THE NATIONAL UNIVERSITY OF ADVANCED LEGAL STUDIES, KOCHI

DISSERTATION

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ON THE TOPIC

FREE TRADE AGREEMENTS AND ITS IMPACTS ON ACCESS TO MEDICINE

Under the Guidance and Supervision of

DR. ATHIRA P. S.

The National University of Advanced Legal Studies, Kochi

Submitted By:

GOURI RAMAN

Register No: LM0220012
LL.M (INTERNATIONAL TRADE LAW)

CERTIFICATE

This is to certify that **Ms. GOURI RAMAN, REG NO: LM0220012,** has submitted her Dissertation titled "**FREE TRADE AGREEMENTS AND ITS IMPACTS ON ACCESS TO MEDICINE**" in partial fulfilment of the requirement for the award of the Degree of Masters of Laws in International Trade Law to the National University of Advanced Legal Studies, Kochi under my guidance and supervision. It is also affirmed that the Dissertation submitted by her is original, bona fide and genuine.

Dr. Athira P.S

Guide and Supervisor

NUALS, Kochi

Date: 11.10.2021

Place: Ernakulam

THE NATIONAL UNIVERSITY OF ADVANCED LEGAL STUDIES

Kalamassery, Kochi – 683 503, Kerala, India

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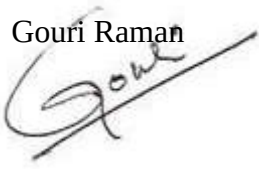

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Dr. Athira P.S

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I declare that this Dissertation titled "**FTAS AND ITS IMPACTS ON ACCESS TO MEDICINE**" is researched and submitted by me to the National University of Advanced Legal Studies, Kochi in partial fulfilment of the requirement for the award of the Degree of Master of Laws in International Trade Law, under the guidance and supervision of Dr. Athira P. S., Assistant Professor, National University of Advanced Legal Studies, Kochi and is an original, bona fide and legitimate work and it has been pursued for an academic interest. This work or any type thereof has not been submitted by me or anyone else for the award of another degree of either this University or any other University.

GOURI RAMAN

REG NO: LM0220012

LL.M, International Trade Law

NUALS, KOCHI

Date: 11.10.2021

Place: Ernakulam

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REG NO: LM0220012

LL.M, International Trade Law

ABBREVIATIONS

AAAQ	Availability, Accessibility, Acceptability and Quality
ADHD	Attention deficit hyperactivity disorder
AIDS	Acquired Immunodeficiency Syndrome
API	Active Pharmaceutical Ingredient
ARV	Antiretrovirals
ASEAN	Association of Southeast Asian Nations
CAFTA	Central America Free Trade Agreement
CL	Compulsory Licensing
DR	Dominican Republic
EML	Essential Medicines List
EU	European Union
FTA	Free Trade Agreement
HIV	Human Immunodeficiency Virus
HLP	High Level Panel
ICESCR	International Covenant on Economic, Social and Cultural Rights
IP	Intellectual Property
IPR	Intellectual Property Rights
ISDS	Investor-State Dispute Settlement

LDC	Least-Developed Country
LIC	Low-Income Country
LMIC	Lower-Middle-Income Country
MPP	Medicines Patent Pool
MSF	Médecins Sans Frontières
NAFTA	North American Free Trade Agreement
OHCHR	Office of the United Nations High Commissioner for Human Rights
R&D	Research & Development
RCEP	Regional Comprehensive Economic Partnership
TB	Tuberculosis
TPP	Trans-Pacific Partnership
TRIPS	Trade related aspects of Intellectual Property Rights
UDHR	Universal Declaration of Human Rights
U.K.	United Kingdom
UNCITRAL	United Nations Commission on International Trade Law
UNCTAD	United Nations Conference on Trade and Development
U.S.	United States
WHO	World Health Organization
WTO	World Trade Organization

WWW	World Wide Web

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CHAPTER 1

INTRODUCTION

1.1 INTRODUCTION TO ACCESS TO MEDICINE.

The World Health Organization asserts that:

"All people have the right to the highest attainable standards of health."

Access to medicine is a substantial public health challenge faced globally, especially by developing countries. Access to medicine is a problem for one-third of all people worldwide[1] , and more than 100 million people are being pushed to poverty because they have to pay for their healthcare.[2] The use of medicines and medical devices has reduced morbidity and mortality rates and has also improved the quality of life all over the world to a considerable extent. Also, there has been an increase in the prevention, screening, detection, and treatment of diseases. Even then, access to medicine is still a significant concern that is to be addressed at the international level.

The Average life expectancy in considerably affluent regions of Europe, America, and the Western Pacific Region was 78.2 years, 77.2 years, and 77.7 years respectively, in 2019. Whereas the life expectancy in the African regions was only 56 years in 2019, clearly indicating the depressing state of health inequity around the world.[3] In the case of child mortality rate, 80% of the deaths are concentrated in Sub-Saharan Africa and central and southern Asia. Similar is the case of maternal mortality rate wherein 94% of the global

[1] Stevens et al, *Innovative Approaches to Increase Access to Medicines in Developing Countries*, Frontiers in Medicine,(2017).

[2] Access to medicine index, Available at https://accesstomedicinefoundation.org/access-to-medicine-index/about-the-index/why-access-matters#, last accessed on 19.08.21.

[3] World Health Statistics, 2021: *A monitoring health for SDGs*, WHO (2021), Available at https://www.who.int/data/gho/publications/world-health-statistics, last accessed on 26.08.21.

maternal deaths were in LICs and LMICs. Also, the highest Tuberculosis deaths occur in the African and the South-East Asia Region.[4]

One reason for the inaccessibility to medicines is the 10/90 gap which is the lack of availability of drugs that targets the diseases that affect the poor due to their non-existence because of a lack of interest shown by the pharmaceutical industries in investing in such areas. The 10/90 gap, as the name suggests, states that only 10 percent of research is done to cater to the health conditions that affect 90% of the total global disease burden.[5]

These staggering inequalities in health conditions are to some degree attributable to poverty and poor living conditions. Nevertheless, the primary reason that can be attributed to these inequalities in health indicators is the lack of access to medicine and the lack of access to healthcare systems. Access to medicine may be affected due to a number of reasons, but one of the major reasons that can be attributed to this is the high price of drugs.

The incidence of high health expenditures has been continuously increasing. Financial protection has been deteriorating, which means that the out-of-pocket expenses for health services are causing financial hardships. The prices of drugs are high due to the strong Intellectual Property protection.[6] The pharmaceutical industry reaps profits by keeping the prices of medicines exorbitantly high during the patent period creating a barrier to access them to millions. The industry tries to gain maximum profit during the period in which patent monopoly is granted. This profit-making motive of the industry keeps the prices of medicine high and inaccessible. In the absence of patents on pharmaceuticals, any manufacturer would be free to produce the drugs if they do reverse engineering. This enhances access to medicine.

Along with the difficulties that the developing and the Least Developing Countries faces with the TRIPS Agreement in accessing medicine, TRIPS-Plus provisions in Free Trade Agreements (FTAs) make the situation onerous. These FTAs contain extensive Intellectual

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[4] Ibid.

[5] Fatal Imbalance. The crisis in research and development for drugs for neglected diseases, MSF, available at https://msfaccess.org/fatal-imbalance-crisis-research-and-development-drugs-neglected-diseases, last accessed on 21.08.21.

[6] Hoen Ellen, "*TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha*," 3(1), *Chicago Journal of International Law* (2000).

property protections that are stricter and higher than the ones that are stipulated in the TRIPS Agreement.

When entering into FTAs, high Intellectual property protection may be required, resulting in a barrier to access medicine by keeping the prices of patented products high and out of reach for many. When entering into FTAs, as a matter of public policies, nations should do what is best in the interest of their people. Ultimately, people should not die because of patents.[7]

There has been a remarkable increase in the number of Free Trade Agreements that is entered into between the Nations. Most of these FTAs seek to incorporate at least some TRIPS-plus obligations that stipulate higher levels of patent protection. This could affect the less resourceful partners to the agreement due to their incompetency in negotiating with the developed countries.

Even though the TRIPS flexibilities were agreed upon by the Doha Declaration, the ability of the nations to use these flexibilities gets restricted due to the TRIPS-plus provisions in FTAs. These limitations on countries to utilize the maximum available policy space and provisions of various laws to strengthen their healthcare system are to a great extent limited by these stricter IP provisions. This ultimately results in an increase in the prices of medicines, creating a barrier to access to medicine.

1.2 STATEMENT OF PROBLEM

Though Free Trade Agreements (FTAs) encourage trade between countries by giving trade concessions to countries that enter into the Agreement, little or no consideration is given to the implications it may have on the public health situation of the nations. These Trade concessions in FTAs carry several obligations that have stricter Intellectual Property protection than that is stipulated under the TRIPS Agreement. These higher IP obligations provided in these FTAs are known as TRIPS-plus obligations and may create a barrier to accessing medicines for the developing countries.

[7] Baker D, "*Bird Flu Fears: Is There a Better Way to Develop Drugs?*", 31, Reports and Briefs, Centre for Economic and Policy Research, p.6, (2005).

1.3 SCOPE OF THE STUDY

The study seeks to analyze the potential impacts Free Trade Agreements may have on access to medicine. The study shall examine various FTAs and the TRIPS-plus provisions incorporated in them and ascertain how they become a barrier in accessing medicine. The study shall also look into the effects the TRIPS Agreement has on access to medicine.

1.4 RESEARCH QUESTIONS.

1. Whether Free Trade Agreements are barriers to access to medicines?
2. What are the effects of Free Trade Agreements on access to medicines?
3. What are the difficulties that developing and least developed countries face in accessing medicines?
4. How are the TRIPS-plus provisions of various FTAs affecting access to medicines?
5. What are the effects of the TRIPS agreement on Access to medicines?

1.5 RESEARCH OBJECTIVES

1. To ascertain the potential impacts of FTAs on access to medicine.
2. To analyze whether FTAs are barriers to accessing medicine.
3. To analyze whether the developing and the least developing countries face difficulties in accessing medicine.
4. To analyze the various FTAs and the TRIPS-plus provisions in these FTAs to ascertain their impact on access to medicine.

5. To ascertain how the TRIPS Agreement affects access to medicine.

1.6 HYPOTHESIS

- The Free Trade Agreements entered into between nations are a barrier to access to medicine.
- The TRIPS Agreement can affect access to medicine and public health of developing countries and least developing countries.

1.7 RESEARCH METHODOLOGY

In the present study, the researcher is using Doctrinal or Non-empirical legal research. The researcher has attempted to analyze the TRIPS-Plus provisions in some of the Free Trade Agreements and has also tried to analyze the TRIPS Agreement and study their impacts on access to medicine. For this purpose, the researcher had gone through various primary and secondary sources of data. The primary sources of data include the TRIPS Agreement and some of the Free Trade Agreements. The secondary sources include books, articles, research papers, recognized reports, and journals on Access to medicine.

1.8 CHAPTERIZATION

CHAPTER I

Introduction- The first chapter deals with an introduction to access to medicine. The chapter analyses the importance of access to medicine.

CHAPTER II

Trade in medicine & International Trade- The second chapter deals with the interconnection between Intellectual property rights and human rights, the right to health, human rights, and patents. The chapter also discusses the international efforts to increase access to medicine.

