

St. Mary's University, School of Graduate Studies

Trademarks in Pharmaceuticals Infringement and Ethical Issues in Retail Outlets: The Case of Addis Ababa, Bole Sub city

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Addis Ababa, Ethiopia

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Declaration

I, Bemnet Girma, ID# SGS4Z/0351/2005, declare that the materials used for writing of this thesis have been acknowledged and the thesis is my original work prepared under the guidance of my advisor, Dr. Elias Nour. All sources of materials used for the thesis have been duly acknowledged. I confirm that the thesis has not been submitted either in part or in full to any other higher learning institution for the purpose of earning any degree.

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February, 2016

Endorsement

This thesis has been submitted to St. Mary's University, School of Graduate Studies for examination with my approval as a university advisor.

Advisor

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February, 2016

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TABLE OF CONTENTS

Acknowledgement	vi
List of Acronyms	ix
List of Figures	X
Abstract	xi

CHAPTER ONE

1. IN	TRODUCTION	1
1.1.	Background of the study	1
1.2.	Statement of the problem	3
1.3.	Research Question	4
1.4.	Objective of the study	4
1.4	.1. General objective	4
1.4	.2. Specific objective	5
1.5.	Definition of terms	5
1.6.	Significance of the study	5
1.7.	Scope and limitation of the research paper	6
1.8.	Organization of the paper.	6

CHAPTER TWO

2. R	EVIEW OF RELATED LITERATURE	7
2.1.	Definition of Trademark	7
2.2.	Trade mark versus Brand	8
2.2	.1. Definition of Pharmaceutical trademarks	9
2.2	.2. Selection, clearance and registration process for pharmaceutical trademarks	10
2.3.	Objective and function of trademarks	12
2.3	.1. Objective and functions of Trademarks	12
2.3	.2. Friends and families of Trademarks	13
2.3	.3. The role of pharmaceutical trademarks	14
2.4.	The need for protection of pharmaceutical trademarks	15
2.4	.1. The need for protection of pharmaceutical trademark	17
2.5.	International perspective	18
2.6.	Trademark and developing countries	19
2.7.	Trademark infriengment as a cultural element	20
2.7	.1. Trademark infringement in pharmaceuticals	21
2.8.	Source of infringement or unfair competition	21
2.8	.1. Law of unfair competition on similarly deceptive pharmaceutical products	22
2.9.	Ethical branding and corporate responsibility	23
2.10.	Nature and characteristics of infringement	23
2.11.	Last words in literature	24
CHA	PTER THREE	
3. R	ESEARCH DESIGN AND METHODOLOGY	25

3.1. Research design	25
3.2. Sampling and sampling techniques	26
3.3. Data Source	27
3.4. Data collection instruments and data collection method	27
3.5. Method of data analysis	
3.5.1. Qualitative data analysis	
3.6. Ethical Consideration	29

CHAPTER FOUR

4.	RESUL	TS AND DISCUSSION	30
	4.1 Chara	acteristics of the study participant	30
	4.2 Trade	emarks in Ethiopia: The law and practice	31
	4.2.1	Overview of Generic Drugs and Drug Naming	31
	4.2.2	Relevant laws on trademarks	33
	4.2.3	Deposition of pharmaceutical trademark	36
	4.2.4	Empirical analysis of marks registered	37
		Establishment of Ethiopian Intellectual Property Authority and its impact on	
	4.2.5	Trademark protection	38
	4.2.6	Arbitration of trademark infringement in Ethiopia	39
	4.2.7	Lists of some cases	40
	4.3 Attitu	ides toward the severity of the problem	41
	4.4 Knov	vledge of the dispenser on the existing policies and guidelines	41
	4.5 Expe	riences with infringed products and measures they are taking	41
	4.6 Effec	t of infringed products on prescription and consumers	42
	4.7 Is sal	es of infringed ethical?	42
C	HAPTER	A FIVE	
5	CONCI	LUSIONS AND RECOMMENDATIONS	43
	5.1 Conc	lusions	43
	5.2 Reco	ommendations	44
	5.3 Futu	re researches	44
	Referenc	es	46
	Question	naire	48

LIST OF ACRONYMS/ ABBREVATIONS

- EIPA Ethiopian Intellectual Property Authority
- EPRDF Ethiopian People's revolutionary Democratic Front
- FDA- Food and Drug Administration
- FDCA Food, Drug and Cosmetic Act
- FMHACA Food, Medicine and Health Care Administration and Control Authority of Ethiopia
- ICT- Information and communication technology
- INN International Non Proprietary Name
- IP- Intellectual property
- MOTI The Ministry of Domestic Trade
- TRIPS- Trade Related Intellectual Property System
- USAN United States Adopted Name
- USPTO United States Patent and Trademark Office
- WHO- World Health Organization

List of figures

Figure 1. Study participants by year of experience in the industry	
Figure 2. Sex composition of the study participants	

Abstract

This study was aimed assessing the situation of deceptive trademark infringements in pharmaceutical business and assess the ethical valuation of the business in the retail outlets in the context of Bole sub city, Addis Ababa, Ethiopia. Besides, the assessment of perceived effect on prescriptions and patients was covered in the study. A descriptive type of study was adapted with the application of both qualitative and quantitative methods. A total of 40 pharmaceutical retail outlets and 40 members of these pharmaceutical retail outlet management and dispensers were involved in the study as respondents. The selection of the retail outlets was made following a systematic random sampling technique while that of the selection of the staff was done via purposive sampling technique. In addition, existing policies were reviewed as source of data for the study. Semi structured questionnaire, interview guide, document review checklist and observation checklist were used to collect data on the variables of the study. The finding of the study revealed Ethiopia has placed sound policy and guidelines to control infringed pharmaceutical products; infringed pharmaceutical products sale is common in the retail outlets; and it does have some level of effect on prescription and negative effect on patients. It also indicated as some of the dispensers think it is ethical to engage in such trade though most of the dispensers reported as they think differently. As a way forward to address the problem and protect patients, recommendations are forwarded. These include, assuring the availability of

drugs in the market with a fair price and make a strict control on distribution. It is also recommended that FMHACA has to play the leadership role in assuring the availability of the drugs and the effectiveness of the control system.

CHAPTER ONE

INTRODUCTION

1.1 Background of the study

Companies whether multinational or national need to produce and offer a product or a service to their customers to stay in business. According to Peter F. Drucker (1971), there is only one valid definition of a business purpose: "To create a customer". And the way businesses create and manage customers varies from one organization to another within one industry and from industry to another industry. Even the physical boundary of countries plays an important role on how businesses create customers and on the general business framework and environment.

Different businesses choose diversified strategies to attract and maintain customers, for satisfying the customer is the sole raison d'etre for businesses. One obvious reason as to why customers are always attached to businesses is the provision of goods and services by the businesses. In other words products and services are the attaching agents between customers and businesses. There are, however, many companies which provide a single product or service to similar groups of customers with a competitive or even a lower price. When it comes to consumers, most products now meet an adequate standard (Cairncross, 2002)

Trademark is a word, phrase symbol or design, or a combination thereof that identifies and distinguishes the source of the goods of one party from those of others (Debra A., 2007). It generally creates expectation with respect to the quality and characteristics of the products concerned, and therefore serves as an important informational tool that consumers use to evaluate different products (OECD, 2007).

A trademark could determine the success or failure of a company in this globalized world (Franklin, 2005). It can give a competitive advantage for the one who use it properly and it is also a means of reducing unfair competition. Trademark to a manufacture or a merchant represents something akin to that which a flag of a country represent to a loyal citizen. They are badges of honor, distinguishing marks, emblems to be proud of, to be kept above reproach and with spotless reputation (Geier, 1934:69)

A company's brand or trademark worth as much as the tangible assets of the company (Franklin, 2005). A study for identifying companies whose brand names or trade names and trademarks worth the highest among the world's largest multinational companies indicated that Coca Cola's brand equity is \$67 billion followed by Microsoft's \$61 billion (The global Brand Scorecard, 2004). This account for the total asset of many large companies summed up and clearly indicates that the trademarks, trade names and good will of companies in undertaking business need to be protected from illegal and unfair use.

Pharmaceutical trademarks are used to differentiate between identical products manufactured by the same company or concern (Stuyck, 1983). It plays an important role by allowing health care professionals to minimize prescription errors, allow consumers to readily identify the specific medications they are taking and also allow drug manufacturers to monitor their products, and to take steps to fight counterfeiting as well as providing manufacturers with the incentive to develop new drugs (Debra A., 2007).

The development of pharmaceutical trademark for a new product is a complex process that involves legal, regulatory, linguistic, and marketing considerations (Debra A., 2007). Drug companies use several criteria in selecting a brand name or trademark. First and foremost, the name must be easy to remember. Ideally, it should be one physician will like, short and with a subliminal connotation of the drug. Gone are the days when the brand names were decided on gut feel or company's employees could submit their favorite name ideas to executives who would choose arbitrarily among them. Today drug companies hire branding consultants two or three years before their drug hits the market to craft a powerful, unique name that will entice physicians and patients. It also takes expertise to create any original name. To develop a trade name, drug-makers often work with branding agencies that use massive databases to help them generate unique names. Marketing departments are often very influential. The cost of the consultation depends on the number of names to be evaluated and ranges from \$100,000 to \$700,000. There must be no trademark incompatibilities, and the company must take account of the drug's expected competition (Gangwal, Amit&Gangwal, Ankit, 2011).

