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Intellectual property rights and pharmaceuticals: The impact of the intellectual property rights regime on the access to medicine in developing states

Hend Youssef Abdel Rahman Hosny

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The American University in Cairo

School of Global Affairs and Public Policy

**INTELLECTUAL PROPERTY RIGHTS AND PHARMAECUTICALS:
THE IMPACT OF THE INTELLECTUAL PROPERTY RIGHTS
REGIME ON THE ACCESS TO MEDICINE IN DEVELOPING STATES**

A Thesis Submitted to the

Department of Law

**in partial fulfillment of the requirements for
the LL.M. Degree in International and Comparative Law**

By

Hend Youssef Abdel Rahman Hosny

December 2016

The American University in Cairo
School of Global Affairs and Public Policy

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INTELLECTUAL PROPERTY RIGHTS AND PHARMAECUTICALS: THE IMPACT OF THE INTELLECTUAL PROPERTY RIGHTS REGIME ON THE ACCESS TO MEDICINE IN DEVELOPING STATES

Hend Youssef Abdel Rahman Hosny

Supervised by Usha Natarajan

ABSTRACT

It is commonly contended that international legal regime aims at promoting equality between states and helping underdeveloped states develop. Amongst the methods that have been argued to promote economic development is increased patent protection. Proponents of the patent regime argue that increased protection will increase foreign direct investment in different sectors of developing countries, such as the pharmaceutical industry, as well as allow for the spread of technology and known how. However, as the thesis will show this has not been the case. The thesis will demonstrate how the current international legal regime has a Eurocentric bias that works to the benefit developed and against developing states. Therefore, perpetuating a cycle of underdevelopment, poverty and inequality, within developing states. Specifically, this argument is made through an analysis of the patent regime and its effects on access to pharmaceuticals, which demonstrates how increased patent protection, especially under the Trade Related Aspects of Intellectual Property Rights Treaty, has resulted in the is lack of access to medicine in developing countries. Consequently, people in underdeveloped countries remain sick, unproductive, and experience high mortality rates from curable diseases, which directly affects the economic development of those developing states.

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Introduction

*Better health is central to human happiness and well-being.
It also makes an important contribution to economic progress,
as healthy populations live longer, are more productive.¹*

The economic development of a nation requires several aspects that contribute to the progress of such nation, one of which is a healthy workforce. A proper healthcare system is necessary to maintaining a healthy population and a healthy workforce, which essential for the state's economic growth and progress. Research conducted by the World Bank confirms that health affects human welfare and directly effects income, productivity of workers, the savings and investments levels in a state, education of children and the lifespan cycle of a population which affects the workforce cycle.² A healthy population requires adequate healthcare, an important part of which is access and availability of medicine. Unfortunately, some parts of the world suffer from the lack of access to even the most basic medicine and healthcare. The World Trade Organization (WTO) estimates that a third of the population of developing countries have no access to medicine on a regular basis, with spending on medicine accounting for a huge portion of the expenditure within developing states' budgets.³ Contradictory, medicine constitutes only 17% of imports in developing countries. This variation between percentage of imported medicine and expenditure is a result of high prices of imported medicine.⁴ High prices of medicine is directly related to patent rights over pharmaceutical and other health care products. Patency rights of non-duplication in the Trade Related Aspects of Intellectual Property Rights

¹ World Health Organization: Health and Development <http://www.who.int/hdp/en/> (Last visited 1 October 2015).

² David E. Bloom & David Canning, Population Health and Economic Growth (2008), http://siteresources.worldbank.org/EXTPREMNET/Resources/489960-1338997241035/Growth_Commission_Working_Paper_24_Population_Health_Economic_Growth.pdf .

³ World Bank: Health Expenditure <http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS> (Last Visited 1 October 2015).

⁴ World Health Organization: Access to Medicine <http://www.who.int/trade/glossary/story002/en/> (Last visited 1 October 2015).

Treaty (TRIPS), prevents the generic production of patented medicine. This accompanied by high prices of medicine, result in the lack of access to medicine in developing countries. Consequently, people in underdeveloped countries remain sick, unproductive, and experience high mortality rates from curable diseases. The WTO estimates that 185 million people are infected with Hepatitis C Virus (HCV), a curable disease that kills almost 500,000 people per year, most of whom are in developing countries.⁵ Although HCV is a highly preventative disease, “less than 4% of all people who inject drugs have access to HCV treatment”.⁶ HIV is another disease where 71% of infected people live in developing countries, most of whom do not have access to treatment, and with a growing number of 2.1 million newly infected individuals per year. Although it is not a curable disease, effective treatment with antiretroviral drugs can control the virus so that infected people can enjoy healthy and productive lives.

The availability of medicines, or lack thereof, is directly related to aspects of trade, the availability of materials, the know-how of production of such medicine, and dissemination of the technology and information of its production. Trade affects the importation of actual medications or materials that help in the production of such medication, while the availability of know-how, technology and information helps in the process of locally produced medicines. If one of those elements is missing, a state faces a lack of availability of medicine for its population. This is directly dependent on different fields of international law including trade law and economic law.

⁵ Marie-Paule Kieny, Opening remarks at the joint WHO, WIPO and WTO technical symposium on innovation and access to medical technologies – challenges and opportunities for middle-income countries, World Health Organization, November 5, 2014, http://www.who.int/medicines/news/mk_technical_symposium/en/.

⁶ Odilon Couzin & Karyn Kaplan: Pills Costs Pennies, Greed costs lives; 1st Hepatitis C Virus World Community Advisory Board Report, <http://www.treatmentactiongroup.org/sites/g/files/g450272/f/201407/1st%20HCV%20World%20CAB%20Report.pdf> (2015).

This thesis argues that the current international legal regime has a Eurocentric bias and perpetuates a cycle of underdevelopment, poverty and inequality, a consequence of a historically unjust international legal and economic system. Specifically, this argument is made through an analysis of trade law and its effects on access to pharmaceuticals, which in turn affects health care in developing countries. This examination is conducted through a historical analysis of the birth and rise of international law, specifically international economic and trade law, alongside the universalization of the capitalist economic system. This thesis builds on Third World Approaches to International Law (TWAIL) scholarly writings and methodology in analyzing the international legal system to demonstrate the predatory nature of the system which legitimizes, reproduces, and sustains the plunder and subordination of the periphery states. This global system of relations has been facilitated and globalized by the rise and expansion of capitalism and modern international law, both of which have created and maintained inequality between center and periphery states⁷. Center/Core states are the developed, dominant capitalist states that have historically exploited periphery states for their raw materials in order to achieve capitalist expansions of their own. Periphery states are the “underdeveloped” states that lack strong economies and governments, and export raw materials to core countries, and as such are dependent on core countries. Specifically, the thesis examines the issues of inter-state inequality through examining the international legal regime that protects Intellectual Property Rights (IPRs), exposing it as both a cause and an effect of an unjust universal system. The thesis focuses particularly on the drafting and application of the TRIPS agreement, its implications for the health of people in periphery states, and the broader consequences for development. It concludes by considering whether and how periphery states can work within such a system to overcome the continuous cycle of underdevelopment and poverty.

Chapter I of this thesis provides the methodological and theoretical basis with which to assess the current global system, using TWAIL scholarship as the main theoretical

⁷ Makau Mutua & Antony Anghie, What is TWAIL. 94 AMSIL, 31-40 (2000).

basis. Following this, the thesis provides a historical analysis of the rise of capitalism and modern international law, their prevalence and universalization, thus creating an unequal and unjust global economic order. This includes an exploration of the rise of international economic law and postcolonial international legal reform in the area of economics, trade, and finance. Having set forth the ground upon which the international global order came to be and the extent of its bias towards center states, Chapter II then explores the historical progression of IPs. There is a two dimensional purpose to this chapter, first it shows that IPs were non-essential to the economic progression of center states. On the contrary because they were not properly applied it provided a leeway that allowed the industrial revolution in center states to develop such states without any barriers. The second purpose is that it shows that the transplanting mechanisms within periphery states (through colonization) and globally did not account for the needs or cultural difference of states. The end result is a global IP order that is biased towards center states and indifferent to the needs of periphery states. Chapter III examines the TRIPS agreement and how it protects the patent rights of the pharmaceutical industry. It considers the resulting effects on access to medicine, the spread of disease, and mortality levels in the developing world. The Chapter also considers the broader impact of TRIPS on development worldwide, considering whether the agreement prevents or exacerbates underdevelopment, poverty and inequality. It concludes with the argument that the TRIPS agreement, particularly when understood against the broader context of the development of global economic governance and the rise of IPRs, is a means for systemically perpetuating underdevelopment, poverty and inequality. This is exemplified by the pharmaceutical industry. The fifth and final Chapter considers terms upon which periphery states can work within such a bias system, bearing in mind that a complete alteration of the system or a decision to not work within the system in a globalized and connected world would be unrealistic. As such, the chapter explores the success of India in building a strong pharmaceutical industry through maneuvering the international system and especially using the loopholes within the new TRIPS regime. The Chapter also explores the case of Egypt, its success and failures, and what lessons it can take from the Indian case. The Chapter concludes by looking at alternative strategies for availability of pharmaceuticals in periphery states and considers future effects of TRIPS on the pharmaceutical industry.

I. Construction of the International Legal and Economic System

*The construction and universalization of international law were essential to the imperial expansion that subordinated non-European peoples and societies to European conquest and domination*⁸

A. Methodology

The main question addressed in this thesis is: what is the effect of the Intellectual Property Rights Regime on the access to pharmaceuticals in developing countries? This question is examined using a qualitative research methodology through a holistic perspective of analysis of both the international legal system and the intellectual

⁸ Mutua, *supra* note 7.

property rights regime and in turn its effect on the availability of pharmaceuticals in developing countries. The thesis uses the Third World Approaches to International Law (TWAIL) as both a theoretical and methodological base. The reason for choosing TWAIL is because its scholarship provides a critical non-Eurocentric analysis approach of the international legal system and presents alternative views on how international law can be understood. TWAIL presents a theoretical alternative to the common understanding of international law which demonstrates the bias against periphery states within the entire international legal system. This approach which deals with inequality between states is an essential foundation towards understanding the grounds upon which the IPR was built and demonstrates how the regime is a replica of a general cycle of global inequality. Further, TWAIL uses a multidisciplinary approach as a methodological basis that focuses on the historical progression of international law. The thesis, uses the same methodology focusing on the historical rise and spread of both international law and the intellectual property rights regime exposing a bias against periphery states which is exemplified through the lack of availability of pharmaceuticals in such periphery states.

1. Third World Approaches to International Law (TWAIL)

In analyzing the evolution of the current global legal system one finds that it corresponds with the economic and political needs of Western states. The evolution of the current global economic order and international law reflected the evolution of an international system that served and continues to serve the best interest of developed states and an economic system which is used a tool to do so. TWAIL provides both strong scholarship that moves away from the Eurocentric approach of analyzing the international global order. It uses a “historically aware methodology”⁹ to address and question the current international legal system. TWAIL is not a monolithic theoretical school, rather it “provides a model for thinking about international law and institutions

⁹ James Thuo Gathii, *TWAIL: A Brief History of its Origins, its Decentralized Network, and a Tentative Bibliography*, 3 *Trade Law and Development* (2011), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1933766.

as a whole and for analyzing particular aspects or segments of our global order”.¹⁰ TWAIL scholars address the issue of the unjust international legal system from a multidisciplinary approach to expose the bias of the global system, and in doing so attempts to formulate a theoretical basis to help reform the system. In that sense TWAIL has contributed in generating a new science of method and of legal studies. The main themes that TWAIL scholarship address are bringing the problem of colonialism to center stage arguing how the power dynamics of the colonial era persist to date. It provides a different historical account of the rise of the current global order thus demonstrating the biased nature of the global system. And finally, it also undermines the inherently Eurocentric nature of the system and proposes drastic changes in the global order. The significance of TWAIL to this thesis is three fold; first the methodology used in TWAIL scholarship with regards to using a historical account of the rise of international law, and specifically to this thesis of the IP laws, is replicated to move away from the Eurocentric approach which justifies the used of IP laws. Rather, much like what Anghie does in demonstrating the bias nature of the international legal system, through using a historical narrative, this is what the thesis does to show the bias nature of the IP regime. Second, much like Anghie and other TWAIL scholars who address the inequality of the system which was amplified through colonialism, the thesis demonstrates how colonialism was a mechanism of embedding IP laws in colonized states and using their control over such states to normalize the regime internationally before the decolonization of such states. Finally, the inherently bias nature of the system, described by Anghie in *The Evolution of International Law: Colonial and Postcolonial Realities*, along with writings by Verzijl and Lenin, are used as basis to exemplify how the unjust nature of the system extends to different parts of the global system, which include the Patent Regime.

TWAIL scholarship focuses on understanding the interconnectedness of the world and examines how different laws and institutions are involved in the phenomena of global interdependence. TWAIL-ers thus address several issues related to society, politics, identity and economics between the periphery and core states.

¹⁰ Chinedu Okafor Obiora, *Critical Third World Approaches to International Law (TWAIL): Theory, Methodology, or Both?*, 10 *International Community Law Review* 371–378, 378 (2008).

Chimni focuses his research on the relationship between international public law and international economic law, and issues of global wealth and poverty. Rajagopal examines the link between development, human rights and international law through resistance, and Gathii among other things sketches notions of social issues from a historical context history and their relation to the creation of the rules of the WTO¹¹. This thesis focuses mainly on the work Anthony Anghie, who explores the historical rise of modern international law contenting that its origins reveal its Eurocentric exploitive and biased nature. He further continues to argue that although the discipline has attempted to renew and reform itself, its imperialist nature has remained constant.