CHAPTER III

Access to Medicine and the role of the TRIPS Agreement- The third chapter deals with the role of the TRIPS Agreement and access to medicine. The chapter discusses the rationale behind the patent system, the provisions of the TRIPS Agreement, the role of the TRIPS Agreement and COVID-19, and the Indian scenario on access to medicine.

CHAPTER IV

TRIPS-Plus provisions in Free Trade Agreements and its implications on Access to Medicine- The fourth chapter deals with the TRIPS-Plus provisions in FTAs that limit access to medicine and analyses various FTAs entered into between nations.

CHAPTER V

Conclusion- The fifth and the final chapter deals with the conclusions and suggestions for enhancing effective access to medicine.

CHAPTER 2

TRADE IN MEDICINE AND INTERNATIONAL TRADE

2.1 INTRODUCTION

"The market fails when it comes to research and development of drugs for the poor."

-Paul Farmer, Co-founder, Partners in Health.[8]

[8] Farmer Paul, *Pathologies of Power: Health, Human Rights, and the New War on the Poor*, University of California Press, p317, (2013).

Universal health coverage will be achieved only if affordable, safe, and quality health products are equally available. Social factors such as employment, education, gender, ethnicity, and income level influence people's health. In all countries that include the low income, middle income, and high-income countries, the health status of people differs. The highest risk of poor health is seen in people with lower socioeconomic conditions. For instance, the average life expectancy in low-income countries is sixty-two years, whereas, in high-income countries, the average life expectancy is 81 years.[9] Also, a substantial part of the world population cannot even access essential medicines.[10]

International trade has been vital in ensuring access to medicine as the unavailability of drugs is a global issue that requires international cooperation. Even though several organizations work in public health and access to medicine, the interference of Intellectual Property, especially Patents in public health, creates difficulty in accessing affordable medicine equally.

The developing countries have not shown a good trail in research and innovations due to their weak socio-economic conditions, low literacy rates, lack of infrastructure, etc. It is in the developing countries where most of the priority diseases are concentrated. Pharmaceutical companies use patent monopolies to prevent competition and keep medicines' prices high, keeping it out of reach to millions who have no means to pay. People who lack proper health insurance will have to pay for these drugs out of their pockets, making their living standards mediocre. The implementation of the TRIPS agreement was itself faced with immediate obstacles to the developing world, such as administrative costs and higher prices for technological inputs to make their IP regime in consonance with the TRIPS Agreement.[11]

Even for diseases that have effective and efficient medicines, accessing them is a struggle for the population of the developing and the Least Developed Countries. Tuberculosis is a

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[9] Health inequities and their causes, WHO, Available at https://www.who.int/news-room/facts-in-pictures/detail/health-inequities-and-their-causes, last accessed on 23.08.2021.

[10] *Promoting access to medical technologies and innovation: Intersection between public health, Intellectual property and trade*, WHO, 2020.

[11] The World Bank, *Global Economic Prospects: Technology Diffusion in the Developing World,* available at https://documents.worldbank.org/en/publication/documents-reports/documentdetail/827331468323971985/global-economic-prospects-2008-technology-diffusion-in-the-developing-world, last accessed on 19.06.21.

disease of poverty, and almost 95% of tuberculosis deaths globally are in developing countries. Another indicator of health inequity is the maternal mortality rate. 99% of the annual maternal mortality is in developing countries, indicating the health inequity gap between the rich and poor.

Numerous medicines are available in the market to treat different illnesses, that ranges from mild ones to fatal ones. Safe and effective drugs are an essential facet for the proper functioning of health systems, and this is faced with several challenges. Along with the accessibility and affordability of medicines, emerging issues such as antimicrobial resistance have become a challenge affecting the effectiveness of medicines. Also, the incidence of substandard adulterated drugs has been growing.

2.2 IP RIGHTS AND HUMAN RIGHTS.

Granting of intellectual property rights, especially the grant of patent rights, affects the human rights of citizens who are part of the same society. In the same way, in which the patent system can be wealthy to many, it has been outrageous to many. Since the entry into force of the TRIPS Agreement, this has become a significant area of debate as it started affecting access to medicine with patent rights on pharmaceuticals. [12] Clearly, a conflict exists between the rights of an Intellectual property right holder and the public concerns in the International human rights laws.[13]

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[12] Sundaram J, *Pharmaceutical Patent protection and world trade law: The unresolved problem of access to medicine*, Routledge, p36, (2018)

[13] The States Parties to the present Covenant recognize the right of everyone:

(a) To take part in cultural life;

(b) To enjoy the benefits of scientific progress and its applications;

(c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.

3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.

4. The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields.

The International Covenant on Economic, Social and Cultural Rights (ICESCR) and the Universal Declaration of Human Rights(UDHR), along with protecting the right to health and the right to enjoy the benefits of science, also guarantees the rights of scientists, artists, and authors to protect their works integrity and reap the benefits arising out of it.[14] Article 15 of the ICESCR identifies the need to strike a balance between protecting public interests and private interests.

According to the Office of the High Commissioner for Human Rights (OHCHR) human rights guidelines for pharmaceutical companies, "The rights to the highest attainable standards of health not only require that the existing medicines are accessible, but also that the needed medicines are developed as soon as possible.[15] One of the main hindrances in accessing medicines is market-driven research and development, which is not equipped to fill the gaps. This market-driven R&D model gives no attention to knowledge sharing, which is a key to protecting patients' lives from potentially harmful treatments and will help develop new drugs. This R&D model makes essential medicines inaccessible and unaffordable to LMICs.

Most of the members of the WTO that have ratified the TRIPS Agreement have also ratified the ICESCR, which means that they have to protect both the Intellectual Property rights under the TRIPS Agreement and the human rights under the ICESR. [16] The conflict here is whether the members of the Agreements only safeguard the interest of the Intellectual Property holders or should these rights be interpreted giving importance to the public interest. Dismally, there is no balance between both rights, and Intellectual property rights seem to be in a more superior position than human rights.

The TRIPS Agreement only considers the IP holder's rights, as stated in the Agreement's preamble that IP rights are private rights. The Paris Convention and the Berne convention have no reference to human rights but can be justified as both were created in the nineteenth century. But worryingly, the TRIPS Agreement does not specify the protection

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[14] Article 27(2), UDHR.

[15] Office of the High Commissioner for Human Rights Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines, General Assembly of the UN Special Rapporteur on the Right to the Highest Attainable Standard of Health, A/63/263, available at http://www.ifhhro.org/images/stories/ifhhro/documents_UN_special_rapporteur/3_4_8.pdf, last accessed on23.08.2020.

[16] Dutfield Graham et. al, *Global Intellectual Property*, Edward Elgar Publishing, p.224, (2008).

of human rights, instead of mentioning it as an exception. The relationship between human rights and IP Laws remains unclear to an extent. This can be considered one of the most significant disadvantages put into use by the pharmaceutical industry. [17]

Resolution no. 2000/7 of the United Nations Commission on Human Rights on intellectual property and human rights says that:

> Since the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, right to health, right to food, and right to self-determination, there are apparent conflicts between the intellectual property rights embodied in the TRIPS Agreement, on the one hand, and the international human rights law on the other.[18]

It can be inferred from the above that the TRIPS Agreement, to an extent, violates human rights or widens the scope of violation of human rights. The commission report also suggests that human rights should be considered above all other economic rights when drafting policies. Even though several economic rights policies have been prepared at the WTO after the resolution was passed, the resolution's recommendations have not been given any serious consideration.

The concept of the right to health found in the international instruments is considered more of an aspirational nature rather than a justiciable one. This difficulty arising due to its vagueness makes it difficult to implement these rights.[19] The current international rules, which are molded mainly by the developed nations, are fashioned in a disadvantageous way to the developing and the LDCs and favorable only to them. These international rules

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[17] Laurence R, *Human rights and intellectual property; mapping the global interface*, Cambridge university press, p32, (2013).

[18] Sub-Commission on Human Rights resolution 2000/7, Available at https://www.aaas.org/sites/default/files/SRHRL/PDF/IHRDArticle15/E-CN_4-SUB_2-RES-2000-7_Eng.pdf, last accessed on 23.08.2021.

[19] Forman Lisa, '*Ensuring Reasonable Health: Health Rights, the Judiciary, and South African HIV/AIDS Policy*,', 33(4), The Journal of Law, Medicine & Ethics, p.712, 711-714, (2005).

fail to protect human rights and actively violate the rights of millions of people around the globe. [20]

2.3 RIGHT TO HEALTH, HUMAN RIGHTS, AND INTELLECTUAL PROPERTY

"The face of HIV has always been the face of our failure to protect human rights."[21]In the 1990s, when HIV/AIDS prevalence was high, the developing nations found it challenging to access medicine to treat the disease, resulting in millions of deaths. Children and young people are also among the worst affected by HIV/AIDS due to mother-to-child transmission. The HIV/AIDS drugs were expensive due to the patents on these drugs. Developed nations had highly effective medicines, which made AIDS a manageable disease from the fatal one it was earlier. But, developing countries suffered due to the high prices that they could not afford, and by 2000, only one in a thousand HIV/AIDS patients in Africa had access to the medicine.[22]

In the early 2000s, countries such as Brazil and Thailand established AIDS treatment programs with 1st line HIV drugs that were not patented and thus produced locally.[23]But many countries could not get affordable ARVs due to the non-availability of generics. These problems faced by countries in accessing ARVs were met with campaigns calling for equal access to medicines as a human right. Until 2000, the concept of the right to health did not encompass access to essential medicines within it.

The general comment 14 of the Committee on Economic, Social, and Cultural Rights interpreted the scope of the right to health, stating that the state parties have an obligation to ensure that there is non-discriminatory access and equitable distribution of health

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[20] Pogge Thomas, *Access to medicine,* 1(2), Public health ethics, (2008).

[21] Navi Pillay, former UN high commissioner for human rights.

[22] Gellman B, *An Unequal Calculus of Life and Death; As Millions Perished in Pandemic, Firms Debated Access to Drugs; Players in the Debate Over Drug Availability and Pricing*, Global Commission on HIV and the Law. (2000)

[23] Hoen et.al, *Driving a decade of change: HIV/AIDS, patents and access to medicines for all*, 14(1), International AIDS society (2011).

facilities, goods, and services. [24] The Doha Declaration also emphasizes the link between human rights and international trade law and clarifies that the priorities under both these laws should go along with one another.

The governments of countries have a primary obligation to protect the health of their citizens and take steps to realize their health rights by investing in the health budgets of the nations. When the governments fail to address these healthcare concerns of its citizens, ultimately, patients who cannot afford expensive medicines suffer. Not only do states have an obligation to protect the health of the people, pharmaceutical companies that hold patents for medicines also have a responsibility to protect the human rights of the people.

The concept of the right to health can be used to frame national health policies and laws to ensure access to medicine to all. Constitutions that recognize the concept of access to medicine to be a part of the right to health can help individuals raise claims for its violation in the national courts. For instance, in Kenya, the constitution played a vital role in advancing access to ARVs for the HIV/AIDS-affected population of the country. Denial to access to medicine and healthcare to neglected communities such as for individuals living in poverty is the denial of their fundamental rights, and recasting these rights can be empowering for them.