Trademark infringement is a violation of the exclusive right attached to a trademark without the authorization of trademark owner. Infringement may occur when one party the "infringer", uses a trademark which is identical or confusingly similar to a trademark owned by

another party (en.m.wikipedia.org). The consequences of marketplace confusion between similarly deceptive pharmaceutical trademarks can be serious. According to the FDA, medication errors injure about 1.3 million people annually and cause at least one death every day in the United States. A significant percentage of those injuries result from prescription communication errors and dispensing errors that result from pharmaceutical name confusion. Even though such an error should not be a reflection on the safety of the prescribed drug, the reality is that bad publicity resulting from a prescription error can harm the marketability of a drug and the viability of the trademark that identifies it (Concannon&Hymel, 2006).

Even in those well developed countries, similar deceptive trade mark is becoming an issue of discussion for different companies. Similar problems also exist in Ethiopia, even though Article 21(2)(a) of Proclamation No. 685/2010 prohibits "any act that causes or is likely to cause confusion with respect to another business person or itsactivities, in particular, the goods or services offered by such business person". This mainly emanates from gaps in law enforcement level of public awareness. Therefore, these similarly deceptive pharmaceutical trademarks create difficulties for consumers to get their proper medication and lead them to wrong medicine with greater degree of toxicity and complications, extra cost which finally impact on their health status. Moreover, pharmaceutical companies with the right product run the risk of losing their goodwill and trust from their customers due to the failure of the medicine. Thus the company ends up losing its market share. And ultimately, the aggregate loss incurred by such companies with the real product adversely affects the economic and social benefits at the national level.

1.2 Statement of the problem

Intangible assets that a company possesses have significant value in the creation and maintenance of its customers. Moreover, the monetary value of these intangibles may worth as high as half of the worth of the whole company, they have to be protected through any means just like the protection given to tangible assets that the company owns and manages.

Trademark is said to be the pillar for a company with a certain products. Pharmaceutical business experiences show that building a product with a certain trademark requires a good quality of ingredients that persist for a long period of time without compromising quality and efficacy, with regard to good compliance in favor of consumers. Once its existence is realized, it

is up to the company to safeguard its product name, so as to steadily benefit from its income. But sometimes it is common to see similar trademark on the market and lose its market share.

This research focused on the real existence of similar deceptive trademark in pharmaceutical products and its consequences mainly, from the business aspect of one product over the other and health impact of consumers. It may have a serious impact on the health status of the consumer. They may develop blindness, kidney faller, gastrointestinal irritation and so on. These unwanted side effects of the drug will lead them to another cost in terms of their financial as well as health status of the consumers. In addition, this infringement cases may cause a lot of investment for the manufacturers as well as importers.

1.3 Research Questions

a) What is the nature and magnitude of trademark infringement in Bole Sub City of Addis Ababa, Ethiopia Pharmaceutical market?

b) What are the effects of deceptive trademark pharmaceutical products on the dispensing pattern of health care professionals and their consumers?

c) What are the ethical issues in deceptive trademarks in Bole Sub city Pharmaceutical market in Addis Ababa, Ethiopia?

1.4 Objective of the study

1.4.1 General objective

The general objective of the study was assessing the situation and ethical valuation of deceptive trademark infringements in pharmaceutical business in retail outlets in the context of Bole sub city, Addis Ababa, Ethiopia.

1.4.2 Specific objectives

a) To identify similar deceptive trademark generic products with its country of origin.

4

b) To assess the impact of trademark infringement on the dispensing pattern of the health care professionals.

c) To determine ethical issues in deceptive trademarks.

1.5 Definition of terms

Trademarks – words legally registered or established by use as representing a product.

Pharmaceutical trademarks- name given to the drug by the pharmaceutical company

Brand name- a name given to the drug by the producer pharmaceutical company

Health care professionals - all professionals who dispenses pharmaceutical products in the retail outlets.

Consumers- Patents who take pharmaceutical products

1.6 Significance of the study

The finding of this research paper is important for healthcare professionals and consumers who need utmost precautions against making medical error due to the confusion of infringed pharmaceutical product trademarks. Due to deceptive pharmaceutical products, an awful result can happen on the health of the consumer. Thus, to protect our citizens from this disaster, all the concerned bodies' should act before the situation gets out of control.

In addition, this study recommends a solution for pharmaceutical importers from losing their goodwill and being discouraged to import the specific brand product to their customers. Thus improper or illegal use of pharmaceutical trademarks done to deceive users of one business with or without the knowledge of the existence of the mark in market will create an opportunity for unfair competition. Unfair competition is the passing of, or attempt to pass off, the goods or business of one person, and any conduct, the natural or probable effect of which is to deceive the public and to pass of the goods or business of one person for that of another amounts to actionable unfair competition (<u>www.wipo.org</u>, 2012 Geier, 1934, and Franklin, 2005). This should be avoided and seriously handled, since customer deception will lead to losing market

and sales and ultimately results in delivering poor quality products. Therefore, researching trademark related issue as a means of protecting unfair competition is advisable and appropriate.

Finally, this research serves as an input for supplementary studies on pharmaceutical trademarks to be conducted by others.

1.7 Scope and limitation of the research paper

The scope of the research covers the effect of pharmaceutical trademark infringement on the retailers and importers from their business perspective as well as on the health of the consumers in Bole sub city and the ethicality of pharmaceutical trademark infringement against the law of the country. The limitation of these paper is time constraint and budget.

1.8 Organization of the paper

The study consists of five chapters; chapter one starts discussion by indicating the importance of protecting pharmaceutical trademarks. Explanation of the statement of the problem, objective, significance and scope of the study will further enhance the knowledge of the reader consecutively.

Chapter two discusses the literature review which shows the nature and finding of related literature to trademark practices. The third chapter briefly states the design and methodology of the research in this thesis. The fourth chapter discusses the analysis of the core themes of the paper and indicates the results or findings of the study. And finally the fifth chapter concludes on the basis of the findings on fourth chapter and states some recommendations to be followed.

CHAPTER TWO

LITERATURE REVIEW

Information age comes with huge opportunities that are impossible to overlook and difficult threats that are unthinkable to ignore. The issue of trademark is on such phenomenon. When it comes to building a trademark the internet makes the task easier in some ways, harder in others (Cairneross, 2002: 53)

Building trademarks involve analysis of three disciplines: economics, law, and management. Just as it is term tuned in three disciplines, it has many names and it is subjected to multiple theories which at times are contradictory but mostly supporting one another as supplementary. For instance, in management a trademark can be a brand whereas in law it is an intellectual property that should be protected. An economic overview of trademarks demonstrates an issue indicating the economic policies of the nations about intellectual property.

This chapter deals with the discussion of some basic concepts about pharmaceutical trademarks and consists of five sections. First section provides definition of pharmaceutical trademarks and its relation to brands and other intellectual property elements. The second section discusses the role of trademarks in pharmaceutical and the need for its protection. The third section discusses the law of unfair competition on similarly deceptive pharmaceutical trademarks.

2.1 Definition of trademarks: an overview

As communication technology advances, words and phrases also changes. A single word takes multiple meanings in a single situation and at times a word can have varying interpretations in different cultures. There is multiplicity of adjectives used in an industry in particular, with meanings that often are neither discrete nor clear. At its worst, this reflects widespread confusion in the field; at best exciting innovation and development (Jevons, 2005: 117). This scenario is exaggerated when it comes to trademarks.

Many authors and scholars give multiple definitions which are most of the time alike but sometimes even tricky to differentiate. The following paragraph discusses three of the widely accepted definitions: • A trademark includes any word, name, symbol, or device, or any combination used or intended to be used, in commerce to identify and distinguish the goods of one manufacturer or seller from goods manufactured or sold by others, and to indicate the source of goods. In short the trademark is a brand name (<u>www.uspto.gov</u>, 2012)

• A trademark is any (poison), name (Giorgio Armani), symbol or device (the Pillsbury Doughboy), package design (coca-cola bottle) or combination of these that service to identify and distinguishes a specific product from others in the market place or in trade. Even a sound (NBC chimes) color combination, smell or hologram can be a trademark under some circumstances. The term trademark is often used interchangeably to identify a trademark or service mark (www.inta.org, 2011)

• Any sign or any combination of signs, capable of distinguishing the goods or service of one undertaking from those of other undertakings, shall be capable of constituting a trademark. Such sign, in particular words including personal name, letters, numerals, figurative elements and combination of colors as well as any combination of such signs, shall be eligible for registration as trademarks, where signs are not inherently capable of distinguishing the relevant good or services (TRIPS, 1994)

A trademark is applied or attached either directly on the product, on the paperwork, on the packaging, or the prints that make the offer of the products, as well (Abebe, 1997).

2.2 Trademark versus Brands

There is a general misconception about the meaning of trademarks and brands. Customers usually mix up brands with trademarks. If, For instance, we take marketers and legal personnel in a certain organization, while the marketer is solely concerned about brands in their products, their legal counterparts are debating in courts about their trademarks. Furthermore, the way the marketer understands trademarks is completely different from the legal personnel. There is a pure confusion in defining brands and trademarks (<u>www.wipo.org</u>, 2012).

