance of emerging markets to company growth

The study sought to determine how important/ the potential of emerging markets to the company growth. The findings were rated in the figure below.

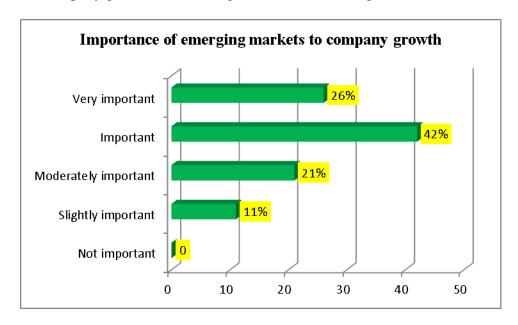


Figure 4.2: Importance of emerging markets to company growth

From the figure above, the majority of the respondents (42%) indicated that emerging markets are more important to the company growth. 26% of the respondents indicated that the potential emerging markets are very important to the company growth. 21% of the respondents indicated that the potential emerging markets are moderately important to the company growth while 11% of the respondents indicated that the potential emerging markets are slightly important to the company growth.

4.4.3 Revenue contribution of emerging markets in the company

The study sought to determine the revenue contribution of emerging markets in the company. The respondents indicated that the revenue contribution of emerging markets in the company as follows: In the next 3 years, the revenue contribution of

emerging markets in the company is about 10% to 15%; in the next 5 years, the revenue contribution of emerging markets in the company is about 20% to 50% and in the next 10 years, the revenue contribution of emerging markets in the company is about 25% to 50%.

The study sought to determine which emerging markets are considered relevant by the pharmaceutical firms. The respondents indicated that all emerging markets are considered relevant by the pharmaceutical firms. The respondents gave their definition of emerging markets as a dynamic, yet highly diverse group of countries and regions. This becomes apparent when one takes a closer look at individual economic potential. The respondents indicated that the survey benchmarked "perceived present relevance" against "expected future relevance." The average perceived relevance today to the expected change in relevance over the next five years. This means that, for example, countries that are considered highly relevant today and whose significance is expected to strongly grow are depicted in the top right quadrant. Respondents agree that emerging markets are currently dominant in relevance. They further expect the emerging markets in the regions to maintain their leading role until at least 2018, as indicated by a further increase of relevance. The most relevant second-tier region is Kenya, while East Africa's relevance is predicted to increase the most. However, with the exception of Central/Eastern Africa, the relevance of all these markets is expected to grow significantly. Sub-Saharan countries are currently viewed as being the least relevant region, yet with very positive prospects for future growth.

The study sought to rate the performance of the company since its entry into emerging markets. The respondents indicated that the performance of the company was very good. The study sought to determine the percentage of growth the company has

experienced since its entry into emerging markets. The response revealed the percentage of growth the company had experienced since its entry into emerging markets ranged from 20% to 60% of performance in growth.

4.4.4 Challenges to further growth in emerging markets

The study sought to determine the key challenges that the pharmaceutical companies face to further growth in emerging markets. The respondents identified some of these challenges as followed: lack of reimbursement and public funding; lack of healthcare infrastructure; lack of affordability; price pressure; local competition; lack of IP protection; challenging/nontransparent contracting and tenders; talent issues (e.g., recruitment, development, and retention); compliance challenges; lengthy product registration processes; regulatory requirements; supply chain and distribution issues and competition from multinationals.

The study further probed the respondents on what other key challenges they had identified and the respondents indicated that while executives share a long list of concerns, each pharmaceutical company needs to evaluate them in the context of its specific portfolio. For example, a lack of healthcare infrastructure and affordability can be expected to be a bigger challenge for the producers of expensive specialty care than for those companies that manufacture primary-care products. Price pressure is aggravated by domestic competition, as local companies typically receive support from their governments, a phenomenon also often seen in public tenders across emerging markets. This situation is further exacerbated by the fact that local companies are typically generics manufacturers that will also benefit from the approaching patent cliff. Legal and regulatory issues are reflected in the lack of intellectual property (IP) protection. The absence of transparency, lengthy processes surrounding tendering and contracting, and compliance challenges also are factors.

