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PATENTING OF MEDICINE AND ITS LEGAL
IMPLICATION ON THE RIGHT TO HEALTH

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A RESEARCH SUBMITTED IN PARTIAL FULFILLMENT
OF LLB IN LAW AT JIMMA UNIVERSITY SCHOOL OF
LAW

JUNE, 2016

JIMMA, ETHIOPIA

Acknowledgments

I wish to thank GOD for the strength to complete this research and indeed the entire LLB course

I thank Instructor Manaye Abera (LLB, LLM), my advisor for his constructive comments which I employ in the write up of this research.

I am greatly indebted to my mom Abebaye Sayid. As I am thinking back all what she did for me in my academic pursuit.

I am indebted to my sister Shemsiya Tesfaye and her husband Kadir Yasuf and to my family for their ever support in my academic pursuit

Declaration

I, Tilahun Tesfaye Bulti, hereby declare that this research is original and has never been submitted before for any degree, diploma and any other similar titles, in any other institution. I also declare that all the sources I have used have been indicated and duly acknowledged as complete references.

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CERTIFICATION

I hereby declare that this research is submitted by Tilahun Tesfaye Bulti for LLB degree at Jimma University School of law is carried out under my guidance and supervision and is a bona fide work. The research has not been previously submitted to any other University for the award of any degree, diploma or any other similar titles.

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CHAPTER ONE

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CHAPTER ONE

GENERAL OVERVIEW

Over the years the role that intellectual property plays in the development of and access to medicine has been examined extensively. The importance of patent to pharmaceutical innovation has been demonstrated by numerous law makers. The usual explanation of why patents are more important to pharmaceutical firms in appropriating benefits from innovation directly flows from the characteristics of the pharmaceutical rights and duties process.

That it takes several hundred million dollars to discover, develop and gain regulatory approval for a new medicine.¹ Absent patent protection or some other form of protection, imitators could free ride on the innovator's regulatory approval and duplicate the compound for small fraction of the originator's costs. So imitation costs in the pharmaceutical industry are extremely low relative to those incurred by innovator to discover, develop and gain regulatory approval.

It is true that there is strong association between patents and investment and that patents offer a significant incentives for innovation of new drugs. The patent system has played a critical role in incentivizing investment for global diseases such as HIV/AIDS, Malaria, cancer and tuberculosis.²

On the other hand, it is true that different international human rights instruments which have got the status of customary international law have dictated that every person(human being) has the right of access to health. This right is applicable to every human kind without any kind of

¹ Daniel Benoliel and Timothy John Chirwa, article on the impact of pharmaceutical patents on health

expenditures in least-developed countries, February 2011, p, 9

² *Commission on Intellectual Property Rights (CIPR), Integrating Intellectual Property Rights and Development Policy: Final Report of the Commission on Intellectual Property Rights(London: CIPR, 2003), p. 2*

discriminations based on color, religion, social status, race, nationality or any other similar grounds.

The first document of human rights, which is considered as an ice breaker in history of human rights is the Universal Declaration of Human Rights (UDHR). This document provides that “everyone has the right to a standard of living adequate for the health and wellbeing of himself and his family, including food, clothing, housing and medical health care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control”.³

Even if this document is a mere declaration without a binding force at the time of its enactment, currently it is considered as customary international law, and hence every state is required to observe it.⁴ As it is provided under this document, a human person is entitled to adequate standard of life which is necessary to ensure his health and incase this health is affected, he/she is entitled to go to a medical health care (institution) and get treatment. As it is provided under this document, a human person is entitled to adequate standard of life which is necessary to ensure his health and incase this health is affected, he/she is entitled to go to a medical health care (institution) and get treatment. So, at first, utmost care has to be taken not to affect the system a human being, and if this failed and a human health is not observed, a medical care service shall be available to treat those in need of it.

In addition to the UDHR, the ICESCR, which is the first binding instrument of economic, social, and cultural rights in the same manner, has given protection to the right. It has dictated that “the states parties to the present covenant recognize the right of everyone to the enjoyment of the highest

³ *Universal Declaration of Human Rights (UDHR), 1948, Art.25(1)*

⁴ <http://www.lrwc.org/education/international-law/non-treaty-standards/>

attainable standard of physical and mental health.⁵ In particular, the covenant under its article 12(2)(c) provides that the action of the states parties to the present covenant shall include the necessary measures for the prevention, treatment and control of epidemic, endemic, occupational and other diseases. From this instrument, it is clear that everyone is again entitled to the highest attainable standard of health for the reason of being a human person, and the states are duty bound to realize these rights. They are required to take necessary measures which can realize those rights. Among these measures harmonizing the patent law of medicine not to affect the fundamental human right to health is one step.

The UN charter under its chapter IX fixes the functions of one its principal organs; i.e. international Economic and Social Council. Article 55 of the charter has set creation of conditions of stability and wellbeing which are necessary for peaceful and friendly relations which the UN shall promote. To this effect, higher standard of life, in which the right health appears on the front page, is recognized under the charter.

From these all documents one can reach at a conclusion that the right to health is a natural right of every person. It is a right to be free from any kind of disease but is not restricted to this alone. The right to health includes physical as well as mental health. It is not limited in place, time other criteria.

1.2 Statement of problem

Among the fundamental human rights the right to health is the principal one. The right to property (intellectual property right) is similarly recognized under different international law and national laws, treaties, and declarations. Currently, the trade related aspect of intellectual property (TRIPS) agreement represent developed countries attempt to link intellectual property to trade. So it gives monopoly rights on the inventions

⁵ *International Covenant on Economic, Social and Cultural Rights (ICESCR)*, 1966, Art.12(1)

(essential drugs). Patent holder acquires monopoly or exclusive right on pharmaceutical products at least for 20 years. This exclusive right of patentee has negative legal implication on the right to health by restricting the accessibility, affordability, availability and quality of essential drugs.

This paper is therefore going to address legal implication of patenting of medicine on the right to health and the way of minimizing the negative implication of pharmaceutical patent on health right.

1.3 Research questions

This research will address the following questions in its entire part.

1. What is the right to healthy?
2. Does patenting of medicine affect the human right of the right to health, particularly of the people living in the least developed countries?
- 3 How we reconcile the right of innovators or patent holder and public health right in general?
- 4 Does trade related aspect of intellectual property agreement would benefit Ethiopia if she accedes to world trade organization?

1.4 Objectives of the study

1.4.1 General objectives

The basic aim of this research is to examine the legal implication of pharmaceutical patent on the right to health and searching for the way of minimizing the effect of patent. So the paper will discuss the normative frame work of health right and patent holder right

1.4.2 Specific objectives of the study

The research is going to address the following issues specifically:

-determine whether the patenting of medicine have an impact on the right to health.

-It will assess the laws that deal with the issues of patent rights and health rights.

-it will highlight the legal implication of pharmaceutical patent on developing countries to access to essential drugs.

-it discusses the would be, pros and cons of TRIPS agreement on Ethiopian public health rights.

Finally the thesis will suggest the possible recommendation to the problems which have been identified as a shortcoming in the entire paper.

1.5 Significance of the study

The research may give some clue for the future researchers to go further and study further. Besides it can help the potential claimants of the rights, particularly the least developed countries which affected by patent system (TTRIPS agreement) of the giant countries do to non-affordability, and accessibility of essential drugs.

Furthermore, it can be used as a call for world community to take important measures to help least developed countries to use trade related aspects of intellectual property agreement flexibilities effectively.