B. Origins of International Law

Examining the origins of international law, and providing a historical analysis of it provides evidentiary basis for the claim that international law and the global system is by nature biased and unjust. Anthony Anghie in several of his writings such as *Imperialism, sovereignty, and the making of international law*¹², *The Evolution of International Law: Colonial and postcolonial realities*¹³ and *Time Present and Time Past: Globalization, International Financial Institutions*¹⁴, examines the rise and evolution of international law and provides a strong account of how it is of purely Western origin and has been reformulated to a universal norm which serves the best interest of Western states. As JHW Verzijl states the body of international law “is the product of the conscious activity of the European mind” and is of “Western European

¹¹ Antony Anghie, *Imperialism, sovereignty, and the making of international law* (2005). At 36

¹²*Id.*

¹³ Anthony Anghie, *The Evolution of International Law: Colonial and postcolonial realities*: Third World Quarterly: Vol 27, No 5, 740 (last visited Sep 10, 2016).

¹⁴ Antony Anghie, *Time Present and Time Past: Globalization, International Financial Institutions and The Third World*, 32 N.Y.U. Journal of International Law and Politics 243–290, 277 (2000).

Origin”.¹⁵ The Eurocentric nature of International law is evidently clear in three manners; first the development of the system through its 3 principles schools of thought, second the development and evolution of the main doctrines of international law such as sovereignty and the relationship between colonialism and international law.

The development of international law has been linked to three main schools of thought during different period of time, characterized by distinctive jurisprudence styles. The first, the Naturalist School of thought, which lasted from the 16th until the 18th century and during which “it could be ascertained through the employment of reason, and this transcendent ‘natural’ law—which had religious origins—was binding on all states.”¹⁶ This “transcendent law” which was seen as global was Eurocentric in nature and none of the thinkers or scholars of such school of thought were non-European. The second, Positivism, which rose during the 19th century and has since prevailed as the dominant school of thought, is bound by the law produced by consent of sovereign states. This idea of the “sovereign state” and what it is to be a sovereign state along with the rules and doctrines that emerged from such states consent is all a European idea and had no non-European influence in it. Most 19th century international law focused on colonial problems; this is evident in the number of “special doctrines and norms had to be devised for the purpose of defining, identifying and placing the uncivilized and this is what the jurists of the period proceeded to do when listing among the modes of acquiring territory, conquest and cession by treaty.”¹⁷ Finally, Pragmatism, which emerged to compliment the emergence of international institutions, and “provided the international system with a new set of technologies with which to address international problems”,¹⁸ emerged with

¹⁵ JHW Verzijl, *International Law in Historical Perspective*, 10 vols, Leiden: AW Sijthoff, 1968, Vol I, pp 435 – 436.

¹⁶ *Supra* note 13.

¹⁷ *Id* at 740-741.

¹⁸ *Id*.

the rise of international institutions in Europe in the late 19th and early 20th century, to fill a necessary gap in the international relations sphere in Europe.¹⁹

International law is the body of law which governs the relations between states and which is based on doctrines, principles and treaties between such states. A close look at such doctrines and principles shows that their development occurred in Europe based on the relations between European states and then extended globally.²⁰ The corner stone of international law is the concept of sovereignty which emerged out of the Treaty of Westphalia in 1648. The concept of sovereignty is a purely European concept created as a means for European states to maintain its integrity and borders without fear of outside intervention from other European States. However, the definition of sovereignty, which entailed requirements such as ruling over a controlled territory with “civilized” people, was then used as a means of legitimizing colonization. This legitimization of colonization was done through justifying the exclusion non-European countries from the definition of sovereign states, since the criteria of controlled territory and civilized was based on European standards, inapplicable to most of the rest of the World.²¹ Vitoria, one of the founders member of modern international law in his jurisprudential account of the Spanish conquest of the “Indians”, as the indigenous inhabitants of the Americas were then known, demonstrates the bias and exclusionary aspect of international law through the sovereignty doctrine. Vitoria justified the conquest of the Indies, as a result of their failure to show “sovereignty” over their territories as sovereignty was understood in Europe. And as a result, this justified the Spanish conquest of Indian territories to further the economic and trade interests of Spain.²² This was to be used a mechanism for the conquest of non-European people by justifying the act of war against them. The result of this was the “disenfranchised and subordinated non-European peoples”²³

¹⁹ *Id.*

²⁰ *Id.* at 740.

²¹ Anghie, *supra* note 13, at 13.

²² *Id.* at 13.

²³ Anghie, *supra* note 13, at 35.

through colonization and through justifying this under international law. This was done through the creating a cultural difference in the “new international law” by crafting a category of civilized and non-civilized states and “asserted that international law applied only to the sovereign states which compromised of the civilized family of nations.”²⁴ Anghie’s analysis of Vitoria’s work in Imperialism, Sovereignty and the making of International Law²⁵ is threefold. First, it established the premise that international as a legal framework has been constructed to serve the needs of European/Core states and to legally justify the acts taken unjustly against other nations. Second, international legal doctrines, some of which stand strong as building blocks of international law today, like the sovereignty doctrine, are at its core biased towards the political and economic needs of core states. Third, it demonstrated “several crucial and enduring aspects of the relationship between colonialism and international law” at heart of which is the centrality of commerce to colonialism and in parallel to international law.²⁶

The European imperialist project expanded from the Spanish conquest of New Americas to Asia and Africa. It reached its peak in the 19th century, the century most known as the colonization period. Its significance lies in how it set forth basic notions and concepts what is to become today’s international law. Most 19th century international law focused on colonial problems; this is evident in the number of “special doctrines and norms had to be devised for the purpose of defining, identifying and placing the uncivilized” and this is what the jurists of the period proceeded to do when listing among the modes of acquiring territory, conquest and cession by treaty.²⁷ An example is the doctrine of terra nullius, which allowed states allowed the legal conquests of uninhabited lands. It also legalized the conquest of lands inhabited by people “regarded as inferior or backwards”, in other words uncivilized from the

²⁴ Id.at 35.

²⁵ Id.at 35.

²⁶ Anghie, *supra* note 14, at 744.

²⁷ Anghie, *supra* note 13, at 36.

European perspective.²⁸ Clearly, the colonial period was also significant in imposing European law in conquered territories and the universalization of that European law, which was purely based on European imperialistic needs. The significant of this on modern international law is threefold; first it created an international law which was non inclusive during a period in which the development of international law was the most creative. Second, doctrines from this century, which clearly reflected the imperialist bias of European states, still stand to this day as foundation of international law. Third, the ultimate effect of this is establishing European standards as the ultimate goal which non-European states aim to reach. Achieving sovereignty thus becomes a form of alienation and non-empowerment and submission to alien standards, which is evident in the decolonization period.²⁹

Decolonization did not come about as a sudden movement rather it was a series of global events heightened by the first and second world wars that eventually lead to decolonization. There were several international factors that aided in the rise of national movements within colonies against the colonizers that began in the 1900s. Most prominent of those factors were: President Woodrow Wilson advocating of the right of self-determination, the rise of Pan-Islam and the Russian revolution³⁰. The effect was the rise of demonstrations and sabotage against colonizers during the period of 1910 until the beginning of the first World War in colonies such as India and Egypt, leading to a decrease in the power of the colonizers. This decrease in power was demonstrated for example by the resignation of the agent and consul general of Egypt, Lord Cromer.³¹ This like many other incidents signaled the end a period of

²⁸ Id.at 59.

²⁹ Id. at 108.

³⁰ Id.

³¹ Roger Owen, *Lord Cromer: Victorian Imperialist, Edwardian Proconsul* (2004). In 1879, Evelyn Baring, the Earl of Cromer, was assigned as as the British controller general in Egypt, the control which reviewed the Finances of Egypt following its Bankruptcy in 1876., Later in 1883, Lord Cromer became the agent and consul general in Egypt, under which he was in charge of all of Egypt's finances, economic development and governance.

uncontested rule especially in British and French colonies³². The decolonization movement was only cemented by the events of the First and Second World Wars. The wars had a two-fold impact on the decolonization movement. First, both wars caused a movement of ideas within lesser social classes as a result of their recruitment into military service. Those coming from uneducated backgrounds were fed slogans of freedom by the educated elite³³. Second, during both wars political concessions and reforms had to be given to colonies in return for “recruitment and mobilization of colonial troops,” to help out during the wars, making it possible for national movements to make demands from the colonizers. During WWI, this helped national movement gain more ground, force concessions, declare most colonies protectorates especially later after the end of the war under the Mandate system, and set new reforms that laid down ground work for future regulations. During WWII “chief colonial powers suffered disastrous setbacks³⁴” and thus they had to promise future emancipation eventually leading to decolonization³⁵.

Because of the weakening position of colonies following WWI, and the concessions to colonies that needed to be given at the time, a new approach towards dealing with the colonies needed to be created. This was done by creating the Mandate System within the League of Nations, which helped in applying the promised concession and justifying a lesser form of colonialism within the context of international law. Under the Provision of the League of Nations, which was only made of Victories states of WWI, the Mandate system aimed to “create sovereignty and to produce functioning nation-states”³⁶ in mandated territories. Lord Lugard, a prominent British supporter of colonization who saw colonies as important sources of raw

³² Id. at 19.

³³ Id. at 20.

³⁴ Id. at 23-26.

³⁵ Id. at 27.

³⁶ Anghie, *supra* note 14, at 36.

materials and “markets for metropolitan cities”, was one of the founding member of the Permanent Mandate Commission. And so, one of the main purposes of the Mandate system is “developing” the “backward” mandated states by influencing the day to day administration of such countries to ensure the wellbeing and “development” of such states.³⁷ The expansion of commerce and commercial laws at the time were thus mechanisms under this system guided by colonial principles. It also clearly demonstrates the bias of the international legal system. More importantly, it had an important effect on the neo-colonial global order, which was setting for the ground to the move from a formal political to an informal economic colonialism, which was cemented following WWII. Thus, shifting the global focus and the focus of international law into areas of economics, commerce and trade. And that is evident not only in the increasing numbers of treaties in trade, but also in the number of institutions that deal with it. The significance of the Mandate system in forming the current legal and global order traces to how it set up the standards, methodology, norms and regulations upon which the global system, including international institutions, were built on afterward. This imperialist system was created through bringing about a new science of systems control through new science of management and administration relying of models of legitimacy. It also produced what was called the ‘science of development’ which provided the legitimating foundation of contemporary development institutions.³⁸ This ‘science of development’, which is a product of the Mandate system, produced a scientific account of causes of ‘underdevelopment’ in non-European states, based on the collection of data from mandated states and comparing it to European standards. The results of which was setting the blame on the economic, social and political structure of periphery states, and generating a universal idea based on the structure of the core states. This became a mechanism of neo-colonial control following WWII and the decolonization of previously colonized states, whereby institutions that came to be afterwards like the IMF and World Bank set economic political and legal policies based on the structure and needs of core states and justifying it under the pretense of development, as per

³⁷ *Id.* at 278

³⁸ *Id.* at 264

mechanisms and arguments laid down through the Mandate system³⁹.

With the end of the Second World War, the fall of the League of Nations, and creation of the United Nations, the Mandate system came to an end. The international system witnessed the creation of the United Nations and the Bretton Woods Institutions along with the exponential growth of a number of international institutions, some of which with the sole aim of aiding development of periphery states. The Bretton Woods institutions, The IMF and World Bank, became the leading actors in pushing and promoting policies of economic and political change, for what they promoted as developmental purposes. However, the entire system had already been built to forcefully integrate newly independent states into an already biased international system. For example, the United Nations, which became central to maintaining international order and applying international law, was based international legal concepts, agreements and treaties between states that already were biased in nature, and became a means of manipulation and control for the benefit of core states. A clear example was that newly independent states had to be recognized by member states, all of which at its establishment were core states, as sovereign states to be allowed into the UN. And in accepting such a requirement states then by default accepted the already existing international legal order, which as shown was based on the needs and benefits of core states. And thus in doing so, forcing periphery states to accept the status quo. This has become a manner to manage and control periphery states to benefit European countries first through the mandate system and now through IFIs, the UN and other institutions; an elaborate way in which colonial relations are reproduced.⁴⁰

Consequently, as Anghie argues International law continues to reproduce the imperialist structures that have existed since the birth of modern international law. “Colonial origins of the discipline are re-enacted whenever the discipline attempts to renew itself, reform itself.” Doctrines created to further colonialism which stand today are difficult to reform; thus new international law doctrines somehow reproduced the

³⁹ *Id.* at 207

⁴⁰ *Id.* at 264.

structure of the imperialist ‘civilizing mission’.⁴¹ Today imperialism is legitimized through the new language of development, economic reform and liberalization policies. All of which serve the capitalist interest of Western states.

C. The Rise and Expansion of Capitalism

Having discussed the rise of modern international law and argued not only that it is imperialistic and bias in nature, but also the centrality of commerce and trade to it, it is important to discuss the rise and expansion of capitalism and how it too furthered and continues to primarily focus of the imperialistic needs of Western states. The rise and expansion of capitalism can be historically traced back to four significant phases; The Mercantilist phase, the Colonial period, the postcolonial period and the post-imperialist phase. Each of these phases as will be briefly discussed, aided in the dominance of Western states globally, and had a regressive effect on periphery states, that has continued to date.