Developing nations, including India, have incorporated into their Constitution commitments that guarantee the right to health. These guarantees made under the International conventions and domestic legislation are jeopardized by the International Instruments such as the TRIPS Agreement, which does not even contain a single reference to human rights in its text, and trade agreements such as RTAs and FTAs entered into between nations.

The WHO, along with the AAAQ guidelines[25](Availability, Accessibility, Affordability & Quality), has outlined guidelines to ensure access to medicines in national health systems, which includes:

[24] UN CESCR General Comment no. 14, Available at General comment No. 14: The right to the highest attainable (ohchr.org), last accessed on 22.08.21.

[25] AAAQ Guidelines of the WHO, Available at https://www.who.int/workforcealliance/media/qa/04/en/, last accessed on 23.08.21.

1. Rational selection and use of essential medicines based on the list of essential medicines and the treatment guidelines.

2. The affordable price of medicines for governments, individuals, and healthcare providers.

3. Fair, equitable, and sustainable financing for essential medicines through adequate funding and pre-payment systems to ensure that the poor are not affected by the price of medicines disproportionately and;

4. Reliable health systems and supply systems to ensure a sufficient and appropriate combination of public and private sector healthcare providers.[26]

The UN special rapporteur on the right to health of 2002-2008 has given guidelines to the pharmaceutical industries in connection with access to medicines, such as to refrain from actions that would limit the accessibility of medicines, to take reasonable steps to ensure access to medicine to the needy, to refrain from acts such as pursuing strong IP protections that would limit the access to essential medicines, take necessary measures to make new medicines to those in need, etc.

Also, the UN guiding principles on business and human rights, which was endorsed by the UN human rights council in 2011, requires the private sector to be responsible for violating the human rights related to access to medicine.[27] Regarding patents, the TRIPS agreement only sets forth the minimum standards, and the states set the patentability criteria. Thus, the states have the discretion to select the parameters of patents that will reflect their healthcare needs adhering to the minimum standards established by the TRIPS Agreement.

While in the 1990s, HIV/AIDS was the most predominant access to medicine issue to be addressed. The present access to medicine issue is mainly the market-driven R&D model, making it challenging to respond to new emerging diseases such as Zika and Ebola. Moreover, another issue is the violation of the human right to health of low-income and

[26] WHO, "Equitable Access to Essential Medicines: A Framework for Collective Action'', Available at http://apps.who.int/medicinedocs/pdf/s4962e/s4962e.pdf, last accessed on 22.08.2021.

[27] A/HRC/8/5 , 'Protect, Respect and Remedy: A Framework for Business and Human Rights', available at https://www.ohchr.org/documents/publications/guidingprinciplesbusinesshr_en.pdf, last accessed on 24.08.21.

neglected populations such as people with rare diseases, etc.[28] , by ignoring research in the area of Neglected Tropical Diseases.

Examples of human rights violations in the right to health include:

- The people of Venezuela belonging to low-income groups do not have the ability to purchase ARVs, and the Ministry of Health and Social assistance has failed to provide them with the medication, making the lives of people who are HIV positive in this area miserable and leaving the patients to live a life of complete health deterioration. [29]

- Buruli Ulcer is an infection that affects over 30 countries worldwide. Combined antibiotics can be used to treat the disease, and research in developing an oral therapy is needed. Still, a shortage in research in this area makes it challenging to treat it.

- Many neglected tropical diseases like this go unattended by pharmaceutical industries as these diseases mainly affect the developing nations. The R&D that is profit-driven gives no importance to these diseases blatantly violating the human right to health of people affected by this. In 2014, 1.7 billion people in 185 countries needed treatment for Neglected Tropical Diseases (NTDs).[30]

- Children also face challenges in enjoying their right to health, and child-friendly drugs are often inaccessible. Even though effective treatments have been developed for many pivotal diseases, a child-friendly version of the same medicines does not exist. The problem with the available medicines is that they are unpalatable and

[28] WHO, *World Health Statistics 2016: Monitoring Health for the Sustainable Development Goals* (2016)

[29] Access to medicine and human rights, health and human rights resource guide, available at Access to Medicines and Human Rights | Health and Human Rights (hhrguide.org), last accessed on 23.08.2021.

[30] WHO, World health statistics 2016, Monitoring health for the SDGs 2016, Available at https://www.who.int/gho/publications/world_health_statistics/2016/EN_WHS2016_TOC.pdf, last accessed on 22.08.21.

indigestible for children. Oral syrups and solutions are tolerable but are usually unavailable and too expensive, making it difficult for low-income groups.

- Commonly, adult dosages of medicines are split into halves and quarters for the consumption of children.[31] But the inefficiency and inaccuracy in doing so makes them less effective and often creates side effects. Even though advancements are being made in this area, the main difficulty in producing child-safe drugs is conducting clinical trials on them.[32]

- Women are also among those whose right to access to medicine gets denied, mainly in sexual and reproductive healthcare services. Women in developing countries face a shortage of medicines that prevent postpartum hemorrhage, which is the leading cause of maternal mortality. Without access to treatment to treat postpartum hemorrhage, women, especially in LMICs, contract severe diseases associated with excessive blood loss and die preventable deaths. [33]

- Persons who live with neglected diseases also suffer from inaccessibility to medicines. Neglected diseases lack sufficient medical innovation due to a lack of R&D and investment in this area. There is a dearth of investment in this area because these diseases are often concentrated in people with little or no purchasing power. This results in having no means to treat these diseases. These diseases reveal how deep-rooted the inequality is in accessing medicines.[34]

2.4 INTERNATIONAL EFFORTS TO INCREASE ACCESS TO MEDICINE.

[31] Elizabeth F, *Children's medicine: a situational analysis* , WHO, (2016).

[32] ibid

[33] World Health Organization, WHO Recommendations for the Prevention and Treatment of Postpartum haemorrhage. (2012)

[34] High-Level Panel on Access to Health Technologies, Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovations and Access to Health Technologies.

2.4.1 WHO MODEL LIST OF ESSENTIAL MEDICINES.

WHO, every two years publishes a list of essential medicines, known as the Model List of Essential Medicines, that contains vital medicines that are important for the treatment of diseases, including medicines for the treatment of diseases such as cancer, TB, Hepatitis C, etc. According to the WHO, Essential medicines are those medicines that satisfy the priority healthcare needs of the population and are selected as essential medicines because of their public health relevance, evidence of safety and efficacy, and comparative cost-effectiveness. The first EML (Essential Medicine List) was published by the WHO in 1977 in response to the resolution of the world health assembly[35] asking the WHO to assist the member states in procuring essential medicines of good quality at a reasonable cost.

If the medicine is in the Model list of essential medicines, these medicines should be made available and affordable to all. A label of essential medicine puts an obligation on pharmaceutical industries and governments to ensure that these medicines are readily available affordably to the needy population.

This essential medicine list acts as a catalyst to balance human rights and intellectual property rights by emphasizing that IP rights should not stand in the way of human rights to health and easy access to medicines.[36] Still, governments that have limited budgets on public health, especially the LMICs, find it difficult to access affordable medicines.

2.4.2 UNITED NATION'S SECRETARY GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINE

The United Nation's Secretary General's High-Level Panel on Access to Medicine (hereinafter referred to as HLP) was announced in November 2015 by the United National Secretary-General Ban Ki-Moon to promote innovation and access to healthcare technologies. The panel was aimed to "review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of the

[35] Twenty-eighth World Health Assembly, Geneva,resolutions and decisions: annexes. Available at https://apps.who.int/iris/handle/10665/86022, last accessed on 25.08.2021.

[36] Perehuddof Katrina et.al, *Human rights and Intellectual property for universal access to new essential medicines*, Equitable access to high cost pharmaceuticals, p67, (2018).

inventors and international human rights law, trade rules and public health in the context of healthcare technologies."[37]

The High -level panel consisted of members belonging to different backgrounds and experiences and different continents. The panel's deliberations were informed and benefited from a consultative process that had a generous response of public contributions. The commission submitted its report in 2016 with recommendations to the governments, policymakers, international organizations, and civil society to improve the healthcare system.

Also, the High-Level Panel directed that the WTO members should make full use of the policy space available under Article 27 of TRIPS by adopting and applying rigorous definitions of invention and patentability to curtail evergreening and also ensure that patents are awarded only for genuine innovations.

The HLP suggested several innovative R&D models, which included the proposal for an "Essential medicine patent pool" which, while reimbursing the patent holder, can allow for generics to be produced for both communicable and non-communicable diseases[38]; a recommendation to initiate a global treaty on biomedical R&D that will enable governments to collectively pool funds and monitor research to improve the affordability of healthcare technologies.

The HLP also called for greater use of TRIPS flexibilities by the member nations and cautioned the governments and non-state actors to refrain from threats and coercive actions that would undermine TRIPS flexibilities by the developing countries. It also recommended that any such acts be reported to the WTO Secretariat and met with punitive measures. [39] The HLP also suggested that the member states should improve the institutional coherence between trade, Intellectual property, and public health at national

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[37] High-Level Panel on Access to Health Technologies, Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovations and Access to Health Technologies

[38] Hoen et.al, Submission to the UN High Level Panel on Access to Medicines by the Global Health Law Committee of the International Law Association, available at Ellen 't Hoen, Global Health Law Committee of the International Law Association — High-Level Panel on Access to Medicines (unsgaccessmeds.org), last accessed on 25.08.21.

[39] High-Level Panel on Access to Health Technologies, Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovations and Access to Health Technologies.

levels, develop an independent review body and an interagency task force by the UN Secretary-General to assess the signs of progress being made on healthcare technologies and recommended to increase the coherence between multilateral organizations.

The wide range of recommendations made by the HLP shows the complexity induced due to the interactions made by intellectual property, international human rights, and public health.[40]The proposals indicate that using accountability frameworks to hold the stakeholders responsible for the adverse effects on accessing affordable health technologies can resolve the dichotomy within the spheres of IP and human rights.

2.4.3 THE ACCESS TO MEDICINE FOUNDATION.

The Access to Medicine foundation was established in 2003 to stimulate the pharmaceutical industry to do more for the billions of people who lack access to medicine. The foundation published the first access to medicine index in 2008 that ranked the first 20 pharmaceutical industries of LMICs on their policies and practices to improve access to medicine. It was the first of a kind index that focused on a specific sector.

The foundation published the latest access to medicine index in 2021, which is the longest-running and the most detailed analysis of pharmaceutical companies on access to medicine.[41] The index shows that progress in pharmaceutical industries is concentrated in a few industries, few companies, few diseases, and a few countries.

2.4.4 DOCTORS WITHOUT BORDERS/ MÉDECINS SANS FRONTIÈRES (MSF)

MSF is an international organization founded in 1971, working independently, and gives emergency aid to people affected by armed conflicts, epidemics, natural disasters, and

[40] Ibid.

[41] History, Access to medicine foundation, Available at https://accesstomedicinefoundation.org/about-us/our-history#, last accessed on 23.08.21.

those excluded from healthcare.[42] MSF was awarded the Nobel prize in 1999. In 1999, MSF launched a campaign for access to essential medicines. MSF aims to provide healthcare to the most disadvantaged people around the world.