A trademark, as discussed previously, is any word or slogan that indicates the origin of products separating them from other similar products by other manufacturers. A trademark indicates neither the type nor the quality of a product it is representing. It can be attached to multiple products which are produced and designed in a single company. For instance, the trademark Toyota exists in all brands of the company like Camry, Carrina, Corolla, Prado, Rav 4 and others as well.

Brand on the other hand is a name, symbol, design or some combination which identifies the product of a particular organization as having a substantial, differentiated advantage (O' Malley, 1991; 107 In Rooney, 1995). The American marketing association defines a brand as a name, term, sign, symbol or design or some combination of them intended to identify the goods or service of one seller and to differentiate them from competitors (Keller and Kotler, 2006). Thus the brand indicates the type of product rather than the organization. It shows quality than origin. A brand is thrust worthy mainly because trust is what secures loyalty. It is means of differentiating a product and an emotional attachment between the consumer and the product.

Sometimes it is possible to have companies with product brands similar to their trademarks. A well known example for this is Coca Colla, the soft drinks, having the brand of the company's trademark (Xie and Boggs, 2006). Ambo, the mineral water, is a local example sharing this concept.

In all situations, there exists a blurred periphery between what a brand is and what a trademark is. As a result of this and other reasons mentioned below, trademarks and brands are treated alike in definitions as well as interpretations in this study.

2.2.1 Definition of pharmaceutical trademarks

Pharmaceutical trademarks are either arbitrary, created names or compositions of the company name of the manufacturer and the international non-proprietary name (INN) pertaining to the active ingredients of the pharmaceutical product (M.Eckhartt, 2013/14).

Pharmaceutical trademarks are made up of words coined to convey a sense of power or speed or tranquility without promising a cure. A brand name is a composition of individual sounds called phonemes, which represent attributes. If these attributes are desired by consumers, they would want to try them instantly (Gangwal, Amit&Gangwal, Ankit, 2011).

Government agencies in charge of intellectual property protection support the business of pharmaceuticals by protecting scientific ideas and inventions using patents, goodwill capitalized in product brands using trademark rights, and also by promoting the proper usage of such Intellectual Property (IP) rights. It is generally assumed that patent protection of pharmaceutical products is achieved solely by a basic substance patent covering the original new active ingredient. In fact, the marketability and competitiveness of medicine relies on the portfolio of patents to protect not only the ingredient, but also its use, process patent, formulation, production intermediates, any related derivatives, and the methods for evaluating diseases markers. The patent portfolio protects the entire business linked to a particular medicine (Yamada, 1995-2014).

2.2.2 Selection, clearance and registration process for pharmaceutical trademarks

Pharmaceutical trademarks are unique due to safety concerns and the chemical nature of the products. A pharmaceutical trademark must avoid confusion with the chemical and generic names of the drug. For instance in the United States, to market a pharmaceutical product a US adopted name (USAN) a generic nonproprietary name must first be obtained. Existing USAN stems that describe the substance, its action or its use should be employed. The USAN is reviewed by the World Health Organization (WHO) to ensure international harmonization.

The WHO also assigns a unique, international nonproprietary name (INN), which is typically identical to the USAN. In the United States, two government agencies with independent statutory authority, purposes and goals oversee the approval of pharmaceutical trademarks: the US Patent and Trademark Office (USPTO) and the Food and Drug Administration (FDA). The Lanham Act grants the USPTO the authority to review and register federal trademarks. Federal registration is not a prerequisite to obtaining trademark rights; however, there are significant advantages to registration, including: presumption of the validity, ownership and exclusive right to use the trademark; constructive notice to third parties; possibility of incontestability after five years; federal court jurisdiction; possibility of treble damages and attorney's fees; and bar to the import of goods bearing infringing and counterfeit marks.

USPTO considerations when assessing an application include whether the mark is sufficiently distinctive and there is a likelihood of confusion with respect to other registered marks. The 'likelihood of confusion' test considers factors such as: similarities in marks, relatedness of goods/services, and relatedness of trade channels, market conditions, and the number and nature of similar marks in use on similar goods. While federal registration of a pharmaceutical brand is not mandatory prior to use, FDA approval is. The FDA's authority to evaluate and regulate pharmaceutical brands is rooted in the Federal Food, Drug and Cosmetic Act (FDCA). Under the FDCA, a drug is misbranded when "its labeling is false or misleading in any particular". Various divisions of the FDA oversee the review process of proprietary drug names, which includes promotional and safety reviews of the proposed names. The promotional reviews evaluate whether the proposed name is overly fanciful, so as to be misleading. The safety reviews involve various methods, including: preliminary screening to identify common errors; USAN stem search; orthographic/phonological similarity assessment, using the 'lookalike/sound alike' test; and drug database searches/computational method and/or prescription studies.

USPTO registration is awarded to the party which is first to file and perfect filing by establishing use. However, FDA approval depends on the lookalike/sound alike test and how quickly the FDA application moves through the approval process. Thus, there exists a potential priority battle between the two agencies (Gilsone & Lione, 2012).

In Ethiopia, where the core element of this paper is done, legally registering trademark is practiced (<u>www.fmhaca.gov.et</u>, 2015). Though, the idea of intellectual property (IP) is in its infancy stage now in Ethiopia, it needs to be supported by researches and studies emphasizing a holistic approach than individualistic differentiation. Hence, differentiating the words and treating them separately is important when it is possible to give a holistic diagram.

Accordingly when it used in phrases like "trademarks should be protected" and "trademark registration and arbitration", it can be equally and interchangeably used as "brand should be protected" and "brand registration and arbitration" respectively as of now.

2.3 Objective and function of trademarks

It has been recognized that the foundation of the business is built upon the significance and guarantee conveyed to the purchasing public through the medium of particular mark, names or symbols applied by the organization (Geier, 1934:69). Consequently, it is safe to say that trademarks are always inseparable with commerce (Abebe, 1997). And a business without appropriately designed mark is doomed to fail in the long run.

2.3.1 Objectives and function of trademark

It has been recognized that the foundation of the business is built up on the significance and guarantee conveyed to the purchasing public through the medium of particular marks, names or symbols applied by the organization (Geier, 1934: 69). Consequently, it is safe to say that trademarks are always inseparable with commerce (Abebe, 1997). And a business without appropriately designed mark is doomed to fail in the long run.

Trademarks have manifold advantages and functions when applied properly. It can provide two major objectives: Economic and Social; which are both of vital importance to the buyer and seller in the course of commerce. The economic objective of a trademark is reflected from three perspectives: owner consumer and the economic policy of the nation. A company's trademark is an asset or equity having a monetary value and like all other tangible assets, it can be sold, bought and franchised. When a product or group of products manufactured by different companies is of the same standard, price become more important variable in purchasing selection. However, consumers can make their own purchase decision based on trademarks, since they convey a certain life style or set of ideas. Therefore, trademarks reduce confusion in decision making when the information available is not adequate. And it also helps in economizing decision making by reducing the time needed. The social objective of the trademark is closely related to that of safeguard the public from mistake, deception and confusion, which is usually termed as unfair competition (Abebe 1997, Tesfaye, 1998 and Franklinn, 2005).

Trademarks in addition to distinguishing products, have multiple other benefits which if applied properly will lead to competitive advantage. They can be used to show quality and functionality of products in directly by associating a certain product to attributes such as after sale service, reliability, timely delivery, technological advancement and other characteristics of the producer produced and distributed by a single manufacturer. Therefore, a trademark on the product answers the question "where did this come from" (Franklin, 2005).

In general trademark perform four functions (Miller and Davis, 1994) namely,

- Product differentiation
- Indication of source
- Standard uniformity
- As a prime instrument advertising and selling of goods and service

2.3.2 Friends and families of trademark

Trademark is misconceived with other related elements which usually come associating it. Some major misconceptions are clarified in the following paragraphs.

A. Trademarks versus Trade Names

A trade name is the name of a business (Franklin, 2005) through which the business undertakes trade and uses it to communicate with others. A commercial name or trade name- the two expressions mean the same ting- is the name under which a person operates his business and which clearly designates the business (Art 135 of Commercial Code of Ethiopia). A trade name unlike a trademark is not required to be physically attached either to the goods or packeges (of products) (Colombia Law Review, 2001). Example of trade names: The Coca Colla Company where the trademark is Coca Colla and Microsoft when the name is Microsoft Corporation, etc.

B. Trademarks versus Trade Dress

A trade dress is the total image of business (Rosen and Alpert, 1994). It shows not only the trademark or trade name of the business but also the overall environment of including the colors, sounds and arrangements. It is overall graphics and shape of a product or its packaging adopted to distinguish goods and services from those of others (Franklin, 2005) A trade dress is infringed if the total combination of the colors, shapes and graphics can make sense to the consumes of a business and if they are used as a promotional means.

C. Trademarks versus Copyright and Patent

Trademarks, Copyright and Patents belong to a large category of industrial properties which in turn is part of the broader concept of intellectual property. The difference lies in the fact that trademark by no means indicates an innovation or exploration of something whereas copyright and patent are always associated with discoveries.

D. Trademarks versus Service marks

While a trademark as the name implies, is used for trading, service mark is used in service organizations such as governmental offices, Nongovernmental organizations and others. Service marks are used for indicating the source of service or product in some cases. TM is used to indicate the trademark of the business which is not registered where asSM is used for unregistered service marks (Franklin, 2005).