1.6 Research methodology

The study employs literature review as a major method. Different legislations at international level that are concerned with the right to health and obliges states to realize the right would be analyzed. Accordingly, the documents like the UN charter, UDHR, ICESCR, ICCPR, IHR, TRIPS, Doha declaration, general comment no 14 and others will be discussed with specific reference to the patenting of medicine and human right to the right to health. The research is

limited to the legal implication of patenting of medicine as the right to health is a very broad concept and cannot be exhausted here.

CHAPTER TWO

PATENTING OF MEDICINE AND THE RIGHT TO HEALTH

INTRODUCTION

A Patent has been defined as a grant to inventors and to other persons deriving their rights from the inventors for a limited period of years conferring on them to exclude others from manufacturing using or selling a patented product or from utilizing a patented method or process.⁶ It is legally binding monopoly which gives to the patentee an exclusive right to exclude third parties. Patenting of medicine and the right to health is some concept which push each other but cannot be fulfilled its goal unless we reconcile them at certain time.

2.2 Historical background of patent in general

Historical development of patent goes back to many centuries in the past. Even some literatures state that around 500B.C. in Sybaris, Greece, there were monopolies granted to new dishes for a period of one year.⁷ From this we can estimate that in one or in other way in the earlier periods there were trends, directly or indirectly related with patent. However, the origin of the present patent system goes back to medieval Europe. In the Medieval period, monopolies were granted by sovereign or a state for one of several reasons including the establishment of commerce, trade and industry.⁸

In the medieval Europe some of these monopolies have been granted to innovations.⁹ Between 1400 and 1432, the senate of Venice enacted a

⁶ Vedaraman .S., "patents recent development and future prospects on national level in india WIPO lectures montreaux, published 1971

⁷ Ibid

⁸ Graham Dutfield and Suthersanen " global intellectual property law" Edward 2008,p,106

⁹ Ibid

statute which gives a ten year exclusive privilege to inventors of any new machine or process. The primary purpose of the enactment was not to encourage local inventive activities rather to attract ingenious persons in to the republic.¹⁰ The first modern patent law was promulgated in the year 1474 by the senate of the republic of Venice with the intent to encourage both ingenuity and the importation of new ideas

In England also a royal monopoly was granted to certain businesses including innovations. In England, it is up to the willingness of the crown to give a monopoly right over certain type of trade or innovation.

Importantly, it is open to bias or we could not sort out a requirement for the purpose of monopoly grant. Even, grant of monopoly right by the crown was against the act of MagnaCarta which was enacted in 1215. Basically, MagnaCarta emphasized on the anti-monopoly nature of commercial law and it advocates the freedom of individuals and groups to practice their professions and trade without domination of others¹¹

2.2.1 HISTORICAL BACKGROUND OF PHARMACEUTICAL PATENT

Medicine has existed since the dawn of civilization. Diseases were originally thought to be caused by deities or supernatural forces. Various ancient civilizations, from the Egyptians to the Chinese, developed their own unique systems for practicing medicine in the fields of herbalism, anatomy, public health, and clinical diagnostics.¹² Medicine was not practiced by physicians, but rather by common people through observation and empiricism. The great Greek poet Homer described Egypt as lands where “the earth, the giver of grain, bears the greatest store of drugs” and where “every man is a physician.”

¹⁰ *Ibid*

¹¹ https://en.wikipedia.org/wiki/History_of_patent_law

¹² https://en.wikipedia.org/wiki/History_of_medicine

Homer's mythology does have some truth to it, But until the 19th century that the pharmaceutical industry evolved more systematic and scientific practices.¹³ According to the 2009 standard and poor's industry survey for the pharmaceutical market¹⁴ Slow growth for the industry was marred by sluggish new product launches and disappointing clinical trials for a number of high profile research and development pipelines patent expirations have led to mergers between large pharmaceutical companies such as merch and co.inc. and schering plough corp. socio political forces, including the new health care reform initiative, economic recession, and increased unemployment levels may also impact the industry.

“Canada-patent protection of pharmaceutical products ((WT/DS114/R)

On 19 December 1997, the EC requested establishment of a panel in respect of the alleged lack of protection of inventions by Canada in the area of pharmaceuticals under the relevant provisions of the Canadian implementing legislation is not compatible with its obligations under the TRIPS agreement, because it does not provide for the full protection of patented pharmaceutical inventions for the entire duration of the term of protection envisaged by articles 27.1, 28 and 33 of the TRIPS Agreement. The two main grounds of complaint were certain provisions under Canada's patent act: (i) regulatory review provision (sec. 55.2(1))” (which permitted the general manufacturers of pharmaceuticals to produce samples of the patented product for use during the regulatory review process) and (ii) “stockpiling provision (sec. 55.2(2))” that allowed general drug manufacturers to override, in certain situation in certain situations, the rights conferred on a patent owner (the stockpiling provision allowed

¹³ *Ibid*

¹⁴ *Standard and poor's industry surveys biotechnology, steven silver, august 13, 2009*

procedures of generic drugs to make the drugs and begin stockpiling them six months prior to the expiration of the patent).

The so called regulatory review exception provided for in Canada's patent act (section 55.2(1))- the first aspect of the patent Act challenged by the EC- was not inconsistent with article 27.1 of the TRIPS Agreement and was not covered by the exception in article 30 of the TRIPS Agreement and therefore not inconsistent with art 28.1 of the TRIPS agreement. Under the regulatory review exception, potential competitors of a patent owner are permitted to use the patented invention, without the authorization of the patent owner during the term of the patent, for the purposes of obtaining government marketing approval, so that they will have regulatory permission to sell in competition with the patent owner by the patent owner by the date on which the patent expires.

The so called stockpiling exception (section 55.2(2)) - the second aspect of the patent act challenged by the EC, was inconsistent with article 28.1 of the TRIPS Agreement and was not covered by the exception in article 30 of the TRIPS Agreement. Under the stockpiling exception, competitors are allowed to manufacture and stockpile patented goods cannot be sold until after the patent expires. The panel considered that, unlike the regulatory review exception, the stockpiling exception constituted a substantial curtailment of the exclusionary rights required to be granted to patent owners under article 28.1 to such an extent that it could not be considered to be a limited exception within the meaning of article 30 of the TRIPS Agreement"

Source: WTO

(<http://www.wto.org/english/tratop-e/dispute/7428d.pdf>)

2.3 NATURE OF PATENT

The exact nature of the right conferred must be carefully distinguished, and the key is in the words “right to exclude” in the phrase just quoted. Most literatures state that the act of invention by itself vests an inventor with a natural right to make, use and sell of that invention.¹⁵ It is not necessary to apply to get permission to exercise positive rights by the inventor. An inventor has a natural right to make, use and sell of his/her invention. The main purpose of patent grant is to enlarge the natural right into the right to exclude others from making, using and selling of patented inventions.¹⁶

In US, until the promulgation of the 1952 patent act, the previous statutes described patent right as an “exclusive right”, which only denotes positive rights to make, use and sell of patented invention by the inventor.