Talent management is known to be a significant hurdle for companies in emerging markets.

Among the manifold challenges that pharmaceutical companies face in emerging markets, one hurdle stands out above the rest: market access. But all these challenges are reflected in the different healthcare development agendas across emerging markets. They fall roughly into three categories: Infrastructure developers: Some countries currently do not have well-developed healthcare infrastructures and thus focus on improving access to healthcare for the general population. Cost containers: Many countries put in place containment measures to manage the costs of their evolving healthcare systems. The simplest and most common method is to not provide reimbursement to patients. Other governments increasingly rely on tendering for hospital business. This second-tier emerging market is implementing a centralized annual tendering program in 2013. As out-of-pocket payments account for approximately 60 percent of the market's healthcare spending, the goal is to make drugs more affordable for patients by introducing a price cap. As a consequence of this program, the cost of some products is expected to fall by 30 percent. Other emerging markets show similar approaches: high out-of-pocket payments (for example, 31 percent in Russia, 61 percent in India, and 14 percent in Thailand) for branded and non-branded pharmaceuticals, while governments support the use of generics and bio-similar, and introduce price restrictions. Value maximizers: Analogous to mature markets, some emerging markets are already moving toward value-driven drug evaluation and pricing. Good examples are China, which is collaborating with the British National Institute for Health and Clinical Excellence (NICE), and Brazil, where an economic evaluation agency has been set up.

4.4.5 Constrains to market access

The study sought to determine how the respondents would rate the following constraints to the market access. The responses were rated on a scale where 1= Not important 2= Slight important 3= Moderate important 4= Important 5= Very important. The findings were established in the table below.

Table 4.1: Constrains to market access

Constraints	Mean	Std. Dev.
Under developed healthcare infrastructure	4.257	1.542
Cost containment	4.531	1.537
Value based drug evaluation	3.854	1.511
Rebate system	3.712	1.507
Research and development	3.942	1.532
Setting up a manufacturing plant	3.414	1.514

From the findings in the table above, the majority of the respondents indicated that under developed healthcare infrastructure is a constrain to market access with a mean of 4.257; the respondents indicated that cost contained is a constrain to market access with a mean of 4.531; the respondents indicated that value based drug evaluation is a constrain to market access with a mean of 3.854; the respondents indicated that rebate system is a constrain to market access with a mean of 3.712; the respondents indicated that research and development is a constrain to market access with a mean of 3.942 and the respondents indicated that setting up a manufacturing plant is a constrain to market access with a mean of 3.414.

The study sought to determine whether the respondents review their market entry strategy. An overwhelming response by the respondents revealed that the firms review market entry strategies after every 2 to 3 years.

4.4.6 Biggest mistake in emerging markets

The study sought to determine some of the biggest mistakes made in emerging markets. The respondents identified some of the biggest mistakes made in emerging markets as: loss of customers; using lower prices of the products; overpricing of products; insufficient tailoring of approaches to local needs; lack of patience and long-term strategy; poor HR management and hiring vs. partnering strategy; underestimating challenges, risks, and investment needs; late/too slow decision making and execution and centralization.

The study sought to determine how the respondents have addressed the lessons learnt to change strategy in the Kenyan markets. The respondents indicated that their firm focuses on the quality of the products.

4.4.7 Entry strategies in emerging markets

The study sought to determine the entry strategies considered a priority in emerging markets over the next 5 years in Kenya. The responses were rated on a scale where 1= Not important 2= Slight important 3= Moderate important 4= Important 5= Very important. The findings were established in the table below.

