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INTELLECTUAL PROPERTY AND ACCESS TO ESSENTIAL MEDICINES UNDER EGYPTIAN LAW

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INTELLECTUAL PROPERTY AND ACCESS TO ESSENTIAL MEDICINES UNDER EGYPTIAN LAW
IS THE RIGHT OF HEALTH IS GUARANTEED?

Submitted on 6 June 2010

by

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Declaration

I hereby solemnly declare that I have written this thesis by myself and without support from any other person or source, that I have used only the materials and sources indicated in the footnotes and in the bibliography, that I have actually used all materials listed therein, that I have cited all sources from which I have drawn intellectual input in any form whatsoever, and placed in “quotation marks” all words, phrases or passages taken from such sources verbatim which are not in common use and that neither I myself nor any other person has submitted this paper in the present or a similar version to any other institution for a degree or for publication.

Indianapolis, 6 June 2010

(Marco M. Soliman)
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List of Abbreviations

CESCR  Committee on Economic Social and Cultural Rights
GATT  General Agreement on Tariffs and Trade
GOE  Government of Egypt
ICESCR  International Convention on Economic, Social and Cultural Rights
IP  Intellectual Property
IPRs  Intellectual Property rights
IFPMA  International Federation of Pharmaceutical Manufacturers Association (USA)
MOH  Egyptian Ministry of Health
NGOs  Non Governmental Organizations
PMA  Pharmaceutical Manufacturers Association (South Africa)
R&D  Research and Development
TBT  Technical Barriers for Trade Agreement
TRIPS  Agreement on Trade Related Aspects of Intellectual Property Rights
UDHR  Universal Declaration on Human Rights
WHO  World Health Organization
WIPO  World Intellectual Property Organization
WTO  World Trade Organization
# Table of Contents

Acknowledgement .................................................................................................................. i

List of Abbreviations ............................................................................................................. ii

Chapter 1: Introduction ........................................................................................................... 1

1.1 Background of the Study ................................................................................................. 1

1.2 Statement of the Research Problem ................................................................................. 3

1.3 Aims and Objectives of the Study .................................................................................. 3

1.4 Significance of the Study ............................................................................................... 4

1.5 Outline of the Chapters .................................................................................................. 4

Chapter II: Access to Medicines under International Agreements and Egyptian Law ...... 6

2.1 Introduction .................................................................................................................... 6

2.2 Access to Medicines in Egypt ....................................................................................... 6

2.3 Egyptian Domestic Laws ............................................................................................... 11

2.4 Egyptian intellectual property law ................................................................................ 12

2.5 International Agreements .............................................................................................. 12

2.6 Customary International law ......................................................................................... 16

2.7 Technical Barriers to Trade agreements (TBT) ............................................................... 17

2.8 WTO and TRIPS Agreements ....................................................................................... 19

2.9 Doha Declaration ......................................................................................................... 21

Chapter III: Egyptian Law and International Agreements to Public Health Issues .......... 25

3.1 Introduction .................................................................................................................... 25

3.2 Egyptian intellectual property law ................................................................................ 25

3.3 Patents ........................................................................................................................... 25

3.4 Patent criteria ................................................................................................................. 27

3.5 Novelty ........................................................................................................................... 27
3.6 Inventive step ...........................................................................................................29
3.7 Industrial application ...............................................................................................29
3.8 Undisclosed information .........................................................................................30
3.9 Egypt: Judicial interpretation of Egyptian and international patent law ........32

CHAPTER IV: Can Egyptian IP and TRIPS be interpreted in ways to facilitate Access to Essential Medicines .................................................................35

4.1 Flexibilities under TRIPS agreement ..................................................................35
4.2 Research exceptions and “Bolar” provisions .......................................................37
4.3 Scientific Activities .................................................................................................38
4.4 Compulsory license and public, non-commercial use of Patents .......................38
4.5 Parallel imports .......................................................................................................40
4.6 Analyzing TRIPS agreement flexibilities ..............................................................41

Chapter V: Conclusions and Recommendations .......................................................43

5.1 Summary of chapters ..............................................................................................43
5.2 Conclusions ..............................................................................................................43
5.3 Recommendations ..................................................................................................45
5.4 On the national level ...............................................................................................45
5.5 To universities ..........................................................................................................47

List of Bibliography .....................................................................................................48
Chapter 1: Introduction

1.1 Background of the Study

“…. Governments promised leadership. The pharmaceutical industry must keep its promise to make AIDS drugs available to developing countries at affordable prices. Scientists to work where the real needs are, not just where the money and the glory lie. NGO leaders to be uncompromising advocates for all their constituencies, not just the elite. For sustained progress against the (AIDS) epidemic it is time to tackle the driving forces of global inequality. To put AIDS firmly on the political agenda that shapes the world order- a world beyond just science and classic public health. International trade negotiations may make as big a difference to AIDS treatment as any number of national treatment plans. Donor imposed caps on public sector spending must not fight inflation at the expense of sustained investment in AIDS....”

P. Piot, Executive Director, UNAIDS

Over 9.5 million people die each year due to infectious diseases, nearly all living in developing countries. Most causes of illness and death in developing countries including Africa, Asia and South American region account almost four-fifth of the world’s population are HIV/AIDS, malaria and tuberculosis (TB). Egypt, as part of the African region, has a similar disease burden. Specifically, in Egypt, the population suffers from a high prevalence of Hepatitis C and a high morbidity and mortality from chronic liver disease, cirrhosis, and hepatocellular carcinoma.

These epidemics had drawn the world attention to the fact that millions of people in developing countries have no adequate access to medicines to treat such diseases, for over more

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3 *Id.*

than sixty years ago the Universal Declaration of Human Rights affirmed the right to health as a fundamental human right and an indispensable component of development under any economic policy model. This right to health is now challenged because patents of importance, the high commissioner report on the Promotion and Protection of Human Rights, the Commissioner described in one of its reports that access to essential is regarded as a “human right.”

The World Trade Organization (WTO) agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), set the minimum standards for the protection of intellectual property, including patents for pharmaceuticals, was criticized due to the effect it had increased in levels of patent protection will have on drug prices. TRIPS attempts to strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations including safeguards to remedy negative effects of patent protection. Yet it is still in practice unclear how countries can make use of these safeguards when patents increasingly present barriers to medicine access.

Whether intellectual property laws are a barrier to access to essential medicines had generated much debate. This controversy reveals the importance of this issue. More importantly the advocacy for human right to health and to treatment in particular in developing country whose interests are against those of the developed rich world and research based pharmaceutical companies. Advocacy for access to treatments is leading to a moral and legal debate on the role of patenting medicines, new attempts to define the boundaries to intellectual property and calls for re-negotiation of the world trade rules.

With globalization, access to health care is widely accepted as a core component of efforts to promote and protect the right to health. However there still exist inequalities in the health status of people particularly between developed and developing countries. It is therefore conclude that globalization has created new opportunities as well as challenges for the protection and promotion of human rights.

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7 This issue will be discussed in details in the subsequent chapter.

Against this background, the thesis of this study is the emphasis that the maneuver within the TRIPS regime is not the end in realizing the right to health. Rather it is only a starting point for the realization. This thesis will examine this issue in Egypt, specifically addressed are Egyptian intellectual property whether and how the law utilize the exceptions to patent protection rights under TRIPS. The thesis concludes that statement that it takes the commitment of the state and other actors concerned, in this case the pharmaceutical companies for the true realization of the right to health and human rights in general.

1.2 Statement of the Research Problem

Trade being the cornerstone of globalization, it is essential that the rules governing trade does not violate human rights but rather promote them. The implementation of the TRIPS agreement has resulted in a conflict between the obligations of states to promote and protect health including access to essential medicines and the achievement of economic goals under the WTO regime. The conflict between intellectual property and the right to access to medicines arises partly from ensuring that the integration of economic rules and institutional operations in relation to intellectual property rights inline with states’ obligations to promote and protect public health. Hence it is essential to analyze laws governing intellectual property laws in order to ensure that it strike this balance.

1.3 Aims and Objectives of the Study

This study aims to investigate to which extent the Egyptian property laws are in conformity with TRIPS agreement and whether the Egyptian law is able to strike a balance between its international commitments and its ability to ensure the access to essential medicines by its citizens. The general objectives of the study are:

a) To examine the current Egyptian laws related to pharmaceutical industry and more precisely Intellectual property laws and how far Egyptian laws are in conformity with international standards;
b) To assess to which extent the Egyptian laws utilizes the flexibilities permitted under TRIPS agreement;

c) To assess to which extent the Egyptian Intellectual property law improves or impedes access to medicines and especially essential medicines.

1.4 Significance of the Study

While technological advancements are necessary for the protection of exclusive exploitation rights, which intellectual property laws to safeguard, the maintenance and improvement of human health must be considered as a primary objective of states ensuring the adequate access to essential medicines. International organizations and states attempt to mitigate in order to enhance the right to health within the TRIPS regime. It is pertinent that in the first place there is real commitment for the said realization. This study will therefore attempt to contribute to the post Doha declaration debate intended to identify avenues for the right to health crystallized in access to essential medicines and whether the challenges for realizing the right to health lie only in the TRIPS regime. It is noteworthy that although the question of access to medicines and related issues are critical to human rights, many traditional human rights NGOs including Human Rights Watch (HRW) and Amnesty International (AI) continue to distinguish the right to health including access to essential medicines and other socio-economic rights from civil and political rights, giving them less attention. The study therefore will also attempt to enhance civil society understanding of the importance and need for socioeconomic rights advocacy.