However, legal scholars like Judge Rich argued that the main purpose of patent grant is to confer the inventor the right to exclude others from making, using and selling of the subject matter claimed in the patent.¹⁷ In my opinion, the inventor has a natural right to make, use or sell of the invention without applying to this effect. Unless otherwise, making, using and selling of that particular invention is clearly prohibited by law. Hence, patent grant confers to the patentee the right to exclude third parties from making, using and selling of the invention protected under the patent. So a patent right like other intellectual property rights (IPRs) entitles the right holder to exclude third parties from exploiting the invention without the right holder’s consent for a limited period of time. A patent is powerful right with important implications on issues affecting public interest such as access to information and the availability and affordability of goods and services.

2.4 PATENTABILITY STANDARDS

¹⁵ *Ibid*

¹⁶ *Ibid*

¹⁷ *Fikre Markos Marso; Ethiopian law of intellectual property rights: copyrights, Trademarks, patents, utility models and industrial designs. Addis Ababa, September, 2012 P, 220.*

All inventions are not patentable. Rather, inventions which are “new, involve an inventive step and are capable of industrial application” are only protected by patent. Article 27.1 sets up patentability standards, without however stipulating the way in which they have to be defined. This provides some sort of flexibility which member or acceding states can define based on their needs and interests. It has been argued that developing or least developing countries can define these terms so as to restrict the number of patents.¹⁸ Three criteria have to be satisfied for a patent to be eligible protection: the invention must be new, it must be industrially applicable and it must exhibit a sufficient inventive step.¹⁹

2.4.1 NOVELTY

In order to get patent protection the invention must be new. An invention is considered new, if it is not anticipated by prior art. An invention lacks novelty, if it is part of the total sum of knowledge available to the public before the filing or priority date. Generally, there are three ways of evaluation of the novelty of the invention, taking in to account the place and modalities of disclosure. These are absolute novelty, mixed novelty and local novelty²⁰

Absolute novelty is ‘held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the application.

Absolute novelty test assesses the existence of the elements of the invention or their equivalent throughout the world before the filing or priority date. The knowledge may be available to the public through different modalities such as written or oral description, by use, or in any other way. In those countries which follow local novelty test only domestically held knowledge, use or manufacture is considered in the evaluation process. In the mixed

¹⁸ *Ibid*

¹⁹ *Ibid*

²⁰ *Graham Dutfield and Umas Suthersanen, supra note at 8, p 120*

novelty test approach, only unpublished foreign use or disclosure of knowledge cannot be taken in to account in the evaluation process.²¹

2.4.2 INVENTIVE STEP

In addition to being new, the invention should also involve an inventive step. So Inventive step is in some respects the heart and soul of patentability. Because, patent associates with the advancement of science and technology and the requirement of inventive step requires highest degree of advancement in comparison with the state of prior art.²² The invention is deemed to involve an inventive step if it would not have been obvious to a person having ordinary skill in the art having regard to the prior art relevant to the application²³ Only those inventions which have advanced technical progress than the state of prior art will get patent protection. In the first place the examiner should identify the scope and content of the prior art and examine the difference between the prior art and the claims at issue.

If the claimed invention is not obvious to a person having ordinary skill, the claimed invention is deemed as involving an inventive step. However, the difficult task is to delimit a boundary between obvious and non-obvious arts. This task becomes very difficult to those countries which do not have sufficient expert power to examine the degree of inventiveness. In Ethiopian Intellectual property office the existence of inventiveness is evaluated based on the evaluation of foreign patent offices to examine obvious and non-obviousness of an inventive step²⁴

²¹ Israel Begashaw *The Ethiopian patent regime and assessment of its compatibility with TRIPS agreement*, December 2010 Addis Ababa p,47

²² *Ibid*

²³ Blakeney, M(1996), *Trade related aspect of intellectual property rights: A concise guide to the TRIPS, agreement*, p, 84

²⁴ Fikre Markos Marso, *Supra note. at 17*

2.4.3 INDUSTRIAL APPLICABILITY

This requirement of patentability requires the practical application of inventions. An invention is considered as industrially applicable where it can be made or used in handicraft, agriculture, fishery, social service and any other sectors. The invention could relate to a product in which case it should be shown it is possible to make that product using the invention. It could also relate to a process in which case it should be shown that it is possible to carry that process out or use it in practice²⁵

In this case 'Industry' includes any physical activity of a technical character. Theories, abstract ideas and business methods are not patentable subject matters because they lack industrial application.

2.5 TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY

HISTORY OF TRIPS NEGOTIATION

In the 1960s and 70s, US private businesses entities actively participated in trade policy making.

Because of different reasons, the door of legislative and executive branch was opened to US businesses entities.²⁶ One factor may be procedural rule of congress "offered new opportunities for special interest to press their proposals. By using these opportunities, U.S.A business entities influence government trade policy making including matters related with IP protection. Their main reason to connect intellectual property and trade was trade distortive impact of weakest form of IP protection.

For the first time in the international arena, IPRs was presented as a trade related issue by Levis

Strauss Corporation with the support of many trade-mark holding firms. These corporations lobbied for the inclusion of an anti-counterfeiting

²⁵ Fikre Markos *supra* note at 17, page 228

²⁶ .Destler, *American Trade Poltics The Globalization of Intellectual Property Rights*, Combrige University Press, 2003, p, 83

code in the 1978-1979 GAAT Tokyo Round but they were not successful.²⁷ In 1986, because of their domestic achievement US business entities were encouraged to continue their movement internationally. To this effect in March 1986, twelve corporation established intellectual property committee (IPC)²⁸

After long and deliberate debate over specific issues between developed and developing countries, TRIPS agreement was concluded on April, 15, 1994²⁹

2.5.1 TRIPS AND HUMAN RIGHTS TO HEALTH

The link between medical patents and the human right to health has become a subject of central concern at the international level, TRIPS agreement introduced intellectual property (IP) rules into the multilateral trading system. Ideas and knowledge are an increasing important part of trade.³⁰ Most of the value of new medicines, vaccines, and other high technology products lies in the invention, innovation, research, design, and testing. The TRIPS agreement establishes minimum level of intellectual property protection that each World trade organization members must afford to creators, thus assuring more uniformity and bringing national policies under international rules with a dispute settlement system.

Intellectual property rights, in particular patents, are deemed to provide the necessary incentives for research and technological development. Patent are time bound monopoly rights. They constitute a derogation from a principle of free trade by offering exclusive right to an inventor to exploit the invention and stop others from using it without his/her consent. The

²⁷ Israel Begashew: *The Ethiopian patent regime and assessment of its compatibility with TRIPS agreement*, December 2010, Addis Ababa.

²⁸ *Ibid*

²⁹ *ibid*

³⁰ William park ; *Global health law and the public's health rights*, oxford university, 2010, p , 664

rational for granting patent is the need to reward inventors, natural right/human rights, and as an incentives.³¹ One of the perceived advantages is that it should give incentives to the private sector pharmaceutical industry to undertake more research and development in finding cures for diseases common in developing countries.³² Patent protection is perhaps most important in matters of health. The TRIPS agreement requires patents for inventions to at least twenty years (art. 33). Patent protection must be available for both products (e.g medicines) and processes (e.g .. methods of producing chemicals ingredients for medicines) in almost all fields of technology, with certain exceptions(art 27)

2.5.2 TRIPS FLEXIBILITIES OR COMPULSORY LICENCES

The TRIPS agreements allows countries to issue a compulsory licenses: a legal vehicle where by a government grants to itself or to a third party the right to produce or import a patented product without authorization from the patent holder³³ compulsory licenses are subject to conditions: 1. The government must first attempt to negotiate a voluntary license from the right holder on the reasonable commercial terms.