India is one of the critical countries focused on the Access Campaign Activities of MSF because of its ability to produce and export affordable generic medicines. MSF takes up various activities, including providing healthcare to different remote areas of countries, providing medical care for severe acute malnutrition, etc. In Afghanistan, after the Taliban takeover, there were urgent medical needs to be addressed. The MSF addressed this by providing essential medical care to people with their medical activities in different regions of Afghanistan.[43]

2.3.5 MEDICINES PATENT POOL

Medicines patent pool is an international public health organization backed by the UN that increases access to and facilitates the development of life-saving medicines for LMICs.[44]UNITAID found MPP in 2010 in response to the HIV/AIDS epidemic crisis in LMICs. The MPP partners with governments, international organizations, patients, industry, and other stakeholders to prioritize essential medicines and pool IP to encourage generic manufacturing and new formulations of medicines.

The idea behind the patent pool is that patent holders including companies, researchers, universities and governments, voluntarily license their patents to the pool under a standard agreement with a set of conditions. It also negotiates with patent holders for licenses on medicines for HIV, TB, and Hepatitis C. In May 2020, MPP became an implementing partner of WHO's COVID-19 Technology Access Pool to increase equitable and affordable access to COVID-19 health products.[45]

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[42] What is MSF, MSF, available at https://www.msfindia.in/what-is-msf/, last accessed on 22.08/21.

[43] Medical needs urgent as ever in Afghanistan after Taliban takeover, MSF Project update, available at https://www.msf.org/medical-needs-urgent-ever-afghanistan-after-taliban-takeover, last accessed on 24.08.21.

[44] Medicines Patent Pool, Available at https://medicinespatentpool.org/, last accessed on 19.08.21.

[45] WHO, WHO COVID-19 Technology Access Pool, available at https://www.who.int/initiatives/covid-19-technology-access-pool, last accessed on 19.08.21.

2.5 CONCLUSION

It is crucial to rescind the existing idea of patents that patent monopoly is the only option available to incentivize the inventor of a new drug or medicine. While a lot of funding is required for the R&D of contemporary medicine, most of this cost is realized from government (tax-based) funding or public-funded laboratories. For example, the drug for Hepatitis C, sofosbuvir, was developed by public funding. Also, many ARVs have been developed through public funding. In such cases, the burden on the public to pay is twice as much. First, they have to pay taxes for subsidizing the medical research and then to access the Medicines.

Moreover, studies have shown that there is, in fact, no relation between patents and innovation. There has not been an increase in inventions due to patenting and, it is high time to reverse this idea of patent monopolizing. The non-availability of R&D is not the only issue in developing medicines. The primary scientific tools such as gene fragments are patented, making them inaccessible to developing countries. Also, the research publications are copyrighted and sold at high prices, making them unaffordable for the scientists of developing countries. Thus, the multilateral trading system has failed in finding a clear-cut solution to address problems faced by the developing countries in accessing medicine and healthcare needs.

The "one size fits all" system of patenting should be avoided because of the differences in the economic, political, and technological developments of countries.[46] Each country evolves differently due to various economic and political reasons. Adopting the "one size fit all" patent regime in such a case would be beneficial for some but may be detrimental to other countries. The developing countries should be given the space to adopt TRIPS flexibilities to help them in their earlier stages of development, and higher IP standards should not be pressed on them.[47]

[46] Pogge T et.al, *Incentives for Global Public health*, Cambridge University Press, Pp38, (2010).

[47] Integrating Intellectual property rights and development policy, Commission of Intellectual Property Rights, available at http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf, last accessed on 16.07.21.

In the post TRIPS era, the condition of access to medicine for developing countries has worsened. This problem in accessing essential medicines is increasing manifold day by day due to the actions of patent-holding countries and the transnational pharmaceutical corporations who are determined to enforce their IP rights blatantly violating the right to health and the right to access medicine of the people of the developing countries.[48] The incapacity of the WTO to question these developed nations and the Transnational Pharmaceutical corporations makes the situation even grimmer for the developing countries to utilize the TRIPS flexibilities available to them.

A human rights approach to accessing medicines can help the countries increase access by giving the state the duty to protect its people's rights. One significant change that can take place when framing access to medicine as part of the right to health is that individuals get the right to appear in courts for violations. This even expands to activism, public awareness, and education in the area when it is considered a fundamental right that cannot be subject to violations by the state or non-state actors.

Pharmaceutical industries have a responsibility to act with due diligence so that they do not violate people's right to health. But the reality is that these industries give priority to enforcing their IP rights, that too at the expense of the right to health of the people. The states cannot shy away from their responsibility to improve the healthcare systems and access to medicine.

The concept which involves the detaching of R&D and price of the medicine known as "delinkage" can help reduce the cost of medicines. According to the idea of delinkage, Incentives for R&D should be provided to the inventor. Still, it should be done through other means than by increasing the product's price, such as through public and private funding, grants, and prizes, among others.[49] Through adopting this mechanism, the burden on the consumers to pay exorbitant prices for patented medicines can be circumvented. It can also increase access to medicine because the medicines will become affordable when delinkage is employed. The delinkage model helps in providing pharmaceutical products at low prices, making them accessible.

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[48] Sundaram J, *Pharmaceutical Patent Protection and world trade law: the unresolved problem of access to medicine*, Routledge Research in Intellectual property. pp 26, (2008).

[49] Hoen t, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines*, Health Action International, (2016).

International organizations can help communities that suffer from a lack of access to medicine by engaging and partnering with governments, private entities, and other stakeholders to promote generic competition and local production of medicines, to give special consideration to those who are denied access to medicine, such as children, women, people with neglected diseases and to the people living in remote areas and to promote the human right of the health of people. A delicate balance should be made between intellectual property protection and the protection of public interest.

CHAPTER 3

ACCESS TO MEDICINE AND THE ROLE OF TRIPS AGREEMENT.

3.1 INTRODUCTION

"There is nothing liberal about the TRIPS agreement. It is a highly protected system, designed to ensure that private tyrannies, which is what corporations are, monopolize the technology and the knowledge of the future."[50]

-Chomsky N.

Towards the end of the twentieth century, there was an escalation in the growth of high technology devices, and there was also reproduction of the same at relatively low costs. Many industries that invested in research and development saw their works being pirated by other companies at low costs and selling them at low prices compared to their inventors. This was profitable to the companies selling the generic ones and a loss for the inventors as they could not even recover the R&D costs, which eventually discouraged innovation.

Before the TRIPS Agreement came into force, the Paris Agreement on the protection of Intellectual property governed International Intellectual Property rights. But the Paris convention was not found adequate to address contemporary issues such as Information technology and biotechnology. The TRIPS Agreement addressed the inadequacies which were previously found in the Paris Convention. From the time of implementation of the TRIPS Agreement, the IP scenario all over the world changed dramatically.

[50] Chomsky N. Asian College of Journalism, Chennai. Available at <http://www.greenmac.com/World_Events/aninterac.html>, last accessed 05.07.2021.

The TRIPS Agreement as such has no internationally established laws for the protection of Intellectual properties. Still, it recognizes minimum standards of protection of Intellectual property that should be adopted by the member countries. This obligation put forth by the TRIPS Agreement has brought about changes in the Intellectual property laws of more than 140 countries.[51]Before the TRIPS Agreement, intellectual property-related laws varied across different nations. With the TRIPS agreement coming into force, all members were to adhere to the standards prescribed therein to bring about uniformity in the IP laws globally.

Members of the WTO agree to these minimum standards and enact their patent laws in accordance with the TRIPS agreement. These minimum standards include provisions such as providing the patents for a minimum period of 20 years, patenting of both product and processes, protection of pharmaceutical test data against unfair commercial use, etc. What is to be patented is to be determined by the countries. The Agreement only provides specific minimum standards, such as that a patent should be granted for new, inventive, and useful inventions without defining any of these terms.

The developed countries were to adhere to the provisions of the TRIPS Agreement from the year 1995, whereas the developing countries were granted a five-year transitional period. The least developed countries (LDCs) were to adhere to the TRIPS requirements by 2016.

The pre-Uruguay Round negotiations received strong opposition from the developing countries on the inclusion of Intellectual Property Rights in the new GATT Treaty because of the concerns they had regarding the increasing prices and the effect it will have on the infant industries of the developing countries. Developed countries asserted that increasing IP Protection would enhance research and development, which would help the infant industries and the Least Developed Countries in the long run.

However, the TRIPS Agreement has been severely criticized for being advantageous to the patent owners. The most significant impact of the TRIPS Agreement as far as the developing countries are concerned is the effect it has on patenting of pharmaceutical

[51] Malhotra P, *Impact of TRIPS in India: an access to medicine perspective*, Palgrave Macmillan p19. (2010)

products. [52] Patenting of pharmaceutical products has an adverse effect on public health and access to medicine by keeping the prices of patented pharmaceuticals high

The rules established by the TRIPS Agreement were developed mainly with little or no participation from health authorities and without giving serious consideration to the implications that such regulations may have on public health. They were shaped primarily by the small group of industry interests. Developing countries were coerced to oblige to these new standards set forth by the TRIPS Agreement in exchange for the trade benefits they would gain in other areas such as agriculture and the textile industry.[53]

The TRIPS negotiation process faced several difficulties as the developed and the developing countries had to reach a consensus on the terms of the Agreement, which is to be accepted by all the parties. The representatives from the developing countries expressed their concern over more robust and stricter Intellectual property protection that was demanded by the TRIPS Agreement. They feared that this would lead to increasing the already widened public health gap between the developed and the developing countries, severely affecting the public health of developing countries. Before the TRIPS Agreement came into force, some countries did not have product patenting for pharmaceuticals, including India.

The impact of the TRIPS Agreement began to be felt in the developing countries, mainly in the African countries and the least developed countries, when the effects of the AIDS/HIV pandemic intensified. Before the TRIPS Agreement came into force, Countries that could not manufacture medicines could rely on the generic drugs produced by other countries like Brazil or India. These generic medicines helped countries by providing them with cheaper alternatives to inaccessible and expensive drugs. With the TRIPS Agreement, affordable medicines to these countries became no longer accessible.

These minimum standards prescribed in the TRIPS Agreement that is to be adopted by the member countries took away the policy space that was available to the member states under the General Agreement on Trade and Tariff (GATT) in establishing domestic Intellectual

[52] Correa M, *'Implications of bilateral free trade agreements on access to medicines'*, 84(5), Bulletin of the World Health Organization, pp. 399–404 (2016)

[53] Correa M, *Public health and intellectual property rights*, 2(3), Global Social Policy, 261, 262, (2002).

Property Laws.[54] The minimum standards set by the TRIPS Agreement on Patents, such as Patent protection for 20 years, restrictions on compulsory licensing, compulsory patent protection, etc., directly affect the availability and access to affordable new medicines. [55] Also, as the TRIPS Agreement is a part of the WTO, it is subject to the Dispute settlement system of the WTO. This means that the Dispute Settlement body can initiate trade sanctions against countries for violation of its rules resulting in economic consequences.

The price of many essential medicines, such as drugs, vaccines, etc., is inaccessible to those in need in the least developed countries and middle-income countries due to patents.[56] The introduction of the TRIPS Agreement brought about product patenting. In process patenting, only the process of developing a drug is patented, and the drug is not patented. Product Patent, unlike process patent, gives monopoly to the patent holder to charge exorbitant prices for the patented drugs. Since there are no alternatives to these medicines due to their patents, access to affordable medicine remains an issue. This charging of exorbitant prices to medicines adversely affects access to affordable medicine, especially for the people living in developing countries.