2.3. 3 The role of Pharmaceutical Trademarks

a) Trademarks Assist Health Professionals Reduce Medication Errors

The rigorous process of selecting a trademark is designed to ensure that the mark is truly unique and distinctive. There is no reason to believe that a drug naming system that relies exclusively on generic names would reduce medication errors that are attributed to name confusion. Indeed, if required to rely exclusively on generic names, many physicians, pharmacists, nurses, and others could encounter difficulty in remembering and properly spelling such names, and would be more likely to be confused by the close similarity of many generic names for pharmaceuticals in the same category, which would likely result in many more errors. By using unique trademarks for each drug, health professionals have a much easier time ensuring that the right medication is being given to the patient (Debra A., 2007).

b) Trademarks Help Consumers Choose the Right Medications

Once consumers find a brand name drug that works for them, they are often reluctant to change to another drug, particularly a generic version, where such is available. In some cases, the generic just does not seem to work as well, perhaps due to the particular consumer's reaction to different inactive ingredients in the new drug. For some, it can also simply be the peace of mind that comes with taking the brand name product that they are familiar with and know is made in a consistent manner that they can rely on. Either way, that comfort level would be lost if drugs were only to be identified by their generic name. In addition, with the advent of direct-toconsumer advertising in many countries, including the United States, consumers are able to learn much more quickly about the availability of new potential treatments for their medical conditions. Such advertising would be far less effective in informing the public of innovative medications if manufacturers were forced to use only complicated, confusing generic names for their products rather than more readily remembered trademarks. Being able to identify a drug by its trademark is also helpful to consumers in the rare event of an adverse reaction. Identifying a particular manufacturer's drug would be extremely difficult if the drug were known only by the generic name. Thus, using trademarks for pharmaceuticals allow the consumer to easily identify the source of any problems they might experience (Debra A., 2007).

c) Trademarks allow manufacturers to monitor their products

The use of trademarks enhances manufacturers' ability to monitor the safety of existing drugs. Reports of adverse events that only mention the generic name of a drug would not aid manufacturers in determining whether their drugs were involved, and would result in time-consuming as well as costly investigations and safety checks that could be avoided if the particular manufacturer involved in an incident were readily identifiable, as it is when the trademark is known. Pharmaceutical trademarks also facilitate taking legal action against counterfeits. If drugs are only marketed by their generic name, it would be difficult to know if a particular formulation is being counterfeited. Additionally, customs enforcement at country

borders to stop trafficking in counterfeit products would be virtually impossible without trademark identification (Debra A., 2007).

2.4 The need for protection of trademarks

Customers neither have the interest nor the courage to look into the ingredients and company name of a product but they do have the urge to look in to the brand that the product bears. A trademark is widely regarded as the most vulnerable asset as well (Fan, 2005). A trademark represents every component of a product summed. In short it is the soul of the product (Geier, 1934).

In today's hotly competitive environment, managers must make optimal use of relevant regulations and laws in order to protect their products from being copied (through the effective use of trademarks) (Rosem and Alpert, 1994). This can be attributed to the fact that trademarks represent critical issues for organizations such as the good will of the owner in undertaking commerce, the company's corporate structure and overall corporate responsibility. A trademark has the capacity to shift customer buying behavior in favor or against.

Moreover, trademark infringers neither produce a quality product nor sell it with a competitive price. Therefore, the company's existence is challenged by the poor product produced and the lower price charged to customers. And its future will be in great jeopardy unless some action is taken, if possible in a proactive manner or reactively (Rosem and Alpert, 1994).

As the number of imitator brand has risen, so too have legal actions for trademark infringement and passing off, because of consumer confusion, unfair misappropriation of brand owners intellectual property, and lost sales revenue (Mitchell, 2002).

The principles of trademark protection throughout the world make up a complex body of law which differs in many respects among different countries (Mitchell, 2002). No given country objects the need for protection of trademarks and all other intellectual properties (TRIPS, 1994). Conferences have been held, meetings were prepared to come up with a consensus to use some common ground on the protection and regulation of trademarks throughout the world. And as a consequence some common standards have been established which every nation require for the protection of marks (TRIPS, 1994).

Distinctiveness

A trademark must be one of that can uniquely identify a product as originating from one source and thus distinguishing it from those coming from another. What the law everywhere does require is that the mark must be "distinct". It allows the owner to communicate symbolically with the public in identifying his/her product and assuring them that the mark appearing there on is a unique product (Gabey, 1981 in Abebe, 1997).

Need for use

A trademark not used does not have a value in the eyes of the judges and does not have any legal premises. More than registration, marks need to be used so as to appeal for protection against illegal use. Without active selling methods the trademark serves no purpose, for its existence can be bypassed extremely easily through employing another name (something which is generally much more complicated to do in the case of a patent) (Xie and Boggs, 2006)

Nations widely differ on how they implement and use registration process. The variation also affects what is a valid trademark and what is not. With all this differences, however, the only way to acknowledge the proper use of a mark by business is registration. \mathbb{R} is used to signify those trademarks which are registered in their country's register center where as TM is used for those used but not registered marks (Franklin, 2005).

2.4.1 The need for protection of pharmaceutical trademarks

Customers neither have the interest nor the courage to look into the ingredients and company name of a product but they do have the urge to look into the brand that the product bears. A trademark is widely regarded as the most vulnerable asset as well (Fan, 2005). A trademark represents every component of a product summed. In short it is the soul of the product (Geier, 1934).

The 2007 Report of the World Health Organization on Look-Alike, Sound-Alike Medication Names began with the statement, "The existence of confusing drug names is one of

the most common causes of medication error and is of concern worldwide". With an estimated 24,000 therapeutic healthcare products currently on the Canadian market, there are likely numerous drug name similarities. Studies have found that errors in drug use are common, costly and often result in injury to patients. The policy considerations relating to mistake of pharmaceutical products are clear. The elderly and most vulnerable members of society are particularly at risk. The use of the correct product can be life-enhancing and even life-saving for a patient. Conversely, in the event of an error, the use of the incorrect pharmaceutical product can have serious and even deadly consequences. There are few other products for which the consequences of a mistake can be so serious. It is important that purveyors of healthcare, including pharmacy technicians, nurses, doctors and pharmacists, be able to easily and accurately determine whether they have selected and are dispensing and administering the correct pharmaceutical product. It is equally important that patients be confident in the system and not be subjected to the stress of uncertainty as to whether they are using the correct pharmaceutical product, particularly when they are seriously ill. While these concerns have sometimes been considered in likelihood of confusion cases in Canada, most decision makers agree that Canadian trademark law is not to be used to determine whether the co existence of two pharmaceutical trademarks is likely to lead to a "mistake." Guarding against trademark confusion between pharmaceutical trademarks is also important from a financial perspective. Pharmaceutical companies spend large amounts of money and expend significant efforts in marketing a particular brand, and therefore it is important that all of the traditional trademark protections be available to pharmaceutical manufacturers (R.Sim&E.Robertson, 2008).

2.5 International perspectives

Globalization result in boundary-less trading between companies and the existence of multinational firm relay on the underlying concept of globalization. Globalization offers plenty of benefits to both MNC's and developing countries. The consumers in the developing nations will have a better quality options for their needs and the multinational firms will have an opportunity to exploit new market and tackle the fierce competition that they face in their homeland (Xie and Boggs, 2006).

This success story has its own pitfalls particularly in the prevention of unfair competition and reaching the final consumers with the proper and right way. Multinational firms face difficulty when trying to protect the industry related intellectual property components of the products or service that they are selling in the foreign markets. Especially if the products are new to certain nations, there is a great possibility of being imitated by other law priced product.

To tackle such problems WTO has made it mandatory to state policies in protecting trademarks and other intellectual properties of all other member countries (TRIPS, 1994). Developing countries particularly face difficulty in enforcing such claims mainly due to the fact that the foreign products are highly priced when compared to the purchasing power of the local community. To change this trend both the WTO and WIPO have facilitated training program for higher policy officials of country representatives to enhance awareness in their home nations.

Moreover, to reduce the administrative obstacles that multinational firms face when dealing with patent and trademarks cases in foreign countries, some actions have been taken in the past 15 years. Consequently, the Madrid system for trademark registration and protection has been crafted to enable MNC's to register trademarks once in the Madrid Registration Center. And then they will be entitled exclusives rights to use the marks.

The establishment of the WIPO, an institution that handles and coordinates activities related to intellectual property is a major achievement, is also another important achievement throughout the world that handles and coordinates activities related to intellectual property. EIPI is working with WIPO to establish standards and code of actions that enhance its operations when dealing with businesses.

2.6 Trademarks and Developing countries

Information and communication technology has enabled MNC's to reach to customers in world wide. The market that MNC's have been capitalizing is no more a motivation to them since companies targeting these customers are expanding. And as a result MNC's are facing a fierce competition in their homelands from other manufactures. Moreover, emerging markets are a key factor in the future growth of the world economy, offering tremendous growth opportunities firms from developed countries such as USA and the member of EU (Xie and Boggs, 2006). These necessities the MNC's to go for new markets and target new customer group in emerging markets and developing countries.

Resource abundance does not benefit the developing in fulfilling the growing demand of their people. Most developing countries are characterized by the surplus of import commodities. However, importing certain goods with or without local offices for the products manufactured outside creates a possibility of inappropriate use of product related element, including trademark.