During the Mercantilist period, from 1500-1800, Europe underwent the biggest phase of trade expansion into Asia, Africa and South America. European merchants conquered shores and trade routes in search for gold, spices and slaves. Trade relations between European and non-Europeans was unequal and unfair, where Europeans basically looted and plundered non-European territories for their raw materials and transferred such economic surplus back to Europe. This economic surplus aided dramatically in paying for the industrial revolution by paying for the technological and industrial advances in Europe. The effect of this period was threefold; first the birth of industrialization and the development of capitalism in Europe, the regression of non-European states development because of the dominate Europe presence in all markets, and the creation of production surplus, especially after the industrial revolution.⁴² This production surplus and the need to acquire more raw material as a result of industrialization led to the need for expansion and dominance of

⁴¹ *Id.* at 303

⁴² Valdim Il'ich Lenin, *Imperialism; the highest stage of Capitalism 17-21* (New York International Publishers) (1984).

markets globally, which eventually after the early 1800s lead to the annexation of non-European territories through colonial policy.

Colonialist expansion led to a division of the world with a center and a periphery; the center states were in control of the global economy and politics and the periphery economically and politically dependent.⁴³ The colonial era between 1880-1945 furthered the already segmented world, and capitalism with its new forms of production and new technologies aided in globalizing this. The colonialist expansion, following the industrial period, and the changes in modes of production and growing role of technology caused an unequal division of labor between core and periphery states that established an unequal global economic division that has since then lasted. For example, while colonies were specialized in producing agricultural goods and thus developing specialized labor in agricultural production, Europeans invested within their own countries and colonies in tertiary and industrial sectors such as banking and trade railways and ports, and the production of manufactured goods.⁴⁴ This meant that while core states industrialized in different sectors and diversified their economies, periphery states remained specialized, with no spark to spur industrialization, keeping them dependent on exporting raw materials. This resulted in the dependency of such periphery states on core states to acquire produced goods. To this end colonized states, that Amin refers to as periphery states, witnessed an era of “blocked development”, while Europe underwent extreme modernization and development.⁴⁵ The result was the creation of two different global social systems, whereby the center produced profitable manufactured goods, and the periphery based their economies on raw materials, a form of unproduced goods which have a lower trade value in the international system. This in itself was a representation of the economic reality of the dominance of core states. Such conditions were the building blocks of the new

⁴³ *Id.*

⁴⁴ Samir Amin, *Unequal Development: An Essay On The Social Formations Of Peripheral Capitalism* 188 (1976).

⁴⁵ *Id.*

capitalist world order and the era under which new international economics was born.⁴⁶

The imposed division of resources, labor and technology during the colonial period laid the foundations for “continued economic control and domination over colonial resources even in the absence of direct political over lordship and administration”.⁴⁷ Capitalist markets and market institutions were established and set in the hands of Western multinational companies, long term concessions granted of such colonies to subsidiaries of those multinationals firms, and agriculture and production of exported crops given to foreign plantation owners. Thus preparing the domestic and international economies into a neo-colonial period of continued Western control. Neo-colonial control as Hoogvelt describes was recognized mainly in the continued” resource bondage” and trade status between Western and non-Western countries.⁴⁸ With independence in sight, another strategy taken by colonial states was the shift of metropolitan states from production of consumer goods to the production of producer goods, and shifting consumer goods into controlled areas of previous colonies. This also created a new kind of dependency and source of surplus extraction through browed or rented technologies that were now needed in newly colonized states from the West, creating a continued dependency with new forms of capitalism taking place⁴⁹. This along with international institution’s, doctrines and treaties embedded colonial relations and solidified it in continued control over the world’s economy

This new international economic system was reflected in the already biased international legal system. The Internationalization of Intellectual Property Rights were used as another mechanism to continue the bias within the international. One such example of this biased international system. This internationalization was

⁴⁶ *Id.*

⁴⁷ Ankie M. M. Hoogvelt, *Globalization and the postcolonial world: the new political economy of development*, 30 (2nd ed ed. 2001).

⁴⁸ *Id.*

⁴⁹ *Id at 31.*

implementation initially through the ratification of the Paris Convention for the Protection of Industrial Property which was adopted in 1883 and the Berne Convention for the Protection of Literary and Artistic works adopted in 1886. The Paris and Berne conventions were created as a mechanism to deal with the expanding needs of colonizing states regarding the protection of patented material, and to globalize it to their colonies. Patent law, which was first internationalized through the Paris Convention, was signed only by 11 countries, most of which were core countries. The rise of patent law can be genealogically traced to the 13th century English inventors patent law, after which Europe witnessed expansion of different forms of patent. Most prominent and influential of such laws was the Republic of Venice Patent Act. From the 15th century onwards the wave of patent laws saw periods of advancement as well as periods of complete silence on the issue until the Industrial Revolution when the situation changed drastically. With the constant growth in innovation during the industrial period, Western countries realized the need to institute patency law. They needed it to protect their own industries from competition with one another, as well as to maintain an upper hand over colonized states by preventing them from copying western technology. The globalization of patency was then achieved through forcing the application of patency laws within colonies and legitimizing them through international conventions drafted by core states such as the Paris Convention of 1883 and the Berne Convention of 1886.⁵⁰

D. The Global Order in The 20th Century

Although the 20th century was the century of decolonization and creation of independent previously colonized states, it was also the century that brought about new players onto the global scene that would embed imperialistic and dominant relations between developed and underdeveloped states. These players were international institutions dominated by Western states who used international law, through doctrines and agreements previously created and new ones created by them to maintain control over underdeveloped states. The United Nations serves as perfect example of how this was done. Although the UN Charter Article 2(1) states that “The

⁵⁰ Xuemei An, *The Review and Forecast on Development History of IPR in the World*, 132-135 (2009)

Organization is based on the principle of the sovereign equality of all its Members”⁵¹ the reality is that the organization structure reflects otherwise. The UN Security Council , which has much of the power of taking action and decision-making within the UN is controlled by 5 permanent members, all of which with the exception of China, are western/core states. This in itself reflects the reproduced imperialistic structure of the 18th and 19th century. Second, within the new global system was the creation of transnational industries on a global scale.

Another example of embedding the relationship between developed and underdeveloped states both through international law and through institutionalization was embedding capitalist liberalism. This was done through several institutions such as the IMF and the World Bank. More prominently, and what this thesis focuses on was through the creation of the WTO and its agreements. The Uruguay GATT rounds of 1994 produced the Trade-Related Investment Measures agreement (TRIMS) and the Trade-Related Aspects of Intellectual Property Rights agreement (TRIPS). Both agreements severely circumscribed the sovereign rights of all member states to regulate investment and trade in pursuit of “developmental” needs. TRIMS phased out previously perceived protocols of development strategies like local content requirements in production, domestic sales requirements, balancing sales requirements and exchange restrictions. TRIPS strengthened property rights of foreign investment, extended patent protection, which in most cases belong to western multinational companies. The result is of this patenting process is that developing countries end up suffering huge drawbacks and regression in several sectors, including the pharmaceutical sector for example, and in turn this affected their development as will be discussed in upcoming sections of the thesis.

II. The Genealogy of IPRs

Since it is rooted in a contradiction, there can be no such thing as an ideally beneficial patent system and it is bound to produce negative

⁵¹ *Id.*

results in particular instances, impeding progress unnecessarily even if its general effect is favorable on balance.⁵²

As discussed in Chapter II the international legal and economic system is characterized by its biased imperialist nature favoring center states over periphery states. The rise and expansion of capitalism was the fuel that caused an expansion of an economic order based on private ownership. The expansion of private ownership rights alongside the emergence of new forms of technology and wide spread need for innovation through the spread of information led to the evolution and globalization of patent and copyrights laws. This chapter explores the nature of Intellectual Property Rights (IPRs), and through a historical discussion argues that European economic progress before, during and following the industrial revolution occurred despite not because of the existence of IPRs. The chapter argues that, much like the rest of international law, non-European states has no input in the creation and evolutions of IPRs, and it was a purely European creation. Also, much like the method upon which international law came to be in that it was forced upon periphery states, IPRs were transplanted in colonized states based on European standards. The result is a now globalized IPR legal system, cemented through the TRIPs agreement, that is biased against periphery states.

A. Private Ownership and The Rise of Intellectual Property Rights

For centuries, the concept of private ownership has been associated with the ownership of tangible objects like land. The right of private ownership has existed in many forms over in history. It has progressed from the communal ownership of land, to the right of an individual to own land, along with other tangible pieces of property like cattle. However, it was only in the Middle Ages that European countries started to acknowledge the need for property rights to take legal form. During this time, rulers gave out concessions to others purportedly giving them control of land, but the land in reality still belonged to the king. It was only later towards the end of the medieval period and the beginning of the Enlightenment that the idea of land ownership took root. It is this idea of private ownership that serves as the basis of the right for

⁵² Joan Robinson, *The Accumulation of Capital*, 1956.

Intellectual Property (IP).⁵³ Unlike the traditional right of private property, which dealt with tangible objects, IPs are rights to intangible objects that result from one's own intellect, creativity, ideas and invention. IPs thus encompasses an array of forms such as copyrights, patents, trademarks, and industrial designs, that cut cross several fields from art and different technological sectors to medical know-how and production. IPs grant a limited type of monopoly over such creations with specific conditions for a certain period of time. The reason for granting IPs as presented by its proponents is to allow innovators ideas, products and technologies to be "compensated".⁵⁴

The history of IP passed through three distinct phases until it reached the point of being the international law concept it is today. The first phase was the emergence of IP in medieval Europe. Although IPs, especially in the field of copyright, emerged as legal rights, the system was very weak legally and administratively. In spite of these weaknesses, the importance of this period lies in the actual codification of the concept in core states as a result of their desire to protect artistic innovation. Notably, until the era of colonialism, periphery states were not involved in either the development or implementation of IP regimes. The second phase is the internationalization of IPs, whereby multilateral agreements started emerging as a means to protect IPs and set standards between states as to what the conditions for protection between signatory states were. During this period, the involvement of periphery states was minimal. The third phase, which set the stage for the current global IP system, originated with the establishment of the WTO and the adoption of TRIPS.⁵⁵

The Middle Ages witnessed the first law related to intellectual property rights. Much like the method by which rulers granted property rights to people in their favor, kings, bishops and other political figures hired engineers and skilled workers to conduct technology intensive manufacturing for military and building cathedrals. Those inventors were granted contracts to keep their invention secret, and were

⁵³ Rami M. Olwan, *Intellectual Property and Development: Theory and Practice* (2013).

⁵⁴ *Id.*

⁵⁵ *Id.*

rewarded for doing so. Out of such practices aimed at monopolizing the market and deterring invention in other states did the first institutional practice of IP protection grow.⁵⁶ An example is the 15th century Venetian patent law, which granted patent rights in the form of a “monopoly awarded for the possession of locally novel craft knowledge or for the invention of new devices.”⁵⁷ The Venetian Patent System aimed at creating an incentive system within its borders but also at protecting its secrets from moving outside them. Its granting was also based on the usefulness of the invention with a standard duration of 10 years.⁵⁸ Thus throughout the 15th and 16th centuries patents were basically forms of monopolies limited to novel machines and processes, and in some cases on the basis of authorship or possession of the knowledge of certain machines. While it was argued that it was a way of forwarding economic development, the reality was that it had a two-fold purpose. First, it was a means for insuring that such innovations remained within their birthplaces to advance their economic status. Second it was granted to powerful rich men, as privileges on the basis of court favors.⁵⁹ During the period prior to the Industrial Revolution, only the crème de la crème of society were able to have access to patent rights due to their high cost and lengthy process. Patent rights prior to the industrial revolution were a mechanism of monopoly and domination for the influential and powerful in European states.

It was during the industrial period that a greater focus on IPs began to emerge, arguably to put in motion economic growth. With the increased efforts of several European countries, especially Britain and France, to produce and implement IP laws,

⁵⁶ Nilamani Das, *Role of patent and IPR laws for bringing economic development in the post globalization era*, 4 *The Journal of Legal Awareness* (2009).

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ Long Pamela, *Invention, Authorship, “Intellectual Property,” and the Origin of Patents: Notes toward a Conceptual History*, 32 *Technology and Culture* 846–884 (1991).

the number of registered patented inventions grew. Many historians, especially proponents of IPRs, argue that the growth of patented inventions during the industrial era is an indicator of the relationship between patent rights accumulation and economic development⁶⁰. Such proponents associated protection of industrial technology with economic growth. However, as Joel Mokyr argues, the increasing number of patent registrations in Britain, for example, was not in fact related to the economic development that was taking place.⁶¹ Rather it was because of the decreased cost of registration of patents and the growing idea of non-cooperative competitiveness: a “race to the bottom” process whereby patents registered preemptively to prevent others from registering similar ideas.

In other words, because patent laws were imperfect at the time, and lacked boundaries that they have today, as the costs of patenting decreased the registration of patent rights increased as means of blocking competition from creating new inventions. The effect was in actuality decreased development and growth, in the same way that patents in medieval times were initially designed to block innovation and growth. Now with the process simpler and cheaper, the blockage spread further. Additionally, many scientists with scientific innovations during that period did not acquire patent rights over their inventions because they saw science as an end in itself not a means to a fortune.⁶² Moreover, the experience of most European countries seems to lend little support to the central role of patents in spurring industrial innovation. The most striking case is the Netherlands, which, despite its high degree of economic development in the seventeenth century, did not figure prominently in the Industrial Revolution. Yet it had a patent system established in the sixteenth century.⁶³

⁶⁰ Joel Mokyr, *Intellectual Property Rights, the Industrial Revolution, and the Beginnings of Modern Economic Growth*, 99 *American Economic Review* 349–355 (2009).