Table 4.2: Entry strategies in emerging markets

Statements	Mean	Std. Dev.
Grow top line through safe launch of generic line	4.218	1.525
Gain market share through line extension	4.351	1.537
Optimize sales through franchise extension	4.422	1.538
Local operations like research and development	4.397	1.527
Research and Development	4.527	1.532
Sales excellence through Local Technical Office	4.681	1.547
Close collaboration with Government	4.324	1.524
Manufacturing with local partner	4.418	1.512
Influencing medical fraternity	3.981	1.504
Branding and Marketing through trade market protection	3.846	1.551

From the findings in the table above, growing top line through safe launch of generic line is an entry strategy in emerging markets with a mean of 4.218; the respondents indicated that gain market share through line extension is an entry strategy in emerging markets with a mean of 4.351; the respondents indicated that optimize sales through franchise extension is an entry strategy in emerging markets with a mean of 4.422; the respondents indicated that local operations like research and development is an entry strategy in emerging markets with a mean of 4.397; the respondents indicated that research and development is an entry strategy in emerging markets with a mean of 4.527; the respondents indicated that sales excellence through local technical office is an entry strategy in emerging markets with a mean of 4.681; the respondents indicated that sales excellence through Local Technical Office is an entry strategy in emerging markets with a mean of 4.681; the respondents indicated that Close collaboration with Government is an entry strategy in emerging markets with a mean of 4.324; the respondents indicated that manufacturing with local partner is an

entry strategy in emerging markets with a mean of 4.418; the respondents indicated that influencing medical fraternity is an entry strategy in emerging markets with a mean of 3.981 and that branding and marketing through trade market protection with a mean of 3.846.

4.5 Attitudes toward Prevailing Trend of Patent Cliff

The study sought to determine the effectiveness of the current strategy in light of the present patent cliff. The respondents indicated that the strategy adopted by the firm is very effective in light of the present patent cliff.

The study sought to investigate whether the organization has engaged in entry strategies in Africa. The respondents indicated their response as shown in the table below.

Table 4.3: Entry Strategies in Africa

Entry Strategy	Yes	No
Mergers	65%	35%
Acquisition	16%	84%
Partnership deals	72%	28%
Lawsuits on patent infringement	21%	79%
Branded generic/clone production	32%	68%
Innovation of new molecules	11%	89%

From the findings in the table above, the majority of the respondents (65%) indicated that the entry strategies in Africa that the organization was engaged in was mergers. 72% of the respondents indicated that the entry strategies in Africa that the organization was engaged in was partnership deals. However, the minority of the respondents indicated that 16% of the respondents indicated that the entry strategies in

Africa that the organization was engaged in was acquisition; 32% of the respondents indicated that the entry strategies in Africa that the organization was engaged in was Branded generic/clone production while 11% of the respondents indicated that the entry strategies in Africa that the organization was engaged in was innovation of new molecules.

The study sought to determine the local infrastructure considered most relevant for commercial success in Kenya. The respondents indicated that the local infrastructure include transportation, communication, human resource and networking with other pharmaceutical firms. These infrastructures were considered to be most relevant for the commercial success of pharmaceutical firms in Kenya.

4.6 Summary discussion

The respondents selected were people with knowledge and experience in strategy development and implementation in the different organizations in the Kenya Pharmaceutical market. The different MNCs indicated to have several drugs in the Kenyan market from their portfolio with loss of exclusivity strategies in place. Main therapeutic areas expecting growth were oncology, anti-infective and endocrinology drugs mainly as prescription only accessible. Emerging markets are expected t drive growth in the life science industry. The most important challenge identified was lack of a proper healthcare infrastructure, affordability and legal regulatory issues not ell defined. These are discussed in detail earlier and summaries in the next chapter.

CHAPTER FIVE

SUMMARY, CONCLUSION AND RECOMMENADTION

5.1 Introduction

This chapter covers the summary of findings, the conclusion and recommendations made on the competitive advantage of brand generic products through entry strategies adopted by multinational pharmaceutical companies in Kenya.

5.2 Summary of Findings

The research was conducted on a sample size of 15 Pharmaceutical MNC companies in Nairobi with targeted respondents were the Country manager, Regional Business Development manager and the Marketing Director or Manager in the Company. The study main objective was to determine if entry strategies influence competitive advantage of Pharmaceutical MNC in Kenya in light of the patent cliff.

Entry strategies influence competitive advantage of Pharmaceutical MNC in Kenya. The study identified some of the entry strategies considered a priority in emerging markets in Kenya. These were: grow top line through safe launch of generic line; gain market share through line extension; optimize sales through franchise extension; local operations like research and development; Research and Development; sales excellence through local technical office; close collaboration with government; manufacturing with local partner; influencing medical fraternity and branding and marketing through trade market protection.