2. The government need not seek a voluntary license in a national emergency or other urgent circumstance.

3. Adequate remuneration must be paid to the right holder, taking into account the economic value, if a compulsory license is issued;

4. The compulsory license must be “pre dominantly for the supply of the domestic market.”

In the aftermath of TRIPS, many developing countries began resisting the restrictive concessions required by the agreement.³⁴ As a result, the

³¹ *Philippe cullet, patents and medicine: the relationship between TRIPS and the human rights to health, unpublished, P ,139*

³² *Ibid*

³³ *Annex 1c, agreement on trade related aspects of intellectual property rights, may, 1994*

³⁴ *William Park supra note at 30, p, 667*

international community gradually became more sensitive to the public health concerns of developing nations, lessening international support for the harsh intellectual property demands of the United States and other industrialized nations.

2.6 THE DOHA DECLARATION

Although compulsory licensing was designed to provide the flexibility necessary to protect the public's health, the HIV/AIDS pandemic brought its shortcomings into stark contrast with its goals." Patented drugs cost anywhere from three to fifteen times that their generic equivalents although the cost of front-line drugs has been sharply reduced." To ensure greater access to life saving medications for resource-poor countries, the WTO Ministerial conference promulgated the declaration on the TRIPS agreement and public health in Nov 2001.³⁵

The declaration explicitly recognized the public health problem facing resource-poor countries especially HIV/AIDS, Tuberculosis, and malaria. The declaration called for the TRIPS agreement's flexibilities to be used to protect the public's health by promoting access to essential medicines. So the Doha declaration was intended to prevent international trade rules from becoming a barrier to the provision of essential drug.³⁶ Many problems remain, however, such as poor healthcare infrastructures in developing countries, making it difficult to deliver medicines to a large population and provide appropriate medical supervision. It is difficult to understand why politically and economically powerful countries would seek to use trade rules to prevent access to affordable treatment for the world's poor.

2.7 THE RIGHT TO HEALTH IN GENERAL

³⁵ Frederic M. Abbott and Rudolf: *Compulsory licensing for public health: a guide and model documents for implementation of the Doha declaration paragraph 6 decision* P, 8

³⁶ *Ibid*

What is the right to Health?

The preamble of the 1946 World Health Organization (WHO) Constitution defines health broadly as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." The Constitution defines the right to health as the enjoyment of the highest attainable standard of health, and enumerates some principles of this right as healthy child development; equitable dissemination of medical knowledge and its benefits, and government-provided social measures to ensure adequate health.³⁷ The right to health is defined by Frank P Grad as "establishing the right to health as fundamental inalienable human right." that government cannot abridge and are rather obliged to protect and uphold

2.7.1 THE RIGHT TO HEALTH UNDER UNITED NATION CHARTER

At the international level, the formulation of health as a human right was initiated at the United Nations Conference in 1945. A special memorandum which declared that 'Medicine is one of the pillars of peace' led to the insertion of a reference to health in Article 55 UN Charter and to the adoption of a declaration on the establishment of an international health organization. The World Health Organization (WHO) came into existence in 1946.³⁸ It was the first organization to formulate an explicit 'right to health' in the Preamble to its constitution at the international level, the formulation of health as a human right was initiated at the United Nations Conference in 1945. It was the first organization to formulate an explicit 'right to health' in the Preamble to its constitution. The WHO text is very important as it inspired the definition of a right to health in the various human rights treaty provisions.

³⁷ https://en.wikipedia.org/wiki/right_to_health

³⁸ *Ibid*

It is difficult to pinpoint exactly what the right to health entails, but specific elements that constitute the core content of the right to health have been identified by scholars, activists and relevant UN bodies. States must guarantee these elements under all circumstances, regardless of their available resources. Inspiration for the core content of the right to health derives from the Health for All and Primary Health Care strategies of the WHO, which stipulate that there is a health baseline below which no individuals in any country should find themselves.

Thus, irrespective of their available resources, states should provide the following basic services: a) access to maternal and child health care, including family planning; b) immunization against the major infectious diseases; c) appropriate treatment of common diseases and injuries; d) essential drugs; e) adequate supply of safe water and basic sanitation; and f) freedom from serious environmental health threats.³⁹ In addition to the scope of core content, a number of guidelines constitute the framework of the right to health: a) availability of health services; b) financial, geographic and cultural accessibility of health services; c) quality of health services; The right to health is not to be understood as a right to be healthy.

The right to health contains both freedoms and entitlements.⁴⁰ The freedoms include the right to control one's health and body, including sexual and reproductive freedom, and the right to be free from interference, such as the right to be free from torture, non-consensual medical treatment and experimentation.

By contrast, the entitlements include the right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health. Accordingly, the core obligations in respect of the right to health, as defined in ICESCR 12, are: (a) to ensure the right of access to health facilities, goods and services on a non-

³⁹ Theo Van Banning, *Human rights reference hand Books, University for peace* P,321

⁴⁰ Nihal Jayawickrama, *the judicial application of human rights law national, regional and international jurisprudence*, cambridge p,881

discriminatory basis, especially for vulnerable or marginalized groups; (b) to ensure access to the minimum essential food which is nutritionally adequate and safe, to ensure freedom from hunger to everyone; (c) to ensure access to basic shelter, housing and sanitation, and an adequate supply of safe and potable water; to provide essential drugs; (e) to ensure equitable distribution of all health facilities, goods and services; and (f) to adopt and implement a national health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the whole population.⁴¹

2.7.2 GENERAL COMMENT NO 14

THE Right to Highest Attainable standard Of Health (art .12 of ICESCR)

The state parties to the ICESCR and the charter of UN are duty bound to realize the right to health indicated under article 12 of the covenant. In the spirit of article 56 of the charter of UN, the specific provisions of the covenant (articles 12, 2(1), 22 and 23) and the Alma-Ata Declaration on primary health care, states parties should recognize the essential role of international cooperation and comply with their commitment to take joint and separate action to achieve the full realization of the right to health.⁴² In this regard, states parties are referred to the Alma-Ata declaration which proclaims that the existing gross inequality in the health status of the people, particularly between the developed and developing countries, as well as within countries, is politically, socially and economically unacceptable and is therefore, of common concern to all countries.

⁴¹ *ibid*

⁴² *General comment no. 14: The right to the highest attainable standard of health(art. 12), Adopted at the Twenty second Session of the Committee on Economic, Social and Cultural Rights, on 11 August 2000 (Contained in Document E/C.12/2000/4)*

To comply with their international obligations in relation to article 12 of the covenant, states and other international actors have to respect the enjoyment of the right to health in other countries, and to prevent third parties from violating the right in other countries, if they are able to influence these third parties by way of legal or political means, in accordance with the charter of the United Nations and applicable international law.⁴³ Depending on the availability of resources, states should facilitate access to essential health facilities, goods and services in other countries, wherever possible and provide the necessary aid when required.

According to this General Comment, states parties have a joint and individual responsibility, in accordance with the charter of the UN and relevant resolutions of the UN General Assembly and of the world Health Assembly, to cooperate in providing disaster relief and humanitarian assistance in times of emergency, including assistance to refugees and internally displaced persons. Each state should contribute for this to the maximum of its capacities

The right to health in all its forms and at all levels contains the following interrelated and essential elements, the precise application of which will depend on the conditions prevailing in a particular State party: Availability, accessibility, acceptability and quality.