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

An examination of patent law during the industrial period shows that the introduction of patent rights did not fuel economic and technological development, rather it held it back. One prominent example is James Watt's patent right over the steam engine. In 1764, after producing a new model of the steam engine with the help of Matthew Boulton, he was able to hold the patent for it until 1800.⁶⁴ During this period, while having a monopoly over it, Watt did not try to improve on it or actually produce many of them because of its high price; he, rather, gained money by receiving royalties from the right of patency over it. After the expiration of the patent right there was "an explosion in the production and efficiency of engines",⁶⁵ produced by inventors who improved on Watt's inventions. Steam power later became the driving force of the Industrial Revolution because of modifications to the engine that drove the Industrial Revolution into full force in the years following the expiration of this patent. This development was blocked for almost 30 years by Watt's hold of the patent.⁶⁶

While it is undeniable that there was growth in the patent system during the industrial period, "there is ample evidence that the patent system did not operate as effectively or as perfectly"⁶⁷ as popularly believed. The patent movement had a number of administrative weaknesses: procedures were cumbersome; there were plenty of opportunities for cheating; the cost of patenting was very high and "the

⁶⁴ Michele Boldrin & David k. Levine, *Against Intellectual Monopoly* Chapter 1 (Cambridge Univeristy Press 2010).

⁶⁵ *Id.*

⁶⁶ Although, Watt did chose to acquire the patent over the steam engine, his motivation behind its invention was not driven by knowing that he would have exclusive patent rights to profit from it. In fact, it was Boulton who took advantage of the patent law to take economic advantage of the invention . Michele Boldrin & David k. Levine, *Against Intellectual Monopoly* Chapter 1 (Cambridge Univeristy Press 2010).

⁶⁷ Mokyr *supra* note at 60.

poorly defined and uncertain nature of the law down to the 1830s tended to erode the value of patent property and consequently tended to shift the terms of trade against the inventor”.⁶⁸ As such, patents actually tended to reduce the expected rate of return for the inventor, and they saw it as being of little value. Moreover, court systems were biased against patent holders in most cases as they saw it as a form of monopoly. Thus, as Dutton argues, the system at the time was imperfect, but it was this imperfection that made it ideal. As Dutton argues, that “which effectively protects inventors in every sense will slow down the rate of innovation and imitation”,⁶⁹ and thus slow down technological change⁷⁰. This flawed system, along with the fact that such laws only applied domestically since no multilateral agreements had been signed between European states, made the system ineffective. The result was the flow of information and technology between European states during that period, which resulted in increased development because of the diffusion of knowledge, information and technological know-how. It was said that, when it came to industrial designs and know-how, Germans copied from the British, Americans copied from the British and Germans; and the Japanese copied from everyone.⁷¹

Up until the 20th century, most European states had imperfect systems of patenting. Such systems mostly operated within their own borders, but some also expanded to operate throughout Europe through trade agreements. The risk was the growing capacity of industrialization and capitalism to transfer technology outside the European region. Europe had to act to prevent that, and the solution was through legalizing patency in colonized areas.

B. The Globalization of Intellectual Property Rights and Transplanting Patent Law During The Colonial Era

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ Olwan, *supra* note 53.

European states soon realized that there was a need to globalize patent and copyrights law to expand their control over their inventions and to prevent the reverse engineering of their products and knowledge that came with it. Therefore, starting in the early 19th century, colonial powers like France and Britain introduced copyright law in all of their colonies and mandates. By 1864, 17 British colonies had adopted patent laws, most of which did so by transplanting British patent law.⁷² Similarly France also transplanted its patent law in its colonies. With these moves came the creation of conventions and treaties that protected patency like the Paris Convention of 1883⁷³ and Berne Convention of 1886⁷⁴. Although such conventions were ratified by European states with very little participation from developing states, they stated that “any country may declare in its instrument of ratification or accession ... that this convention shall be application to all or part to those territories... for the external relations of which it is responsible”⁷⁵. As Olwan states, “IP law was not merely an incidental part of the colonial legal apparatus, but a central technique in the commercial superiority sought by the European powers in their interaction with each other in regions beyond Europe”⁷⁶. This was further cemented through internationalizing IP laws through international conventions and agreements, which colonies had to abide by⁷⁷, thus demonstrating Anghie argument of the purely

⁷² Alexander Peukert, *Intellectual Property: The Global Spread of a Legal Concept* (2013).

⁷³ Paris Convention for the Protection of Industrial Property, *adopted* 20 March, 1883, *U.N.T.S.*

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⁷⁴ Berne Convention for the Protection of Literary and Artistic Works S. Treaty, *adopted* 9 September, 1886, 1161 *U.N.T.S.*

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ Peukert, *supra* note 72.

Eurocentric nature of international law which was globalized to continuously provide for the needs of European states.

1. The Paris Convention of 1883

The Paris Convention was the first multilateral treaty on IP, and is thus seen as one of the two building main blocks that have led to the globalization of the IP regime⁷⁸. The Paris Convention was drafted after various conferences were held between 1873 to 1882, and is considered one of the foremost international treaties with regard to the protection of industrial property. Its main aim is the protection of patent, trademarks, industrial designs, utility models, trade names, geographical indication, and repression of unfair competition, while at the same time facilitating more trade. The vast majority of developed countries adopted the treaty and transplanted it into their own domestic laws and the laws of their colonies as a means of “civilizing” those countries. Article 2 of the convention facilitated the transplanting process through the “colonial clause,” which obligated the colonized to adopt the Paris Convention as they were part of the colonial power that had adopted the Convention and were under its jurisdictional powers⁷⁹. The process ignored the various developmental stages, and the social and cultural differences between developed and developing countries. This one-size-fits-all ideology resulted in hampering rather than aiding the developmental process in colonized regions.⁸⁰

In realizing that the international patent system was imbalanced in favor of core states, periphery states attempted to amend the Paris Convention to protect their own interests and meet local conditions. The main proponent of this was Brazil, a signatory to the Convention, who first brought up the issues to the UN in 1961. Brazil contended that the IP system was a barrier to economic development and requested an investigation into its effect in underdeveloped countries. The report, published in 1964, saw no reason for revising the system itself, but rather on working on reforming the internal institutions of periphery states. The report saw that the lack of strong

⁷⁸ *Supra* note 73.

⁷⁹ Peukert, *supra* note 72.

⁸⁰ Olwan, *supra* note 53.

governance in periphery states caused ineffective administration, court systems and forms of monitoring, which lead to the lack of proper application of IP laws. Thus, the report attributed the lack of developmental progress to weak internal governance rather than a result of the nature of IP laws or its system. In spite of this conclusion, and after considerable pressure from developing nations in 1970, the UN General Assembly Resolution entitled the International Development Strategy for the Second UN Development Decade recommended a revision of the IP system. Although the Convention was amended in 1900, 1911, 1925, 1934, 1958, 1967, and 1979, it was unsuccessful in working towards the benefit of developing countries and later attempts to change it were blocked by core states, especially the US.⁸¹

2. The Berne Convention for The Protection of Literary and Artistic Works

The Berne Convention, the second cornerstone of the international IP regime, focused on the protection of literary and artistic work⁸². Thus, its main concern was copyright. The Convention was drafted in 1886 and went into effect in 1887 with ten states signing on, only two of which were developing countries, Tunisia and Haiti, clearly demonstrating that there was almost no representation of the ideologies or policies of periphery states. The Convention, much like the Paris Convention, had a colonial clause, Article 19, which extended the obligations of the Convention to colonized states. Much like the Paris Convention, following their independence, periphery states were not happy with the copyright system and argued that it needed revision to address the interests and conditions of their states. They proposed that the Convention have “concessions for their benefit and a system of reservations that they could use when needed.”⁸³ After years of debate, and politicization of the Berne Convention, the

⁸¹ *Id.*

⁸² *Supra* note 74.

⁸³ Olwan, *supra* note 53.

status of the Convention as a whole was endangered. In 1971, an *Appendix on Special Provisions Regarding Developing Countries* allowing developing countries “non-transferable licenses to its nationals, for the translation or reproduction of foreign owned-copyright works for education or research purposes.”⁸⁴ This appendix allowed periphery states to copy any copyrighted material if it was used to further research in certain areas or for educational use, to enable periphery states a greater chance of development. However, this process was not facilitated easily. Getting such an exception was a lengthy and costly process for developing countries.⁸⁵

C. The Transplanting of IPs in Periphery states

In analyzing the transplanting experience of IPs on periphery states, we find that several TWAIL scholars like Gathii and Anghie argue that in the postcolonial realities IPS was and is a method of domination and control that did not fuel economic development. Rather is demonstrated a repetitive cycle of colonial relations. The Indian case serves as a very good example.

British influence in India started in 1600 with Queen Elizabeth I chartering the Governor and Company of Merchants of London Trading into the East Indies, commonly known as ‘The Company’ or ‘The East India Company’. It laid the foundation for British rule in India, until the British Crown directly took over control of India in 1858, following a massive revolt against the Company,⁸⁶ After this, a patent law was introduced to “grant certain exclusive privileges to inventors for a period of fourteen years”, and this required prior sanction by the Crown or its representative: “Thus, the 1856 Act was repealed when the Indian Legislative Council passed Act IX of 1857; Act IX was followed by a new law enacted in 1859 that granted inventors the exclusive privilege to make, use, and sell their invention in

⁸⁴*Id.*

⁸⁵ *Id.*

⁸⁶H.I. Dutton, *The Patent System and Inventive Activity During the Industrial Revolution*. 324 (1984).

India.”⁸⁷ The purpose of this was to allow the British patent holders to gain control over Indian markets. The law had huge restrictions on the importation of technologies and inventions, leading technology to become “highly complex and prohibitively expensive”. Over the following decades under British colonization, patent laws continued to be developed and refined. In 1872, the Patents and Designs Protection Act was enacted, followed by the Protection of Inventions Act in 1883.⁸⁸ In 1911 the Invention and Design act came into force, with two important consequences resulting from it. First, it consolidated the Patents and Designs Protection Act and the Protection of Inventions Act. Second, it increased patent protection period to 16 years. This Act continued to govern India until after India’s independence in 1947, when it was finally repealed by the Patent Act of 1970. All of the various versions of the Act “allowed for product patents in all fields of technology, including pharmaceuticals.”⁸⁹ The effect of the British transplant and the evolution of the Patent Act in India was massive, and it weakened India’s industries. One such industry was the pharmaceutical industry. The 1911 Act, for example, prevented the manufacturing of reverse engineered drugs owned by foreign drug manufacturers that held patent rights, even after India gained independence.⁹⁰ This included most life-saving drugs such as insulin, streptomycin, and penicillin. Thus, they were imported at high prices, and outside the reach of most of the Indian population. The result was one of the largest populations in the world gaining independence with weak industries, a sick and poor population, and a hindrance to development. It was only after the amendment of the Patent Act that Indian industry developed, especially its pharmaceutical industry.

As discussed, imperial powers approached the issue of IP law in colonies in a manner that advanced and protected the interests of empire. The application of IP laws in colonies using a one-size-fit-all methodology that was based on the economic, social and political interests of imperial powers was a setback for the development of

⁸⁷ V.K. Unni, *Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Context of Public Policy and Health*, 25 McGeorge Global Bus. & Dev. L.J 323–342 (2012).

⁸⁸ *Id.*

⁸⁹ Dutton *Supra* note 86 at 325.

⁹⁰ *Id.*

the Third World, and aided in creating a globally divided system that is unequal and biased.

D. The Debate on IPRs

The historical narrative so far, detailing the emergence transplanting and globalization of IPs, argues that IPs were not drivers of innovation in Europe or the rest of the world. Contrary to common perception, IPs were mechanisms of monopoly and control by the elite in core states to generate profit and maintain control by very few in the West. Capitalism was the mechanism for doing so, and colonial policies along with IP laws were the tools. Following decolonization, Western states had reached a high level of industrialization and technology was becoming an important factor in capitalism. The result was a push by the United States and European countries for the globalization of the IP regime, to maintain their hegemonic power through monopolizing knowledge and technology.

During the industrial period, proponents of patent law had four main rationales for justifying patent protection. The first was the natural-law thesis, which asserts that individuals have a natural right to own their own ideas.⁹¹ If a patent holder is not compensated it is a form of theft and thus government intervention is needed to protect such a right. This also means that inventors invent more since their own ideas are protected. This is like the government's protection of private property, arguing that investments in property increase, because investors feel safe and protected. In the same way, the government should protect inventions and ideas, since intellectual property is as much a natural right as property, and protection will allow inventors to feel free enough to innovate and create.

The problem is that patenting inventions infringes on the public right of society, which is an indirect contributor to such inventions. Hindmarch argued that "no inventor can, in fact, have any natural right to prevent any other person from making and using the same or similar invention."⁹² For Hindmarch, an invention is a result of several factors that fosters one's own creative and innovative thinking; such

⁹¹ Olwan, *supra* note 53.

⁹² Dutton *Supra* note 86.

factors include societal motivation, education, and governmental support. Without such factors, this invention could not exist. It is no one's right to have a monopoly over thoughts and ideas that the public have, in various ways, aided in creating.⁹³

The second argument was the reward-by-monopoly argument, which is still widely used to justify patent laws. The basis of this notion was that the reward to the inventor should be according to the usefulness of the invention. Since such a reward cannot be guaranteed purely by market forces, the state should intervene to guarantee it temporarily. By doing so, inventors are more inclined to invent since their reward for their ingenuity and effort is protected.⁹⁴ Without such rights, competitors would reduce their prices, and inventive output would decrease. Moreover, the quality of the invention would be subject to market forces; that is, if the product was not good, it would not be profitable. Consequently, this does not harm the market, rather it benefits it.

The problem with this argument is that contradicts the primary assumption and basis of the global economic order based on the capitalist system. The assumption is that market forces should be the only forces setting demand, supply, and thus the price of products. Thus, this contradicts the ideas that there should be an outside element, through law, that needs to adjust the market for the benefit of inventors.