Bitzenis and Ersanja (2005), while discussing the major obstacles for entrepreneurship in businesses environment that are in transition (case of Albania), found out that one of the three major impediments that negatively affect entrepreneurship is unfair competition which is far from being prevented by the largely ineffective legal infrastructure. The probability is high for MNC's to face a vital risk in trademark infringement and in the general protection of the intellectual property while opening business in developing countries.

Legal infrastructure has proven to be soft to solve trademark infringement cases particularly in developing nation. And local government officials have huge responsibility in changing this trend as means of cheering foreign investors. Moreover, MNC's need to follow a new brand strategy when initializing a market in developing nations: like following corporate branding than product branding (Xie and Boggs, 2006).

2.7Trademark infringement as a cultural element

Trademarks are subject to multiple studies and theories. Unfortunately, the divergence in perspective of trademarks creates confusion among literatures of the different field (management, law and economics). To make it worse, legal issues have been entertaining new aspects. In positively shaping the attitude the local community toward the issue of intellectual property theft or infringement, the local government needs to shape the idea of the local community about intellectual property and their benefit to the society in question. Clearly IPRS have serious economic and political implication (Berrell and Wrathell, 2007). And this is especially the case in both the newly industrialized countries and emerging market economies which are generally characterized by an embryonic legal infrastructure (komen et al, 1994 in Berrell and Wrathell, 2007). Therefore it is healthy and manageable to change the attitude of local community about IPR than trying to enforce legal measurement.

For instance China, the population of more than 1.5billion, is highly condemned for copycatting all intellectual properties (<u>www.wipo.org</u>, 2012). Nowhere in the world exist as high

infringement cases as in China. The local and regional governments in China have tried to implement some legal measurement which results even in an augmentation on the number of pirates.

2.7.1 Trademark infringement in pharmaceuticals

Trademarks are multiple theories and studies. Unfortunately, the divergence in perspective on the trademark creates confusion among literatures of the different field (Management, law and economics). To make it worse, legal issues have been entertaining new aspects.

Trademark infringement is a violation of the exclusive rights attached to a trademark without the authorization of the trademark owner or any licensees (provided that such authorization was within the scope of the license). Infringement may occur when one party, the "infringer", uses a trademark which is identical or confusingly similar to a trademark owned by another party, in relation to products or services which are identical or similar to the products or services which the registration covers.

Trademark protection is very important for the pharmaceutical industry in order to generate revenue for continued research for new drug product to bring into the market for pharmaceutical product the question of induced and contributory infringement becomes quite complicated in certain situation. In different countries, the courts have delved in great details, the different facets and issues involved in contributory infringement and have pronounced land mark judgments' (Banerjee &Panikar, 2003).

2.8 Sources of infringement or unfair competition

There is an unsettled debate among lawyers and law practitioners on whether to define unfair and use it accordingly or to list all those action that might result in unfair competition (Montague, 1995). On one hand, defining the law and forwarding statements crate confusion since most legal actions are subject to interpretation. And on the other hand, listing all actions related to unfair method of competition cannot go in line with the ferocity and speediness of the invention of unfair competitors. Nearly all normal business men can distinguish between "fair competition" and "unfair competition". Efficiency is generally regarded as the fundamental principle of the fair competition-efficiency in production and selling, while oppression or advantage obtained by the deception or some questionable means is the distinguishing characteristic of "unfair competition" (Cong. Rec, 1915). Accordingly there has been an ongoing practice to identify major activities that might result in unfair completion and source of imitation.

2.8.1 Law of unfair competition on similarly deceptive pharmaceutical products

The law of unfair competition includes several related doctrines. Nevertheless, some courts have attempted to simplify the law by defining unfair competition as any trade practice whose harm outweighs its benefits. The U.S. legal system is a corner stone of the free enterprise system. But the freedom to compete does not imply the right to engage in predatory, monopolistic, fraudulent, deceptive, misleading, or unfair competition. On balance, competition becomes unfair when its effects on trade, consumers, and society as a whole are more detrimental than beneficial. When competitors share deceptively similar trade names, trademarks, service marks, or trade dress, a cause of action for infringement may exist. The law of unfair competition forbids competitors from confusing consumers through the use of identifying trade devices that are indistinguishable or difficult to distinguish. Actual confusion need not be demonstrated to establish a claim for infringement, so long as there is likelihood that consumers will be confused by similar identifying trade devices.

The law of unfair competition helps protect consumers from injuries caused by deceptive trade practices, the remedies provided to redress such injuries are available only to business entities and proprietors. Consumers who are injured by deceptive trade practices must avail themselves of the remedies. In general, businesses and proprietors injured by unfair competition have two remedies: injunctive relief (a court order restraining a competitor from engaging in a particular fraudulent or deceptive practice) and money damages (compensation for any losses suffered by injured business) (kinter, 1971).

The Ethiopian Trade Practice and Consumers' Protection Proclamation No.685/2010 provides for protection against unfair competition under Article 21. Unlike Article 39(2) of TRIPS, the protection against unfair competition concerns any information, whether the owner has kept the information as confidential or not. The prohibition of unfair competition also includes comparative advertisement falsely or in equivocal manner. Such prohibition does not cover generic manufacturers request for marketing authorization based on bioequivalence and other comparative presentation of information to regulatory authorities. It will, however, affect their marketing (e.g., announcement that the generic company is manufacturing the generic version (brand x) of the originator drug (brand y)). Unlike the Proclamation, the Directive for the Regulation of Promotion & Advertisement of Drugs (2008) appears to permit comparative, advertisement when it states under paragraph 12.4 that "Comparisons of products must be factual, fair and capable of substantiation."

2.9 Ethical branding and Corporate Reputation

With the continuous advancement and technology, most consumer products have become a kind of commodity, i.e. there are fewer and fewer genuine and tangible differences between competing offers. This provides brand advertisers with a powerful tool to manipulate the consumer's emotion in order to achieve brand differentiation (Fan, 2005).

A brand simply becomes the easy target or scapegoat for corporate misbehavior. Unethical branding can be prevalent in companies with less corporate responsibility. If marketing is like some researchers believe, the most prone to unethical behavior due to its inherent attributes, then branding must share some of the blame (Fan, 2005).

The above statements indicate that a good brand emanates from a highly reputable company which cares about the future and have a strong corporate responsibility.

2.10 Nature and characteristics of infringing companies
In satisfying the need and wants of the society, businesses follow and take different business ideologies and strategies. For it is the sole definition of a business to satisfy the society (Drucker, 1971), it is necessary for business to follow distinct and stylish strategies to cope up with the environmental needs. Time is a witness as to the number and quality of techniques businesses have followed in interacting with customers. Successful and successive innovation is one way as highly customer orientation in a company (j. Peters and H.Watterman, 1982).

The nature and characteristics of businesses illegally using products, services, marks and trade names of other highly profitable and successful companies share some common elements (Franklin, 2005). These are business which

- Lack vision related to the business
- Lack strategy to make the vision a reality
- Lack adequate knowledge on managements
- Are highly concerned with high profits
- Lack adequate knowledge of the business legal frameworks
- Lack deep urge to work with customers
- Lack corporate responsibility

Consequently, it can be easily concluded that the products and services from these organizations are of low quality and often highly priced sold and offered for customers which are option less.

2.11 last words in literature

Despite the fact that intellectual property is an issue, it takes only a glance to understand unfair competition and act of illegal trade practices in the pharmaceuticals market of Bole Sub city, Addis Ababa, Ethiopia. Even though, the legal statement is there, still deceptive pharmaceutical exist in the market.

CHAPTER THREE

RESEARCH DESIGN AND METHODOLOGY

Research methodology

This chapter focuses on the research design, sampling instrument, data collection and data analysis.

3.1Research design

Research design is a blue print for selecting the sources and types of data relevant to the research questions. It basically, provides answers for such questions like: what techniques to be used to gather data? and what kind of sampling to be applied? (Zikgmund et al., 2003). This research adopted cross sectional descriptive type of research design. The choice of the research design was dictated by the purpose of the study. The study described the effect of trademark in pharmaceuticals infringement retailers, present the ethical issues that are related to the infringement and its effect to the retailers and customers' interims of the customers complain. To collect data the research employing large number of people questioning about their attitudes and opinions towards the specific issue, events or phenomena (Marczyk&Dematteo,

2005). It also enables the researchers to effectively administer and manage the tasks when the data collection takes place. In light of this, the study was predominantly qualitative with some quantitative methods. Mixed method is considered as a tool to triangulate the result of single approach through multiple methods (Johnston, 2010). These methods were employed in the effort of responding to the research questions and with a view to addressing the objectives of the study. Qualitative method was used to assess the perspectives of the pharmacist or druggist regarding the ethical issues that are related to infringement and the nature and effect of trademark infringement in the business; on the other hand, the quantitative method was applied in the assessment of the magnitude of the infringement, its effect on prescription and customers' complaint.

3.2Sampling and sampling techniques

Study population and sampling frame

The populations of the study were the retailers of pharmaceutical products in Bole Sub city of Addis Ababa, Ethiopia. The data from FMHACA shows as there are 200 retailers. Thus, the sampling frame was the list of retailers in Bole Sub city. Besides, the management body members of the retailers and dispensers involved in the direct sales of the items were considered as elements of the population.