It was established that the type of drug in the Kenyan market; those that have lost patent protection; loss of exclusivity strategy are in place; time period to loss of patent protection; therapeutic area expected high growth rate in Kenya in the next five years; generation of revenue by over the counter medicine versus prescription only

medicine; revenue before generic version of products entered in the market and revenue after loss of exclusivity and competition from generic version of drug in Kenya.

The study established that over the counter medicine (OTC) market, whereby customers can buy drugs or medicines without a prescription is increasing in value and volume across the world, with the potential for growth in emerging markets even more exciting. The respondents indicated that in recent years, the decline in the growth of the prescription-only sector is due to a number of factors such as: Lower value generics dominating large therapy areas; Demand-constrained payers needing to demonstrate better value for money disappointing growth from emerging markets and Life sciences research and development delivering fewer, high quality assets.

In contrast, the OTC market has experienced higher year-on-year growth as: Payers shift the cost burden of relevant diseases onto patients by promoting self-medication and the use of OTC medicines; Pharmaceutical companies seek to exploit switch opportunities the formal process of switching a prescription-only medicine to an OTC medicine to protect revenues from branded drugs that are about to lose their patent protection; new channels become available e.g. supermarkets and the internet increasing access to OTC medicines and emerging markets add critical mass to the patient population available for self-medication.

Intellectual property (IP) regulations are typically weak or poorly enforced in emerging economies. Governments of emerging economies argue that this is driven by the need to provide wide access to basic medicines for large but low income populations. Multinationals seeking to launch branded or original OTC medicines in

these markets need to consider the likely level of IP protection that is available and to what extent this will be enforced.

5.3 Conclusions

Competitive strategies are critical factors on entry strategies adopted by pharmaceutical firms. The study shows that in companies where product advantages provide very strong competition there was increased marketing. With competitive advantage in place, entry strategies ensure that the pharmaceutical firms are able to give quality output, increased quantity production, customers' satisfaction and amount of sales brought.

The findings on the strategies used by pharmaceutical to enter into the Kenyan market established that most of the pharmaceutical companies allow other companies to use their brands in marketing their products through licensing arrangement, followed by the pharmaceutical companies are using technology to manufacture products to ensure that they are of high quality to match customer specifications, the products are easily available, and the products are affordable. The least utilized marketing strategies included the distribution of pharmaceutical products handled by an agent or distributor.

The key challenges faced by pharmaceutical companies included poor infrastructural development driving up operational costs, rules on taxation were not fair, customers still relied on traditional medicine practices and there is a poor legal infrastructure. The least challenge was on the instability of the local currency leading to losses or uncompetitive pricing, huge investment outlay in buying state of the art technology for manufacturing pharmaceutical products, strong customer loyalty from

multinational pharmaceutical companies and the government is reluctant to develop and enforce laws protecting intellectual property rights.

5.4 Limitations of the study

The study cannot be used in general since it only covers one aspect of competitive advantage of brand generic products through entry strategies adopted by multinational pharmaceutical companies in Kenya while Pharmaceutical in the country is a broad industry compounding several factors of competitive advantage in Kenya there could therefore be other factors limiting entry strategies in the sector. A recommendation is for studies to be done on other aspects of entry strategy.

Due to time limitations the study was not able to identify all the policies in place in regards to Pharmaceutical industry. The bias in this study is on competitive edge. Since the sector deals with local consumers there could be some limiting policies that needs to be identified and can help the stakeholders as well as the government in coming up with effective policies to be put in place to broaden the scope of entry strategies adopted by multinational pharmaceutical companies in Kenya.

5.5 Recommendations

The study recommends that pharmaceutical MNCs should engage with emerging markets more closely. The study recommends that planning of loss of exclusivity should be an ongoing product lifecycle strategy initiated at the launch of the product up until loss of exclusivity. The study recommends that international business participant should have an understanding of economics, finance, marketing and strategy, a social understanding of culture and managing across culture. The brand drug manufacturers should plan and launch next generation line extensions with precision and advice from physicians and patients. The study recommends that the

patent protection should have lapsed and the corporation set up a defined strategy. The study also recommends that leaders should also understand where growth is concentrated, what challenges they are likely to face, and how to work collaboratively with health systems to overcome the barriers to fulfill Africa's full potential.