Inventions relying on a patented idea, product or process would have to pay royalties, amounting to considerable sums of money to use the patent right. In most cases, other inventors will not want to pay the royalty, and thus will have to wait until the expiration of the royalty before developing patented ideas. The result is that, if royalties are paid, the patent holder profits; and because most people will not want to pay them new inventions that could override the invention of the patent holder are delayed, and the patent holder continues to benefit from the right over the invention for the period of time the law guarantees. Thus, patenting holds back innovation instead of spurring it on.

The final argument is the exchange for secrets proposition, which is concerned with the dissemination of information. The argument proposed is that protecting the

⁹³ *Id.*

⁹⁴ *Id.*

information regarding such an invention would to protect the interests of the inventor. The result is an increased flow of information since the inventor/investor is guaranteed profits by selling such information. He also has a motive for allowing the propagation of information and product processes.⁹⁵

On the other hand, it is argued that the monopoly over royalties, and their expense, hinders innovation. In areas such as pharmaceuticals, which rely on building new ideas on the success of old ones, innovation would remain at a standstill since methodologies and processes would have to wait until the expiration of the patent right unless vast royalties could be paid.⁹⁶

Today, proponents of the IP regime argue that the system promotes investments in knowledge creation and business innovation by creating exclusive rights to sell technology, goods and services. This motivates investors to invest more since the risks of return of investment in research and development, is guaranteed through patency rights. Without such protections, investors are less inclined to spend money on research and development.⁹⁷ In a related argument, it is claimed that with such protection there is also an increase in the amount of Foreign Direct Investment (FDI) because of the security they are guaranteed for their ideas and products and the ability of governments to enforce royalty and contractual obligations. Increased FDIs are not only important for the economic benefits to periphery states, they also allow for the transfer of knowledge and information from core states to periphery states. The second argument of the IP regime is that it allows for the dissemination of information; inventors allow the flow of information into the market knowing that they are compensated for it, thus increasing innovation growth that builds on previous ideas. Consequently, the argument is that global IP regimes allow for growth and development to all parties.⁹⁸

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ Keith E. Maskus, *Intellectual Property Rights and Economic Development*, 41-75 (2005).

⁹⁸ *Id.*

E. The Anti-Patent Movement

Unlike proponents of the IP regime, the anti-patent movement proposes several arguments to explain the adverse effects of IPs on economic growth and development. They range from holding back development and advancement in new fields because of high royalties, to the lack of evidence supporting the need for profits from patented products outside core states. The first argument is that patents are harmful as they are means to shift the focus of inventors from advancements in their field to making profits.⁹⁹ It shifts the focus to monetary gains and business profitability, which in many industries hold back innovation. This has drastic effects in fields such as healthcare and medicine, where advances are necessary for the survival and improvement of life. This previously described trend of holding back new developments from reaching the market is described by the United States Food and Drug Administration (FDA) as “pay to delay”. An example, published by the UK Office of Fair Trading, showed that between 2001 to 2004 four pharmaceutical companies delayed the supply of paroxetine, a widely known anti-depressant, in the UK so that GlaxoSmith Kline could monopolize and benefit from the sale of Seroxat - an anti-depressant - in the British market.¹⁰⁰

IPs, via several means, place economic and social costs on periphery states that they cannot afford. The first reason is that many people are employed through copying unauthorized goods, and thus there are employment losses if they are unable to reproduce such goods. Moreover, the cost of essential products like food and pharmaceuticals become unaffordable when produced by monopolizing companies for people in periphery states. The effect is the lack of essentials of life. Governments of such countries cannot afford to subsidize products imported at monopoly prices, as is the case with food and pharmaceuticals. In this case, the end result is lack of access. IPs not only limit the availability of essential products but also the information to imitate them. For example, many countries, like Brazil and India, have been able to build their industries through the available knowledge of products in the markets and

⁹⁹ Dutton, *supra* note 86.

¹⁰⁰ Mae-Wan Ho & Peter Saunders, *End of Drug Monopolies & Mega-profits?*, 58 Institute of Science in Society (2013).

the ability to reverse engineer them, without which the industries of such countries would not have been able to prosper. The pharmaceutical industry in India provides an excellent example of this, and is discussed in full in the final chapter of this thesis.¹⁰¹

F. The International Institutionalization of IPRs

As previously stated, the Paris and Berne Conventions marked the first step towards the internationalization of the IP regime. The coming into effect of these Conventions and the need to establish bodies to administer them lead to the creation of the United International Bureaux for the Protection of Intellectual Property (BIRPI). BIRPI was the predecessor of the World Intellectual Property Organization (WIPO), a specialized UN agency aimed at promoting the globalization of intellectual property rights.

1. Establishment of BIRPI and WIPO

The BIRPI and WIPO marked the global institutionalization of IPs. BIRPI was established in 1883 in the city of Berne, following the adoption of the Paris Convention, as a mechanism for administering both the Berne and Paris Conventions. Its membership was dominated by core states to promote awareness and protect the IP system. It also attempted but failed to pursue an IP agenda that took into account periphery states' needs. After almost a century, WIPO, the successor to BIRPI, was established in 1970, and in 1974 was recognized as a UN agency. WIPO, an intergovernmental organization, aimed at the "protection of IP throughout the world through cooperation among states."¹⁰² It distinguished itself as an agency that recognized the problems of developing countries and put as its main goal helping such countries into the world economy. A proponent of IP, its aim was to engage more periphery states in implementing IPs as a method of economic development, through arguing that it helped increase FDI and therefore technology transfer. The reality was that WIPO was a mechanism for informing periphery states that implementing IPs was necessary for economic integration into the world system. Instead of taking into account the different social, economic, cultural and political needs of different periphery states, WIPO pressured states into accepting the already established IP

¹⁰¹ Dutton,, *supra* note 86.

¹⁰² *Id.*

regime and working within its boundaries¹⁰³. The problems within WIPO were that for core states it had a weak implementation mechanism of the Paris and Berne Conventions; and for periphery states, they realized that multinational corporations funded and controlled WIPO's activities.¹⁰⁴

With the failure of WIPO to create a strong trade regime, and the growing political and economic pressures within core states to establish a strong international IP regime, it became necessary for core states to establish a new institution that would serve the interest of core states through promoting the agenda of IPs. The establishment of the WTO provided such an opportunity. The WTO was meant to provide a forum for equal treatment among states. However, this proved not to be the case. The WTO is seen as a mechanism to further the agenda of core states with regards to trade and also IPRs through the TRIPs agreement. In discussing the establishment of the WTO and creation of TRIPs, the following chapter shows that, while core states pushed for the establishment of a stronger IP regime, periphery countries fought against it, but were ignored and pressured to accept TRIPS.

III. Healthcare and Pharmaceuticals under The TRIPs Regime

*Access to medicines is a pressing, global issue, closely linked to trade and intellectual property issues. We do not know how long the health systems of industrialized countries can continue to meet the increasing cost of reimbursements given the emergence, for example, of very costly new drugs to treat such widespread conditions as cardiovascular diseases or cancer, treatments that will be developed and patented on the basis of research into the human genome—even though this research is publicly funded.*¹⁰⁵

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ German Velasquez, Intellectual property and access to medicines: papers and perspectives:

Three out of four people living in periphery states do not have regular access to medicine. The global percentage of sales of medicines in periphery countries accounts for only 8% annually of global sales.¹⁰⁶ This means that the average spending per capita in core countries is more than 100 times that in periphery countries. This is a result of the monopolized prices of medicine as a result of patent laws. This coupled with the lack of purchasing power of periphery states results in lack of ability to buy medicines. Consequently, the supply of medicines in periphery countries is very low. This directly affects the healthcare and wellbeing of people living in periphery countries. International law should promote one of the most basic of human rights, the right to health. Instead, the TRIPS agreement provides a clear example of the use of international law to advance center states' agenda over the periphery while ignoring the basic right to health. To understand how this is achieved an analysis of the TRIPS agreement how it came about, and an assessment of the arguments for and against patent rights in the particular context of pharmaceuticals is necessary.

A. Historical Analysis of The TRIPs Agreement

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an agreement under the auspices of the World Trade Organization (WTO). Any member state of the WTO has to apply TRIPS in its national law.¹⁰⁷ The WTO defines intellectual property rights as “rights given to persons over the creations of their minds. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time.”¹⁰⁸ Intellectual property rights extend to different areas such as copyrights and patent rights. However, as this thesis focuses on health and medicines, patent rights are the focus.

Trade agreements, intellectual property and access to medicines: An introduction (2010), <http://apps.who.int/medicinedocs/documents/s17521en/s17521en.pdf>.

¹⁰⁶ *Id.*

¹⁰⁷ WTO | intellectual property (TRIPS) - agreement text – contents, https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm (last visited Nov 10, 2015).

¹⁰⁸ William Fisher & Talha Syed, *Global Justice in Healthcare: Developing Drugs for the Developing World*, 40 Berkeley Law Scholarship 581–678.

An historical analysis of the TRIPS agreement reveals that it only reflects the interests of core state and multinational companies within such states, while ignoring the calls and needs of periphery states demonstrating the continued colonial relation between core and periphery states discussed by Anghie. Adopted on April 15 1994 in Marrakesh, TRIPS was an essential topic of discussion during the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), and the establishment of the WTO. GATT was established in 1948 and was the single most important multinational agreement in international trade. Until the establishment of the WTO in 1995, GATT set the main legal economic, financial and trade principles on the international scene, and was the only organization successful in maintaining such a regime in one sole organization for 48 years. In parallel, the IP regime was managed through WIPO, which administered the Berne and Paris Conventions. However, with the growing importance of technology and information and their protection for multinationals in core states, multinationals lobbied politicians for increased protection, especially with the increase in copying and counterfeiting by developing states. The result was that in the Uruguay Round of 1986 to 1994, the eighth and last round of the GATT, the focus was on the establishment of the World Trade Organization, with a special focus given to strengthening the IP regime through the TRIPS agreement.¹⁰⁹

The TRIPS agreement, which became obligatory on all signatories to the WTO, is an expansion of the Paris Convention on the Protection of Industrial Property and the Berne Convention for the Protection of Literary and Artistic Works. It was established to provide adequate standards of protection for intellectual property and provide greater predictability and stability in international economic relations. Although it was a continuation of the IP regime its novelty was, first, in setting minimum standards for the global application of an IP regime; second, in its creation of “detailed rules on enforcement rights before judicial administrative authorities; and third, the creation of a binding and effective mechanism to settle disputes between states.”¹¹⁰ During the Uruguay Rounds, a coalition of 100 participating multinational corporations (MNCs) pushed governments to strengthen protection against

¹⁰⁹ Olwan, *supra* note 5.

¹¹⁰ Duncan Matthews, *Globalising Intellectual Property Rights: the TRIPS Agreement*, 11 (2012).

counterfeiting. On the other hand, periphery states argued intensely about the disadvantages that further development of patent rights protection would bring. They also argued that the WTO was not the forum to discuss this issue and WIPO was the appropriate forum. This tension was reflected in the negotiation process, and is the main reason why the first three years of the rounds were stalled.

A mid-term review lead by India and Brazil in Montreal highlighted this polarization. Their main argument was that IPRs belonged outside the context of GATT and belonged to WIPO instead. They also expressed major concerns about TRIPS effect on technology transfer, especially the “increased costs of pharmaceutical and agrochemical products.”¹¹¹ Periphery states feared that the new IP regime would negatively affect primary industries, which in turn affects the well-being of their people and their economic growth. They contended that the “TRIPs Agreement would mean the surrender of sovereignty over national development objectives and the denial of access to technology”.¹¹² Developed countries argued that TRIPS would increase domestic research and development (R&D), and would not harm the availability or pricing of agrochemical products or pharmaceutical products. Surprisingly to developing states, when the draft agreement was proposed, none of their concerns had been included, following intense pressures especially by the US regarding the placement of bilateral trade sanctions on the periphery states. Moreover, periphery states had very limited expertise in IP issues and trade and did not work well together for their own benefit in this regard, and thus did not realize the full of effect of applying IPs in the manner proposed in TRIPS.¹¹³ Additionally, they thought that by giving up IPs they would gain benefits in other areas such textiles and agriculture – benefits that in fact did not eventually materialize.¹¹⁴ Such benefits were supposed to come as a result of decreased tariff and non-tariff restrictions in areas like textiles and agriculture, the main exports and comparative advantage of periphery

¹¹¹ Olwan, *supra* note 53.

¹¹² *Id.*

¹¹³ Olwan, *supra* note 53.

¹¹⁴ *Id.*

states. The reality was that this did not happen, and core states still set tariff and non-tariff restrictions in such areas, even after the adoption of the WTO and TRIPS.

The period of negotiations of the WTO and TRIPS coincided with debt crisis in periphery countries, faced as a result of loans they had taken out from the Bretton Woods institutions following decolonization. Having emerged as newly independent states with very weak economies, and in debt to previous colonizers, periphery states borrowed from international banks as well as developed states and the IMF in order to develop, and were unable to pay back such loans leading such countries into a sovereign debt crisis. In the aftermath of the debt crisis, debtor countries were forced to adopt liberal economic policies by lenders such as the IMF. Such policies included opening up borders against tariff and non-tariff restrictions as well as protection of intellectual property rights. Thus, several periphery countries were forced to accept the WTO and along with it TRIPS as a condition of getting more loans and aid from the IMF and World Bank.¹¹⁵

TRIPs was adopted as a mechanism for setting minimum standards of IP protection and establishing adequate mechanisms of conflict resolution with regards to IP issues.¹¹⁶ TRIPs imposes three main obligations on its members: first, it sets minimum standards for a global IP regime to be applied at the domestic level of signatory states. These standards were novel because they went beyond the standards of the Berne and Paris Conventions and because they set an unprecedented minimum guideline. Second, it requires members to have in place an effective mechanism for imposing such requirements. Finally, it also requires WTO members to submit to dispute settlement mechanisms in the event that disputes arise over a patent, copyright or any IP measure mentioned in the agreement. All these requirements translated into a new global IP regime based on Western ideologies, economic, political, and administrative standards, all of which were identified as lacking in periphery states and thus demanding significant legal reform.