When a new drug enters the market and is patented, it gets a monopoly over that market and will be able to fix the price at exorbitant prices for a period of 20 years(Article 33 of the TRIPS Agreement). Since the medicine is patented, the generic version won't be available in the market. This results in limiting access to those who cannot afford to pay for expensive medicines.

Prices of medicines reduce when there are multiple players in the market manufacturing generic versions of a medicine creating competition. This gets hindered by Intellectual property laws that prevent generic manufacturers from entering the market and thus keep medicines prices high, making them inaccessible to the disadvantaged.

3.2 THE RATIONALE BEHIND THE PATENT SYSTEM

[54] Gopakumar KM, *Twenty years of TRIPS agreement and access to medicine: a development perspective*,) 55(3), Indian Journal of International Law, p.383, 367–404 (2015)

[55] Ibid.

[56] Isabelle Huys , *Innovative Approaches to Increase Access to Medicines in Developing Countries*, Frontiers in Medicine, pp3, (2017).

Pharmaceutical industries all over the world are capital-intensive and research-intensive industries. Companies in the manufacturing industry depend mainly on patenting newly developed drugs to retain their investment and for profits. The main justifications put forth by the pharmaceutical industry for Intellectual property protection are that the IP provides an incentive for developing innovative drugs and that IP protections enable the industry to recoup the capital it had spent on research & development and encourages investment.

The need for Intellectual property protection has always been debated and controversial, having two sides. On one side, there are debates that the creation of Intellectual property would be affected without incentives through the IP Protections. .[57] If there are no patents, someone investing their time and money in creating an invention will not get a return as some other people would imitate the same. When imitators imitate these inventions, competition occurs in the market for such products, and eventually, the inventor cannot recover the amount they have invested in its creation. Therefore, potential inventors would hesitate to invest. The other side debates the need for open access because it helps create new works and helps increase accessibility to these intellectual properties.

Even though it is advocated that the Patent system encourages innovation, many studies and literature show that the number of inventions induced by the Patent system is relatively low.[58] There is an increase in patent thickets, strategic patenting, patent trolls, etc. It is relatively easy to obtain patents. The patent system, which is generally considered to foster innovation, leads to uncertainties and threatens the innovative process.[59] Also, in the last 20 years, R&D performance has lowered as the number of new medical entities have been approved, and the therapeutic usefulness of new products has considerably reduced.[60]

The controversy over patents has continued, with some arguing in favor of patents while the others are against it. But it is pertinent to understand the difference in patents in

[57] Grabowski, Henry et al, *The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, 34(2) Health Affairs p 305, 302-310. (2015)

[58] Cohen, W.M et al, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not*), National Bureau of Economic Research, (2000).

[59] Burcu Kilic, *Boosting pharmaceutical innovation in the post-trips era: real life lessons for the developing world, Edward Elgar publishing Limited*, Centre For Commercial Law Studies, University of London (2011).

[60] Correa et.al, *Access to medicines: experiences with compulsory licenses and government use- the case of hepatitis C*, 85, research paper, South Centre (2019).

pharmaceuticals from patents in other Industries. For example, Patents in other areas such as that of the music industry or the animation technologies will not have any extreme effects on the lives of the people, and they can forgo such an expense. The same is not the case with patenting in the pharmaceutical industry. Patenting in pharmaceutical industries increases the price of drugs, and people in need of essential medicines cannot forego such an expense as other entertainment industries. The same is a matter of deciding between life and death for people in need of drugs.

The problem with the present patent system is that when the R&D costs are recovered through patents, the more spent on research, the more will be the price of the drugs. So, when massive amounts are spent on the R&D of a product, a barrier is created to access the product due to their high prices. Another problem is that pharmaceutical companies tend to invest very little in diseases that affect the people belonging to smaller economic markets because of the inability of that economy to pay enormous amounts for medicines. Investments are made in the R&D of medicines wherein they can reap huge profits ignoring the social relevance of the medicines.[61]

3.3 THE TRIPS AGREEMENT.

In total, the TRIPS Agreement contains 73 articles which can be divided into three components which are; the first component that sets out the aims and objectives of the TRIPS Agreement, comprising Article 1 to Article 40. The second component deals with the enforcement mechanisms that include Article 41 to Article 61. The third component of the Agreement deals with specific instruments such as technology transfer, monitoring, and review, etc., comprising Articles 62 to 73.

Part II, section 5 of the TRIPS Agreement contains nine articles from Articles 27 to 34 and also includes Article 31bis that are relevant for patents. These trip provisions include:

1. Article 27: patentable subject matter.

2. Article 28: rights conferred by a patent.

[61] Emanuel J et.al, *The Patents-Based Pharmaceutical Development Process- Rationale, Problems and potential reforms*, Special Communcation, American Medical Association, (2005)

3. Article 29: conditions on a patent applicant.

4. Article 30,31 and 31bis: addresses the exceptions to the rights conferred to the patent holder.

5. Article 32: procedural requirements including forfeiture, revocation, judicial review.

6. Article 33: term of protection of the patent.

7. Article 34: burden of proof in-process patents.

3.3.1 PRODUCT PATENT PROTECTION

Before the TRIPS Agreement came into force, many countries had pharmaceuticals exempted from their Intellectual property protections. It was applicable to some high-income countries such as the US, but rarely in the lower- and middle-income countries before the TRIPS agreement entered into force. Approximately fifty countries did not have any form of patent protection before the TRIPS agreement came into force.[62]

According to article 27 of the TRIPS Agreement, which deals with the patentable subject matter, patents shall be available for both products and processes in all technology fields, provided that they are new, involve an inventive step, and are capable of industrial application. However, exceptions are provided for the same.[63]

The TRIPS Agreement at the time of coming into force had a provision for a transition period of 10 years for the developing countries to make their domestic laws in compliance with the TRIPS Agreement. Countries like South Africa and Brazil, without using the transition period of10 years, introduced product patents on their domestic laws. This

[62] Helfer, Laurence R & Austin, Graeme W, *Human Rights and Intellectual Property: Mapping the Global Interface, New York and Melbourne*: Cambridge University Press, p120. (2011)

[63]Article 27(3) of TRIPS Agreement- Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

resulted in an access to medicine crisis within the five years that followed. The medicines for the treatment of HIV AIDS (Antiretroviral drugs) became highly expensive and thus inaccessible to the developing countries, which resulted in the death of thousands of people.[64]

What happens with product patenting is that when a new drug enters the market and is patented, it gets a monopoly over that market and will be able to fix the price at exorbitant prices. Since the medicine is patented, the generic version won't be available in the market. This results in limiting access to those who cannot afford to pay for expensive medicines. The product patent protection eliminates the generic manufacturing of new drugs as a statutory monopoly in the absence of mechanisms such as compulsory licensing. The only exception that can be availed is using compulsory licensing or government use provisions for the production of generic drugs of the patented medicines.

Prices of medicines reduce when there are multiple players in the market manufacturing generic versions of a drug. This is hindered by Intellectual property laws, including product patenting which prevents generic manufacturers from entering the market and thus keeps the prices of medicines high, making them inaccessible to the economically weaker sections of society.

When the transition period provided under the TRIPS agreement was over, all the developing countries introduced product patent protection, including India. This affected the generic producers in India, but India incorporated the TRIPS flexibilities into the Patents Act, which helped India continue to be one of the largest generic producers in the world.

3.3.2 PATENT PROTECTION OF 20 YEARS

According to Article 33 of the TRIPS Agreement, the term of a patent shall be for a period of 20 years from the date of filing of the patent. TRIPS Agreement called for a broader scope of granting patents in all fields of technology, and it restricted the exceptions of

[64] Gopakumar KM, *Twenty years of TRIPS agreement and access to medicine: a development perspective*, 55(3), Indian Journal of International Law, p.390, 367–404 (2015)

patent rights establishing longer-term for patents which required 20 years of patenting from the term of application.

Although the patent term is for 20 years which is similar to the US patent system, Article 31 of the TRIPS Agreement deals with compulsory licensing, which addresses the health and humanitarian concerns of accessing technologies by countries that experience a national emergency or other extreme emergencies. Even though there is a requirement for the countries to negotiate with the patent holder in issuing a voluntary license prior to the issuance of compulsory license, in case of emergencies such as a public health crisis, the need for the issuance of a voluntary license shall be waived.[65]

3.4 FLEXIBILITIES UNDER THE TRIPS AGREEMENT

The Term flexibility is seen in the TRIPS Agreement in the 6th paragraph of the preamble and in Article 66.1 of the Agreement, which states that:

"In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period".

The flexibility above mentioned indicates that the LDCs need not comply with the obligations of the TRIPS Agreement except Article 3 and 5 during their transitional period.

Also, under Article 30 of the TRIPS Agreement, the Agreement provides with flexibilities viewed as 'limited exceptions to the exclusive rights that are 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 into account the interests of third parties. The logic behind this provision is to provide alternatives to high-cost patented medicines at the time of national emergencies and under other circumstances. These conditions remained a controversial matter until the Doha Ministerial conference of 2001.

[65] Article 31, TRIPS Agreement.

Provisions for compulsory licensing and parallel importing have existed in the TRIPS Agreement since the time of its inception. Even then, countries never took the effort to interpret these provisions in a way to enhance the public health scenario. Certain countries even enacted legislation that maximized the protection of Intellectual property rights, completely ignoring the public health scenario. TRIPS Flexibilities are used within and also outside the realm of the TRIPS Agreement to address the concerns on the patent regimes. The use of TRIPS flexibilities is essential to meet the right to health obligations and ensure access to medicine.

When developing countries started facing the threat of sanctions for using the Compulsory licensing provisions and parallel importing, public health advocates globally acknowledged the need to interpret the requirements considering the public health scenario and the public health crises faced all over the world. By 1999, NGOs working in the area of public health and access to medicine started actively supporting the developing countries in finding solutions to the problems arising from the high prices of patented drugs.

The historic Doha Declaration was made in November 2001 in Doha, Qatar. The members agreed on a declaration relating to the TRIPS Agreement and acknowledged the importance of the TRIPS Agreement in enhancing public health globally. The main concerns that were raised by the developing countries at the Doha ministerial conference were the doubts as to whether the member nations would interpret the TRIPS Agreement in a way that would enhance and advance public health. Another concern was the pressure that the developing countries faced to remove TRIPS provisions favoring public health from their national legislation. Also, the viability of the provisions such as compulsory licensing and parallel importing was also raised.

To address these concerns of the member states, Paragraph 4 of the Declaration on the TRIPS Agreement and Public Health (Doha Declaration) states that: ...the TRIPS Agreement does not and should not prevent members from taking measures to protect public health (and)... We affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

The Doha declaration confirms the availability of various TRIPS flexibilities and recognizes and reaffirms each member's right to determine grounds to use the flexibilities,

and allows the members to assess and define a national emergency. Even though these flexibilities were considered to be helpful in developing countries with a developed pharmaceutical industry, they were not of any help to LDCs with no pharmaceutical industries or the manufacturing industries that meet their needs.