REFERENCES

Alaric D. (2011), *Branded generic offer new ways to reformulate drugs*, Drug Store News retrieved on 23rd August 2015.

Andrei A. (2012), Market reaction to FDA Announcements in the context of Patent Cliff, Aarhus University research paper

Andres W., (2013) Branded Generic Pharmaceuticals; Strategic Analysis and Comparison of the North American and Indian Markets, Applied Research project paper

A Sunny day in Pharmaland, The 2015 Pharma Report by MM&M, www.mmm-online.com, retrieved on 3rd July 2015.

Barasa A., (2013) Foreign Market Entry Strategies Used By Multinational Pharmaceutical Firms In Kenya, Research Project Submitted to School Of Business, University Of Nairobi.

Berndt E.R et al., (2007) Authorized generic drugs, price competition, and consumers' welfare, Health Aff/Pub Med (Millwood). 2007 May-Jun; 26 (3):790-9

Caves R.E et al., (1991) *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry* Brookings Papers on Economic Activity Microeconomics, 1991, p.p 1-66.

Chief Pharmacist, Ministry of Medical Services (2010), *Kenya Pharmaceutical Country Profile*, Published by the Ministry of Medical Services in Collaboration with World Health Organization.

Cui Q. (2014), *Generic Drug Industry*, The Henry B Tippie School of Management, www.HenryFund.org, retrieved on 3rd July, 2015.

David Reiffen and Michael R. Ward, *Generic Drug Industry dynamics*, published in The Review of Economics and Statistics, February 2005, 87(1): 37–49, 2005 by the President and Fellows of Harvard College and the Massachusetts Institute of Technology

Dipak C.J, James G.C (2012) Patent Expiry and Pharmaceutical Market Opportunities at the Nexus of Pricing and Innovation Policy, Insead University, Research and Working Paper

Donald A.B., (2010) Problems Facing the Pharmaceutical Industry and Approaches to Ensure Long Term Viability, University of Pennsylvania, Master of Science in Organizational Dynamics Theses

Dunne C. et al. (2013), A review of the differences and similarities between generic drugs and their originator counterparts, including economic benefits associated with usage of generic medicines using Ireland as a case study, Pharmacology and Toxicology 2013, 14:1, http://www.biomedcentral.com/2050-6511/14/1

Elizabeth W. (2012), Entry Strategies Adopted by Multinational Manufacturing Companies in Kenya, University of Nairobi, MBA research Project

Greg F., Cherry G., et al, (2006) *Global Business Entry Strategies*, University of Maryland, University College

Henrik A., (2013), Foreign market entry Strategies in developed and emerging economies, Unpublished Case study Norwegian University of Science and technology,

Harvard Business Review, 2005, *Strategies That Fit Emerging Markets*, hbr.org/2005/06/strategies-that-fit-emerging-markets retrieved from online article on July 4th 2015

Harvard Business Review, 2012 What Being Global Really Mean, hbr.org/2012/04/what-being-global-really-means retrieved from online article on July 4th 2015

Harvard Business Review, April 2012, What Being Global Really Means

Hollis A (2002). The Importance of Being First: Evidence from Canadian Generic Pharmaceuticals." Health Economics, Vol 11, pp. 723-734.

Jerry C. and Mark M., *How ACA Could Transform the U.S Pharmaceutical Marketplace*, Oliver Wyman, Health & Life Sciences publication

Jack N. B. (1992), *Theory in International Business*, School of Business Administration, University of Miami, Transnational Corporations, vol 1, no 1 pp. 93-126 February 1992.

Jon Hess et al. (2005), *Battle for the market: Branded drug companies' secret weapon generic drug makers must know*, Henry Stewart Publication, Journal of Generic Medicines, vol 3, no 1 pp 20-29 October 2005

Jonathan D. Rockoff, Dana Mattioli, Liz Hoffman (2015) Wall Street Journal, Business articles, *Teva-to-buy-allergan-generics-for-40-5-billion* retrieve July 27th 2015

Kate K. (2011), Approaching the patent cliff: how did we get here and what comes next, Generics & API Intelligence Thomson Reuters 2011.