B. The Content of TRIPs

¹¹⁵ *Id.*

¹¹⁶ Olwan, *supra* note 53.

The main objective of TRIPs is set out in Article 7 and states that the aim of the agreement is transfer and dissemination of information and technology, and balancing rights and obligations of users and producers. The reality is that high royalties over patented technology has resulted in the decreased transfer of information and technology to periphery states.¹¹⁷ Article 8 was developed because of concerns that were voiced by developing nations; with 8.1 stating that:

In amending national laws and regulations, members may adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors vital to their socio-economic and technological development, provided that such measures are within the TRIPs Agreement.¹¹⁸

Article 8.2 further states that:

Appropriate measures may be needed to prevent the abuse of intellectual property rights, or the use of practice which unreasonably restrain trade or adversely affect international technology transfer, provided that such provisions are consistent with the TRIPs Agreement.¹¹⁹

The patent subject matters outlined in articles 27 to 34 established high protections; this includes inventions of both products and processes so long as they are “new, involve an inventive step and are capable of industrial application”.¹²⁰ Moreover, Article 33 requires patent law to afford a minimum of 20 years to the patent holder, and hold a monopoly over all aspects of this patency. Article 28, regarding the rights conferred by patents on their owner, in conjunction with Article 31 regarding other uses without authorization of the rights holder, limit the extent to which countries can engage in compulsory licensing of either a product or a process without the prior consent of the patent holder.

These stipulations have had a deleterious effect on periphery states. Prior to the integration of TRIPS into the WTO, countries especially periphery states,

¹¹⁷ Sangeeta Shashikant & Martin Khor, *Intellectual Property and Technology Transfer Issues in the Context of Climate Change, Third World Network 1–68 (2010)*.

¹¹⁸ Matthews, *supra* note 111, at 49.

¹¹⁹ *Id.*

¹²⁰ *Id.*

facilitated and encouraged the flow of information and technology to aid the development process. Countries such as India and Brazil used this technology transfer to aid their industries, especially in the areas of pharmaceuticals and health care. Pharmaceutical industry protection has been one of the biggest areas of debate since the application of the TRIPs. In periphery states, poverty is a result of several dynamics. One of them is the lack of proper healthcare, which is directly related to limited technological progress in pharmaceuticals in developing countries. The lack of government funds to finance the increasing cost of medicine affect the importation of products and technology due to monopolized prices by multinationals holding patency over such products and technology.¹²¹

C. The TRIPS Agreement, Healthcare and Pharmaceuticals

With growing epidemics of HIV and Hepatitis C and other treatable and preventable diseases in periphery countries, the questions scholars such as TWAIL-ers attempt to address is how periphery states can work around this unjust system and what legal arguments may be advanced in support of periphery states.

1. Core Countries Perspective

The need for patent rights in pharmaceuticals remains contentious. There are several justifications that economists and the pharmaceutical industry propose to justify why patenting is essential nationally and internationally. The first justification for having robust IP system for pharmaceutical products is that drug patents provide social welfare commodities and has economic externalities that benefit society by prompting the creation of new medicines. This outweighs the social welfare costs. The argument is that although society does have to pay in many cases large amounts of money to have access to medicine especially under a patent system, the availability of such medicines, which benefit the social good as a whole, outweighs the price that society has to pay. Their second justification, which supplements the first, is that “the

¹²¹ Tzen Wong and Graham Dutfield, *Intellectual Property and Human Development: Current Trends and Future Scenarios*, Chapter Two (2010).

pharmaceutical firms deserve the financial returns made possible by strong patent protection because they have invested so much effort and money — and run such big risks — in producing their socially valuable products.”¹²² The argument is that because they take such huge risks in investing money into research and development, that in turn benefit society, then they have the right to profit greatly from such investments. PHARMA president Gerald Massinghoff posits that the continuation of research and development technology depends on “the extent to which foreign governments allow innovators to be rewarded for their inventiveness, monetary investment, and intellectual labor”,¹²³ and there needs to be incentives for investors through the guarantee of financial return through patent protection.¹²⁴ The main argument thus revolves around reaping the financial rewards of the investment made in R&D to develop the drugs, and that the developed nations alone should not be held responsible for paying back the money invested in this. Thus, if profits are not protected, pharmaceutical companies will stop producing new drugs, which will leave the whole world worse off.

The second argument for implementing a strong IP regime is an increase in the level of FDI by multinational pharmaceutical companies in periphery states, as they feel safe that their innovations and products will be protected. There will be an increase in the levels of technology transfer and/or licensing because there is a secure legal environment which “will ultimately lead to the transfer of know-how and expertise that will contributed to local economic growth”.¹²⁵ The contention here is that technology transfer happens because of the publication of patented information, which stimulates inventions in developing countries. Consequently, this will lead to an increase in the number of innovations in the field domestically, which in turn will help the economy as well as the people over the long run.¹²⁶

The third significant argument, with regards to human rights, is found in the

¹²² Fisher & Syed, *supra* note 100.

¹²³ *Id.* at 668.

¹²⁴ *Id.*

¹²⁵ Olwan, *supra* note 53, at 75.

¹²⁶ Matthews, *supra* note 110.

TRIPS agreement's articles 7 and 8, which allow for exceptions to patent law to accommodate human rights. Article 7 specifies the objectives of TRIPS and states that IP protection should facilitate technology and information transfer:

[t]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology . . . in a manner conducive to social and economic welfare, and to a balance of rights and obligations.¹²⁷

Article 8 acknowledges and allows member countries to adopt measures to promote the public interest in sectors that are vital to their individual socio-economic and technological development:

Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Consequently, it is contended that Articles 7 and 8 provide a mechanism for exceptions to the application of patent laws, as well as preventing the monopolization of the patent holder when it is a matter of advancing the public good.

Complementary to the flexibility provided in Article 8, Article 32 relating to compulsory license states that under Article 31 the rights of patent holders can be circumvented in certain situations. More specifically, member governments are given the authority to grant a license to a party willing to commercialize an invention protected under patent without the consent of the patent holder. Unless there is a “national emergency”, the proposed licensee is required to make reasonable efforts to seek a voluntary license. If the patent holder refuses to grant a license, the government can grant a non-exclusive license. Consequently, subject to other provisions of the

¹²⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994)

TRIPS Agreement, compulsory licensing allows generic drug companies to manufacture patented drugs and sell them at a fraction of the price that the patent holder might, since only the costs of producing the medication and not the costs of research and development need to be recovered.¹²⁸

2. The Problem with Patents Under International Law

The TRIPS agreement is very problematic as it contradicts other fundamental international laws. International human rights law, including the right to health and the right to life, are impeded by IP laws that prevent the availability of medicine. In general, the agreement narrows developing countries' access to technology and discourages the rapid diffusion of new technology needed for economic growth, although the aim of the agreement as stated during the Uruguay round is the diffusion of technology and helping in the development and growth of underdeveloped states.¹²⁹

In addition to the contradictions brought about within the general scope of international law by the IP regime, as well as a result of the actual application of IPRs and the general purpose of the agreement there are problems within the agreement itself. Although articles 7, 8 and 31 allow for exceptions to override patent rights, there are two major problems that render these exceptions ineffective. The first is that governmental approval is required to override the patency of a drug. This is virtually impossible since developed countries continue to dominate the global IP system. Politicians and multinational company lobbyists profit from adherence to patent laws and play a hand in the formation of government policies and legislation that it is not in their interest to reform. Second, developing nations frequently do not have the infrastructure to produce sophisticated drugs.

As stated by Syed and Fisher, 9 million people die annually because of diseases that can be prevented but are not because of the lack of affordability and availability of those drugs in the periphery. This is a result of several factors:

¹²⁸ *Id.*

¹²⁹ Human rights: a compilation of international instruments, (United Nations ed., 2002).

First, the majority of the most effective drugs are covered by patents, and the patentees typically pursue pricing strategies designed to maximize their profits. Second, pharmaceutical firms concentrate their research and development (R&D) resources on diseases prevalent in Europe, the United States, and Japan — areas from which they receive 90-95% of their revenues — and most of the diseases that afflict developing countries are uncommon in those regions.”¹³⁰

By comparison, the same diseases cause the death of nearly 200,000 lives a year in the developed world.¹³¹ Moreover, data shows that there was no increase in R&D and the creation of new chemical or medicines following the application of TRIPs. In the period between 2007 and 2011, the number of new chemical or biological entities launched on the world market fell in one decade from 196 to 149.¹³² Patent laws effectively contributed to an increased percentage of the number of people dying from curable diseases as a result of lack of availability of medicine. Moreover, the IP regime made no contribution to promoting research and development in the field of pharmaceuticals.

There are several arguments that propose how allowing the reproduction of medicines at lower prices would benefit developed nations. One is ensuring that diseases such as infectious diseases do not spread, especially with the frequency of international travel. The spread of the Ebola virus in the past year, for example, shows how interconnected our world is. Consequently, eradicating disease in periphery states through allowing removal or exception to patent rights, and allowing the production of generic medicines and/or parallel importation of cheap medicine, benefits the world as a whole. Moreover, the development of a strong health care system through the

¹³⁰ Fisher & Syed, *supra* note 108.

¹³¹ Id at 51 “In other words, the mortality rate from infectious diseases is over ten times higher in the developing world than in the developed world.”

¹³² The Pharmaceutical Industry and Global Health: Facts and Figures 2012, *IFPMA* (2012), http://www.ifpma.org/fileadmin/content/Publication/2013/IFPMA_-_Facts_And_Figures_2012_LowResSinglePage.pdf.

availability of medicine translates economically into a healthier work force.¹³³

With regard to the argument of returning the cost of money spent on R&D, Syed and Fisher argue that the average citizen in developed states on average pays \$100 per year to patented medicines. This means that, in a period of 8 to 10 years, R&D investments made by pharmaceutical companies are profitable to them, even if they only depend on income from core states. Thus, although profits made by firms are hard to assess because of the financial secrecy of firms, the bottom line is that “despite recent setbacks, the firms are still making plenty of money, substantially more than comparable firms in other industries. And the reforms we advocate would cut only modestly into their profits.”¹³⁴ In Syed and Fisher’s view, those involved in R&D do deserve a fair reward for their labor and medical creations:

the profits necessary to sustain incentives for pharmaceutical research — profits which, as indicated above, would still be reaped after adoption of our proposed reforms — seem more than adequate to supply the firms the “just deserts” to which they are entitled because of the effort their employees expend.¹³⁵

Keep in mind that the return of investment in R&D is in addition to profitability made regardless of the application of patent laws in developing countries.

Lock argues that “parties contribute to a socially valuable product, they deserve rewards commensurate with their respective contribution.”¹³⁶ With drug patents, the pharmaceutical innovations are “publically funded federal and university labs in which the majority of basic midstream biomedical research is carried out”,¹³⁷ and thus subsidized by governments. Most research into new medical breakthrough come from labs funded by government sectors either in universities or through grants. After such research has been done, it is bought by multinationals who patent it and benefit, although the reality is that the public through the government funding has actually paid for it.

Additionally, adequate knowledge can be achieved by limiting the duration of

¹³³ Fisher & Syed, *supra* note 108.

¹³⁴ Fisher & Syed, *supra* note 108, at 669.

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *Id.*

exclusivity rights to the time taken for a field practitioner to have independently come up with the invention, which in most cases amounts to much less than the 20 years set in TRIPS.¹³⁸ As previously discussed, investors usually make back their money in addition to profitability within 10 years of the release of the medical product. Thus, decreasing the ceiling internationally of the duration of IPs will not only guarantee the rights of the patent holder, but also allow periphery countries the ability to recreate the drug within a shorter period of time than is currently possible.

D. Legal Analysis of TRIPs

Having established that the current system is built on the needs of core states and serves their interests and the interests of multinationals through international regimes like the IP regime, the question is how to move forward and create a fairer and more balanced system. One of the problems within periphery states, which has helped the rise of the IP regime, is the lack of legal knowledge in such states and awareness of the consequences of their actions when signing TRIPS. Because developing states had little or no experience legally with regard to the IP regime, they were not able to defend their arguments during the Uruguay Rounds. Further, they did not fully realize the consequences of the application of IPs on their industries, nor the legal and administrative mechanisms needed to uphold such a system. Given that core states continue to dominate the economic, political and legal field internationally it would be unrealistic to argue today for a comprehensive revamp of the system.

That is not to say that challenges to the system cannot be successful. India, provides a good case study as to how periphery states can formulate IP laws that both abide by the rules of TRIPS, while at the same time protect and foster the domestic pharmaceutical industry. To appreciate the Indian example, there needs to be a legal understanding of TRIPs and how states can use its mechanisms to decrease the level of IPs in the pharmaceutical industry and initiate economic growth within their borders. The Doha Declaration, which “mandates that the agreement be interpreted in a manner that supports public health interests and promotes access to medicines for

¹³⁸ *Id.* at 674.

all”,¹³⁹ can be used as a tool to interpret TRIPs in a new manner that helps periphery states. In reinterpreting articles 30 and 31, periphery countries can find more flexible policy options with regard to compulsory licensing and parallel importation to increase the supply of low-price medicines and vaccines. This is one mechanism that can be used under the current system to combat its biased and harmful impact on periphery states.