CHAPTER THREE

PATENTING OF MEDICINE AND ITS LEGAL IMPLICATION ON THE RIGHT TO HEALTH

3.1 INTRODUCTION

⁴³ www.un.org/press/en/2014/sc11566.doc.html

The right to property, specifically the right to intellectual property and the right to health is recognized under different international and regional treaties, declarations, and national constitutions. As patenting of medicine give exclusive right to the inventors or pharmaceutical industries it restrict the availability, accessibility and affordability of patented pharmaceutical products.

As the right to health is the cornerstone to exercise the other rights recognized by international instruments. And this the right to health consists many right

This chapter of my thesis is going to discuss if there is/are any legal implication of patenting of medicine on the right to health and its solution to minimize the implication of pharmaceutical patent on the right to health. Accordingly the two rights are protected by united nation charter, universal declarations of human right (UDHR), international conventions on economic social and cultural rights (ICESCR) and other regional and national laws.

3.2PATENTING OF MEDICINE AND ITS LEGAL IMPLICATION ON THE RIGHT TO HEALTH

There are many dangers associated with patent right such as overcharging, manipulation of markets or refusal to make the product available. As monopolies are a good way of raising revenue. The patent was held to be invalid as being inter alia, a common law monopoly. Adoption of the patent regime will intensify the trend of private monopolization of knowledge and medications, markets, and distribution.⁴⁴

What is the right to health? None of the international or regional instruments have adopted the definition of health contained in the preamble to the constitution of the world health organization (WTO), which conceptualizes health as state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity. However, the

⁴⁴ Kinsella, N.S, (2001), *Against intellectual property*, 15 *journal of libertarians* vol. 13

reference in international convention on economic, social and cultural rights (ICESCR) article 12 to “the highest attainable standard of physical and mental health. The right to health embraces a wide range of socio economic factors that promote and conditions in which people can lead a healthy life, and extends to the underlying determinants of health, such as food and nutrition, housing, access to safe and potable water and adequate sanitation, safe and healthy working conditions and health environment.”⁴⁵

The united nation committee on international covenant on economic, social and cultural rights a treaty body which is responsible for the monitoring and implementation of ICESCR has issued the General comment number 14 on May 15, 2000 which clarifies the content to the rights to health.⁴⁶ The General comment no 14 provides the authoritative interpretation of the right to health and addresses the content of the right to health and its implementation and enforcement.

The General comment 14 noted that the right to health is not the right to be health but it must be understood as the right to the enjoyment of variety of facilities, goods and services and conditions necessary for the realization of the highest attainable standard of health including the right to access and afford the essential drugs.⁴⁷ Accordingly, the General comment clarifies the content the right t health in the following manner.

3.2.1 The right to health as a broad and an inclusive rights

⁴⁵ *Nihal Jayawickrama ,supra note at 40, p, 883*

⁴⁶ *General comment no 14 supra note at 42*

⁴⁷ *Committee on economic, social and cultural rights*

3.2.1.1 Freedoms and entitlement

The right to health contains both entitlement and freedoms including freedom from discrimination. Freedoms include the right to control one's health and body including sexual and reproductive health freedom, and the right to free from interference, such as the right to be free from torture and other cruel, inhuman or degrading treatment or punishment, non-consensual medical treatment research and experimentation.⁴⁸ The right to health includes an entitlement to a health protection, including health cares, access to medicine and the underlying determinants of health, which provides equality of opportunity for people to enjoy the highest attainable standard of health, the right to prevention, treatment and control of disease, maternal, child and reproductive health, equal and timely access to basic health-related education and information, and participation of the population in the health related decision making at the national and community levels⁴⁹

3.2.2 Available, accessible, affordable and good qualities

Availability: functioning public health and health care facilities, goods and service must be available in sufficient quantity with in a state. This includes adequate numbers of health-related facilities and support services, and adequate numbers of medical and other professionals trained to provide these services .But the legal implication of patent of medicine barriers to the distribution of essential drugs and other equipment. The nature of patent gives exclusive right of distribution of pharmaceutical product to the holder by manipulating of markets or refusal to make product available. Patenting of medicine can affect the right to health of human being specially, people who live in the least developed countries.

Accessibility: The accessibility issue has four dimensions: non-discrimination, physical accessibility, economic affordability and information accessibility.

⁴⁸ *Ibid*

⁴⁹ *Ibid*

Non- discrimination: health facilities, especially drugs like to malaria, HIV/AIDS, tuberculosis and cancer diseases must be available to all people specially for those vulnerable or marginalized section of the population with-out discrimination on any of the prohibited grounds.⁵⁰

Physical accessibility: health facilities, goods and services must be within safe physical reach for all sections of the population, especially vulnerable or marginalized groups, such as ethnic minorities and indigenous populations, women, children, adolescents, older person, persons with disabilities and persons with HIV/AIDS. Likewise, healthcare facilities, goods, and services, must be accessible physically and geographically-in other words, in safe physical and geographical reach of persons in need of it.

Affordability (economic accessibility): health facilities, goods and services, pharmaceutical products must be economically affordable for all. As all human rights are equal, indivisible and inviolable, a person must not sacrifice his other rights to buy a drug.⁵¹ So payment for health care services as well as services related to the underlying determinants of health, has to be based on the principle of equity, ensuring that these services, whether privately or publicly provided, are affordable for all, including socially disadvantaged groups. Equity demands that poorer households should not be disproportionately burdened with health expenses are compared to richer households.

Patenting of pharmaceutical inventions has negative legal implication on the rights to exercise the right to accessible to the health facilities especially, to the essential drug by giving monopoly right to health as monopoly right is the way of raising price of drugs and revenue to the patentee

⁵⁰ Kidus Meskele Ashine: *Legal and policy framework for the realization of the right to health*, 2011, P , 45

⁵¹ Nihal Jayawickrama *Supra* note at 45

Quality. Health facilities, goods and services must be scientifically and medically appropriate and of good quality. This requires, inter alia, skilled medical personnel, scientifically approved and unexpired drugs and hospital equipment, safe and potable water, and adequate sanitation.⁵²

Generally, patent has negative legal implication on the right to health based on its nature, it gives exclusive rights to the patentee, in the sense that the owner is the only one allowed to exploit the invention and excluding others from exploiting the invention.⁵³ So patent system does not protect and represent the interest of the least developed countries and TRIPS affect the fundamental human right to health. The most obvious arguments against pharmaceutical patents is that they artificially raise prices and therefore restrict access to product, which can be crucial for the enjoyment of rights to life and health.

Many non-governmental organizations and lawyer associations argue that the trade related aspect of intellectual property agreement provides unnecessary strong protection of intellectual property rights which serves to prevent the ill in developing nations from having access to affordable essential medications.

3.3 RECONCILING OF PATENT RIGHT AND THE RIGHT TO HEALTH

3.3.1 Are a patent rights human right?

Article 15(1)(c) of the international convention on economic, social and cultural rights(ICESCR) recognize the right of every one to "benefit from the protection of moral and material interests resulting from any scientific, literature or artistic production of which is the author." A similar provision is also contained in art 27(2) of the universal declaration of human rights (UDHR) at first reading of these two provisions appear to equate IPRS with

⁵² L. Temkin: *quality of health service*, New york: oxford university press, 1993, P, 101

⁵³ Art. 33.The trade related aspects of intellectual properties agreement, April 1994.

other types of human rights, this has led some authors to conclude that they provide a human rights basis for patent rights and other forms of IPRs.⁵⁴

However, the CESCR in its general comment no 17 has made it clear that human rights are not on the same level and it would be erroneous to rely on article 15(1)(c) to equate intellectual property right specifically patent right with human rights⁵⁵

The CESCR adopted the view that article 15(1)(c) solely safe guards the personal link between authors and their creations as well as their basic material interests which are necessary to enable authors to enjoy an adequate standard of living “while” intellectual property regimes primarily protect business and corporate interests and investments.⁵⁶ In a sense, the human rights contained in article 15(1)(c) is not equally supported by the drafting history of both article 27(2) of UDHR and article 15(1)(c) of the ICESCR.