The Doha declaration also recognized these difficulties of LDCs. In paragraph 6, the Declaration stated that: "members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002".

Even though the effectiveness of the Doha declaration has been skeptical and it was seen as a mere political declaration, the decision of the WTO against Australia in Tobacco plain packaging[66] has confirmed the legal validity of the declaration. It also upheld the principles of the Doha declaration by stating that pro-public health measures should be taken by the nations without having a fear of costly litigations under the Dispute Settlement Understanding.

Members lacking a proper manufacturing capacity could not take the appropriate advantage of the flexibilities available under Article 31. This problem came to be addressed widely, leading to August 30, 2002, when the WTO made a decision known as article 31bis. This article made any LDC import low-cost generic drugs from any source other than that of the originator. Although on the face of it, this article seems to help the LDCs, the complexity of this provision makes it difficult for these countries to make use of this provision. Rwanda was the first country to make use of this provision in 2008 after four years of effort to import generic drugs into the country. The whole process of implementing this article itself is highly complex and time-consuming, which is evident where Rwanda took four years to implement Article 31bis.

Even though there have been no systematic studies conducted to evaluate the effects of TRIPS flexibilities, experiences of countries that have used TRIPS flexibilities show enhanced access to medicine. In Malaysia, the use of compulsory licensing for HIV/AIDS

[66] DS467.

medicine reduced the price of drugs to 81 percent, reducing the cost per person to USD 58 from USD 325.[67]

3.5 COVID-19 AND THE TRIPS AGREEMENT.

The deadliest in the history of pandemics can be considered the bubonic plague, which is said to have taken more than 200 million lives during the 14th century. The bubonic plague has wiped out half the population of Europe. In another two centuries, smallpox took more than 56 million lives. Later on, nearly 40 to 50 million lives were lost due to the Spanish flu, and from the 1980s, 35 million lives were lost to HIV/AIDS.[68]

The COVID-19 pandemic has caused the national economies to plunge and has pushed the countries into recessions.[69]By June 2021, globally, more than 4 billion covid-19 deaths have been reported, and more than 153 million people had been infected.[70] The COVID-19 can be referred to as one of the biggest health crises the world has been through in the 21st century. At the time of the COVID-19 pandemic, many of the developing countries, including India and South Africa, have initiated in WTO a proposal for the TRIPS waiver that would help countries in coping with the pandemic.

Even though the USTR has shown support for the IP waiver, the support extends only to vaccines and not to drugs and other medical equipment that are essential to treat COVID-19. The US has also supported the IP waiver proposed by India and South America at a later stage. Also, several countries have enacted laws that would provide compulsory licensing to deal with the COVID-19, one among which is Israel's compulsory licensing on

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[67] Ling Chee, *Malaysia's Experience in Increasing Access to Antiretroviral Drugs: Exercising the Government Use Option*, Third World Network, available at IPRS9.final (twn.my), last accessed on 07.07.2021.

[68] Durkin A, *Free trade in medicines and supplies is the healthiest approach*, Available at https://www.globaltrademag.com/free-trade-in-medicines-and-supplies-is-the-healthiest-approach/, Last accessed on 20.08.21.

[69] Olivier J Wouter et.al, *Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment*, Health Policy Paper,(2021).

[70] Global COVID-19 death toll goes past 4 million; US, Brazil & India top contributors, Available at https://indianexpress.com/article/world/global-covid-19-death-toll-exceeds-4-million-7364274/, last accessed on 20.06.21.

Abbvie's Kaletra.[71] The initiation of several countries in enacting Compulsory licensing laws was also opposed by the US as usual. A Compulsory License issued by Hungary on the COVID-19 treatment drug Remdesivir was also opposed by the US Chamber of Commerce and Pharma Associations.[72]

Compared to all the pandemics that the world has witnessed until now, this turns out to be history's deadliest pandemic.[73] There exists a severe problem of accessing vaccines to the developing and the Least Developed Countries. Patents in vaccines prevent countries from accessing them. A WHO estimate shows that most of the people in Low- and Middle-Income Countries (LMICs) will not be vaccinated until 2023. [74]

Developing Countries and LDCs have called for the adoption of TRIPS flexibilities in the absence of a general waiver. Still, since the process of adopting flexibilities is a complex one, they refrain from doing it. These complexities in the IP regime result in deepening the already existing global health inequalities between the developed countries and the developing and the LDC.

The current distribution of the COVID-19 vaccine is through contracts of high-income countries with pharmaceutical companies leaving the LMICs facing inequalities in accessing the vaccine. [75] The only way in which these countries can access vaccines is through pushing themselves into debts. These debts in turn, worsen the inequalities already existing between the lower-income countries and the developed countries by undermining

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[71] *AbbVie will allow generic copies of its HIV pill in Israel after the government approved a license*, Available at https://www.statnews.com/pharmalot/2020/03/20/abbvie-israel-hiv-kaletra-coronavirus-covid19/, last accessed on 11.05.2021.

[72] *Hungarian compulsory license for remdesivir raises a stir with BIO, PhRMA and the US Chamber of Commerc*e, Available at https://www.keionline.org/35558, last accessed on 11.05.2021.

[73] Farquhar H, *Redefining the TRIPS Agreement to Accommodate en Masse Compulsory Licensing of Vaccines & Other Pharmaceuticals for the Treatment of Covid-19*, 22 N.C. J.L. & TECH. 259 (2020).

[74] UN News. *WHO chief warns against 'catastrophic moral failure' in COVID-19 vaccine*. Available at WHO chief warns against 'catastrophic moral failure' in COVID-19 vaccine access | | UN News, last Accessed on 03.06.21.

[75] Sharifah Sekalala et.al, *Decolonising human rights: how intellectual property laws result in unequal access to the COVID-19 vaccine*, BMJ Global Health, available in BMJ Global Health | Open access journal for a healthier world, last accessed on 02.08.2021.

development in these countries. [76] These countries, instead of investing in improving their healthcare sector, are forced to invest in paying off the debts. Twelve billion dollars has been set aside, and 500 million dollars has already been given to the LMICs for obtaining vaccines by the World bank. [77]

Very few countries globally have the capacity to manufacture the vaccine at the scale that is required. This inequality in the production of vaccines can only be balanced with the help of countries that have production capacity helping other countries realize their need for vaccines. This will also set a precedent in solving the ever-growing problem of access to medicine all over the world.

The concerns on the rising cost of medicine and the inability of low- and middle-income countries to produce generic drugs essential for their population were already there before the COVID-19 crisis. These concerns increased at the time of pandemic wherein it was understood that most of the crucial technologies, Active Pharmaceutical Ingredients (API), and essential equipment that is essential for the treatment were concentrated in a small number of industries and nations. As the panic and desperation soared due to COVID-19, firms looked for capturing monopoly, and certain countries started placing control on the exports making the situation worse for the low-and-middle-income countries. [78]

Even though effective vaccines for covid-19 have been developed, there is an inequality in the way in which they are launched in different countries due to variations in domestic regulations. Countries then have brought the bilateral and multilateral treaties they have entered into for scrutiny as they started recognizing the need to foster the capacity for production of drugs and other technologies to safeguard them against pandemics like the covid-19 and other health emergencies. [79]

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[76] Meier BM, *Development as health: employing the collective right to development to achieve the goals of the individual right to health,* 30, Human Rights Quarterly:259–355, (2008)

[77] World Bank. *World bank supports first COVID-19 vaccine Rollout in Lebanon*. Available at World Bank Supports First COVID-19 Vaccine Rollout in Lebanon , last accessed on 20.05.21.

[78] Olivier J Wouter et.al, Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment, Health Policy Paper,(2021).

[79] Thrasher R, *Patents, protections and pandemic: a trade and access to medicines roundup,* Global Development Policy Center, Available at https://www.bu.edu/gdp/2021/06/02/patents-protections-and-pandemic-a-trade-and-access-to-medicines-roundup/, last accessed on 22.08.2021.

COVID-19 disproportionately impacts the population, including the economically disadvantaged people, the older people, and those who have underlying health conditions. The already existing health inequities among the LICs pose challenges in accessing effective and affordable healthcare. The shortage of medicines, oxygen, health staff, diagnostic tools, and transport services has become widespread at the time of COVID-19.

In addition to the effect COVID-19 has on the health of the population, it has also affected the lives of millions, as evidence shows an increase in poverty and income shrinking among the people. Effective mechanisms are required to ensure that the low-income and middle-income countries have affordable and sustainable financing to procure the vaccines. These countries accommodate about 85% of the world population.[80]

3.6 INDIAN SCENARIO

India is the 4th largest drug producer by volume and 13th largest by value in manufacturing drugs around the world. India first introduced its patents protection in 1856, and the patent protection system has since then undergone drastic changes. The first act relevant to the current patent regime was the Indian Patents and Designs Act of 1911.

The act of 1911 provided patents for pharmaceutical products and processes for a period of 16 years. It was extendable for a period of 10 years if the patent holder was not sufficiently rewarded by the patent. This act, to a large extent, restricted the growth of the industry by granting patents to products and patents. This resulted in innovations and opportunities being denied to the local pharmaceutical industry.

Until the Patents Act, 1970 came into force, India's patent regime provided for both product and process patents in pharmaceuticals. The Indian healthcare market was dominated by large MNCs that held patents in drugs and medicines, and the domestic pharmaceutical industry was dormant at that point of time. When the Patents Act 1970 came into force, India abolished Product patents which resulted in generic drugs entering the market. Indian generic pharmaceutical industries used this opportunity and their skills in reverse

[80] Crager SE. *Improving global access to new vaccines: intellectual property, technology transfer, and regulatory pathways* , 108, Am J Public Health, (2018).

engineering by reproducing a drug using a different method resulting in the dropping of drug prices in India.

The sudden change in the patent regime was mainly because of the industrial policies that were introduced in the 1970s, and this also resulted in new entrants to the market, increasing competition within the market. High competition within the market reduced the prices. This made India self-sufficient in medicines and increased access to medicine not only within the country but around the world. Even when the prices of medicine were low due to high competition, medicines were beyond the reach of two-third of the Indian population.[81]

The Indian Patent's Act of 1970 has also allowed the Indian pharmaceutical manufacturers to produce a generic version of drugs that were patented in other countries. The Indian pharmaceutical manufacturing industry established itself as one of the primary sources of generic medicines in the world. India was supplying at that time low-cost generic versions of patented drugs to a large number of poor countries, helping them access essential medicines.

The implementation of the TRIPS Agreement in the Indian Patents Act came as bad news to the Indian pharmaceutical companies. Not only were the Indian manufacturers affected, but also those countries which had India as a source of their generic medicines were also highly affected. At the time of TRIPS negotiations, developing countries like India and Brazil strongly opposed the inclusion of certain provisions that created barriers in accessing medicine to the common people. Because of the efforts put by these developing countries, access to medicine and public health concerns were addressed at TRIPS negotiations, and flexibilities such as parallel importation and doctrine of exhaustion were incorporated into the agreement.