Sampling technique

The sampling technique applied in the selection of samples for the study was systematic random sampling. In some instances, the most practical way of sampling is to select every ith item on a list. Sampling of this type is known as systematic sampling. An element of randomness is introduced into this kind of sampling by using random numbers to pick up the unit with which to start. The sample size is limited, as the study will target only 20 percent of the total pharmacies. A sample size between 5-20% is ideal to represent the entire population according to Amedeho (2002). Accordingly, given that 20 per cent sample is desired, the first item was

selected randomly from the first five and thereafter every 5th item were automatically included in the sample; making the total retail outlet selected 40.

The total population is 200

Desired sample size is 20% which is 40

Thus, the first ith item should be selected from the first five items 200/40

The first item selected using a lottery method was the 5th retail out let on the list

This is because the first number selected randomly from the first 5 was the 5th retailer. In systematic sampling only the first unit is selected randomly and the remaining units of the sample are selected at fixed intervals.

Although a systematic sample is not a random sample in the strict sense of the term, it is often considered reasonable to treat systematic sample as if it were a random sample. Systematic sampling has certain plus points. It can be taken as an improvement over a simple random sample in as much as the systematic sample is spread more evenly over the entire population. It is an easier and less costlier method of sampling and can be conveniently used even in case of large populations(Kothari, 2004). Nevertheless, there are certain dangers too in using this type of sampling. If there is a hidden periodicity in the population, systematic sampling will prove to be an inefficient method of sampling. Yet, given the absence of periodicity in the pharmaceutical in this study, the method appears appropriate.

Based on the selection of the retail outlet, one pharmacist/druggist from the selected retailer waselected using simple random sampling and participated in the study as a respondent. The selection of dispensers and management members was done using purposive sampling technique. Some types of research design necessitate researchers taking a decision about the individual participants who would be most likely to contribute appropriate data, both in terms of relevance and depth (Paul, 2005). The purposive sampling technique is a type of non-probability sampling that is most effective when one needs to study a certain cultural domain with knowledgeable experts within. Purposive sampling may also be used with both qualitative and quantitative research techniques. The inherent bias of the method contributes to its efficiency, and the method stays robust even when tested against random probability sampling(Tongco,

2007). In connection to this, 40 dispensers and management members who were found to having more stay in the retail outlet and the management were included. In most cases, the dispensers and the management were found to be managed by the same person. Where there was only one pharmacist, the available pharmacist was included in the study.

3.3 Data sources

Primary sources of data were used in the study. The primary sources of data were the management members of the pharmaceutical outlets; dispensers working as dispensers at retail pharmaceuticals shops in Bole Sub city of Addis Ababa. In addition enterprise policies, list of items in the shops and records of complaints were used as a source of data.

3.4 Data collection instruments and data collection method Data collection

Primary data were collected from pharmacists/druggist of the retail shops using a semi structured questionnaire through questionnaire and interview guide. Checklists were used on the review of the lists and review of documents. Secondary data were collected from various literatures and enterprise policies and other relevant documents.

Questionnaires were used to collect data on the variables of the study. The nature of variables addressed through the different data collection tools are discussed hereunder.

The questionnaire was used to collect data on the location of the retail out lets, characteristics of respondents including sex, years of work experience the attitude and perception of the dispensers on product counterfeiting in the pharmaceutical market of Ethiopia and ethicalness. In addition their knowledge of policies and strategies that deal with pharmaceutical trademark infringement framework in Ethiopia, measures they take to avoid/minimize the possibility of being affected by deceptive products, the major suppliers for the stores, the country of origin for medicine with infringed trademarks, manufacturers and suppliers of the products, the legitimacy of their suppliers and the manufacturers; how they verify the legitimacy of the manufacturers and suppliers before they buy the products; presence of any similar deceptive pharmaceutical trade mark in their outlet, and their experience in buying deceptive products were collected using the questionnaire. Moreover, data on the name of the generic products that have trade mark infringement; trademarks and the frequency of the experience of facing such

infringements (by product and supplier) at the outlet and the price deferential with the original one were generated using the questionnaire.

3.5 Method of data analysis

3.5.1 Qualitative data analysis

The qualitative data analysis involved thematic coding of transcribed and translated interviews recordings and observations. Data was analyzed and compiled using a thematic approach by conducting an ongoing content analysis of the transcripts (Patton, 1990). Data analysis based on various strategic options was utilized. These include categorization via chronology, key events, settings, relationships, people, processes, and issues (Patton, 1990). Emerging themes were developed and expanded as a result of the interviews. The constant-comparison method as developed by Glaser and Strauss (1967) was used to create categories of relationship between data units. The qualitative data analysis on the data collected using document review was analyzed using a narrative approach.

3.6 Ethical consideration

The data collectors obtained informed verbal voluntary consent after fully informing the research respondents about the purpose of the research. In disclosing the information the methods and procedures to be followed; foreseeable risks and discomforts; extent of confidentiality and expected benefits to respondents as well as the community at large and the nature of the participation expected of the respondents was clarified.

CHAPTER FOUR

RESULTS AND DISCUSSION

4.1 Characteristics of the study participants

The characteristics of the respondents of the study were assessed to see the extent to which they are in a position to provide appropriate data for the purpose of the study. The major variables considered important in this regard were the professional background of the study participants and their year of experience in the field. Besides, to take account of the attitudes and perceptions both sexes towards infringed products, the sex of the dispensers participated in the study was analyzed.

Figure 1.below shows that all of the respondents have experience in the industry. Looking at the year of experience, around 38 percent of the study participants had 3-5 years of experience in the pharmaceutical industry, around 30 percent had experience of 11-15 years, 25 percent had experience of 6-10 years. More interestingly, around 8 percent of the study

participants were veterans with experience of more than 15 years. This implies that the study participants are well positioned to provide accurate data on the subject of the study.



Figure 1. Study participants by year of experience in the industry

Source: (Own Survey, 2015)

As can be seen from figure 2 below, the majority of the study participants were male. Around 63 percent of the respondents were male while only around 38 percent were female. This is actually the result of the fact that most of the professional workers in Ethiopia are male due to historical and cultural factors. Yet, the sex composition of the respondents could be taken as sufficient to entertain the views of both sexes.



Figure 2. Sex composition of the study participants

4.2 Trademarks in Ethiopia: The law and practice

In this section, multiplicities of issues related to trademarks in Ethiopia are discussed. It is to be noted that most of the information contained in this chapter are gathered through interviews carried out in pharmacies and drug shops, questionnaires distributed to business and with the help of secondary data sources.

4.2.1 Overview of Generic Drugs and Drug Naming

Time is a witness for the escalating private sector involvement in the economic activity of Ethiopia. Two decades back economic activities had been dominated by the state ownership of almost all economic sectors. But after the introduction of market led economy by the Ethiopian Peoples revolutionary Democratic Front (EPRDF) and subsequent privatization policies, dramatic growth in private business has been noted.

The government is paving the way for foreign investors to invest in Ethiopia through different incentive packages which range from small scale tax exemptions to provision of lands with less or no cost (EIA, Internal Activity Report, 2005). Consequently, the number of foreign investors in Ethiopia is increasing gradually (Melat, 2007). To further encourage foreign direct investment, the government has been spending a lot in the development of basic infrastructure.

This being positive development, the increasing number of small and medium level businesses is creating critical problems as most of trademark imitators are likely to be small and medium enterprises (Dodd and Zaichkwosky, 1999). Furthermore, the present legal structure is neither sufficient nor explained enough to support the current composition and structure of businesses (Tesfaye, 1998).

The fact that Ethiopia is on the process of joining WTO is also a critical issue that should be consider with respect to trade mark registration and arbitration of its infringement. This is vital since WTO requires every member country explicitly state and implements various policies supporting the protection of foreign trademarks.

Recent actions, however, signify trademark and other intellectual property elements will have a protection under a government authority. The establishment of EIPA implies the government's commitment towards protecting intellectual property rights, which helps all parties involved in the course of business and increases the confidence of customers on businesses.

Drugs often have several names. When a drug is first discovered, it is given a chemical name, which describes the atomic or molecular structure of the drug. The chemical name is thus usually too complex and cumbersome for general use. Next, a shorthand version of the chemical name or a code name (such as RU 486) is developed for easy reference among researchers.

When a drug is approved by the Food and Drug Administration (FDA—the government agency responsible for ensuring that drugs marketed in the United States are safe and effective), it is given a Generic (official) name and Brand (proprietary or trademark or trade) name

When a drug is under patent protection, the company markets it under its brand name. And, when the drug is off-patent (no longer protected by patent), the company may market its product under either the generic name or brand name. Other companies that file for approval to market the off-patent drug must use the same generic name but can create their own brand name. As a result, the same generic drug may be sold under either the generic name or one of many brand names

Generic and brand names must be unique to prevent one drug from being mistaken for another when drugs are prescribed and prescriptions are dispensed. To prevent this possible confusion, the FDA must agree to every proposed brand name.

Government officials, doctors, researchers, and others who write about the new compound use the drug's generic name because it refers to the drug itself, not to a particular company's brand of the drug or a specific product. However, doctors often use the brand name on prescriptions, because it is easier to remember and doctors usually learn about new drugs by the brand name.