In an analysis of the relationship between human rights and intellectual property rights the CESCR noted

*“ In contrast with human rights, intellectual property
Rights are generally of a temporary nature, and
Can be revoked, licensed or assigned to someone else.
While under most intellectual property systems, may be allocated,
Limited in time and scope, traded, amended and even forfeited
human rights are timeless expressions of fundamental entitlements of the human
persons.”⁵⁷*

Intellectual property rights (including) patent rights are instrumental rights that should serve those needs and interests which human rights discourse

⁵⁴ [www.hhrjournal.org/2013/12/incorporating a right to health perspective into the resolution of patent disputes](http://www.hhrjournal.org/2013/12/incorporating-a-right-to-health-perspective-into-the-resolution-of-patent-disputes)

⁵⁵ Committee on economic, social and cultural rights(CESCR), General comment no 17, The rights of everyone to benefit from protection of the moral and material interests resulting from any scientific, literature or artistic production of which he or she is author(General comment no 17).

⁵⁶ Ibid

⁵⁷ Ibid

identifies as fundamental. As the CESCR emphasized in General comment no 17 intellectual property is a social product and has a social function while human rights are timeless expressions of fundamental entitlement of the human person. So In any principled national legal system fundamental rights such as the right to health should take health should take precedence over utilitarian considerations.⁵⁸

The rights of authors to benefit from the protection of the moral and material interests resulting from their scientific, literary and artistic productions cannot be isolated from other rights recognized in the covenant. State parties are therefore obliged to strike an adequate balance between their obligation under art 15(1)(c) on one hand and under the other provisions of the covenant. On the other hand, with a view to promoting and practicing the full range of rights guaranteed in the covenant. In striking this balance, the private interests of author should not be unduly favored and the public interests in enjoying broad access to their productions should be given due consideration.⁵⁹

There are different methods of reconciling the right of patent holder or patentee with the rights of public at large on the health rights:

3.3.2 Compulsory licensing:

Under article 31 of TRIPs agreement the right of patent holders can be circumvented in certain situations.⁶⁰ More specifically, member governments are given the authority to grant a license to a party willing to commercialize an invention protected under patent without the consent of the patent holder. Unless there is a "*national emergency*" the proposed license is required to make a reasonable efforts to seek a voluntary license⁶¹ if the patent holder refuses to grant a license, non-exclusive license can be granted by the government. Consequently, subject to other provisions of the

⁵⁸ P . Drahos and J. Braith Waile, information fendalism: Who owns the knowledge economy? P 200

⁵⁹ Ibid

⁶⁰ www.ncbi.nlm.nih.gov/pmc/article/pmc2323529

⁶¹ Ibid

TRIPS agreement, compulsory licensing allows generic drug companies to manufacture patented drugs and sell them at a fraction of the price that the patent holders would charge, since only the costs of producing the medication and not the costs of research and development needs to be recovered.⁶² Critics of the compulsory licensing must be used “predominantly for the supply of the domestic markets of the authorizing such use.” These critics contend that this clause developing nations to issue makes it exceedingly difficult for governments of developing nations to issue compulsory licenses to quell public health crises, because it would require that the drugs be manufactured in developing countries where little infrastructure exists to support this ultra-sophisticated industry.

3.3.3 Parallel importing:

The TRIPS Agreement provides a second possibility for developing countries to reduce costs of vital medications. Pharmaceutical companies sell identical pharmaceutical products at different prices in different countries.⁶³ Parallel imports effectively allow countries to purchase patented medications at the lowest global price. The right to parallel import under the TRIPS agreement is based on a fundamental legal principle called “exhaustion” of intellectual property rights which defines the point at which a patent holder ceases to have exclusive rights in the context of resale of its product.⁶⁴

Article 6 of the TRIPS agreement states that member countries can independently decide at which respect to resale are terminated. But issues of exhaustion cannot form the basis of a dispute brought to the WTO for resolution. In effect, article 6 of the TRIPS agreement allows member

⁶² World Trade organization website, <http://www.wto.org>

⁶³ Striking a balance: patent and access to drugs and health care. Editorial. world intellectual property organization

⁶⁴ Art.6 of TRIPS agreement, supra note at 53

countries to engage in parallel importing. The parallel importation of drugs would undermine the ability of pharmaceutical companies to charge different prices in different countries or parts of the world. And that a tiered pricing strategy allows wealthier countries to subsidize poorer ones, and the drug companies still get profits they need for research.⁶⁵

3.3.4 Restrictions on patentability

One crucial problem faced by patent arrangements for medication is the enormous number of new patents awarded each year. Each country has to award one patent for one product (or one process) which “is new, can be produced industrially and constitutes an innovative step. TRIPS does not specify, however, what an innovative step is supposed to mean. This makes it possible for countries to avoid patents on products which are not considered to be innovative enough. Because patents on vital drugs restrict its availability by reducing the quantity produced, hence raising the price, this TRIPS flexibility is very important in providing access to new, improved vital medication.⁶⁶

Indian patent law takes advantage of this. It says discoveries of a new form of a known substance are not eligible for patenting because they are not able to demonstrate any enhancement of the known efficacy.⁶⁷ This relative exception in patentability reduces the number of patents issued and protects public health by not affording patent protection to new medications that are beneficial to patients but only marginally innovative and can therefore be inexpensively reproduced as generic products. Patents have accordingly been rejected for the merely marginally innovative.

The restriction on patentability is viewed to be the most important flexibility offered under TRIPS for the protection of public health: excluding products

⁶⁵ Prof William W. Fisher: the south Africa AIDS controversy. A case study in patent law and policy, 2005, p, 6

⁶⁶ Supra note at 63

⁶⁷ *Christiane Fischer: Equality and justice in healthcare perspective 2013, p 6*

which are not innovative enough from patent protection has a positive impact on access to vital medication.⁶⁸

3.3.5 Preserve or Abolish

TRIPS

Everyone has the right of access to vital medication and research results. This is stipulated under art.12 and 15 of ICESCR. Withholding drugs and medication from people in developing countries that are vital to their survival is not only unethical – it also constitutes a violation of human rights.⁶⁹ Governments are hence obligated to allow access to innovative medication at a reasonable price. If this is in conflict with the profit motives of pharmaceutical companies, governments have to act in the interest of human beings. The question is, however, what alternatives there are to the TRIPS arrangements? Because revocation of the agreement would probably lead to each state which has strong pharmaceutical industry to seek bilateral patent Protection treaties, it would probably spawn a plethora of bilateral and regional trade agreements. This is also not the good way to solve the problem of developing countries. It would appear to make more sense to expand on the existing protective clauses of the TRIPS Agreement. Compulsory licenses must be awarded in a more consistent manner. Parallel imports should be optimized within the realm of the possible.