1.5 Outline of the Chapters

Chapter II will provide background information on the situation regarding essential medicines in Egypt as well as relevant Egyptian and international law. This part will discuss in

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9 See reports published by Amnesty international and Human rights watch in this regard.
detail the situation of access to medicines in Egypt with reference to most updated surveys conducted by WHO in this regard.

Furthermore, this chapter will provide an overview to Egyptians laws regulating medicines in general and emphasizing on commercial law, Egyptian intellectual property laws. Subsequently, this chapter will discuss international laws governing health related issues such as Technical Barriers to Trade agreements (TBT), World Trade Organization (WTO) agreements with emphasis on trade-related aspects of intellectual property rights (TRIPS) and finally the Doha deceleration.

While chapter III will provide in depth analysis to the Egyptian laws pertaining to health related issues such as commercial law and intellectual property laws. Furthermore this chapter will discuss in detail Egyptian patents and undisclosed information in relation to medicines such patentability criteria.

Chapter IV will discuss the flexibilities mentioned in international agreements and how far those flexibilities are incorporated in Egyptian laws and whether Egypt had used those flexibilities and what are the cases pending before the judiciary or being resolved pertaining to access to medicines in Egypt.

Finally, Chapter V will provide an overall summary to the previous chapters and what are the recommendations that Egyptian government and universities can do in order to enhance the access to medicines within already existing laws.
Chapter II: Access to Medicines under International Agreements and Egyptian Law

2.1 Introduction

This chapter is divided into two parts. The first part introduces the situation regarding essential medicines in Egypt as well as relevant Egyptian and international law. This part will discuss in detail the situation of access to medicines in Egypt with reference to most updated surveys conducted by WHO in this regard. Furthermore, this chapter will provide an overview to Egyptians laws regulating medicines in general and emphasizing on Egyptian intellectual property law. Subsequently, this chapter will discuss international laws governing health related issues such as Technical Barriers to Trade agreements (TBT), World Trade Organization (WTO) agreements with emphasis on trade-related aspects of intellectual property rights (TRIPS) and finally the Doha Delegation.

2.2 Access to Medicines in Egypt

Egypt is the most populous nation in the Middle East and North Africa (MENA) region and also its largest drug consumption market.\(^\text{10}\) The government of Egypt is managing to maintain access to relatively low drug prices through price controls and subsidization.\(^\text{11}\) Additionally, drug prices are state controlled through an official Drug Pricing Committee, which sets the retail price for drugs. The government also subsidizes medicines to ensure that they remain affordable.\(^\text{12}\) Despite that, individuals in Egypt still rely heavily on private pharmacies and many purchases are unsubsidized. It is therefore critical that the drugs available in private pharmacies are affordable, so that every sector of society is able to access needed medicines.

\(^{11}\) NAGLA RIZK & LEA SHAVER, ACCESS TO KNOWLEDGE IN EGYPT, NEW RESEARCH ON INTELLECTUAL PROPERTY, INNOVATION AND DEVELOPMENT (2010).
\(^{12}\) AmCham Egypt Business Studies and Analysis Center, Pharmaceutical Sector Developments in Egypt (2006).
Patients in Egypt have traditionally accessed to low prices drugs, due to a strong local generic pharmaceutical industry and a price control regime run by the state. In 2006, The American Chamber of Commerce in Egypt reported that “Egypt’s retail drug prices are currently among the lowest in the Middle East.”

Egypt has a pharmaceutical industry that is a dominant within the Middle East and North Africa (MENA) region. In 2005, Egypt’s private pharmaceutical market was judged to be the second most valuable in the Middle East region. Its local drug manufacturing industry supplies 30% of the market in the MENA region.

Furthermore, Egypt has a well-established pharmaceutical regulatory system that was initiated in the middle of the twentieth century. The law of Pharmacy was promulgated for drug regulation in the country. Pharmaceutical legislations in Egypt govern registration, manufacturing, importation, promotion and distribution of medicines. The Drug Planning and Policy Centre (DPPC) is the national drug regulatory body, and it operates under the Ministry of Health (MOH). It is responsible for pricing and registration of all drugs, whether locally produced or imported, according to the Law of Pharmacy. It also maintains a National Essential Drug List.

Although Egypt’s production of medicines covers more than 90% of its domestic consumption, these medicines are not usually up to date or technologically advanced drugs. This reflects a limited domestic manufacturing capacity. At least 85% of raw materials are imported for assembly, packaging and distribution in Egypt. It is estimated that the average spending on research and development (R&D) is limited to 1.3% of total spending for public sector companies and 3% for private ones. However, some efforts taken by foreign subsidiaries to introduce new technologies for domestic manufacture in Egypt, these promises remain

13 Id.
14 Id. at 10.
17 Wanis, supra note14, at 27.
20 Id. at 107.
unfulfilled. The absence of such technologies and the existence of poor level of R&D might lead to dependency on imported materials and technologies. This situation is becoming more critical with the enforcement of the IPR protection provisions of the TRIPS Agreement and might weaken Egypt’s ability to ensure the accessibility to affordable medicines by its citizens.

It has been debated that “dramatic rise in prices of pharmaceuticals will occur as a result of the implementation of TRIPS.” However, without providing any solid explanations for this argument. While others other reports attempted to provide basis for this argument. Finally other commentators believed that drug prices would increase as a consequence of introducing new standards of patents protection under the current IPR law and that such increase will not occur instantly but from the end of a period of 5-8 years, commencing from the end of the additional grace period starting from 2005.

A study commissioned by the World Health Organization (WHO) and Health Action International (HAI) in 2004 found that Egypt achieved low public sector procurement prices compared to an international reference price based on the standard price survey methodology. Furthermore, the study revealed that the cost of a month’s treatment using generic medicines costs the equivalent of only half a day’s wage of an unskilled Egyptian worker.

Furthermore, public sector firms play a curial role in making affordable drugs accessible. These firms are commonly criticized for the “poor profitability, the relative inefficiency, and the low labor productivity,” these firms constitute 30% of the local drug manufacturing at affordable prices. However, capital investments in the public pharmaceutical sector have been decreasing by an average of 2.4% each year.

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21 Id. at 108.
26 Id. at 2.
27 Supra note 19, at 98.
28 Id. at 106.
On the other hand, the private pharmaceutical might be sighted as a greater barrier for access to medicines. According to the WHO/HAI study, private sector retail pharmacy selling innovator medicines are higher than generic medicines prices 1.5 to 2 times and in some cases as high as 10 times.\(^\text{29}\)

However, in attempt to maintain low drugs price, the Egyptian Ministry of Health (MOH) had compiled a list of essential drugs which is updated every two years. MOH had also established a Pricing Committee to set the retail price at which the drug will be sold in both private and public sectors.\(^\text{30}\)

The MOH’s National Drug Policy mandates this committee to achieve “the availability of safe and effective drugs at the lowest possible cost… [by] rationalizing the drug pricing system.”\(^\text{31}\) This is a cost-plus system which enables the Pricing Committee to fix the retail price of the drugs based largely on manufacturing expenses, which vary according to the drug in question. Other inputs, including taxes and profit mark-ups, are often calculated as a fixed percentage mark-up on all drugs within a given category.

The Ministerial Decree number 314 of 1991 enables the MOH to set a profit margin of 15% for essential drugs and 25% and up to 40% for over-the-counter drugs such as vitamins and painkillers.\(^\text{32}\) Although the said decree is yet still in force, the subsequent Ministerial Decrees regulating the Pricing Committee did not make explicit reference to method of calculation made in decree number 314. For example, Ministerial Decree number 148 of 1996, as well as, Ministerial Decree number 96 of 2004, instructs the Committee to undertake the necessary research to determine the prices of medicines “taking into account its economic cost, as well as the pricing guidelines approved by the Minister of Health.”\(^\text{33}\) This might lead to a variation in determining the retail price as ascribed by the Price Committee.

The Egyptian government subsidizes a number of key commodities in order to assist lower-income families. In 2007, the Government of Egypt had subsidized “278 pharmaceuticals for the

\(^\text{30}\) The Drug Pricing Committee was established by virtue of Ministerial Decree number 404 of 1976 and amended by several decrees most recently decree number 96 of 2004.
\(^\text{33}\) Egyptian Minister of Health Ministerial Decree, no. 96 of 2004.
treatment of chronic diseases such as tumor, renal failure, hepatitis and high blood pressure, in addition to subsidizing insulin and imported infant milk.” The subsidies system works through the government commissioning a pharmaceutical distribution company, the Egyptian Company for the Sale of Drugs, owned by the Drug Holding Company, to distribute the medicines at set fixed prices. Although the value of subsidy amounts to LE120 million, the government only pays around LE72 million. The LE48 million deficits is borne by the distributing company, which manages to cover for this financial shortfall by compelling pharmacies to purchase other medicines in addition to the subsidized ones.

Egypt accession to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) by virtue of presidential decree number 72/1995 and published in the official gazette on 15 June 1995 had imposed further obligations on the Egyptian government to fulfill its obligations under the TRIPS agreement including providing patent protection to pharmaceutical products. Furthermore, the Egyptian government had been under pressure to implement “TRIPS-plus” provisions that would further limit pharmaceutical competition.