Recent action, however, signify that trademarks and others essential intellectual property elements will have a protection under a government authority. The establishment of EIPA implies the government's commitment towards protecting intellectual property rights, which helps all parties involved in the course of business and increases the confidence of customers on businesses.

4.2.2 Relevant laws on trademarks

The Commercial Code

Businesses are ruled and guided by the commercial law. It facilitates the course of trading. The following statements are derived from the Commercial Code.

Article 133- Cases of unfair competition

• Any act of competition contrary to honest commercial practice shall constitute a fault

The following shall be deemed to acts of unfair competition

• Any acts likely to mislead customers regarding the undertaking products or commercial activities of competitor;

• Any false statements made in the course of businesses with the view of discrediting the undertaking products or commercial activities of the competitor.

Article 134- Effect of unfair competition

• The court may, in cases of unfair competition;

• Order the damages to be paid by the unfair competitor

• Make such orders are necessary to put an end to the unfair completion

The court may in particular

• Order the publication, at the cost of the unfair competitor, of notices designed to remove the effect of misleading acts or statements of the unfair competitor, in accordance with Art. 2120 of the civil code.

• Order the unfair competitor to cease unlawful acts in accordance with Art. 2122 of the civil code.

Article 140- Definition

• A distinguishing mark is the name, designation, sign or emblem affixed to the premises where the trade is carried on and which clearly designated the business.

• The use off the mark is not compulsory.

The Civil Code

Article 2057 stipulates that a person commits an offence where, through falls publications or by other means contrary to good faith, he comprises the reputation of a product or the credit of a commercial establishment.

Article 2122 is concerned with the mode of compensation. As per the article the court may order abandonment of the dishonest practices used by the defendant.

The Criminal Code

Article 720(1) of the 2004 Criminal Code provides the following with regard to infringement of marks:

"Whoever intentionally

a) Infringes, imitates or passes off, in such a manner as to deceive the public, another's mark or distinctive signs or declarations of origin on any produce or goods or their packing, whether commercial or industrial or agricultural; or,

b) sells or offers for sale, imports or exports, distributes or places on the market produce or goods under a mark which he knows to be infringed, imitated or passed off improperly affixed; or

c) refuses to declare the origins of the produce or goods in his possession under such marks

35

shall be punishable with rigorous imprisonment not exceeding ten years".

The Criminal provision is self explanatory and there is no need for further explanation. Rather, we can, in short, say once a trademark right is ascertained, it is protected pursuant to the above provision and the offender is punishable. Under Article 674 of the 1957, the punishment was with simple imprisonment or fine. Moreover, the case was initiated upon complaint of a party that is affected by the infringement. However, such complaint is not necessary under the current Criminal Code and the punishment is graver than the previous punishment of simple imprisonment or fine.

Trademark Registration and Protection Proclamation No. 501/2006

The latest legal statement governing and managing the use of trademarks in Ethiopia is the Trademark Registration and Protection Proclamation No. 501/2006. It, not only, defines right and wrong action of trademarks but also explains the duties and responsibilities of all bodies such as the EthiopianIntellectual Property Authority. It has the following components:

- Part 1- General provisions
- Part 2- Acquisition of rights and registration of trademark
- Part 3- Procedures for registration of trademark
- Part 4- Collective trademarks and well know marks
- Part 5- Duration and Renewal of registration of trademark
- Part 6- Rights conferred by Registration and license contracts
- Part 7- Renunciation, cancellation and invalidation of right on registered trademark
- Part 8- Enforcement of Rights
- Part 9- Miscellaneous provision
- The pharmaceutical trademark law by FMHACA

• Brand (Trade Name)-Generally the first and the last three letters of any trade name should not be identical with a registered product in Ethiopia (www.fmhaca.gov.et)

4.2.3 Deposition of pharmaceutical trademark

In the absence of trademark law, the practiced of depositing trademark and issuance of certificate of deposit has been practiced in MOTI (The Ministry of Domestic Trade) as of 1978. The Proclamation in practice with this regard was Proclamation No 4/1978 Article 14. Currently pharmaceutical products registration is carried out through FMHACA. The registration process allows the screening of valid mark from invalid and ends in a cautionary notice to notify the healthcare professionals about the trademarks and thereof about the owner of the mark.

Up on completion of the pharmaceutical products registration and affirmative process, the importer will be entitled the right to use the mark on the pharmaceutical products that it offers. To guarantee this, the owner or importer of the pharmaceutical trademark will be presented a certificate that will be used in the case of infringement. The owner or pharmaceutical importer will be protected by the law of for the coming five years with renewal. Nevertheless, not all of the trademarks for which applications are filled would qualify for registration (Abebe, 1997 and Public proclamation No. 501/2006 Art. 6 and Art.7)

Intellectual property rights is a pharmaceutical company's most valuable asset and IP protection is essential to the success of pharmaceutical and pharmaceutical outsourcing industry. In Intellectual property right Trademark protection has important status and it has significance in pharmaceutical company.

Trademark protection applies to words, short sentence, and symbols the manufacture used to identify and distinguish their products from those of others. The name of pharmaceutical companies and the pharmaceutical products are invariable trademarked.

In most countries in the world, the use of a trademark will not give you any exclusive rights to that trademark or any legal protection against unauthorized use of that mark by third parties. Only on the basis of a registration will you be able to take action against trademark infringement by third parties who use your product names, designs, logos, or packaging without

your permission. And, if you do not register your trademark, you may even risk that at a later stage you will no longer be able to use that trademark because a third party has successfully registered it.

4.2.4 Empirical analysis of pharmaceutical trademarks registered

The number of registered pharmaceutical trademarks in Ethiopia is bit by bit increasing mainly due to the increasing pressure from the government and by increasing number of foreign firms. Comparison of the number of registered pharmaceutical trademarks from local companies and foreign companies working in Ethiopia clearly shows that the number of foreign registered marks is higher than the local one's. This can be attributed to many reasons of which lack of awareness among local business on how to use and register trademarks takes the lion share (EIPA, Internal Activity Report, 2006).

The high number of registered foreign trademark is due to the high level of awareness among foreign business about trademarks and intellectual property. In general, the practice of registering trademarks, both for local and foreign companies, is increasing steadily.

4.2.5 Establishment of Ethiopian Intellectual Property Authority and its impact on trademark protection

Ministry of Trade and Industry has been carrying out the process of trademark registration since 1978 upon the assignment by public proclamation no. 4/1978. As it is not compulsory to register trademarks as is registering businesses, the process is barely practiced resulting in a few numbers of the registered trademarks. On the other hand unfair competition is increasing and creating critical problems to local investors (FHC, Internal Activity Report, 2006)

To minimize the adverse effects of stealing intellectual property right on investment, EthiopianIntellectual Property Authority (EIPA) is established for registering, controlling and guiding the use of trademarks and other intellectual property components. EIPA is now exclusively responsible government agent for issues related trademarks.

The major duties of EIPA are

• Registration and protection of trademarks

- Registration and protection of copyrights
- Registration and protection of patents

Each component of intellectual property has its own offices and experts handling its activities. The trademark registration and protection office perform the following activities.

- New registration of trademarks
- Renewal of registered marks
- Change of the name of the owner of the trademark

• Merger of companies and thus stopping the use of two marks and starting a new trademark

- Change of the address of the owner
- Document copy for international business
- Substitution of certificate if lost or damage
- Returns if the owner does not want to use the trademark anymore

Registration and renewal of trademarks are the major activities.

Establishment of the EIPA has its own influence on intellectual property protection legal structure and on the attitude of the public (both individual and businesses). In addition to the activities mentioned above, the authority organizes a negotiation process to arbitrate an infringement case before going to court. This is helpful since most disagreements on trademarks can be solved on primary negotiation between the infringer and the mark owner (EIPA, Internal Activity Reports, 2006).

These activities, however, are not without their obstacles. Some of the major challenges that EIPA faces and has to deal with are (EIPA, Internal Activity Reports, 2006)

• Absence of integrated action from concerned government and private bodies

• Lack of properly collected and organized data about businesses

• Absence of trademark attorneys specializing in protection and assessment of trademarks

• Inadequate information among businesses about the existence of EIPA and its operations

• General lack of public awareness about EPIA

4.2.6 Arbitration of trademark infringement in Ethiopia

Nothing has ever transformed the way we do business and we live in general more than information and communication technology (ICT) (Marcus and Watters, 2002). Easy access to information on trademarks around the world increases awareness of trademarks already in use. However, this some information can prompt companies to use trademarks used in other distant countries for two reasons: the lack of knowledge about legal implications and the owner company operates far away.

When trademark infringement cases are arbitrated, the number of government agents involved in solving the disputes can vary from one case to another. And, the process can also vary from case to case.

As it is the duty of the owner of a trademark to protect and forbid illegal use of trademarks, the owner takes the first move by warning the infringers and warns customers to take care when buying its product. If the illegal user does not refrain from using the marks, the owner informs EIPA for possible reminders and actions.

Then EIPA facilities process of arbitration by negotiation and try to settle the case between the parties through discussion. If this does not satisfy the plaintiff, the case goes to the FHC to be handled according to public proclamation No. 501/2006. The decision of the court will be implemented in all other government as well as private business bodies. The court decision could take one or more of the following forms

- Prohibition of using the mark by both the infringer and the owner
- Import restriction of the infringer
- Imprisonment and fine

4.2.7 Lists of some cases

In recent years the increasing number of infringed pharmaceutical products has altered the government to work more on the intellectual properties, registration and protection.