Above all, however, there needs to be a global campaign to establish more stringent requirements for patenting. If only medication for which real therapeutic progress is demonstrated is eligible for patenting, a large portion of patents would be eliminated. People in the developing countries would profit directly from this. This narrow definition of innovation would preclude the need to abrogate TRIPS and avoid the danger that the TRIPS Agreement could be replaced by even worse TRIPS plus agreements.⁷⁰

⁶⁸ *Ibid*

⁶⁹ *Ibid*

⁷⁰ *Ibid*

3.4 PATENT AND PUBLIC HEALTH RIGHTS IN ETHIOPIA

3.4.1 Emergence and development of intellectual property protection in Ethiopia

The emergence of legal recognition and protection of the creations and inventions of individual in Ethiopia spans about five decades.⁷¹ Until recently, people engaged in technical works such as artifacts were often seen as inferior members of society.

The oldest known law of Ethiopia, the Fetha negast (law of kings) does not directly address property rights overworks of mind.⁷² Mirroring the then prevalent perception in society, it actually discouraged people from pursuing a trade as a way of life and recognized the practice of crafts to the extent necessary to supply the necessary needs. It also ordered traders to be limited to something necessary to sustain the body.

Specific rules on intellectual property rights targeting authors and inventors emerged towards the end of the 1950s and the beginning of the 1960s when Ethiopia embarked upon codification of its laws. The preface of the 1960 civil code of Ethiopia clearly states that Ethiopia requires the modernization of its legal framework so as to keep pace with the changing circumstances in the world, to consolidate the progress already achieved and to facilitate further growth and development. In this respect, the civil code, with specific rules on copyright is seen as an instrument for growth and development in the country achieved by promoting innovative activities and transfer of technology. Title XI of the code entitled literary and artistic ownership deals with different aspect of copy right.⁷³ Similarly, the 1957 penal code of Ethiopia established criminal offenses and set penalties relating to infringement of copy right works. However, the provisions were

⁷¹ Fikre Markos Marso *supra* notes at 17, p, 216

⁷² *ibid*

⁷³ *Ibid*

not applicable with regard to patents due to a lack of specific law on the subject until 1995. In 1993 the transitional government of Ethiopia (TGE) declared the national science and technology policy (NSTP) to build national capacity on science and technology. Patent system was taken as one strategy in the NSTP which specifically seeks to establish an efficient patent and technology transfer system and support local technological innovations and creative activities.⁷⁴ The federal democratic republic of Ethiopia constitution recognized the patent and copyrights.⁷⁵

3.4.2 PUBLIC HEALTH RIGHTS IN ETHIOPIA

Legal and policy framework

3.4.3 FDRE Constitution

The right to health has been mentioned under FDRE Constitution of 1995. According to article

41(4), the State has the obligation to allocate ever-increasing resources to provide to the public

Health (health services for the public at large). As per article 41(3), every Ethiopian national has

the right to equal access to publicly funded social services, which apparently include health related services. It is also implicit in the obligation of the State to provide rehabilitation and assistance to the physically and mentally disabled, the aged, to children who are left without parent or guardian under article 41(5) that health services be provided to these groups of people.⁷⁶

⁷⁴ Dejene Girma Janka: *material on the study of Ethiopian intellectual property law*, Addis Ababa 2008, p, 27

⁷⁵ *The constitution of the federal democratic republic of Ethiopia, proclamation no 1/1995, Federal Negarit gezeta, 1st year no 1/1995, art 51(19)*

⁷⁶ Alemahu, Sisay. "The Constitutional Protection of Economic and Social Rights in the Federal Republic of Ethiopia." *Journal of Ethiopian Law* 22, no. 2 (2008), p. 140.

Furthermore, the FDRE Constitution provides that all international agreements ratified by Ethiopia are an integral part of the law of the land.⁷⁷ Accordingly, international treaties and conventions have to be ratified by the House of Peoples Representatives to become an integral part of the law of the land. In addition, the Constitution states that fundamental rights and freedoms specified in the third chapter shall be interpreted in a manner conforming to principles of the Universal Declaration of Human Rights, International Covenants on Human Rights and International Instruments adopted by Ethiopia.⁷⁸

Ethiopia has ratified or accessed most of the international and regional human rights instruments which give recognition to the right to health. The most important ones are the International Covenant on Economic, Social and Cultural Rights (ICESCR), the International Convention on the Elimination of All Forms of Racial Discrimination (CERD), the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW) and, the Convention on the Rights of the Child (CRC). At a regional level, Ethiopia has ratified the African Charter on Human and Peoples Rights (ACHPR). Consequently, all the above international and regional human right instruments are an integral part of the law of the land.⁷⁹

Furthermore, chapter ten of the FDRE Constitution is devoted to National Policy Principles and Objectives. Accordingly, the Constitution obliges the State to design policies that would provide all Ethiopian access to public health and essential drugs. This is one of the social objectives under Article 90 of the Constitution. The obligation of the state extends to the extent the

⁷⁷ *FDRE Constitution, art. 9(4).*

⁷⁸ *Id at art13(2)*

⁷⁹ *Supra note at 50, p 64*

resources of the country permit and it is expected to design policies that aim to provide all Ethiopian access to public health, clean water, food and social security.⁸⁰

3.4.3 Public health proclamation no 200/2000

In its preamble, the proclamation stresses the need for the believed to be important step for the assurance of public health law is believed to be important step for the society and for the creation of health environment for the future generation their by enabling it assume its responsibility. Considering that the legislation has a stated assuring public health by facilitating the way accessibility, affordability and quality of medicine is an important step in carrying out the obligation to fulfill the right to health of the nationals or residents as stipulated under the FDRE constitution.⁸¹

3.4.4 NATIONAL HEALTH POLICY

The National Health Policy of the Transitional Government of Ethiopia was launched in 1993. In

its preamble the policy stresses the needs of the less privileged rural population which constitute the overwhelming majority of the population and the major productive force of the nation and reaffirms the interdependence, interrelatedness and association of health with other fundamental rights.

The National Health Policy underlines the importance of achieving universal access to a basic package of quality primary health care services to all people to decentralized preventive, promotive and basic curative services.

⁸⁰ *Ibid*

⁸¹ *Proclamation no 200/2000 preamble*

The Government therefore accords health a prominent place in its order of priorities and is committed to the attainment of these goals utilizing all accessible internal and external resources. The major contributors to the burden of disease at all levels will be given the highest priority. These include HIV/AIDS, malaria, tuberculosis, leprosy blindness, child mortality and maternal mortality and onchocerciasis. These priority health problems shall be implemented through the Health Sector Development Program.⁸²

Regarding to the would be pros and cons of accessing to the world trade organization of Ethiopia, of all the agreement administered by WTO, the agreement on trade related aspects of intellectual property rights(TRIPS) is undoubtedly the most controversial with respect to its development related aspects. The agreement requires all WTO member states to establish minimum standards of legal protection and enforcement for a number of different forms of IPRs.