1. Analysis of Article 30 and 31 and Article 8

An analysis of articles 30 and 31 read in the context of Article 8 reveals that there is a space for TRIPS members to allow for exceptions to patent rights, for parallel importation of cheaper products and for compulsory licensing. Article 8(1) allows the adoption of necessary measures to protect public health provided it is “consistent” with the terms of TRIPS. This sets the basis for the adoption of internal measures to protect the interests of the states within the parameters of the agreement. The constraint is that the measures they adopt should not violate the terms of the agreement. For this reason, many states believe that there are measures that can be taken to push the boundaries of the agreement. However, this Article read in light of Articles 30 and 31 reveals otherwise.

a. Article 31 on Compulsory Licensing

Compulsory licensing is an essential exceptional element of the TRIPS agreement, which can have a positive impact on the production and availability of medicine in periphery states. Compulsory license is “when a government allows someone else to produce the patented product or process without the consent of the patent owner.”¹⁴⁰ It is considered one of the most important mechanisms in addressing the public welfare.

¹³⁹ Frederick M. Abbott, WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries, IPR Commission (2002).

¹⁴⁰ WTO | intellectual property (TRIPS) - TRIPS and public health: Compulsory licensing of pharmaceuticals and TRIPS, https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (Last visited 15 October 2015).

Periphery states may use it to increase the supply of low priced drugs through allowing their local producers to produce the drug or import it under a compulsory licensing agreement with the patent holder. However, the right to apply compulsory licensing is attached to certain conditions. First, there must be a party within such a country that has the technical ability to produce the product. This requires technical and financial capacities. Second, there must be sufficient purchasing power to justify the investment. This means that unless a country can show the need to produce such medications, the ability for its government is subsidize it to make it affordable, or for its people to afford it on their own, compulsory licensing will be precluded. Finally, there needs to be adequate compensation for the patent holder. Without this, compulsory licensing would be seen as illegal under TRIPS.

Although the terms of Article 31 are generally flexible with regard to the grounds for permitting the licensing and administrative process, there are still problems with its application. Two problems are the wording of the Article and the effects of applying it. With regards to the legal application, TRIPS establishes several obstacles to the actual application of compulsory licensing. The most widely noted obstacle is found in section (f) of Article 31 which states that “any such use (of compulsory licensing) shall be authorized predominantly from the supply of domestic market of the Member authorizing state”. This limits the importation of products from countries that have already applied compulsory licensing. This means that very poor developing countries with no mechanism for producing through compulsory licensing still do not have the ability to import such products. Also, the word “predominantly” means that most of the production, more that 50% should be for the supply of local markets. Thus, half of the amount of produced goods under compulsory licensing must be distributed in local markets. This is to limit parallel importation because, through limiting the exportation of products under compulsory licensing as much as possible, this limits the degree of infringement on the rights of the patent holder. The limitation of 31(f) has two interlinked problems: First, it limits the ability of countries unable to support the production of drugs to import them at lower prices from those countries who reproduce it. Second, countries able to produce generic drugs have less incentive to do so because of limitations on meeting the demand for such drugs.

A third issue that arises with Article 31 concerns the remuneration to the patent holder when compulsory licensing is applied. Section 31(h) states that

“The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization. The remuneration requirement depends on the particular circumstances of the case and may take into account various factors, including (but not limited to) the economic value of the authorization.”¹⁴¹

In many cases such compensation to the patent holder, which is either adjudicated or set through administrative mechanisms, can be of high value or can be through the dispute settlement mechanism of TRIPS, which can take a lengthy period of time and a lot of legal expertise and resources. Additionally, minimum standards for compensation need to be met, taking into account the balance between public welfare and amount of royalties of patented products, and balancing them off. Article 31(k) expressly recognizes, “the need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases.” If a compulsory license is issued to remedy a situation in which the patent holder has unfairly benefited, the remuneration may be correspondingly diminished.

One solution to the problem of Article 31 is the creation of regional market arrangements. Much like what the EU has created, creating an economic bloc that functions as a representative of periphery states interest would mean that countries in such blocs are treated as one domestic border. The countries with the capability to reproduce drugs can thus produce drugs under the Article of compulsory licensing, guaranteeing that any investment made is returned with profit, aided by the knowledge that there will be high demand because of consolidating an economic bloc. Moreover, countries with no ability to produce can import it without the “predominant” requisition since it would be all within one border.¹⁴² Another mechanism to address the issues of Article 31 is the creation of pharmaceutical production export zones,

¹⁴¹ Abbott, *supra* note 139.

¹⁴² *Id.*

which operate much like free trade zones, and allow for cooperative production among periphery states.¹⁴³

b. Article 30 on Exceptions to Rights Conferred

Article 30 is considered one of the most important opportunities for developing countries. The Article provides an exception to overriding the rights of a patent holder:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 30 expressly allows exceptions to patent rights under specific conditions. This means that certain activities can be defined under national laws as an exception to the patent holder and yet are not seen as infringements on the patent itself. This exception can include a “production for export” exception, which means “that the necessary production for export could take place without being an infringement of the patent.”¹⁴⁴ It also means that countries would have the capacity to produce their own pharmaceutical products.¹⁴⁵ The use of the expression “exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner” balances the interests of those periphery states with those of patent holders.

As previously stated, patent holders of pharmaceutical products can guarantee a return on investment in addition to profits through the exploitation of their patent rights in developed states alone. It is therefore logical to conclude that providing legal exceptions to patent rights in periphery countries does not necessarily affect the commercial and financial interests of the patent holder, and provides grounds for allowing the production and importation of reproduced drugs to periphery states.

¹⁴³ *Id.*

¹⁴⁴ Why Article 30 will work. Why Article 31 will not, (24 June 2002), <http://www.msfaaccess.org/content/why-article-30-will-work-why-article-31-will-not>

¹⁴⁵ *Id.*

IV. India, Egypt, and Some Ways Forward

Having examined the history of the IP regime and the creation and application of TRIPs, and recognizing the dire effects it has had on periphery states after the application of the new IPR regime, the question is what can be done? The case of India provides an excellent example of how a country was able to move from having no pharmaceutical industry whatsoever, in one of the largest and poorest countries in the world, to having one of the strongest domestic pharmaceutical industries in the world. It also provides mechanisms for utilizing the flexibilities within the TRIPs agreement to structure domestic IPR laws that are both compliant with TRIPs and able to protect domestic interests. This chapter describes the development of the Indian pharmaceutical industry in parallel with the development of Indian patent laws. It then investigates and compares the Egyptian Pharmaceutical Industry to the Indian pharmaceutical industry, as well as the similarities and differences between both IP regimes within both countries. Finally, it deduces the lessons learned from both cases and what can be done to improve legislation in Egypt, and how it can be applied to other periphery states.

A. India

India's achievements in the pharmaceutical industry since its independence are remarkable. It provides an example of how to create an industry within the current global system, as well as substantiates the linkage between healthcare, access to medicine, economic growth, and development. The legal framework of the Indian patent system has gone through three major historical periods that shape the way the industry operates today.

The first was during the colonial era and ended in 1970. It was implemented under British Administration through the Indian Act VI of 1856, which was based on the British Patent Law of 1855. It provided certain privileges to inventors for a period of 14 years. Patent granting was mainly given to British companies operating in the colony; domestic filing at the time was very low: "India had virtually no domestic pharmaceutical industry during the British colonial rule."¹⁴⁶ While the country industrialized, the pharmaceutical industry did not. By the time it gained independence, its health care system was in disarray. While it was one of the poorest countries in the world, it imported medicines in high volume and sold it at higher prices than in most western countries. Multinationals monopolized the little drug manufacturing that existed.¹⁴⁷ Following its independence in 1947, India strived for a patent system tailored to its national needs. The government commissioned reports on the situation and in 1959 the Ayyangar Report revealed a situation that "multinational companies were exploiting India's patent system to achieve monopolistic control; foreigners held about 80-90% of Indian patents, but practiced less than 10% of those patents in India."¹⁴⁸ This report recommended radical reform, which came in 1970. This marked the beginning of the second stage of development in the Indian patent system.¹⁴⁹

¹⁴⁶ Linda L. Lee, Trials and TRIPS-ulations: *Indian Patent Law and Novartis AG v. Union of India*, 23 Berkeley Tech. L.J. 281 (2008). Available at: <http://scholarship.law.berkeley.edu/btlj/vol23/iss1/12> .

¹⁴⁷ *Id.* at 295.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

The second stage of patent development in India was the period from 1970 to 1986. This period was known as the period that stimulated India's generic drug manufacturing industry and set the country in the right direction. It revolved around the Indian Patent Act of 1970. The 1970 Act revoked the patentability of pharmaceutical products and only allowed patenting of the process of making medicines. This Act was able to stimulate the then lagging pharmaceutical industry by promoting domestic drug manufacturing. As Linda Lee describes in her exploration of one of India's recent and prominent patent cases:

Over the ensuing years, India developed a worldwide reputation as a producer of low-price generic drugs. India is currently the biggest producer of generic drugs by volume and the leading exporter of medicine to developing countries and it supplies a large percentage of AIDS medicines used in developing countries.¹⁵⁰

Within a decade, the number of foreign owned patent files decreased drastically as a result of the reverse engineering of drugs that was taking place. The country was able to produce large quantities of generic drugs at low costs that not only fulfilled commitments of the needs of the nation, but also increased its exports of drugs dramatically. The effect today is that its domestic generic drug industry directly competes with drug manufacturers in the US and Europe. Indeed, India and Japan are the only two countries whose generic drug manufacturers compete with multinational corporations. The industry became divided among large companies who were not only engaged in producing generic drugs but in also doing original research and development. They operate alongside hundreds of other smaller companies and multinationals. For India, this has made the field extremely competitive. It employs large numbers of the population, and allows access to more affordable healthcare and medicines. This is reflected in a growing middle class and expanding health industry.¹⁵¹

The third and final stage of development is concerned with the Indian reforms of patent laws in the period starting 1989. Although an original member of the WTO,

¹⁵⁰ *Id* at 295.

¹⁵¹ *Id* at 296.

India along with Brazil were the main opponents of the TRIPs agreement during the Uruguay Rounds. They argued that a patent system should not be universalized. Rather, it should be tailored to suit the domestic needs of each country. In spite of their resistance, due to the India's weak economic situation in the 1980s, and the threat of bilateral economic sanctions by the US and other Western states, India like many developing countries was forced to agree to include TRIPs as part of the WTO. As a developing country, India was granted a grace period until 2005 to comply with TRIPs. For this reason, during the period between 1989 and 2005, the Indian Patent Act went through three main amendments. The first stipulated that the patent system must be developed during the transition period, and that the Indian Patent Office would examine applications when India began to grant pharmaceutical product patents. The second amendment increased the term of patent rights to 20 years and modified the compulsory licensing and burdens of proof for infringement. Finally, it made pharmaceutical products patentable through the Patent Act of 2005. This was the final stage of development of Indian patent laws to ensure their compliance with TRIPs.

The Indian approach illustrates how it is possible to promote access to medicine while still implementing an IPR. India's success in implementing TRIPs while still protecting its industries, lies in the manner which it was able to use the flexibility in the open definition of invention, as well as exceptions permitted under articles 30 and 31.¹⁵² An analysis of the Patent Act against the terms of the TRIPs illustrates how India protects its pharmaceutical industry while complying with TRIPs.

1. Analysis of The Patent Act of 2002

¹⁵² Cynthia M. Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights*, SSRN (2011).

India's patent act is an excellent example of how to promote access to medicine while still abiding by the current global IP regime. With regard to the definition of invention, the TRIPs agreement Article 27 (1) states that:

Patents shall be available for any 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 ... [and] patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.¹⁵³

In other words, all processes and inventions are covered by this provision including pharmaceutical products.

Since the definition of invention was left open to interpretation, India included within its own national patent law two exceptions that would help the development the pharmaceutical industry. The amendment of Article 3 clause j of the original act then modified in article 3 section (f) states that:

(j) "Invention" means anew production or process involving an inventive step and capable of industrial application;

(ja) inventive step means a feature that makes the invention not obvious to the person skilled in the art.¹⁵⁴

This means that the following are not patentable: new uses of known substances (for example a compound of a cream that treats acne to also be used for wrinkles) and new forms of known substances unless they are significantly different.¹⁵⁵ However, this does not preclude their showing efficacy. This is not defined in Indian law but generally means a desired effect. In 2013, the Indian Supreme Court announced its

¹⁵³ The Patents (Amendment) Act, 2002, Ministry of Law, Justice and Company Affairs, New Delhi, 25 June, 2002.

¹⁵⁴ *Id.*

¹⁵⁵ Ravinder Gabbie & Jillian Kohler, "To patent or not to patent? the case of Novartis' cancer drug *Glivec in India*," 10 *Globalization and Health* 3 (2014).

judgment in the *Novartis v India*, one of the most important judgments in the interpretation of the concept of novelty of invention under TRIPS. The Court concluded that Novartis, which produced Imatinib, a leukemia drug, applied in 1998 for patenting of a new drug Glivec, which was a “beta crystalline form of Imatinib.”¹⁵⁶ The only novelty in the drug was that it absorbed 30% more easily in the bloodstream. After having its patent application rejected in India in 2006, Novartis filed a case against the Indian government asserting that “Imatinib, was only the first step in developing the current version, and could not be administered to patients”¹⁵⁷ and that only Gilvec is a viable treatment. For this reason, the new 30% absorption of the drug falls under a second generation patent. Novartis not only challenged the rejection of the patent right but also challenged the legality of section 3(d). The Supreme Court of India in its judgment held that the changes made in Gilvec were too minor to be considered as ‘efficacy’ under section 3(d). Further, it ruled that section 3(d) is legal under TRIPS and confirmed “the right of India’s Parliament to implement public health safeguards available under the TRIPS Agreement.”¹⁵⁸ What it means for the industry is that it limits the pharmaceutical companies ability to extend their patent right over a compound or medicine making a minuscule change and then to ask for a new patent right to extend its monopoly over the product and preventing other companies from using the product. By setting this limitation, the general welfare of society is protected and it also helps with advancements of products.¹⁵⁹ Article 3(d)’s compliance with TRIPS has been settled in the *Novartis* case. The Supreme Court found that, since the Article does not discriminate against a certain industry or technology, it complies with the flexibilities provided under TRIPS with regards to the definition of invention.¹⁶⁰

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ Ho, *supra* note 152.