Against this background, it is essential that the Government of Egypt (GOE) adopt a carefully considered policy that focuses on ensuring affordable access to medicines. In its 2009 report, the UN special rapporteur on the right to health emphasized that “access to medicines forms an indispensable part of the right to health.” The report of the Special Rapporteur specifically addressed the ways in which Free Trade Agreements (FTAs) and TRIPS-plus provisions negatively impact access to medicines and called on states to resist such negative effects and to develop and implement laws and policies that protect the right to health. As recommended by the Special Rapporteur, the Egyptian government should develop a consistent and predictable policy on public health, trade and intellectual property that is firmly based on human rights perspective. A rights-based IP policy would require Egypt to ensure that its laws and practices explicitly confirm human rights principles over trade and IP related interests. In

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35 Fayyad, supra note 18, at 54.
38 Id. para. 10.
addition, Egyptian government through various departments must coordinate their approach so that policies regarding issues such as IPR are underpinned by Egypt’s commitment to respect protect and fulfill the right to health. Finally, a rights-based approach also will ensure more transparency and public participation so that civil society and all interested stakeholders can be involved. Only with this firm basis Egypt might be able to resist increasing pressures to place the commercial interests of pharmaceutical manufacturers over the obligation to protect the right to health.

2.3 Egyptian Domestic Laws

The right to health is enshrined in various international and regional human rights agreements as well national constitutions. In Egypt safeguards the right to health in various articles of the constitution. Article 16 stipulates that “The State shall guarantee … health services, and work to ensure them for the villages in particular in an easy and regular manner in order to raise their standard.”

Furthermore, the Egyptian constitution stipulates that “The State shall guarantee … health insurance services and all the citizens.”

The aforementioned articles are treating the right to health as the right of access to health care which differs from ICESCR which it is referred to as the right to the highest attainable standard of health.

Additionally, Article 7 stipulates that “social solidarity is the basis of the society.” This article empowers the Government of Egypt to promulgate laws to provide organize medical insurance services in accordance with the constitution and to meet the requirements stipulated by international agreements on human rights.

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39 The Arab Republic of Egypt constitution after the amendments ratified on March 26, 2007.
40 Id. art. 17.
41 For further discussion on the right to health and its standards, see Eleanor D. Kinney, Recognition of the International Human Right to Health and Health Care in The United States, 60 Rutgers L. Rev. 335 (2009).
42 Supra note 33, art. 7.
2.4  **Egyptian intellectual property law**

Egyptian intellectual property law had gone through various phases and reforms. The first reference to IP is cited in article 12 of the abolished Egyptian civil code.\(^{44}\)

In year 1940, law number 11 of year 1940 promulgated regarding sales and mortgages of shops\(^ {45}\) and in year 1951 law number 55 of year 1951 promulgated regarding trade names which was amended by virtue of law number 67 of year 1954.\(^ {46}\)

In year 1949, law number 132 of year 1949 was promulgated regarding patents and industrial designs. This law was abolished also by virtue of the aforementioned law of 82 of year 2002.

Finally, in year 2002 law number 82 of year 2002 was promulgated regarding IP abolishing the aforementioned laws with exception to chemicals of nutrition-related products, and chemical products related to pharmaceutical and micro-organisms and products that were not subject to protection by the issuance of the aforementioned law that shall be in force from 1\(^ {st}\) of January 2005.\(^ {47}\)

It worth to mention that Egypt was not a member to international agreements governing protection of trade names and trade marks, patents and utility models, layout-designs for integrated circuits prior to the current IP law of 2002, nevertheless, Egypt had incorporated the principles of international agreement related to IP.

2.5  **International Agreements**

The right to health is embodied in international and regional human rights treaties. However, every agreement had its own approach to the definition of the right to health. A close look at how it has been defined historically, however, as well as how it has been and is being enforced, will help clarify the scope of the right to health and what is required of those countries that recognize

\(^{44}\) The abolished civil code stipulated that “with respect to the rights of the manufacturer on the ownership of its products according it shall be governed by a special law for these purposes.” However, this law was never promulgated.

\(^{45}\) **GAAL MOHAMED EN, LEGAL PROTECTION OF INDUSTRIAL PROPERTY ACCORDING TO TRIPS AGREEMENT** (2004).

\(^{46}\) *Id.*

\(^{47}\) Official gazette number 22 *bis* issued on 2 June 2002.
and support this right. This definition can then be analyzed in the context of providing access to essential medicines.

The right to health has been developed and clarified through its use in numerous international human rights treaties over the past sixty years. The World Health Organization (WHO), defined health in its preamble broadly, as a “state of complete physical, mental and social well-being and not merely the absence of disease and infirmity.” Although some commentators had criticized this definition as being too broad, however, WHO had adopted it and incorporated it in its Constitution, this become definition binding to all member states that are party to the WHO.

Furthermore, The Universal Declaration of Human Rights is regarded as the basis of much of the internationally recognized human rights instruments stipulates that” Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services.” The Universal Declaration remains the “primary source of global human rights standards, and its recognition as a source of rights and law by states throughout the world distinguishes it from conventional obligations.” Almost every international instrument focusing on human rights contains at least a reference to the Universal Declaration.

On the other hand, the International Covenant for Economic, Social and Cultural Rights (ICESCR), adopted a “dual principle” requiring member states to adopt “highest attainable standard of physical and mental health,” but subject to an “allowance for local conditions.” Although the ICESCR did not explicitly adopt the WHO’s broad definition of “health” it was implicitly adopted through the four specific steps stipulated in article 12(2) which are steps taken by states are “(a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child; (b) The improvement of all aspects of environmental and industrial hygiene; (c) The prevention, treatment and control of epidemic, endemic,

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53 Id. art. 12.
occupational and other diseases; (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.” These are regarded as the basic requirements for the realization of high standard of physical and mental health for all citizens.

Many UN bodies had interpreted the right to health to include a right to available and accessible health care. WHO adopted a strategy entitled “Health for All” it articulated a “core content” of the right to health, including a set of elements which could be regarded as “most essential” from a human rights perspective. The “core content” included the appropriate treatment of common diseases and injuries, and the provision of essential drugs. The WHO’s “Health for All” strategy required that the entire population living on the territory to be covered and to have access to the services both financially and geographically. A comment from the Committee on Economic, Social and Cultural Rights (CESCR) suggested that the right to health should be available and accessible to all, regardless of economic status, including essential drugs.

The U.N. Economic, Social and Cultural Committee issued in 2000 a General Comment number 14 to ICESCR that outlines states obligations under the international right to health and its implementation and enforcement. However, in attempt to materialize the right to health on the international context, the General Comment number 14 had interpreted the right to health stipulated under article 12.1 of ICESCR to include not only rights pertaining to health but also rights associated to health such as access to safe and potable water and adequate sanitation. Furthermore, the General Comment had adopted criteria to ensure the application of the right to

54 Id. art 12 para. 2.
56 Id.
57 Id.
58 See ICESCR General Comment 14, para. 31.
59 There are other international treaties that recognize the right to health such as the International Convention on the Elimination of All Forms of Racial Discrimination and The Convention on the Elimination of all Forms of Discrimination against Women (CEDAW) Kinney, supra note 41, at 342.
61 Id. para. 11.
health in states such availability of health services, accessibility, acceptability and quality of such services.\textsuperscript{62}

Additionally, General Comment number 14 also imposed three categories of obligations on states namely: the obligations to respect, protect, and fulfill. The obligation to respect requires states parties to abstain from interfering directly or indirectly with the enjoyment of the right to health by the residents of its territories. The obligation to protect requires states parties to adopt measures that prevent third parties from interfering with Article 12 guarantees. The obligation to fulfill requires states parties to adopt appropriate legislative, administrative, budgetary, judicial, promotional, and other measures toward the full realization of the right to health.

General Comment 14 explicitly addresses the implementation by states. It imposes a duty on states parties “to take whatever steps are necessary to ensure that everyone has access to health facilities, goods and services so that they can enjoy, as soon as possible, the highest attainable standard of physical and mental health.”\textsuperscript{63} Implementation also requires the adoption of “a national strategy to ensure to all the enjoyment of the right to health based on human rights principles which define the objectives of that strategy, and the formulation of policies and corresponding right to health indicators and benchmarks.”\textsuperscript{64} The national health strategy and plan of action should “be based on the principles of accountability, transparency and independence of the judiciary, since good governance is essential to the effective implementation of all human rights, including the realization of the right to health.”\textsuperscript{65}

Finally, the General Comment provides remedies to individuals on the national and international levels if states did not fulfill its international obligations under international human right to health. General Comment 14 explicitly stipulates that if any state party “which is unwilling to use the maximum of its available resources for the realization of the right to health is in violation of its obligations under Article 12.”\textsuperscript{66}

\textsuperscript{62} Id. at 12.
\textsuperscript{63} Id. at 53.
\textsuperscript{64} Id.
\textsuperscript{65} Id. at 55.
\textsuperscript{66} Id. at 47.
Also the right to health is enshrined in regional conventions such as article 16 of the African Charter on Human and Peoples' Rights.\textsuperscript{67} Although, the wording is made similar to the wording of ICESCR. However, it does not cite the principle of “progressive realization.” This poses the African countries an obligation to ensure the right to health is not limited only to health care. As states are obliged to promote and respect other rights associated to the realization to the right to health.\textsuperscript{68}

2.6 Customary International law

A tribunal might treat the right to health as to the level of “customary international law,” it would have to consider this right when interpreting international treaties related to the right of health. The International Court of Justice (ICJ) statute stipulates that the Court apply both “international custom, as evidence of a general practice of international law,” and “the general principles of law recognized by civilized nations,” in deciding disputes brought before it.\textsuperscript{69} Customary international law has a binding effect and can be used to interpret international agreements.\textsuperscript{70} Although Egypt is a signatory to most international agreements related to human rights. However, an Egyptian tribunal might consider the right to health as a customary international law while interpreting of treaty provisions and domestic statutes.