3.4.5 The pros and cons of acceding to world trade organization of Ethiopia

Many developing countries including Ethiopia hold that the TRIPS agreement- which came into force in 1995 is unbalanced in that it favors developed countries and transnational corporations. And at the same it is unhelpful or even harmful to their own interest.⁸³ In addition, concerns have been raised about the moves to ensure that developing countries accept higher standards of intellectual property protection than the WTO requires, even before they have determined how best to implement the TRIPS agreement in ways that support economic development and poverty alleviation.⁸⁴

Also in 2001, the United Kingdom government established a commission on intellectual property rights to look at how IPRs might work better for poor

⁸² *Ethiopian Health Sector Development Programs Ministry of Health, (Addis Ababa: Ethiopia) (2002/2003).*

⁸³ [www. Sc/dev. Net/global/police-brief/TRIPs and its on developing countries.html](http://www.Sc/dev.Net/global/police-brief/TRIPs%20and%20its%20on%20developing%20countries.html)

⁸⁴ *Ibid*

people and developing countries. The commission's report covers the following issues. Over all, the commission expresses serious doubts that the international IPRS regime in its present form, and current processes to further strengthen IPRs protection, are in the interests of poor. It also considers that the TRIPS agreement imposes onerous costs on most developing countries.

Ethiopia is not a party to the major treaties on IPRs such as, Paris, Berne and Rome conventions and does not have treaty obligations to make its IPR laws compatible with the standards laid down by those treaties. However, Ethiopia is in the process of accession to the WTO since January 2003. The country will be bound by the TRIPS agreement If and when it joins the WTO, even if it has not ratified any of the existing international intellectual property conventions.⁸⁵

3.5 Does the Economic, Technological and public health interests of Ethiopia Requires strong protection of patents?

It is already stated that the view that the importance of intellectual property varies according to countries economic level is widely accepted truth.⁸⁶ Countries with lower per capita income and technological capability are unlikely to benefit from IPRs. Countries not conducting innovative research or conducting limited amount would enjoy few, if any of the benefits of intellectual property protection, because an innovation sector through which IPRs affect economic growth is absent.⁸⁷

According to united nation list Ethiopia is one of the list developed countries in the world which are characterized by weak human and

⁸⁵ *Fikremarkos Marso supra note 17, p, 39*

⁸⁶ *Walter G. park and Juan.C Ginrate(1997), intellectual property rights and economic growth, contemporary economic policy, vol 15 , p, 51*

⁸⁷ *Ibid*

institutional capacities, low and un equally distributed income, and scarcity of domestic financial resources. There is negligible existence of manufacturing industries .These fact revealed that Ethiopia is in the low level of economic development and technological capacity. Given the very low per capita income, the great share of its population is unable to pay for high prices of essential drugs which are the results of stronger protection of patenting medicine.⁸⁸

In Ethiopia the majority of technologies improved by local industries do not demand stronger patent protection. There is no substantial application for patent protection by Ethiopian nationals. This is simply because of the fact that the problem of exploiting invention arises once enterprises acquires capability to invent new essential drugs.

So providing stronger protection of patents as required by trade related aspect of intellectual

Property agreement in this early stage of innovative capacity hampers Ethiopia from developing her technological capability, So as to benefit from stronger protection in the long run and rights of people to the access to essential drugs on the other hand.

CONCLUSION

The interface between TRIPS, patent rights and right to health has been one of the most hotly debated issues on the international arena in the past

⁸⁸ *Assefa Endeshaw(1996) intellectual property policy for non- industrialized countries, Dartmouth publishing company, p, 265*

years. The reason for this ongoing debate is underlying controversy between developed countries and developing countries regarding the nexus between intellectual property rights protection and public health. Patent right is one of the intellectual property right granted for the inventors for a limited period of years, if the invented product or process fulfilled the patentability requirements such as novelty, inventive step and industrial applicability. And patent right is an instrumental right unlike the health right as a fundamental human right. Historical development of patent goes back to many centuries in the past. Even some literatures state that around 500B.C. in Sybaris, Greece, there were monopolies granted to new dishes for a period of one year. From this we can estimate that in one or in other way in the earlier periods there were trends, directly or indirectly related with patent.

The right to health is not the right to be health but it must be understood as the right to the enjoyment of variety of facilities, goods and services and conditions necessary for the realization of the highest attainable standard of health including the right to access and afford the essential drugs.

Patent right is an instrumental right which has negative legal implication on the right to health. Which affect right to accessibility, affordability and quality of healthcare service and goods.

By its nature patent confer on inventors to exclude others from manufacturing, using or selling patented pharmaceutical products.

TRIPs negotiation was started by American and unitedkingdom pharmaceutical companies and other transnational companies and it protect the right of developed countries. By recognizing flexibilities to the enforcement of patent rights, the TRIPS agreement aims at reconciling the interests of the patent owners with those of the consumers. However TRIPS has been criticized as not being flexible enough for developing countries facing acute health issues. Even by providing

exceptions to patent rights in defined circumstances such as compulsory licensing, parallel importation, restriction on patentability, TRIPS Members were aware of the potential negative impact of strong patent protection on access to medicine in developing countries.

The developments in the framework of Doha with the Doha declaration and the waiver decision of the TRIPS Council can be analysed as evidence of the unsatisfactory framework the TRIPS agreement set up for access to medicine. Hence Article 30 and 31 of the TRIPS agreement which provide exception to patent rights are of limited applicability. Even though, the developments in the framework of Doha are a big victory for developing countries towards improved access to medicine, they are hindered by factors extrinsic to TRIPS. Hence, the so called “TRIPS Plus” agreements and the United States and other developed countries political involvement have a negative impact on access to medicine in developing countries.

The last but not the least, the patent and its legal implication on the right to health of Ethiopian people is also raised as one topic. The emergence of legal recognition and protection of the creations and inventions of individual in Ethiopia spans about five decades. Until recently, people engaged in technical works such as artifacts were often seen as inferior members of society. Specific rules on intellectual property rights targeting authors and inventors emerged towards the end of the 1950s and the beginning of the 1960s when Ethiopia embarked upon codification of its laws.

The right to health was also mentioned and recognized under different laws of Ethiopia such as: FDRE Constitution, different international instruments Ethiopia has ratified or accessed most of the international and regional human rights instruments which give recognition to the right to health. The most important ones are the International Covenant on Economic, Social and Cultural Rights (ICESCR), the International Convention on the Elimination of All Forms of Racial Discrimination (CERD), the

Convention on the Elimination of All Forms of Discrimination against Women (CEDAW) and, the Convention on the Rights of the Child (CRC). At a regional level, Ethiopia has ratified the African Charter on Human and Peoples Rights (ACHPR). Consequently, all the above international and regional human right instruments are an integral part of the law of the land. As a patenting of medicine restricts the right to health of people in least developed countries, Ethiopia is one of the list developed country in the world. So providing stronger protection of patents as required by trade related aspect of intellectual property agreement in this early stage of innovative capacity hampers Ethiopia from developing her technological capability, So as to benefit from stronger protection in the long run and rights of people to the access to essential drugs on the other hand.

Recommendation

Based on the search and research I have made on the title “patenting of medicine and its legal implication on the right to health” I would like to recommend the following points as an outcome of my research.

1. The duration of exclusive rights of patent holder on pharmaceutical product should be reduced.
- 2 The right to health (fundamental right) should prevail over the right to property (instrumental right) when conflict exist between the two
- 3 Developing countries and LDCs should establish high patentability standards and provide for exclusions from patentability of essential drugs to uphold the right to health effectively
- 4 Developing countries and LDCs should review their laws and policies and consider whether they have made full use of TRIPS flexibilities or included TRIPS-plus measures, and if necessary consider amending their laws and policies to make full use of the flexibilities.

- 5 Developing countries and LDCs should not introduce TRIPS-plus standards in their national laws.

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