Lamb M. (2008), *Branded Generics: Misunderstood, but lucrative*, Pharmacy Times publication

Mutambah E., (2012), Entry Strategies Adopted By Multinational Manufacturing Companies In Kenya, Research Project submitted to the University Of Nairobi, School Of Business

Ministry of Health (2014), Kenya Household Health Expenditure and Utilization Survey 2013.

Nicole G., (2006) The World's Top 50 Pharmaceutical Companies, *Changing Landscapes*, Special Report, www.pharmaexec.com, retrieved on 19th August 20, 2015.

Organization for Economic Corporation and Development report (2008), Pharmaceutical Pricing Polices in a Global Market, OECD publication www.oecd.org/publishing/corrigenda.org Paul B., (2013) Management decisions regarding end of patent strategies in the South African private pharmaceutical market, Gordon Institute of Business Science, research project published by the University of Pretoria 2014.

Peng M., (2009) Global strategic Management, 2nd edition

Pharmaceutical Price Controls in OECD Countries Implications for U.S. Consumers, Pricing, Research and Development, and Innovation, U.S. Department of Commerce International Trade Administration Washington, DC December 2004

Private Sector Innovation Programme for health (PSP4H), (2014), *Health Spending Behavior among Low Income Consumers in Kenya:* The myth That "The poor Can't Pay", Series No.15.

Rizwan A. (2014), *The Patent cliff: Implication for the Pharmaceutical Industry*, www.triplehelixblog.com, retrieved on 3rd July 2015

Salil P., *Impact of the Affordable Care Act on Pharmaceutical and Biotech industry*, Ockham development group, Paper PH-80

Scott G., (2012), what does a new drug cost? Part II: The productivity problem, online article on www.sciencebasedmedicine.org, retrieved on 3rd July 2015

Sigrid S., (2004), Patent and Access to Drugs in Developing Countries Ethical Analysis, Developing World Bioethics; 1471-8847 (online) Vol.4 No. 1 2004.

Silvia A. (2010), Authorized Generic Entry Prior to Patent Expiry: Reassessing Incentives for Independent Generic Entry, University of Munich Discussion Paper No. 2010-23

Silvia A. (2010), Entry and Competition in the Pharmaceutical Market following patent expiry, University of Munich Ph.D. Dissertation

Slovic P.t al., (2011), Making decisions about prescription drugs: A study of doctor-patient communication, Health, Risk & Society, 13: 4, 347 — 371

Stephen D., Matthias B., Susanne W. et al, (2013), *How emerging markets are driving the transformation of the Pharmaceutical Industry*, Strategy& report published by Booz & Company 2013.

Steve S. (2011), *Strategies for Drugs Going off Patent, PriceSepective*, Value Strategy Consultant, Gerson Lehrman Group

Tania H. et a, (2015) *Africa: A continent of opportunity for Pharma and Patients*, Insights into Pharmaceutical and Medical Products published by Mckinsey&Co, April 2015

Tim W., (2014) *Update and Implication of Obama care*, Mizuho Industry Focus Vol. 163

APPENDICES

Appendix I: Questionnaire for International Business Management M.B.A Research project

PA

PART	1: GENERAL INFORMATION
1.	Please indicate your current designation in the company?
2.	How long have you worked in your current position?
3.	What is the registered name of the company?
4.	How long have had business operations in the Kenyan market?
PART	2: MEDICINES IN THE PORTFOLIO GOING OFF PATENT
1.	Which drugs in your portfolio are in the Kenyan market?
2.	How many of these have lost patent protection?
3.	How many will lose patent protection?
4.	Do you have a loss of exclusivity strategy in place?
	a. YES NO
5.	What is the time period to loss of patent protection?
6.	In which therapeutic area do you expect high growth rate in Kenya in the next
	five years?
	a. Anti-infective drugs
	i. Antibiotics
	ii. Antivirals
	iii. Vaccines