There has been support for the concept that the rights embodied in the ICESCR should be regarded as an integral part of customary international law.\textsuperscript{71} There are 143 states parties to the Covenant, and many of its provisions, including the right to health, are enshrined in other treaties. Many states have included provisions granting a right to health along with other economic, social and cultural rights in their constitutions, usually as directive principles to be considered by legislatures in passing laws and to be used by courts in interpreting laws.\textsuperscript{72} The recognition of the right to health may be inline with the ICJ's use of the “general principles of

\textsuperscript{68} Sandra Kiapi, \textit{Interpreting the right to health under the African charter}, 11 EAJPHR. 1 (2005).
\textsuperscript{69} International Court of Justice statute art. 38(1)(b).
law recognized by civilized nations. “Cases interpreting the right to health provide an example of how this right can be used to help interpret ambiguous meanings of certain provisions.73 Although the Government of Egypt had ratified the ICESCR,74 however, courts may resort to customary international law to interpret ambiguous provisions of law to provide to recognize the right to health.

2.7 Technical Barriers to Trade agreements (TBT)

WTO rules that govern technical barriers to trade applied for reasons of protecting health are in the Agreement on Technical Barriers to Trade (TBT Agreement).75 Members have the right to restrict trade for “legitimate objectives” set by standardization bodies under the TBT Agreement.76 Under TBT, health is regarded a legitimate objective for restricting trade.

Technical on trade were first introduced in the Tokyo Round of multilateral trade negotiations (1973-1979).77 The first agreement is referred to as the “Standards Code,” which came into force in 1980.78 The “old” TBT was ratified only by 46 members only.79 However, the new TBT Agreement, which came into force with the WTO in 1995, is binding on all WTO Members as it embodies more stringent obligations than the preceding version of the agreement.80

The legitimate objectives include the protection of human health or safety, the protection of animal or plant life or health, the protection of the environment, national security interests, and the prevention of deceptive practices.81 The aim of TBT Agreement to ensure that product requirements, and procedures that are used to assess compliance with those requirements, do not create unnecessary obstacles to trade, including health, However, the measures should not

74 Government of Egypt had ratified the convention on 14 January 1982.
76 PETER VAN DEN BOSSCHE, DENISE PRÉVOST & MARIELLE MATTHE, WTO RULES ON TECHNICAL BARRIERS TO TRADE (2005).
78 Id. at 35.
79 Id.
80 Id.
81 Supra note 76.
unnecessarily restrict trade by member states. The Agreement distinguishes between “technical regulations” as well as “standards.” It covers such requirements developed by member or private entities at either national or regional level.

The Agreement sets number of principles. First is non-discrimination, whereby if a member state applies certain requirements to imported products, it has to apply the same requirements to like domestic products. Moreover if a member state applies a requirement to imports from one country, it has to apply same measurements or requirements form other countries as well.

Protection of human health is regarded one of the legitimate objectives for which product requirements may be developed. For example all TBT regulations notified to the WTO in 2000, 254 notifications, out of the total of 725 that were received had human health or safety as their objective. It worth mentioning that, GOE did not make any notification to with regard to human health or safety requirements under this agreement.

The TBT Agreement promotes the use of international standards. However, member states may abandon them if they consider that their application would be ineffective or inappropriate for the fulfillment of certain legitimate objectives. For example if a member state regard that other standards appropriate to be adopted as national standards or technical regulations, it should adopt them. Nevertheless, member states are free to determine the standards at a level they consider appropriate. However, member states must justify their decisions if so requested by other member state. The TBT also calls upon Members to play an active role in the process of international standardization, particularly for any product for which it is developing a national requirement.

Article 15.4 of the TBT Agreement states that “[n]ot later than the end of the third year from the date of entry into force of the WTO Agreement and at the end of each of three-year period thereafter, the Committee shall review the operation and implementation of this Agreement.” As of the date of enforcement of this Agreement it has been reviewed more than two times. The

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82 Id.
83 Annex 1 paragraphs 1 and 2 of the TBT Agreement defines these two concepts.
84 Supra note 76.
85 Supra note 77, at 33.
87 Supra note 77, at 34.
88 TBT Agreement, art. 2.6.
review examined the operation of the Agreement with respect to notifications, obligations, the use of international standards, guides and recommendations, conformity assessment procedures the provision of technical assistance, and further issues.\textsuperscript{89}

\section*{2.8 WTO and TRIPS Agreements}

IP protection for patents was first addressed in a multilateral agreement was Paris Convention for Protection of Industrial Property in 1883 (the Paris Convention).\textsuperscript{90} Prior to Paris convention, there was a variation in national patent laws, creating obstacles to the protection of patent rights, and allowing patents to be used as a mechanism for protection of the locally-produced goods and to exclude other products from competition.\textsuperscript{91} The Paris Convention was thus created to prevent this kind of protection mechanism through the “national treatment” principle, enshrined in article 2(1) whereby nationals of any member state to the treaty enjoy the same intellectual property protection in all member state party to the convention.\textsuperscript{92} The Paris Convention has created exceptions to patent protection, such as compulsory licensing.\textsuperscript{93} However, recognizing these exceptions is up to the discretion of member state party to the convention, subject to non-discrimination basis.\textsuperscript{94} Currently the World Intellectual Property Organization (WIPO) is administering the Paris convention and further it is responsible to intellectual property disputes and to provide assistance in implementing the new provisions.\textsuperscript{95}

The increase of trade between countries and the emerging of globalization lead to the importance of intellectual property in trade in the second half of 20\textsuperscript{th} century. Developed countries addressed concerns about the lack of standardized, strong protection of intellectual


\textsuperscript{90} Paris convention was revised at Stockholm 1967 and was last amended in 1979 See generally WIPO INTELLECTUAL PROPERTY HANDBOOK: POLICY, LAW AND USE (2004) for detailed discussion about IP international conventions history.

\textsuperscript{91} AL QALIOUBY supra note 36.

\textsuperscript{92} Article 2(1) of Paris convention.

\textsuperscript{93} Article 5(2) of Paris convention.

\textsuperscript{94} Supra note 76.

\textsuperscript{95} Article 13 of Paris convention.
property rights. Member states complaints about the Paris Convention regime suggested that it lacked sufficient enforcement of intellectual property rights mechanism that do not require domestic legislation for protecting these rights. Furthermore, Paris convention did not cover certain types of technological developments, including new pharmaceuticals. Another complaint by member states about the Paris convention was the “misuse of compulsory licensing programs.”

Several industry trade associations, including the Pharmaceutical Manufacturers Association (PMA) and the Pharmaceutical Research Manufacturers Association (PhRMA), had began an aggressive lobbying to increase protection of intellectual property rights because losing profits as a result of the sale of generic products overseas. The pharmaceutical industry argued that monopolistic pricing made available through strong patent protection system was necessary to regain the costs of research and development. The TRIPS hence become an ideal platform for the developed countries to pursue the increased protection of IPRs. Furthermore, the TRIPS provided minimum standards for protecting and enforcing nearly all forms of intellectual property rights, including patents applying to pharmaceuticals, on which all member states adhere to.

TRIPS had initiated a new principle in international law through incorporating all preceding international treaties that govern IPR. TRIPS also initiated a stronger mechanism for industrialized countries to enforce IPRs. TRIPS agreement is regarded as the first international treaty whereby it embodies a dispute resolution mechanism.

Articles 63 and 64 of the TRIPS agreement regulates if a violation of the treaty provisions are brought before a dispute settlement panel, which decides on whether a country's actions, laws or regulations violate the

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97 Id.
99 Id.
100 Harvey E. Bale, Jr., Patent *Protection and Pharmaceutical Innovation* 29 NYU JILP. 95 (1997).
102 Article 9.1 of TRIPS agreement obliges member states to comply “with Articles 1 through 21 of the Berne Convention (1971) and the Appendix thereto.”
103 HOSSAM AL SHAGHIR, FOUNDATIONS AND PRINCIPLES TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHT (TRIPS AGREEMENT) WITH ANALYTICAL STUDY INCLUDE THE CONDITIONS OF DEVELOPING COUNTRIES FOCUSING ON PATENTS (1999).
treaty. Any failure to comply with the panel's decision may result in multilateral trade sanctions.\textsuperscript{104}

\section*{2.9 \ \ Doha Declaration}

Developing countries, in attempt to mitigate the strict application of TRIPS agreement on essential medicines, collaborated to demand that public health be given a wider interpretation and implementation of the TRIPS agreement.\textsuperscript{105} Zimbabwe, on behalf of the African group demanded that the TRIPS council convene a special session on access to medicines. However, developed countries led by US\textsuperscript{106} and EU\textsuperscript{107} supported the PhRMA position regarding the importance of strict patent application to pharmaceuticals-related patents. This resulted in a strong position by developing countries embodied in their submissions which stressed on the following points: (1) developing countries have a broad spectrum of public health concerns, not just HIV/AIDS, and they are particularly concerned about the lack of research on so-called neglected diseases; (2) patents raise prices and thus impede access to medicines; (3) developing countries should be free to use existing TRIPS flexibilities including compulsory licenses and parallel importation without being threatened by developed countries; (4) least developed members needed an extension of transitional periods beyond 2006; (5) developing countries needed to be able to source generic medicines from exporting countries despite the “predominately for domestic use” rule in Article 31(f) of the TRIPS Agreement, preferably through an Article 30 limited exception; and (6) developing countries needed assurances that data protection rules in Article 39.3 would not impede registration of generics.\textsuperscript{108}

\begin{flushleft}
\textsuperscript{104} \textit{Id.} at 96.
\textsuperscript{105} Frederick M. Abbott, \textit{The Doha Declaration on the TRIPS Agreement and Public Health: Lighting the Dark Corner at the WTO}, 5 J. INT’L ECON. L. 469 (2002).
\textsuperscript{106} U.S. Statement on TRIPS Council Meeting 2001.
\textsuperscript{107} Communication from the European Communities and their members states, W.T.O. Doc. IP/C/W/280 (2001).
\end{flushleft}
The U.S continued to minimize the effect of patent protection on either price or access to treatment\textsuperscript{109} and to strict the discussion to “emergences” like HIV/AIDS, malaria and TB and further to restrict parallel importation.\textsuperscript{110} However, the negotiations took a sharp diverse after the emerging of Anthrax crisis that hit the doors of U.S. forcing both American and Canadian governments Bayer, the patent owner of Ciprofloxacin, to sell Ciprofloxacin on a reduced rate or it will face issuance of a compulsory license.\textsuperscript{111}