4.3 Attitude towards the severity of the problem

Almost all of the study participants think that FMHACA has a serious controlling system on the counterfeit products in the pharmaceutical market. In connection to this, around 75 percent of the respondents think that counterfeit could not be their concern in the present pharmaceutical business of Bole Sub city, Addis Ababa, Ethiopia. This is primarily they assume it is the institutional responsibility of the government bureau. Yet, the remaining 25 percent reported as it is a serious issue and should be taken as a concern by concerned stakeholders.

4.4 Knowledge of the dispensers on the existing policies and guidelines

Given the educational background and experiences of the study participants is druggists or pharmacists, almost all of the study participants were found being aware of the existing policies and guidelines. All reported as Ethiopia has policies and strategies that deal with pharmaceutical trademarks infringement; they have the concept about the FMHACA law. They also firmly mentioned that it is not legal to have infringed pharmaceutical product in their outlet from the law perspective.

4.5 Experience with infringed products and measures they are taking to protect themselves from infringed products

The data from the retail outlets showed that infringed products are common. 30 percent of the retail outlet dispensers reported as they have infridged products at their outlet at the time of the study. The products were mainly, specifically lozenges, Sildinafil citrate, kenacort injection, diclofenac and Betametason cream, commonly due to the need of the patients. These deceptive pharmaceutical products are coming from different countries, especially from India and China through black market with cheap price than legally registered ones. This figure(30%) should be taken as an alarm given the sensitivity of the case and its effect on human life.

On the other hand, 70 percent of the respondents indicated as they do not have similar deceptive pharmaceutical trademarks in their dispensaries. In order to minimize the possibility of being affected by deceptive pharmaceutical product, these outlet dispensers indicated as they avail all the necessary ones in the market with a reasonable price to the consumers. Speaking about the factors that force one to engage in the sale of infringed products the dispensers reported as the lack of available of some items is one key factor. Accordingly, they recommended availing the demanded products in their outlet to satisfy their customers and have their market share is instrumental in tackling the problem.

4.6 Effect of infringed products on prescription and customers

As to 40 percent of the study participants, the infringed trademarks have no impact the prescription pattern of the health care professionals. Whereas the rest do believe it has an impact on their prescription pattern in terms of their sales of their specific brands due to its law price. Regarding the effect of customers/patients, around 60 percent of the respondents as they have faced complain from mild to moderate side effect. These dispensers have also reported also efficacy of the infringed pharmaceutical products questioned based on the feedback from their customers.

4.7 Is sales of infringed ethical?

Attitude is believed to affect behavior. Cognizant of this, the dispensers were asked to express their views on the ethicalness of selling infringed pharmaceutical products. Accordingly, 75 percent of respondents expressed as having similar deceptive trademark is not ethical. Nevertheless, 25 percent of the respondents believe that is ethical. They justify this based on the high price of some products. They argue that in such cases the patients should get options; and that option is sometimes using infringed products.

In their suggestion to address the problem, the respondents said that FMHACA has to make all the necessary drugs available in the market with a fair price and make a strict control on the distribution, to protect patients.

CHAPTER FIVE

CONCLUSION AND RECOMMENDATION

5.1 Conclusion

Unfair competition is condemned by the whole world irrespective of economic development and culture. As a result, reducing or eliminating has been one of the hot issues throughout the world in the last two decades. The introduction of worldwide organizations incorporating trademarks as major elements has further accelerated the effort of eradicating unfair trade practice.

Ethiopian government is discouraging unfair trade mark practices by taking multiple consecutive measures. The enactment of the Trademark Registration and Protection Proclamation No. 501/2006 is exclusively concerned with trademark and their protection is a significant stride. In support of the law, Food, Medicine and Health Care Administration and Control Authority of Ethiopia (FMHACA) have been established with the objective of

registering and controlling of pharmaceutical products to the market. And also protection of intellectual property right of the companies.

Pharmaceutical trademarks in Ethiopia can be registered in FMHACA. Upon successful completion of the registration process, a certificate of registration is provided to the owner which can be used as a means of protecting its trademark from infringement for 5 years before renewal.

However, these efforts had little impact on the overall fight against unfair competition. This is the result of combined effect of a multiplicity factors.

First and for most, lack of awareness among consumers and business about pharmaceutical trademarks, their value and their proper use and their infringement had immeasurable impact on the issue of their health condition and as well as on the business of the company. Second, lack of strict control by FMHACA and ethical concern in protection of pharmaceutical trademarks played a dominant role on the business. A third factor in bringing about this negative result was lack of the availability and shortage of pharmaceutical products due to lack of hard currency and tedious importation process. Furthermore, the affordability issue of pharmaceutical products to the consumers.

5.2 Recommendation

Although a number of infringement cases are increasing, the growth can be hampered by the proper implementation of successive measures which are mentioned below.

• Establishing customer association and increasing public awareness on consequences of pharmaceutical trademark infringement on the health of consumers.

• Availing all the necessary products on the retail outlet

• Firm price regulation and fair distribution of products has to be done by FMHACA

• Providing training which is aimed at raising the awareness level of business about pharmaceutical trademarks to health care professional. This helps in protecting theft of identity and enables business to have strong brand: one that is in every one's heart.

• Creating awareness on the level of business about ethical issues of pharmaceutical trademarks to health care professional.

5.3 Future researches

Completion law and the law of trademarks can make a great body of knowledge if studied and applied properly. Ethiopia can protect unfair trade practices and unfair competition only through the effective implementation of researches focusing on trade related industrial practices. This not only helps encouraging the investors but also helps the nation to achieve long term objectives.

To support this and other crucial action FMHACA has to be supported by different researches in order to protect company's property right. The following list shows some of the areas that should be prioritized to be studied so as to hamper unfair trade practices.

• How to implement successful training programs about trade practices

• What the pharmaceutical trademark law states and what the government body apply

• Pharmaceutical trademarks and its impact on the health of the consumer

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Annex 1Questionnaire

Assessment of the nature and magnitude of pharmaceutical products trade mark infringement in Bole Sub City Retail Stores

Interview Schedule

Respondents Identification Number	er]qualification of the
respondent	
Sex of the respondent	
Years of work experience	
Data collected by : l	Data reviewed by :
Date of interview: (mm/dd/yy) ///	

Introduction and Consent

Greetings.

How do you do?

I am _______. I am conducting a study as part of a requirement for a partial fulfillment of masters of business administration. I have selected the assessment of the nature and magnitude of pharmaceutical infringements trade mark and its effect as an issue for my study. From the retail shops, your store is selected for this study randomly. The information you will give me will help in realizing my study and will add value in the understanding of the situation by different stakeholders so as to come make sure nobody is harmed due to its possible effects. The interview will approximately take 30 minutes to complete. Whatever information you provide will be kept strictly confidential and will not be shown to other people.

Participation in this survey is voluntary. However, I hope that you will participate in this survey because your views are important. Are you willing to be interviewed to share your view with a maximum of half an hour stay together?

- 1. Do you think product counterfeiting is an issue (concern) in the pharmaceutical market in Ethiopia? Probe why? What about in Bole Sub city?
- 2. Does Ethiopia has policies and strategies that deal with pharmaceutical trademark infringement framework? If the respondent indicated as there is policy or strategy, request him/her to explain it
- 3. What measures do you take to avoid/minimize the possibility of being affected by such deceptive products? Probe who are the suppliers for the store, who are the manufacturers of the products they get from their suppliers, do they verify the legitimacy of their suppliers and the manufacturers before they buy the products, if so how do they verify, are the packages and contents of medicines checked before being bought(by the government facility or the staff of the store)
 - 4. Is there any similar deceptive pharmaceutical trade mark in your outlet?

A. Yes B. No

5. Have you ever bought a deceptive product within the last 12 months? Assuming they have learnt the deceptive nature after they have bought it

6. If the answer for question 5 is yes, ask the name of the trademark and the frequency of the experience(by product and supplier) and the price deferential with the original one

a) If yes, how frequent is it?A. RareB. Common C. Uncommon

b) Which generic products have trade mark infringement?

1.	
2.	
3.	
4.	

c) What is its country of origin?(use the order in a manner that match with the above)

1.	
2.	
3.	
4.	

d) What is the price of similar deceptive trade mark pharmaceutical products?

A. Low B. Medium C. High

7. Does the infringed trade mark have impact on the prescription pattern of the health care professionals?

A. Yes B. No

8. If yes, does the infringed trade mark have impact on the sales of specific brand?

A. Yes	1	B. No		
9. Do the consumers have complained about their health after taking the similar deceptive trade mark pharmaceuticals product?				
A. Yes	B. No			
10. If yes, was the problem serious?				
A. Mild	B. Moderate	C. Severe		
11. If moderate, How much is the frequency of the side effect of similar deceptive trademark				
A. Rare	B. Common	C. Uncommon		
12. If Severe ,How much is the frequency of the side effect of similar deceptive trademark				
A. Rare	B. Common	C. Uncommon		
13. According to your personal experience similar deceptive trade mark is ethical?				
A. yes	B. No			

14. If No, What do you think is the solution?

15. If Yes, What do you think is the reason?