India first introduced the Patents Amendment Act of 1999, which provided for a mailbox system for filing patent applications. The actual processing of these applications began only after 2005. Under this amendment act, those applying for a patent through a mailbox system could also apply for the Exclusive Marketing Rights (EMRs) for the drug for a period of five years or until the grant or rejection of the application, whichever was shorter. In India, patent protection was not provided until 2005, and for process patents, the protection was

[81] Malhotra P, *Impact of TRIPS in India: an access to medicine perspective*, Palgrave Macmillan p2. (2010)

for seven years from the date of filing or five years from the date of grant, whichever is shorter.

There were many concerns that India had when equating its patent regime with the TRIPS Agreement, such as drugs becoming expensive, the threat of product patenting on traditional knowledge, etc. But by 2005, India amended its Patents Act changing its nature itself by introducing product patents for pharmaceutical products. India, before amending the Patents Act, had clear benefits from producing generic drugs, which is lost with the introduction of product patents.

When the transition period ended in 2005, it marked the beginning of the vanishing of generic drugs in India. Before the year 2005, India did not have a patent on medicines that helped grow the Indian generic industry. This has helped many countries around the globe to treat diseases like tuberculosis, HIV/AIDS, Cancer, etc. Before 2005, sick people across the world depended on Indian manufacturers to manufacture cheap and affordable generic drugs. [82]

After 2005, Indian drug manufacturers started investing in R & D for the development of new drugs and started developing new chemical entities. Prior to the coming into force of the TRIPS Agreement, only 2% of the industrial sale was spent on R&D. Still, now, more than 10% is spent on R&D. With Indian companies like Ranbaxy and Cipla investing in R&D of new drugs, the pharmaceutical industry has been moving up in the value chain.[83] As of 2020, India is the world's largest generic drug provider, and its products account for 20% of the total generic exports globally.[84]

The Trade negotiations between European Union and India started in 2007. Since then, it has been controversial as it threatens some of the health safeguards of India by bringing in TRIPS Plus provisions that will affect India's generic industry. The FTA negotiations

[82] . Médecins Sans Frontières, *"Will the Lifeline of Affordable Medicines for Poor Countries be Cut? Consequences of Medicines Patenting in India*," Briefing document, February p. 2.(2005)

[83] Kanike, Atsuko, The TRIPS Agreement and the Pharmaceutical Industry: The Indian Experience, Available at https://src-h.slav.hokudai.ac.jp/rp/publications/no11/11-07_Kamiike&Sato.pdf, last accessed on 22.05.21.

[84] Pharmaceuticals, IBEF, Available at https://www.ibef.org/download/Pharmaceuticals-March-2020.pdf, last accessed on 26.08.21.

between the countries have resumed after Brexit, and there is a global concern about the impact this FTA will have if it is entered into.

If the demands that are put forth by the EU in the EU-India FTA are agreed by India, it will not only adversely affect the health scenario and access to medicine in India but will also affect the patients all over the world who are dependent on the generic supply of India. This is because of the potential impact the FTA will have on India's manufacturing, supply, and distribution of generic medicines.

It is of utmost importance that the EU-India FTA should be free of TRIPS Plus obligations because India plays a pivotal role in enhancing access to medicine globally by its supply of generic medicines. The supply of generic medicines to the world is vital for the public health systems. The generic drug production of India has helped save millions of lives around the world from diseases such as HIV, TB, Hepatitis C, Malaria, etc.

A number of Intellectual property enforcement measures are being suggested by the EU that go well beyond what the TRIPS Agreement stipulated. The enforcement mechanism proposed by the EU itself seems to be ambitious as it involves courts, private parties, executive authorities, and customs authorities. The TRIPS Agreement limits its stringent enforcement mechanisms to copyright and trademark but does not include patent infringements.

This is because patent infringement cases can be complex and more complicated to determine compared with copyright piracies and trademark counterfeiting. Technical analysis is required in case of patent claims to determine whether a breach has been done or not. The EU proposes to include a stringent patent infringement mechanism in the FTA, which means that the generic manufacturer will be subject to unwarranted enforcement measures and claims against them for patent infringement.

The EU also proposes to include third parties in the enforcement mechanisms. The EU proposes to give the patent holder to involve into litigation actors involved in the manufacturing, supply, and distribution of the medicines. The possibility of such litigations against third parties will dissuade them from working with the generic manufacturers. Other proposals such as border measures, temporary injunctions, strict injunction system, etc., are proposed by the EU in the FTA.

The TRIPS agreement has itself substantially affected the production of generic drugs in India. If the EU implements TRIPS Plus provisions in the FTA with India, it will eventually take away the very little space that remains for these generic companies to continue their production of generic medicines.

3.7 CONCLUSION

The TRIPS Agreement was influenced by the Intellectual property regime of the United States. Because of that, the US had only a few changes to make in their IP regime to conform with the TRIPS Agreement without incurring much expense. The US already had the Trade remedy law under section 377 of the US Tariff Act, which allowed withdrawal of tariff concessions for countries that were considered to have weak Intellectual Property protections, but this only allowed for action against importing into the US that had a suspicious origin and did not protect the IP rights of the US industries in the foreign markets.

This was overcome by the US through the TRIPS Agreement, which protected IP rights regardless of the source or the destination. No country could refrain from any one of the agreements of WTO, they had to either accept all the agreements or accept none, and thus, all countries signatory to the WTO had to make amendments according to the provisions of the TRIPS Agreement.

Also, by 1989 the United States Trade Representative (USTR) started issuing annual 'special 301' reports that evaluated the IP regime and practices of countries and listed countries in the watch list and the priority watch list. Being on the watch list and the priority watch list increased the threat of penalties to these countries. When a country becomes a Priority Foreign country, the USTR will initiate proceedings that bring sanctions against these countries. This made the countries who resisted the Uruguay Round negotiations targeted by the USTR. The pressure brought about by the threats made by USTR made many opposing countries agree to the rules made at the UR negotiations.

The cost incurred by the developing countries is difficult to estimate because of the associated human and social cost that is to be considered.[85] According to a study conducted by Oxfam in 2007, the annual cost of implementing the TRIPS Agreement in developing countries exceeds 40 billion US dollars annually.[86]The TRIPS Agreement implementation is said to have enormously drained the resources of the developing countries who were already under pressure to meet the healthcare needs of the citizens.[87] For the people living in developing countries, the medical expenses are borne out of their pockets as they face an absence of proper health coverage systems. For various segments of the population, this out-of-pocket expense is unrealistic, making them inaccessible to essential medicines.[88] The failure of the governments in providing adequate healthcare to their people is a serious concern that has far-reaching implications

The objective of the Intellectual property rights enshrined under Article 7 of the TRIPS Agreement includes 'mutual advantage of producers and users and a balance of rights and obligations. Even then, the Agreement obviously favors the drug manufacturers. The Agreement is said to favor the drug manufacturer because even though it provides for penalties of imprisonment or fine for commercial infringers of IPRs. It provides for punishing firms or individuals that inflict monetary damage on the rights holder; it does not offer similar provisions against the drug manufacturing companies for their infringements or for excessive patenting of a single medicine.

Thus, there is an imbalance in the rights and obligations available to the drug manufacturer and the users. This imbalance gives an advantage to the drug manufacturers as even in cases like excessive patenting, there is no provision to penalize it. This results in denying access to medicines to the needy population.

To conclude, access to medicine can be enhanced if generic medicines are made available in the market. The product patenting that came about with the TRIPS Agreement eliminated

[85] 8 Lopert et al*, The High Price of "Free" Trade: US Trade Agreements and Access to Medicines,* 41(1) The Journal of Law, Medicine & Ethics. p218,199–223. (2013)

[86]TRIPS and Public health, the next battle, https://policy-practice.oxfam.org/resources/trips-and-public-health-the-next-battle-115047/ , last accessed on 23.06.2021.

[87] Sundaram J, *Pharmaceutical Patent Protection and World Trade Law The unresolved problem of access to medicines*, Routledge, p.242, (2018).

[88] Correa et.al, *Access to medicines: experiences with compulsory licenses and government use- the case of hepatitis C*, 85, research paper, South centre (2019).

the availability of generic drugs. Ideally, patents should be available only to new molecules, and old molecules should remain in the public domain for developing generics. But the situation is such that pharma companies obtain patents for new single molecules and prevent others from producing generic versions of the same.[89] This patenting of even single molecules prevents generic companies from even having medicines that are not patented. It can be concluded that patent monopolies, even after more than 25 years of implementation of the TRIPS Agreement, deny access to medicine due to the high price of patented drugs.

[89] Gopakumar KM, *Twenty years of TRIPS agreement and access to medicine: a development perspective*,) 55(3), Indian Journal of International Law, p.372, 367–404 (2015)

CHAPTER 4

TRIPS PLUS PROVISIONS IN FREE TRADE AGREEMENTS AND ITS IMPLICATIONS ON ACCESS TO MEDICINE.

4.1 INTRODUCTION

In the majority of the developing and the least developed countries, health systems are under-resourced. To add to this are the provisions in the TRIPS Agreement and the TRIPS Plus conditions in some Bilateral and Regional Free Trade Agreements (FTAs), which adversely affect the healthcare system's resources. The situation is already grim in access to medicine; the provisions in the TRIPS agreement and the TRIPS-plus conditions in Free Trade Agreements make it even worse.

While pharmaceutical companies have a strong case for protecting the patents due to the investment and R&D involved, these companies pressurizing the government to monopolize the drugs adversely affect access to medicine. Pharmaceutical companies that hold patents over the drugs have almost monopolistic control over the price of their medicine.[90] When pharmaceutical companies set prices for their medicine in a market, they

[90] Kaminski Margot, *The Origins and Potential Impact of the Anti-Counterfeiting Trade Agreement*, 34 Yale J. Int'lL. 247, (2009).

usually pursue a strategy to maximize their profit rather than consider a measure that would increase access to medicine. [91]

The TRIPS Agreement was seen as the last step towards strengthening the developing countries' intellectual property regime. The TRIPS Agreement carried some room for the developing countries to incorporate public interest measures for the protection of public health. With the disappointment brought with the TRIPS Agreement, the U.S. has been trying to insist on maximum restraints possible into these agreements by incorporating protective mechanisms not envisaged under the TRIPS Agreement.[92] Soon after the TRIPS negotiation, Countries such as the U.S. and the E.U. started to pressurize the developing countries to adopt more robust standards of I.P. protection than that is required by the TRIPS Agreement. This was done mainly by threatening to remove the trade preferences and by cutting the developmental aids that are given to these countries.

Concerns were raised about the high-level patent protection under the TRIPS Agreement affecting access to medicine, especially the African Countries when negotiating the TRIPS Agreement. Academicians and NGOs significantly criticized these threats, and it finally led to the adoption of the Doha Declaration on TRIPS Agreement and Public health at the Doha Ministerial Conference. Through the flexibility available under the TRIPS Agreement, the governments could address the problems that affect their population and allow various types of exceptions to make affordable medicines open to the general public.

Even though several TRIPS flexibilities were agreed upon under the Doha declaration to enhance the public health situation around the globe, this gets compromised with the TRIPS Plus Provisions that transpires with the Free Trade Agreements entered into between nations. The incorporation of TRIPS Plus provisions into FTAs often raises concern concerning its impact on medicine and public health access. Many countries are increasingly entering into bilateral Free Trade Agreements and Regional Free Trade Agreements in addition to the global TRIPS agreements that are entered into by Nations under the backing of the WTO.