Accordingly, on November, 2001, WTO members unanimously approved the Doha Deceleration as drafted by developing countries.\textsuperscript{112} Doha Deceleration emphasized on the importance to take measures to protect public health interests of WTO member states and to adopt measures meant to increase access to essential medicines, the Doha Deceleration stated that:

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.
5. [..] we recognize that these flexibilities include:

   a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

\textsuperscript{109} U.S. relied on making this argument on a study entitled “Do Patents for Anti –retroviral Drugs Constrain Access to AIDS Treatments in Africa?” \textsuperscript{supra} note 8 at the time of making this argument this study was not yet published.
\textsuperscript{110} W.T.O Doc. IP/C/W/313(2001).
\textsuperscript{112} Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference, 4th Sess. W.T.O Doc. WT/MIN (01)/DEC/2 (Nov. 20, 2001) [hereinafter Doha Declaration].
b. Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.

c. Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN[Most Favored Nation] and national treatment provisions of Articles 3 and 4.\textsuperscript{113}

Additionally, the Doha declaration emphasized on the importance of access to medicines and the flexibilities enshrined in the TRIPS agreement, the Doha declaration had attempted to resolve this problem:

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.\textsuperscript{114}

According to paragraph 6, all WTO member states recognize that countries with insufficient pharmaceutical industry capacity will not be able to meet their needs through local manufacturing or through extensive issuance of compulsory licenses.\textsuperscript{115}

However, the Doha Declaration does not flexibilities made under the TRIPS Agreement, such as the exceptions to patent rights (Article 30) and the protection of data submitted for the registration of pharmaceutical products (Article 39.3). Furthermore, the Doha Declaration does not refer to the options left to member states to determine the patentability standards that may hinder patenting strategies aiming at expanding or temporally extending the protection conferred in the pharmaceutical field.\textsuperscript{116}

\textsuperscript{113} Doha Declaration, supra note 112, arts. 1-4 [emphasis added].
\textsuperscript{114} Id. art. 6.
\textsuperscript{115} Least Development Countries(LDCs) had been granted a longer transitional period from 2006 to 2016 (Art. 7 of Doha Declaration).
\textsuperscript{116} CARLOS M. CORREA, IMPLICATIONS OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH (2002).
There had been proposals made by different Members to prevent diversion of drugs sold at discounted prices in developing countries to high-income markets, and to ensure that data protection requirements of Article 39.3 do not constitute a barrier to the registration and introduction of generic drugs and the use of compulsory licensing.\textsuperscript{117}

\textsuperscript{117} Id. 46.
Chapter III: Egyptian Law and International Agreements to Public Health Issues

3.1 Introduction

Chapter III will provide in depth analysis to the Egyptian laws pertaining to health related issues such as commercial law and intellectual property laws. Furthermore this chapter will discuss in detail Egyptian patents and undisclosed information in relation to medicines such patentability criteria.

Moreover, this chapter will discuss the flexibilities mentioned in international agreements and how far those flexibilities are incorporated in Egyptian laws and whether Egypt had used those flexibilities and what are the cases pending before the judiciary or being resolved pertaining to access to medicines in Egypt.

3.2 Egyptian intellectual property law

Egyptian IP law had gone through major developments marked last with the promulgation of law number 82 of 2002. The current law abolished all preceding law governing all aspects of intellectual property including law 57 of year 1939 related to industrial property, law number 132 of year 1949 related to patents and industrial designs and law number 354 of year 1954 related to copyrights law. The current law is regarded as a unified code to govern all aspects of IP. The said law was promulgated to be in line with international agreements including TRIPS agreement. Patents are governed in the first chapter while chapter three governs undisclosed information.

3.3 Patents

Article one of IP law number 82 of year 2002 defined patents as “…any industrially applicable invention, which is new, involves an inventive step, whether connected with new industrial products, new industrial processes, or a new application of known industrial
processes."\textsuperscript{118} A patent can be also granted for “…any modification, improvement or addition to a previously patented invention, which meets the criteria of being new, inventive and industrially applicable… to the owner of the modification, improvement or addition.”\textsuperscript{119}

The current law gave a broad definition to patents other than the definition given in the abolished patent law.\textsuperscript{120} This is definition was made broad to be inconformity with GOE obligations under TRIPS agreement.

However, the said law excludes certain subjects from being patented if they are

“(1)… contrary to public order or morality, or prejudicial to the environment, human, animal or plant life and health. (2) Discoveries, scientific theories, mathematical methods, programs and schemes. (3) Diagnostic, therapeutic and surgical methods for humans and animals. (4) Plants and animals, regardless of their rarity or peculiarity, and essentially biological processes for the production of plants or animals, other than microorganisms, nonbiological and microbiological processes for the production of plants or animals. (5) Organs, tissues, live cells, natural biological substances, nuclear acid and genome.”\textsuperscript{121}

The above exclusions are accorded with the stipulations under the TRIPS agreement which grant member states to exclude some subjects from patentability.\textsuperscript{122} A case may arise of the double usage of an invention that may be used in a manner contradicting to public order or morality. The executive regulations of IP law had regulated such assumption through requesting the patentee to issue undertaking that the invention will not utilized in any manner contradicting to public order to morality.\textsuperscript{123}

Egyptian IP law regulated the grant of pharmaceutical-related patents according to the general patent criteria. However, according to IP law provisions related to pharmaceutical patents will took effect after January 2005, due to the reason that Egypt had benefited from the transitional period made under the TRIPS Agreement. Article 43 of IP law had maintained the “mail box” provision for receiving pharmaceutical-related patents to start examining these

\textsuperscript{118} Article no. 1 of law on the protection of intellectual property rights number 82 of year 2002[hereinafter IP law].
\textsuperscript{119} Id.
\textsuperscript{120} SAMHIA AL QALI'OUBY supra note 36, at 80.
\textsuperscript{121} IP law, art. 2.
\textsuperscript{122} TRIPS Agreement, art. 27 para. 2 and 3.
\textsuperscript{123} Article 18 of the executive regulations of IP law 82 of 2002[hereinafter IP exec. reg.].
applications after 2005. However, the patent applicant may request to be granted “exclusive marketing rights”\textsuperscript{124} for his product in Egypt provided that” (1) the applicant has submitted an application for this product to the Patent Office in Egypt as of 1\textsuperscript{st} of January 1995; (2) the same product was patented in a country member of the World Trade Organization on the basis of an application submitted in that country as of 1\textsuperscript{st} January 1995; (3) the applicant has obtained the approval for the circulation of that product in the same country where he was granted the patent as of 1\textsuperscript{st} January 1995 and (4) the applicant has obtained the approval of the competent ministry for the circulation of that product within Egypt.”\textsuperscript{125} The said “exclusive marketing rights” is granted only for the period of five years or till a decision by the competent body is rendered with regard to the applicant file.

\textbf{3.4 Patent criteria}

Egyptian IP law stipulates that any invention should comprise of certain criteria for granting a patent, a new invention must be novel, consists of an inventive step and be industrial applicable.

This criteria for patentability laid down by Egyptian IP is consistent with the criteria laid down by the TRIPS agreement which stipulates that patents are granted for “…inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”\textsuperscript{126}

\textbf{3.5 Novelty}

Novelty is regarded one of the essential requirements for an invention to qualify for patent protection. As per this requirement, a patent application for an invention needs to be “novel” or new before the date of filing of a patent application.\textsuperscript{127} Novelty means that third parties have no

\textsuperscript{124}IP law, art. 44.
\textsuperscript{125}Id.
\textsuperscript{126}TRIPS Agreement, art. 27 para. 1.
\textsuperscript{127}CARLOS M. CORREA, PROTECTION AND PROMOTION OF TRADITIONAL MEDICINE IMPLICATIONS FOR PUBLIC HEALTH IN DEVELOPING COUNTRIES (2002).
knowledge about the invention subject to patent protection prior to filing before the competent bodies. The Egyptian supreme administrative court had ruled that “the rationale behind this provision that the law provides the patent holder the exclusive rights to utilize the patent...[h]ence if there is no novelty regarding the patent subject matter there is no exclusive rights granted to the patent holder.”

McCarthy’s Desk Encyclopedia of Intellectual Property states: “Novelty is opposite to anticipation. For example, an invention that is ‘anticipated’ by the disclosure of a prior art patent or publication lacks ‘novelty’. “It is essential then to prove that there is no novelty in an application, the prior use is to be in a manner wherein access to the information concerned would allow a third party to execute the invention without significant further research. Hence, novelty is required to confirm that the claim of the applicant is the first to make the invention and it qualifies under the requirements set for the granting of a patent.

Novelty can be either regarded as absolute or relative. Absolute novelty means it is universally new while relative novelty means it is new within a particular area or country. The TRIPS agreement required that member states provides patent protection to products and process that are regarded as “new.” However, it does not stipulate how novelty to be treated. Both current and abolished Egyptian IP laws treated novelty as absolute novelty. According to current IP law “An invention shall not be considered wholly or partly new: (i) if, before the filing date of the patent application, a patent application has been filed for the same invention or a patent was already issued in or outside Egypt for the invention or part thereof; (ii) if, before the filing date of the patent application, the invention was used publicly in or outside Egypt, or the description of which was disclosed in a manner so as a person having expertise in the art is able to exploit it.” The rationale behind this provision is that the patent holder will be granted exclusive rights to exploit his invention to the extent permitted by law including financial exploitation of the patent.