b. Endocrinology drugs

- i. Lipid regulators
- ii. Anti-diabetics
- iii. Anti-hypertensive
- iv. Platelet Aggregate inhibitors(Anti-coagulants)
- c. Oncology drugs
 - i. Immuno-suppressant
 - ii. Immuno-stimulant
- d. Respiratory drugs
 - i. Asthma
 - ii. CoPD
- e. Central nervous system
 - i. Anti-epileptics
 - ii. Antipsychotics
- f. Analgesics
 - i. Narcotics
- g. Gastrointestinal
 - i. Anti Ulcerants
- h. Contraceptives
- i. Ophthalmology
- 7. Over the counter medicine versus prescription only medicine, which generate more revenue for your company in Kenya?
- 8. How your revenue before generic version of your product entered the market?
- 9. How is your revenue now after loss of exclusivity?
- 10. How do you describe competition from the generic version of your drug in Kenya?

PART 3 ADOPTIONS OF FUTURE STRATEGIES IN EMERGING MARKETS

1.	Who is involved in the planning, formulation, implementation and control of
	business strategies?

How important/potential are emerging markets to your company growth?
 (Please indicate the extent rate: 1. Not important 2. Slight important 3.
 Moderate important 4. Important 5. Very important)

1	2	3	4	5

- 3. What is the revenue contribution of emerging markets in your company now?
 - a. In the next 3 years?
 - b. In the next 5 years?
 - c. In the next 10 years?
- 4. Which emerging market do you consider relevant?
- 5. Which markets in Africa do you see growth?

Region	Countries	1	2	3	4	5
	Nigeria					
	Ghana					
	Liberia					
	Egypt					
	Kenya					
	Rwanda					
	Tanzania					
	Namibia					
	South Africa					

6. How do you rate the performance of the company since its entry into emerging markets?

$\overline{}$	XX 71 / 1	D 4	C	41	1		' 10
/	w hat I	Percentage	OŤ.	growth	nave	VOII	experienced?
<i>,</i> .	11 IIac I	i creciitaçe	U I	510 11 111	mu v C	, 00	emperiencea.

8. In order of relevance, how would you rate the following constrains to market access

(Please indicate the extent rate: 1. Not important 2. Slight important 3. Moderate important 4. Important 5. Very important)

	1	2	3	4	5
Under developed healthcare infrastructure					
Cost containment,					
Value based drug evaluation					
Rebate system					
Research and development					
Setting up a manufacturing plant					

- 9. Do you review your market entry strategies?
- 10. How long does it take to review?
- 11. What are some of the biggest mistakes you made in emerging markets?
- 12. How have you addressed the lessons learnt to change strategy in the Kenyan markets?
- 13. Which of these entry strategies do you consider a priority in emerging markets over the next 5 years in Kenya?

(Please indicate the extent rate: 1. Not important 2. Slight important 3. Moderate important 4. Important 5. Very important)

	1	2	3	4	5
Grow top line through safe launch of generic line					
Gain market share through line extension					
Optimize sales through franchise extension					
Local operations like research and development					

Research and Development			
Sales excellence through Local Technical Office			
Close collaboration with Government			
Manufacturing with local partner			
Influencing medical fraternity			
Branding and Marketing through trade market protection			

PART 4 ATTITUDES TOWARD PREVAILING TREND OF PATENT CLIFF

- 1. How effective is your current strategy in light of the present patent cliff?
- 2. Has our organization engaged in the following entry strategies in Africa:

Mergers	
Acquisition	
Partnership deals	
Lawsuits on patent infringement	
Branded generic/clone production	
Innovation of new molecules	

- 3. What is the companies stand on rebate facility in the international market?
- 4. How would you welcome such a government intervention over pricing considering the generic version might be pleased with such a decision?
- 5. Which local infrastructure do you consider most relevant for commercial success in Kenya?
- 6. Do you expect other pharmaceutical companies to apply similar go-to market models in emerging markets as in mature markets?
- 7. Any other comments...

Appendix II: Pharmaceutical MNCs with Local Representative Office

Source: "The World Top 50 Pharmaceutical Companies" 7th annual report by Nicole Gray, retrieved on 19th August 20, 2015.