¹⁶⁰ Lee, *supra* note 146.

A second feature of the Act allows for compulsory licensing. Article 31 of TRIPS read in light of Article 8(1), permits adopting measures necessary to protect the welfare of the state. Using the flexibilities of this article, the Indian Patent Act provides extensive grounds for issuing compulsory licensing under certain conditions. Such conditions include: the patent holder not satisfying the requirements of the public, excessively high pricing of medication making it unaffordable for the population, or not fully commercially exploiting, which means the patent holder fails to work/produce the patent locally.¹⁶¹

Another feature of the Act is the provision concerning international exhaustion. This provision considers the patent exhausted without authorization by the patent owner after the first unrestricted global sale by the patent owner.¹⁶² This means that once the patent has been registered in another country, and the holder has initiated sale of the product or information globally, the patent holder cannot reapply for extending the patent right again in India. This limits abuse of the patent law by companies that otherwise reapply for patent rights in different countries at different times to extend the right granted.

Finally, the Indian Patent Act allows a regulatory exemption of patent rights for generic production drugs and use of research information. India permits what it calls the ‘mailbox’ application of patents. Under this rule, companies that produced generic drugs prior to the coming into force of the 2005 Act, are allowed to continue making such drugs, and that generic production would not constitute an infringement on the patent holder of the original drug. As per Indian interpretation of TRIPS, this is in compliance with TRIPS Article 30.

India has clearly been successful in using the wording and flexibility in TRIPs to cater to its own needs of having a huge generic drug manufacturing industry, and companies are able to compete with multinationals. This promotes FDI in the Indian pharmaceuticals industry. But India is not the only developing country with a

¹⁶¹ *Id.*

¹⁶² *Id.*

pharmaceutical manufacturing capacity. Other periphery states such as Brazil, Egypt, Kenya, South Africa, and Thailand also have such capabilities and also face increasing need with regards to diseases such as Hepatitis C, HIV/AIDS and cancer. Such countries also stand as regionally significant producers of medicine. As such, developing countries have been demanding changes in IP policies that suit their needs rather than one global regime that serves the needs of developed countries over those developing countries. Moreover, developing countries that possess pharmaceutical manufacturing capacities should not merely incorporate these key flexibilities into their national patent laws; they should equally take steps to encourage and facilitate the effective utilization of these flexibilities in order to enhance access to medicines for their citizens. This is why countries such as Brazil are attempting to reform their laws much like India has to suit their national needs.¹⁶³

B. Egypt

Like India, Egypt after independence established a strong pharmaceutical industry, the strongest in its region, one that is considered the supplier of pharmaceuticals within its region. Egypt is one of the major producers of pharmaceutical in the Middle East and Africa; it contributes greatly to the distribution and availability of affordable medicines in the region through its manufacturing of generic drugs¹⁶⁴. It generates approximately three billion Egyptian pounds annually and is an integral source of income for the country deriving valued foreign currency from the export of its products. The sector is comprised of 35 pharmaceutical factories, consisting of public sector, private sector, and joint venture companies as well as subsidiaries of several multinational pharmaceutical companies. The sector is considered to be highly

¹⁶³ Emmanuel Oke, Exploring the flexibilities in TRIPS: lessons from India's pharmaceutical patent law, 41 (1) Commonwealth Law Bulletin (2015).

¹⁶⁴ Mohamed Abou EL Farag Balat and Mohamed Hossam Loutfi, *The TRIPs Agreement and Developing Countries: A Legal Analysis of the Impact of the New Intellectual Property Rights Law on the Pharmaceutical Industry in Egypt*, Web Journal of Current Legal Issues (2004), <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.469.9234&rep=rep1&type=pdf>.

competitive and open to investment. Prices of drugs in Egypt are one-sixth of the prices compared to those produced by multinationals in spite of importing many raw materials, which are very expensive. An important feature of the industry is that the Ministry of Health controls drug pricing.¹⁶⁵

1. Historical Development of Patent Law in Egypt

The historical development of patent law in Egypt is similar to that of India. It is characterized by two main developments: the creation of Law 132 of 1949 in its postcolonial era and the enactment of Law 82 of 2002 as part of fulfilling its obligations under TRIPS. Prior to the current IPR law set in 2002, patent law was covered under Law 132 of 1949. Under this Act, pharmaceutical products were not patented; rather what was patented was the process of production. The term of protection for all inventions was fifteen years from the filing date and could be extended by five years for inventions; for the patents of processes of production of pharmaceutical and agricultural chemical products, the term is ten years and not eligible for renewal. The main purpose for eliminating pharmaceutical patency was the protection of Egyptian companies from powerful multinational competitors and the encouragement of national industry. The result has been the emergence of a strong national industry developed enough to support strong regional export and continuously increasing sales and profits. The national industry has grown from generic production to original research and development.

2. The New IPR Law

Following the adoption of the TRIPs agreement, Egypt had to amend its patent law so as not to conflict with TRIPS. Law 82 of 2002 was adopted but came only into force in 2005 coinciding with the grace period given to developing members of the WTO. According to Article 1 of the Egyptian law, a patented invention should be novel,

¹⁶⁵ *Id.*

include an innovative step, and be industrially applicable. Unlike the Indian law which has a specific definition and limitations sets on novelty, the Egyptian law is undefined and thus leaving it open to the opportunity for companies to pursue reverse engineering of production. The period for the patency increased to 20 years as per the minimum requirements of TRIPS. The law does set exclusions from patentability such as inventions that affect the public welfare and security of the state.

The new IPR law in Egypt also has several features similar to the Indian law. First, like the Indian law, Egyptian law contains a doctrine of exhaustion following the first global sale and thus allows for parallel importation. Parallel importation allows for importing products at lower prices by the patent owner or anyone else with the authority. The effect of this is significant in disseminating lower priced products globally especially in developing countries like Egypt.¹⁶⁶

Exception and compulsory licensing are addressed in Article 17 of the new law, which entitles the Egyptian Ministries of Defense, Military Production, Internal Affairs and Health to reject the patent application within the context of securing the welfare of the state. The problem is, unlike the Indian system, the Egyptian law is vague when it comes to the scope of the articles and procedures for implementing them. Further, the court systems are not specialized in the area of IP and find it hard to adjudicate in IP related cases. This is problematic since to comply with TRIPS the scope of the Article needs to fall within the object and purpose of Article 8 of the TRIPS Agreement. Moreover, Article 23(1)(3) is designed to address the issue of developing the local pharmaceutical industry to deal better with the problem of access to necessary medicines. Article 23(2) expressly provides for the compulsory licensing of pharmaceuticals in a way that mirrors the French Intellectual Property Code's provisions. It provides that the Minister of Health may impose a compulsory license on a patented pharmaceutical whenever the supply does not satisfy local need, the

¹⁶⁶ Farag, *supra* note 164.

pharmaceutical is of unacceptable quality, or is offered at an unreasonable price.¹⁶⁷

Although the new Egyptian law is similar to that of India's, it does lag in certain aspects such as the lack of detailed administrative and judicial overview and the presence of trained government officials and lawyers who can deal within an IP regime. In addition, it is silent on monopolistic pricing, unlike the Indian law, which specifically addresses the issue and sets it as an exception to patent rights. A key element is that the Indian law protects generic production through having strict forms and definitions of innovation and through having the mailbox application system for drugs prior to the application of the law in 2005. Such elements, if integrated, would strengthen the Egyptian patent law and protect the already thriving pharmaceutical industry in Egypt, which is necessary in a country like Egypt with high poverty rates. The UNICEF statistical report of 2015 shows that 20.15% of the population are living below lower poverty line, and 49.6% below the upper poverty line.¹⁶⁸

C. India's Lessons for Egypt

As discussed above, the Egyptian Patent law of 2002 is similar in many ways to that of India patent law. However, it would benefit further from adding other features found in the Indian Law. First, with regard to definition, although the Egyptian law does have an absolute definition of novelty, it does not link invention with production ability within the country. This leaves Egypt vulnerable to having patents registered in the country but not actually being produced in the country. This negatively affects the progress of the industry. Second, although the concept of mail boxing is available in Egyptian law, its meaning differs drastically from that of the Indian law. The Indian law, as discussed, focuses on previously produced unpatented drugs. It allows India's

¹⁶⁷ Nermien Al-Ali, The Egyptian Pharmaceutical Industry After TRIPS — A Practitioner's View, 26 (2) FILJ (2002).

¹⁶⁸ The international PPP statistic used in the report is based on USD1 per day . The lower poverty line according to the World Bank is cost of consuming a basic set of non-food goods for extreme poor households whose total expenditures equals the food poverty line. The upper poverty line is the moderate poor households whose food expenditure is at the food poverty line. UNICEF (2015) Children in Egypt: a statistical digest, UNICEF Egypt, Cairo

already existing pharmaceutical industry to continue to grow providing its people with affordable alternatives to multinational medicine. Applying this in Egypt would benefit the country greatly as Egyptian generic production is a large reason for the availability of drugs, it is mostly what the industry is built on, and it supplies 30% of the total regional market.¹⁶⁹ Thus is it integral to protect it as much as possible. Finally, while the Egyptian law might be strong in many aspects it needs to also be supported by a strong administrative revision board as well as a well-informed judiciary on IPs.

D. A Step Forward with The Doha Round

As a means of promoting the agenda of the WTO, the organization adopted mechanisms like the panel report and Round negotiations that take place every few years, to develop and discuss the trade and IP regime every decade, much like what GATT did. The Doha Round of 2001 was important for the IP regime and for developing countries since the focus of the Round was the discussion of the issue of availability and access to medicine and the effect of patent law on these issues in periphery states. With the HIV/AIDS and Hepatitis C epidemics ravaging developing countries, core states could no longer ignore the demands of periphery states. Although the Round failed in addressing all of the concerns of periphery states, there were some successes. First, while it acknowledged the limitation of the compulsory licensing mechanism within the TRIPs agreement,

members acknowledged that providing patent protection for pharmaceuticals in the developing countries would not encourage R&D expenditure for cures of local diseases such as malaria, tuberculosis given the low expected financial returns. This has been characterized by a number of non-governmental organizations (NGOs) including Oxfam, as the “fundamental imbalance in TRIPS.”¹⁷⁰

Moreover, within the Doha Declaration, countries acknowledged the limitation of the compulsory licensing system in the access to medicines and availability of public

¹⁶⁹ Nagla Rizk & Lea Shaver, Access to Knowledge in Egypt: new Research on Intellectual Property, Innovation and Development 59 (2010).

¹⁷⁰ Al-Ali, *supra* note 167.

health care in periphery states, especially the ones that lack the technological capacities.¹⁷¹ Thus, the Declaration as a whole reinforces and restates the flexibilities in TRIPs. However, no real action was taken to amend the articles of TRIPs to suit the needs of periphery member states. In spite of this failure, in Abbott's view, it was a positive step that reflected the higher level of cooperation between periphery states. This needs to be aided with more knowledge about IPRs and cooperation between periphery states.

E. Conclusion

The current international legal system is based on the needs of core states. As illustrated the current system is built on neo-colonial ideas and relationships between core and periphery states, that benefit core states and create a perpetual cycle of underdevelopment and poverty in periphery states. The IPR regime and its evolution until the creation and application of TRIPs is a clear example of this detrimental global world order. From its inception, the drafting of the TRIPS agreement reflected core states IP regimes and their corporate interests, and the controversial debates between core and periphery states showed the resistance of periphery states to accept IPs in the manner presented in the GATT Uruguay Round. It was only through economic and political pressure that periphery states agreed to TRIPS, which did not address their needs or voiced concerns. The effects of TRIPS on availability of medicines in periphery states has resulted in increased disease and deaths from curable diseases. As seen from the Indian and Egyptian examples, the industries have to develop, mainly through generic production and become strong first, in order to compete with Western multinationals and simultaneously have IP protection.

It is undeniable that TRIPs creates a biased globalized IP system, within an already biased international global system, that aims to benefit already developed countries, at the expense of developing countries. It would thus be in the best interest

¹⁷¹*Id.*

of periphery states to completely reject and change such a system. However realistically speaking, and as the failure of the New International Economic Order has demonstrated, the system at this point in time will not change to the benefit of developing countries. Thus, the solution is working within this system to benefit developing countries. India provides an example of how this can be done while dealing with TRIPs. The problem is that, even with such strategies, there needs to have been a domestic pharmaceutical industry to begin with. Both India and Egypt were able to do so by generically producing medicines through reverse engineering patented medicines, followed by growing an industry to a stage that it conducts its own research and development. The problem then lies with countries that have no infrastructure, information, knowledge or technology in the industry and what choices they have. If the status quo remains, periphery states can protect their industries through amending their laws to accommodate TRIPS as well as meet domestic needs, like India has done. However, there needs to be trained legal professionals able to draft legislation that protect industries. This will directly impact the availability of medicine, the ability of periphery states to eradicate curable diseases, and consequently build a healthy workforce able to push it towards its developmental goals.