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130 CARLOS CORREA INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES (2000).
131 SAMIHA AL QALIOUBY, supra note 36, at105.
132 CORREA, supra note 130.
133 TRIPS Agreement, art. 27 (1).
134 IP law, art. 3.
3.6 Inventive step

There is no constant definition to the inventive step. However, it might be regarded as the gap between what is known already and what the invention claimed by the patent applicant.\textsuperscript{135} Egyptian IP law did not define what may be regarded as an inventive step. Furthermore, Egyptian IP law did not set any criteria to determine what may be regarded as an inventive step.

Current Egyptian IP law stipulates that the invention must be “new and involves an inventive step.” Hence, it should be differentiated between novelty and inventive step. It is not necessarily that the invention is based on new specific scientific theories. Nevertheless, it might be based solely on the application of other inventions that leads to constituting new inventions.\textsuperscript{136}

The issue of inventive step may arise in inventions involve claims specific to the chemical and pharmaceutical sectors, such as using an active ingredient in different forms. Some companies might resort to change the form of the active ingredient to seek additional patent protection to their products.

The TRIPS agreement did not specify what can be regarded as an inventive step. Article 27.1 stipulates that patents shall be granted to protect inventions which “involve an inventive step” further, the TRIPS Agreement in a footnote, allows member countries to interpret “inventive step” as synonymous with “non-obvious”. Additionally, the TRIPS Agreement restricts discrimination as to the field of technology.\textsuperscript{137} Hence, it might be difficult to apply specific industry standards. However, patent office might attempt to define and apply strict criteria for inventive step for avoid granting of patents that might restrict competition especially in pharmaceutical products.

3.7 Industrial application

The current IP law stipulates that any invention must be “industrially applicable.” The rationale is that patent protection should not be granted for abstract ideas or purely intellectual

\textsuperscript{135} \textsc{correa}, \textit{supra} note 127.
\textsuperscript{136} \textsc{samiha al qaliouby}, \textit{supra} note at, 98.
\textsuperscript{137} \textsc{trips} Agreement art. 1.
creations that cannot be applied in real world. A patentable invention has to be tangible and should have a technical character. Industrial applicability might be used as a factor to exclude other inventions from patentability. “Industrial” is used in a very wide sense, irrespective of the for-profit or non-profit nature of the industry.138

The TRIPS agreement did not provide any specific standard or guidelines. As per article 27 paragraph 1, patents shall be granted for inventions “capable of industrial application” or “useful.”139 Countries, including developing ones, can adopt their own standards that ensure that the invention can be industrially applicable.

3.8 Undisclosed information

Inventors and indeed multinational companies may resort to protect their invention through undisclosed information instrument. A patent applicant might consume much time in order to obtain protection under patent protection scheme. Undisclosed information covers any secret information of commercial value, including technical know-how, such as design, process, formula and other technological knowledge often resulting from experience and intellectual ability; data of commercial value, such as marketing plans, customers lists and other business-related information that provides an advantage over competitors and finally, test and other data submitted for the approval of pharmaceutical and chemical products for agriculture.140

Undisclosed information is granted protection under current Egyptian IP law. However, in order to obtain protection under this scheme if they meet the following criteria: “(1) Information which is confidential, in the sense that it is not, as a body or in the precise configuration or assembly of its components, generally known or common among those involved in the industrial art within the scope of which the information falls, (2) Information that has commercial value

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139 | This term is used in the footnote of the TRIPS agreement as synonymous for capable of industrial application.
140 | UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT (2005).
because it is confidential and (3) Information that depends on the effective measures taken by the person lawfully in control of it, to keep it confidential.”  

On the other hand, the law obliges the competent bodies to keep the information it received confidential information to protect it against disclosure and unfair commercial use. Provided that the person whether natural or corporation is lawfully in control of undisclosed information and taking appropriate measures to maintain the confidentiality of such information and prevent its circulation amongst unauthorized persons.

Protection of undisclosed information is also extended to for marketing of pharmaceutical products if the said products contain new chemical components. The competent authority shall protect the said information against disclosure and unfair commercial use from the date of the information is submitted until it is no longer confidential, or for a period not exceeding five years, whichever comes first. However, the competent body has the right to disclose such information to protect the public. The executive regulation gives the competent minister to issue the cases of necessity by which protected information can be disclosed.

Article 39 of the TRIPS obliges the member states to provide protection of undisclosed information from” against unfair competition. However, Article 39.2 does not define what “undisclosed information” consists of. It only specifies the conditions that the information needs to meet in order to be deemed “undisclosed” and protectable: it should be secret, possess a commercial value and be subject to reasonable steps, under the circumstances, to be kept secret.

Additionally, the scope of Article 39.3 is limited to undisclosed data which are required by a national authority as a condition for obtaining approval for the marketing of pharmaceutical products “which utilize new chemical entities,” provided that the origination of the data involved a “considerable effort.” However, the TRIPS Agreement did not stipulate any duration to the protection of undisclosed information by member states.

141 IP law, art. 55.
142 IP law, art. 56 para. 2.
143 IP law, art. 57.
144 IP law exec. reg., art. 67.
3.9 Egypt: Judicial interpretation of Egyptian and international patent law

Egypt’s judiciaries had played and continue to play a crucial role in deciding on claims related to the area of the manufacture and marketing of medicines and intellectual property even prior to TRIPS Agreement entry into force regarding extension of protection to pharmaceutical products in January 2005. Egyptian courts were a venue to a number of important lawsuits challenging decisions by health authorities or practices of local producers of generic medicines. The below cases might be regarded as the bases whereby the judiciary secured the access to affordable medicines.

a) Apex Pharma vs. President of Academy of Science and Technology and others145

It is worth to mention that this is regarded as the first health-related law suit filed before Egyptian courts. The suit was filed after the ratification of the TRIPS Agreement by GOE however, prior to the promulgation of IP law of 2002. The dispute was brought by Apex Pharma, a local generic manufacturing company, against the President of Academy of Science and Technology (the patent office) and others requesting the nullification of the prime minister decree to grant the exclusive marketing to a foreign company in Egypt.

The compliant had based it argument that the TRIPS Agreement had allowed for a 10-year transitional period in relation to pharmaceutical patents. Countries availing themselves of this period were required to establish a “mailbox” as soon as the agreement entered into force. The mailbox meant that applications for patents could be filed immediately, notwithstanding the fact that no applications would be examined until January 2005.

Apex Pharma, based its argument that the Prime Minister had no authority to issue decrees implementing an international agreement without the approval of the peoples assembly. The plaintiffs also requested to nullify the decree as that they had intended to sell its generic product at one-fifth of the price of innovator brand name drug, and that the exclusive marketing

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145 Egyptian Supreme Administrative Court ruling, case number 6965/45.
authorization would thus hinder competition by more affordable generic versions of the same medicine. The Court, however, found against the plaintiffs upholding the challenged decrees.

The Court ruled that “Egypt, having ratified the TRIPS Agreement, came under an obligation to implement it immediately and that the appealed decree fell under the government’s duty to respect its contractual obligations.”

Apex Pharma had, however, appealed the decision before the Supreme Administrative Court. The court ruled in favor of the plaintiff although the court did not address the substantive matter of access to affordable medicines and public health policy priorities. Instead, the decision was based on the procedural grounds that the defendant should have secured the people’s assembly approval prior establishing the implementation of TRIPS regulations.

This case *prima facie* appear to be a legal dispute over whether TRIPS was a self-executing treaty, and whether ratification is sufficient for immediate enforceability, or whether it required endorsement by the legislation before it became an integral part of Egyptian law. As stated, the case was decided on procedural bases. The case could, however, be regarded as a pioneer case if the tribunal addressed the substantive issue of the state’s obligation to ensure access by citizens to affordable treatment.

a) Pfizer vs. EIPICO\(^{146}\)

The dispute was brought by Pfizer against Egyptian International Pharmaceutical Industries Company (EIPICO) claiming that the generic version registered by the latter is based on confidential clinical data provided by the plaintiff to drugs registration authority claiming among other things that, the clinical tests fall under “undisclosed information” which is protected by the TRIPS Agreement and that the drugs registration authority must ask the generic drug manufacturer to repeat the same clinical tests while attempting to register a generic version of a drug during the period of enjoying the data exclusivity.

\(^{146}\) Zagazig court of first instance ruling case number 1855/2002.
The plaintiff claimed also that the case involves unfair competition practices made by the defendant due to discrepancy between the retail prices of the generic version compared to the innovator version of Pfizer.

The expert witness had played a prominent role during the lawsuit. The defendant submitted a report issued by a private research unit at the Pharmacology School of Ain Shams University in Cairo. The report clarified the technical issues and supported the claim of the defendant is able to manufacture resorting to undisclosed information. The report demonstrated numerous examples of other companies around the world who have produced generic versions of drugs.

However, the court had resorted to constitute a three-expert committee to examine the case due to complication of technical issues. The committee submitted its detailed report discussing complicated web of IP issues and explained all the relevant provisions in both the TRIPS Agreement and Egyptian laws. The report concluded that the defendant did not violate the law. The Court endorsed the expert recommendations and ruled against Pfizer.

Although the court relied on the experts report and there was no mention to access to essential medicines as a right, the outcome of this case is regarded positive as it ruled against a company attempted to bar a local pharmaceutical company from exploiting existing knowledge related to essential medicines.