- 1. Pfizer
- 2. GlaxoSmithKline
- 3. Sanofi-Aventis
- 4. Novartis
- 5. AstraZeneca
- 6. Johnson & Johnson
- 7. Merck & Co.
- 8. Eli Lilly
- 9. Roche
- 10. Boehringer-Ingelheim
- 11. Schering-Plough
- 12. Bayer
- 13. Novo Nordisk
- 14. AbbVie
- 15. Gilead Sciences

DECLARATION

I declare that this is my original work and has not been presented in any other
University or College for Examination or Academic purposes.
Signature: Date 19/10/15
MAINA CATHERINE MWENDWA
D61/60207/2013
This project has been submitted for examination with my approval as the university
supervisor.
Signature: Date
Myaf! 19/10/2018
Supervisor: Dr. JOHN YABS
Lecturer,
School Of Business Administration,
University Of Nairobi

Clean S.t. 311
CHAIRMAN CHA
DEPARTMENT OF BUSINESS ADMINISTRATION MBA PROJECT SUPERVISION ALLOCATION FORM SECTION A: (To be completed by the student) all details are mandatory.
Name of student. CATHERING MICENSWH MATINA Mobile phone No. D.721-276654
Reg. No. DG1 60207 2013 Email address Munacot 69 49hpp. com
Proposed Title of the Study A CROSS SECTIONAL STUDY OF THE PHARMACEUTICAL INDUSTRY ENTRY STRATEGY OF ORAMBED GENERIC PRODUCTS IN KEMYA-
Specialization (Tick as appropriate)
Marketing [] Human Resource Management [] Strategic Management [] International Business [] Insurance / Risk Management [] Other (specify) []
Preferred Supervisors (in order of preference): 1
SECTION B: (To be completed by Allocation Committee)
Name of Supervisor Allocated. Ar J - Yab 5 Mobile No
Name of Co-Supervisor, if any
Total number of students allocated to the supervisor within the year to date
Name of person who will Moderate the Proposal hof, J. Munyoki
Committee Secretary:
Name
Thematic Coordinator:
Name Signature Date
Chairman of Committee: Name br - 1 - Yabs Signature Date 17/07/15
Chairman of Department;

Note:

1. This form is available in the department. Students get their copies later from the department after allocation is done.

2. The approved copy of this must be attached to the proposal when submitting for moderation and presentation.

Original to be filled in the Department Copy 1 (photocopy) to be filed by Thematic Coordinator Copy 2 (photocopy) to be filed by the Supervisor Copy 3(photocopy) to be filed by the student

UNIVERSITY OF NAIROBI

SCHOOL OF BUSINESS

PROPOSAL CORRECTION FORM

Student Name MAINA CANHOLING MWENDWA
Registration Number 661 60207 2013
Department BUSANESS ASMIMISTRATION
Specialization. INTERMATIONAL BUSINESS
Title of Project Proposal.
PRODUCTS 1HLDUGH GILL SILATGGE ADPTES BY MULTI HIPTOPH PHILL PHILL COMPANIES IN ILEMYA - The student has done all the corrections as suggested during the Proposal Presentation and cannow proceed to collect data.

Name of Supervisor AR - JOHN YABS Signature Myst Date 4/9/15



UNIVERSITY OF NAIROBI

SCHOOL OF BUSINESS
MBA PROGRAMME

Telephone: 020-2059162 Telegrams: "Varsity", Nairobi Telex: 22095 Varsity P.O. Box 30197 Nairobi, Kenya

DATE # 19/2013

TO WHOM IT MAY CONCERN

The bearer of this letter CANHENIHE MWC/SWA MAINA

Registration No. 561 60207 2013

is a bona fide continuing student in the Master of Business Administration (MBA) degree program in this University.

He/she is required to submit as part of his/her coursework assessment a research project report on a management problem. We would like the students to do their projects on real problems affecting firms in Kenya. We would, therefore, appreciate your assistance to enable him/her collect data in your organization.

The results of the report will be used solely for academic purposes and a copy of the same will be availed to the interviewed organizations on request.

Thank you.

MBA ADMINISTRATOR
SCHOOL OF BUSINESS

66