The cases above highlight the prominent role of judges in interpreting IP law in light of access to the right to health in general and the access to essential medicines. It is worth to mention that these cases all reached “access-friendly” solutions. However, based on procedural grounds or through general endorsement of expert witness reports.
CHAPTER IV: Can Egyptian IP and TRIPS be interpreted in ways to facilitate Access to Essential Medicines

4.1 Flexibilities under TRIPS agreement

The TRIPS agreement provides flexibilities against those embodied in the agreement itself. As mentioned in paragraph 5 of Doha Declaration “…we recognize that these flexibilities include:” the Declaration stresses that these flexibilities are made for the purpose of adopting measures to protect public health.

The flexibilities embodied in the TRIPS Agreement can be classified into two categories. The first is classified as a time-based, in the form of transition periods, which grants both developing and LDCs extended time to implement their TRIPS obligations. Three transition periods are provided for in the Agreement: 1) the 1995-2000 period, at the end of which developing countries were obliged to implement the TRIPS Agreement; 2) the 2000-2005 period, which provided an additional period of five years to put in place product patent protection for pharmaceuticals. Egypt had benefited from both transition periods. IP law of 2002 extended the application of pharmaceutical protection to 2005 through providing a “mail box” to receive pharmaceutical related patents147 and 3) 1995-2006, after LDCs would be required to implement their TRIPS obligations.148

Second are the substantive flexibilities in the TRIPS Agreement. This concept of flexibility had generated a lot of debate between pharmaceutical companies backed by some developed countries who prefer to apply strict interpretation to the TRIPS Agreement and developing countries specially in sub-Saharan African countries, focusing on the manner in which intellectual property protection, as enshrined by the TRIPS Agreement, has an impact on areas of public policy making, and in particular public health.

Developing countries attempted to seek greater recognition for their position that the TRIPS Agreement provides countries flexibility and discretion. These countries argued that the

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147 Article 2 of the promulgation law number 82 of year 2002.
148 This period, however, was extended to year 2016 W.T.O Doc. IP/C/W/25 (2002).
provisions of the TRIPS Agreement did not hinder them from adopting measures to ensure access to medicines and to meet other public health needs.\(^{149}\)

Developing countries efforts were crystallized in the adoption of the Doha Declaration on the TRIPS Agreement and Public Health at the Fourth WTO Ministerial Conference in 2001. Subsequently, the WTO General Council adopted the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, to address the problem of countries with insufficient or no manufacturing capacity to effectively use compulsory licenses.\(^{150}\)

However, the flexibilities embodied in the provisions of the TRIPS Agreement are not per se self executing and are not automatically embodied into the national laws. Hence, it will be necessary for specific legal provisions to be enacted in domestic laws to enable countries to utilize the flexibilities available to them.

Furthermore, the Doha Declaration re-affirmed that the flexibility available in the TRIPS Agreement does permit governments the ability to consider and implement the said options that take public health into account when formulating the domestic intellectual property laws and polices.\(^{151}\) The Declaration referred to several aspects of the Agreement, including the right to grant compulsory licenses and the freedom to determine the grounds upon which licenses are granted; the right to determine what constitutes a national emergency and circumstances of extreme urgency and, the freedom to establish the regime of exhaustion of intellectual property rights.\(^{152}\)

The Declaration also clarified how the Agreement should be interpreted and implemented. In Paragraphs 4 and 5(a), the Doha Declaration gives guidance for the overall interpretation and implementation of the TRIPS provisions. WTO Members, by virtue of the Doha Declaration,

\(^{149}\) See generally, TRIPS Council submissions from developing countries and the EC to the TRIPS Council Special Session, W.T.O Doc. IP/C/W/296 and IP/C/W/280 (2001).

\(^{150}\) W.T.O Doc. WT/L/540 (2003).


\(^{152}\) Doha Declaration para. 5.
have therefore agreed to a rule of interpretation, which will guide future WTO panels and the Appellate Body.\footnote{153}{CORREA, supra note 130.}

Paragraph 4 of the Declaration lay out the fundamental principle whereby member states implement the TRIPS Agreement in a fashion supportive of their rights to protect public health.\footnote{154}{Id.} In the light of the abovementioned, developing countries should consider public-health-sensitive options for implementing the provisions of the TRIPS Agreement relating to the following: research exceptions and “Bolar” provisions, compulsory licensing and public, non-commercial use of Patents (Government Use), and parallel importation.

4.2 Research exceptions and “Bolar” provisions

The research or “Bolar” provisions are not explicitly provided in the TRIPS Agreement. However, it is widely accepted exception under article 30. The exception relates to a situation where a potential competitor uses an invention without the authorization of the patent holder.\footnote{155}{SISULE supra note 151.} However, such use is only for purposes related to research and other acts necessary for obtaining regulatory approval and registration of a generic product before the expiry of the patent term. In the pharmaceutical industry, the purpose of the exception is to permit the performance of technical activities necessary in obtaining regulatory approval and securing capital.

Article 10.6 of IP stipulates that “any other acts by third parties, provided that they shall not unreasonably hamper the normal exploitation of the patent, and shall not be unreasonably prejudicial to the legitimate interests of the patent owner, taking into consideration the legitimate interests of others.”

Under this exception, generic manufactures are not allowed to commercially exploit the invention before the expiration of the patent term. This mechanism ensures that generic versions of the product will be available on the market after the expiry of the patent.
4.3 Scientific Activities

Under the new Egyptian law, use of the protected product is permitted in all scientific activities without considering these activities as infringement. This is a very important provision since the pharmaceutical companies could use it to undertake research and analysis for the protected pharmaceutical products to obtain better results. However, it is not clear what classify as scientific activities under which Article 10(6) permits.\(^{156}\)

4.4 Compulsory license and public, non-commercial use of Patents

A compulsory license, also referred to as a non-voluntary license,\(^ {157}\) is a license granted by the government to a third party to exploit a patented invention, without the consent of the patent holder.\(^ {158}\) The TRIPS Agreement permits the usage of such licenses by member states. This license is regarded as exception to patent rights granted to the patent holder that enables to prevent third parties from exploiting his invention. However, when reasons of public interest arise, national authorities may grant the exploitation of the patent to a third party without the patent holder’s consent or authorization. In such cases, the public interest of ensuring broader access to the patented inventions is deemed to be more important than the interest of the patent holder in retaining his exclusive rights.\(^ {159}\) Compulsory licenses can therefore play a vital role in meeting public health needs, and that patent holder do not unreasonably hinder or prevent access to affordable medicines. Compulsory licenses may be granted to enable the production of generic versions of patented medicines or to be imported from foreign producers. Both developing and developed countries had incorporated this license in their national legislation.\(^ {160}\)

Egyptian IP law enables the patent office, subject to the approval of a ministerial committee to be established by a decision of the Prime Minister, grant compulsory licenses for the

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\(^{157}\) This terminology is used in the text of the Egyptian law.

\(^{158}\) Sisule *supra* note 151.

\(^{159}\) *Id.*

\(^{160}\) See for example Canadian Patent act R.S., c. P-4, s. 1.
exploitation of an invention, in any of the following cases “(a) Public non-commercial interest. This includes the preservation of national security, health, environment and food safety. (b) Cases of emergency or circumstances of extreme urgency. A non-voluntary license to counter the conditions mentioned in items 1 and 2 is granted without prior negotiations with the patent owner or after a certain period of negotiations with the patent owner or offering reasonable conditions to acquire his agreement to the exploitation. (c) Support of national efforts in vital sectors for economic, social and technological development, without unreasonable prejudice to the rights of the patent owner and taking into consideration the legitimate interests of third parties.”

Furthermore, the Egyptian IP had regulated granting compulsory licenses in cases related to pharmaceutical products if the quantity of patented medicines made does not adequately meet the national needs, or that the medicines are of poor quality furthermore, the patent office can grant compulsory license if the drugs are offered at a prohibitive price, or if the patent is related to medicines addressing critical cases, incurable or endemic diseases or products used in the prevention of these diseases, or where the invention is related to the medicines, their manufacturing process, the raw materials necessary for their preparation or the process of manufacturing of those materials.

Public, non-commercial or government use is similar to compulsory licensing. However, government is directly grants itself a license or appoints an agent to act on its behalf to exploit a patented invention.

Egyptian law permits expropriation of patents, through the government, on grounds relating to national defense and in cases of emergency which the grant of a non-voluntary license is insufficient to counter.

Under the current IP law, compulsory licensing for drugs will be available in some cases particularly in circumstances relating either to drugs quality, quantity, prices or to patents that are

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161 IP law art. 23 para.1.
162 IP law art. 23 para. 2.
163 IP law art. 25.
granted for a number of serious illnesses, or to drugs cases.164 It is worth mentioning that there were no provisions for compulsory licensing in Egypt under the abolished Patents law. It is a good development that the current IP law adopted provisions on granting of compulsory licenses. The opportunity to grant or use compulsory licenses scheme has been described as “equivalent to reducing the strength of the exclusive rights conferred by a patent.”165 The compulsory licenses scheme would definitely aid to make drugs available to the public in Egypt at affordable prices.

4.5 Parallel imports

Parallel import is a process where import and resale in a country, without the consent of the patent holder, of a patented product that has been legitimately put on the market of the exporting country under a parallel patent. A patent holder may have the exclusive right to manufacture his product and to put it on the market. But once the product is placed on the market, the principle of exhaustion means that the patent holder has no further right over the product. Thus, a patent holder cannot prevent the subsequent resale of that product since their rights over the product have been exhausted by the act of selling it.166

Parallel importation is permitted under the TRIPS Agreement. Article 6 of the TRIPS Agreement provides that matters relating to exhaustion of rights shall not be subject to dispute settlement. Member states may opt to adopt the principle of international exhaustion of patent rights. Adoption of this principle in the national patent law would allow any party to import into the national territory a patented product from any other country in which the product was placed on the market by the patent holder or any authorized party.

Second, member states may adopt regional exhaustion of rights, where adoption of this principle would allow the possibility of importing into the national territory a patented product originating from any other member state of a regional trade agreement.

164 Balat, supra note 24.
165 Id.
166 Sisule supra note 151.
The third option is that of national exhaustion of rights. This principle limits the circulation of products covered by patents in one country to only those put on the market by the patent owner or its authorized agents in that same country. In this case, there can be no parallel importation.167

Egyptian law does not explicitly stipulate on the possibility to use parallel importations. However, Egypt had adopted the international exhaustion of rights principle through granting the minister of health the right to import directly drugs in cases of emergencies where compulsory license is not sufficient, this including importation from other countries.168

4.6 Analyzing TRIPS agreement flexibilities

The text embodied in the TRIPS Agreement is dynamic and developing. Hence it is crucial while determining new provisions to attempt to strike a balance between public health interest and commercial interests.

TRIPS allows for the adoption of measures necessary to protect public health169, such resorting to compulsory licensing and other means, and waiver of the requirement to obtain authority in cases of national emergency.170

Current IP law stipulates that if a patent application is related to micro-organisms (micro-biological) then the applicant is obliged to disclose such micro-organisms and deposit a viable culture with the authority determined by the executive regulation.171 It is worth mentioning that the use of the deposited sample of the micro-organism is widely known in the pharmaceutical industry particularly after the expiry of patent term. The deposition requirements therefore may form a significant tool in disseminating, promoting, and practicing new technology.172

167 Id.
168 IP law, art. 23.
169 Id. art. 8.
170 Id. art. 24.
171 Id. art 13.4.
172 Balat & Loutfi, supra note 24.
Furthermore, the current IP law stipulates that a patent application must be accompanied by a detailed description of the invention including a full statement of the patent subject matter and the preferred method that enables a person skilled in the art to carry out this invention in respect of each product and process of the subject matter of the application. Since disclosure makes publicly available significant technical information which may be beneficial to third parties in advancing technology in the area. Furthermore, disclosure aims at ensuring that, after the expiry of the patent term, the invention truly falls into the public domain because others have the necessary information to start manufacturing a generic type of the said drug.  

The current IP law aims to save the interest of the public through non-extension of protected patents. The local pharmaceutical manufacturers will be seeking to produce a generic version of the protected patent after the falling in the public domain. Furthermore, the Egyptian laws are consistent with the TRIPs provisions which do not incorporate obligations to the effect.

Finally, the IP law had incorporated a number of restrictions that aim to limit the potential increase in prices or in case the protected medicines are not sufficiently available or available only under unacceptable conditions, have been considered by the Egyptian law makers. The same could be said in specified circumstances aimed at preventing the abuse of patent. In such circumstances, the grant of compulsory licenses  is permitted and the patent may even be revoked if it is obvious that such licenses are not sufficient to remedy or overcome the adverse effects that have been caused to the national economy because of the abusive activities by the patentee in exercising his rights.

Hence it is crucial that GOE to utilize the flexibilities to the most possible extent as permitted under the TRIPS Agreement and national law.

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173 AL SAGHIR, supra note 103.
174 IP law, art. 23.
175 Id.
Chapter V: Conclusions and Recommendations

5.1 Summary of chapters

In chapter two addressed the status of access to essential medicines in Egypt as well as relevant Egyptian and international law. Furthermore, chapter two attempted to provide an overview to Egyptians laws regulating medicines in general and emphasizing, Egyptian intellectual property laws. Finally, this chapter analyzed international laws governing health related issues such as TBT TRIPS agreement and finally the Doha delection.

While chapter four provided analysis to the flexibilities available in international agreements and to which extent those flexibilities are incorporated in Egyptian laws and how far Egyptian laws had utilized those flexibilities analyzing the cases before the judiciary. Finally, this chapter provided analysis to the Egyptian laws pertaining to health related issues such as intellectual property law.

5.2 Conclusions

The following conclusions can then be drawn. Egypt maintains relatively low prices for pharmaceutical products. To date, Egyptians continue to have access to relatively inexpensive medicines because of government price controls and subsidization. However, the government of Egypt should keep this trend through maintaining databases for announcement about the patents that will fall in the public domain in order to enable local manufactures to exploit these patents and to make it available in the market in a cheaper price.

Current IP law attempted to strike a balance between the interests of patent owners and accessibility of the medicines through providing patents protection to pharmaceuticals products, the law does consider the interests of the patent holders and the general public taken into account through the disclosure provisions, limitations and exceptions that are permitted under the law.
The exact implications or impacts of the new patent protection scheme for pharmaceutical products are difficult to predict. As patent protection is a very important instrument for industries like pharmaceuticals.\textsuperscript{176} It is aimed that by providing such protection, Egypt grabs more foreign direct investment (FDI) and technology transfer will increase. Furthermore, R&D directed at the specific needs of Egypt such as certain diseases will increase. It worth mentioning that Egypt has competitive advantages as far as R&D is concerned, because Egypt posses local experts and a reasonable infrastructure offering research prospects at considerably lower costs than in developed countries.\textsuperscript{177}

With regard to pharmaceuticals prices, the improved levels of patent protection will not lead to “dramatic” increase in drug prices. The new patent protection scheme will have no direct impact or effect on existing drugs available in the local market. The increase in prices will not be felt until the end of a period of 5-8 years, counted from the day the new IPR law enters into force in relation to protection for patents for pharmaceutical drugs products i.e. after January 1, 2005.\textsuperscript{178}

Domestic factors have played, and continue to play, a crucial role as determinants to access to medicines even prior to implementation of TRIPS Agreement some of the underlying issues that influence access to affordable medicines include economic conditions, budget allocated to health by the government, out of the pocket expenses on healthcare and prescription and consumption patterns.\textsuperscript{179}

Until now, it has not been possible to foresee all implications of the TRIPS Agreement within the Egyptian context. Access to affordable treatment is certainly not the only concern, but the future of a whole well-established pharmaceutical industry, and an important element of the national economy. It could be argued that Egypt possesses the “theoretical” basis for protecting public health and ensuring accessibility to essential medicines, particularly that all the TRIPS Agreement flexibilities have been incorporated in the current IP law. In the presence of a long -

\textsuperscript{176} Balat & Loutfi, supra note 24.  
\textsuperscript{177} Supra note, 22 at 10.  
\textsuperscript{178} Balat & Loutfi, supra note 24.  
\textsuperscript{179} Id.
established pharmaceutical regulatory system which maintains strong price controls, if flexibilities are enforced, they could certainly guarantee access to affordable medicines. Non-awareness of flexibilities available under the law and the TRIPS Agreement might hinder the use of flexibilities. For example it has been reported that Egypt had never resorted to compulsory license since adoption of current IP law.

5.3 **Recommendations**

The study has raised questions and attempted to provide answers. Conclusions have also been drawn. From all this, it is found that more needs to be done in order to ensure that access to essential medicines is fulfilled to the most extent permitted under law.

5.4 **On the national level**

A broad definition of drug should be adopted. Any definition of drugs should include not only medicines that are necessary to cure people from diseases, but also any other materials that are to be used to prevent such diseases. Furthermore, a definition should include materials that might be used to improve public health, such as vitamins.

The current IP law did not contain, following TRIPS pattern, any provisions dealing with the patentability of new uses of known substances or products, especially second or subsequent therapeutic uses for known pharmaceutical products. Hence it is essential to exclude from patentability second use of known substances, which are already exists in the public domain.

It is crucial to highlight the importance of utilizing of inventions that already exists in the public domain. The use of these inventions would be royalty-free. Hence, both government and non-governmental organizations develop databases of pharmaceutical patents that exist in the public domain and to share them with concerned stakeholders. Further such organizations should network with other regional and international organizations in order to have impact on local, regional and international arena.
Furthermore, capacity building should be conducted for government agencies including foreign affairs officials, patent office officials and the offices of the competent ministers mentioned in the IP on the role of the flexibilities under TRIPS such as parallel importing and compulsory licensing that can play a crucial role in improving access to medicines.

Additionally, it is important to consider improving and developing the Egyptian Patents Office in order to be able to meet the requirements of the current IP law along with equipping the Office with the needed experience, equipment, and references to examine the submitted patent applications particularly those patents related to pharmaceutical products.

On the other hand capacity building should be conducted for judges and public prosecutors on IP law to learn about the new trends of IP, understand the international agreements including those related to IP and to human rights and to be able to apply the flexibilities permitted under law to cases pending before them.

Finally, an ongoing policy for R&D based on local raw materials and traditional plant varieties should be adopted. In this regard, it is important to establish new scientific research centers to modernize the domestic drugs industry and in creating new pharmaceuticals in order to be available for the public at reasonable prices.\textsuperscript{180}

The Government of Egypt should also ensure the efficiency of the Drug Pricing Committee regulated under IP law through building its capacity and to equip this committee with legal tools to ensure its role.

Furthermore, Government of Egypt should initiate public private partnerships in the field of public health to ensure that there are local industries are capable of producing essential medicines.

\textsuperscript{180} Osama Abd El Aziz, \textit{Al Ahram newspaper}, (Dec. 25, 2002).
5.5 To universities

Universities can benefit from the waiver of filing fees for patents which will enable universities to save a lot of funds to be allocated to research and development and act as patent holder.

Universities in cooperation with national, regional and international universities and institutes should maintain patent pools whereby it gives these institutions to hold patents with less cost.

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