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[91] Sean F, Aidan Hollis & Mike Palmedo, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries,* Available at https://core.ac.uk/download/pdf/327252791.pdf, last accessed on 23.05.21.

[92] Armouti W, Nsour M, *Data Exclusivity for Pharmaceuticals in Free Trade Agreements: Models in Selected United Sates Free Trade Agreements*, 40 Hous. J. INT'l L.105 (2017).

Free Trade Agreements have been controversial because a trend is seen in the Free Trade Agreements that establishes Intellectual Property protections that are more challenging than the ones that are already provided by the TRIPs agreement. These are known as the "TRIPs-plus" provisions. These FTAs seek significant changes in the domestic laws of the participating countries. Even though the countries accept that they lose the TRIPS flexibilities available to them while entering into FTAs with TRIPS-plus provisions, they consider a net gain overall. The I.P. protections affecting medicines are justified.[93] Regardless of the commercial gains that these countries will receive in the short term and the long term, the changes in the level of IP protection will have a notable impact on the public health scenario of the nations.

Most of the Free Trade Agreements, be it bilateral or multilateral, are entered upon by the nations in the guise that these FTAs provide economic benefits to the countries' signatories to it by removing the barriers in trade in goods and services. The FTAs allow developed countries to obtain what they cannot quickly obtain through multilateral agreements because multilateral agreements may have other economically powerful countries present, making it difficult to negotiate.[94] Gains from multilateral trade agreements are less as there are numerous opinions and interests in achieving a consensus. For, e.g., In the case of WTO, every member can participate in the decision-making process even if the country is a low-income country in the same way as the developed countries. Thus, the interest of a more powerful country cannot overpower in the case of multilateralism.

However, Free Trade Agreements allow countries with greater bargaining power to negotiate trade policies with countries that have lesser bargaining power without dealing with organized opposition to the demands made by them and without the same transparency that takes place with the WTO negotiations.[95] These TRIPS-plus obligations are imposed

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[93] Abbott, "*The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Trade Agreements*", Occasional Paper 14, QUNO (2004).

[94] Correa M, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36(1), Case western Journal of International Law (2004).

[95] Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317, 349 (2005)

upon the countries for the trade concessions made available to them through Free trade Agreements.[96]

Among the number of issues that arise concerning Free Trade Agreements, one of the significant issues that have been inviting a great deal of publicity is the potential impact the TRIPS-plus level patent protection would have on pharmaceutical costs and its availability.[97]

The WTO does not have any control over the FTAs or other agreements entered into by Nations. It was not the case before, and the WIPO had control over the administration of international protection of IP rights. The change from the administration of IP rights from WIPO to WTO can be seen as a move of the developed countries to serve their interests[98].

Free Trade Agreements can increase the market price of the medicines due to their increased regulatory nature in the protection of Intellectual property. Brazil and Thailand had experienced a hindered access to HIV/AIDS medicines protected by intellectual property.[99] Situations like this show how the increased regulatory nature of Intellectual property can affect the access to medicine scenario in developing and least developed countries.

U.N. Political Declaration of 2011 on HIV/AIDS recognizes the role public health-related TRIPS flexibilities can play in increasing access to treatment. It asks the U.N. members to "ensure that the intellectual property right provisions in the trade agreements do not undermine these existing flexibilities."[100]

Research findings prove a negative impact arising from the implementation of Free Trade Agreements in developing countries, particularly in public health and access to

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[96] Correa M , *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicine*s, 36 Case W. Res. J. INT'l L. 79 (2004).

[97] Keith E. Maskus, Access to Essential Medicines and Affordable Drugs: Ensuring Access to Essential Medicines: Some Economic Considerations, 20 WIS. INT'L L.J. 563, 564 (2002).

[98] Sundaram J, *Pharmaceutical Patent Protection and world trade law: the unresolved problem of access to medicine*, Routledge Research in Intellectual property. pp 73, (2008).

[99] Jing Luo et.al, *Antiretroviral drug expenditure, pricing and judicial demand: an analysis of federal procurement data in Brazil from 2004–2011,* BMC Public Health 14, 367, 2014.

[100] G.A. Res 65/277, 2011, Political Declaration on HIV and AIDS.

medicines.[101] The U.S. Regional FTA includes the CAFTA- D.R. (Dominican Republic-Central America Free Trade Agreement), US-SACU (United States-Southern African Customs Union Free Trade Agreement), and Bilateral FTAs such as the US-Peru Bilateral FTA, US-Thailand Bilateral FTA seek TRIPS-plus Provisions. Similarly, Countries Like Europe, Japan, and EFTA (Iceland, Liechtenstein, Norway, and Switzerland) also desire TRIPS-Plus provisions in their FTAs.

TRIPS history tends to show that the U.S. has been using the FTAs to enforce the TRIPS Plus provisions. The U.S. has opposed the WTO members in exercising TRIPS flexibilities by threatening trade sanctions against them even at times of health crises. At the AIDS pandemic, the U.S. continuously pressurized South Africa to refrain from enacting legislation that brought about TRIPS flexibilities. This was even met with sanctions from the U.S. until 20% of the U.S. population was affected by AIDS, and the U.S. had to bring changes to its policy. [102]

Similarly, Roche's decision to reduce the price of Anti-AIDS drugs because of the pressure from Brazil was met with a WTO dispute by the U.S., which ultimately had to be dropped. [103]India's compulsory license on Bayer's anti-cancer drug Nexavar was faced with dire responses from the US.

In the Trans-Pacific Partnership negotiations, the United States in 2016 attempted to introduce patent protection for diagnostic methods, therapeutic methods, and surgical methods. Nevertheless, this attempt by the United States did not succeed. It could be made apparent from these attempts by the United States of how the developed countries push for higher standards of Intellectual Property Protection through TRIPS Plus provisions by incorporating them in Free Trade Agreements. [104]

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[101] Oxfam Int'L, All Costs, No Benefits: How Trips-Plus Intellectual Property Rules In The US–Jordan FTA affect Access To Medicines (2007).

[102] Correa M, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines, 36(1),* Case western Journal of International Law(2004).

[103] Ibid

[104] Hembadoon Iyortyer Oguanobi , *Broadening the conversation on the TRIPS agreement: Access to medicines includes addressing access to medical devices*, The Journal of World Intellectual Property, (2018)

The Doha Declaration was conceived to rectify the problems that were faced by the developing countries, and it stated that no provision in the TRIPS Agreement would be implemented in a manner that would be damaging to the public health of developing countries. Even after the adoption of the Doha Declaration on TRIPS and Public health in 2001, the United States has sought to limit the use of the flexibilities provided under the declaration by incorporating TRIPS Plus provision in Free Trade Agreements.

Thus, for most of the countries that experience a health care crisis, the reality is not in conformity with the confidence that the Doha Declaration made, and the higher IP protections stipulated in these FTAs are in direct contravention with the main objectives of the Doha Declaration.

4.2 TRIPS PLUS PROVISIONS IN FREE TRADE AGREEMENTS THAT LIMITS ACCESS TO MEDICINE.

The TRIPS Plus provisions that hinder access to medicine in Free Trade Agreements include:

- extension of the patent period beyond the minimum required twenty years.
- Data exclusivity provisions.
- Restrictions that would limit the use of compulsory licenses.
- Reduction or even the elimination of transitional periods.
- Restrictions on parallel importation.
- Data exclusivity requirements.
- Market approval requirements etc.

All these TRIPS-plus provisions, in turn, affect the pricing of the medicine and thus results in essential medicines becoming expensive.

TRIPS-plus provisions in FTAs affect access to medicines significantly in the following ways:

(1) by increasing IP protection available to the patent holder under the TRIPS Agreement,

(2) by introducing new standards of Intellectual Property rules and protections that are not present in the TRIPS Agreement,

(3) by eliminating the use of flexibilities available under the TRIPS Agreement; and

(3) by raising the enforcement requirements for Intellectual Property violations. [105]

4.2.1 EXTENSION OF PATENT DURATION.

The TRIPS agreement provides for a patent term of 20 years from the date of application of the patent.[106] It says that 'Members may implement in their domestic law more extensive protection than is required by this Agreement.[107] This provision, to some extent, can be construed ambiguously for the fact that to what time the extension can be made and the conditions in which such extension to Patent term shall be done is not adequately explained. In some Free Trade Agreements, this 20-year protection of patents which is provided under the TRIPS Agreement, is further extended. It is also important to emphasize that there is no limitation to the extensibility under the TRIPS Agreement. This uncertainty over the patent term in almost all the FTAs can result in a delay to the generic producers and also the drugs being costly for a more extended period of time.

Article 4.23 of the U.S.-Jordan FTA says that:

With respect to pharmaceutical products that are subject to patents:

1. Each party shall make available an extension of the patent term to compensate the patent owner for unreasonably curtailing the patent term as a result of the marketing approval process. This extension of the patent term is provided in the U.S.-Jordan FTA to

[105] *Rethinking Trade Treaties & Access to Medicines*, Report by the Working Group on Trade, Investment Treaties & Access to Medicines, (2019).

[106] Article 33, TRIPS.

[107] Article 1, TRIPS.

compensate the applicant for the time that is spent during the patent examination and the time taken for market authorization.

Article 14.8(7) of the U.S.–Bahrain FTA provides that:

When a Party provides for the grant of a patent on the basis of a patent granted in another territory, that party, at the request of the patent owner, shall extend the term of a patent granted under such procedure by a period equal to the period of the extension..., if any, provided in respect of the patent granted by such other territory.

Article 15(10)(2) of the Dominican Republic-Central America Free Trade Agreement (CAFTA-DR) states that:

With respect to any of the pharmaceutical products that are subject to a patent, each party shall make available restoration of the patent term to compensate the patent owner for unreasonably curtailing the effective patent term as a result of the marketing approval process.

A study conducted in the Republic of Korea on Patent term extension found out that the extension of patent terms is likely to cost the Korean National Health Insurance Corporation what amounts to 504.5 billion won (the U.S. $529 million) for extending drug patents for three years and 722.5 billion won (the U.S. $ 757 million) if it had to agree to a four-year extension as proposed under FTA negotiations Korea has with the United States.[108]

As regards the developed nations are concerned, an extension of the patent term duration may not have any severe consequences. But that shall not be the case in developing countries where there may be a severe consequence to the public health because of the reason that, as long as the patent is in place, there is no generic competition which results in the prices of medicines remaining high. Affordable medicines would not be accessible to a large percent of the population in developing countries in such cases.

[108]U.S. FTA may cost drug industry $1.2 billion: gov't, https://www.hani.co.kr/arti/english_edition/e_business/165065.html, (last visited 10 May 2021).

4.2.2 DATA EXCLUSIVITY REQUIREMENTS.

At the negotiation of the Trips Agreement, the U.S.' and E.U.'s attempt to include Data Protection into the TRIPS Agreement was resisted at the WTO. It resulted in excluding the data exclusivity from the TRIPS Agreement. Since then, The E.U. and the U.S. have been pursuing their data exclusivity agenda by incorporating data exclusivity requirements into various Free Trade Agreements that are entered into by them. These agreements create a de facto legal international protection regime for data exclusivity by virtue of Article 4 of the TRIPS Agreement, relating to the Most Favoured Nation ―MFN principle.[109]

Article 39.3 of the TRIPS Agreement does not require data exclusivity, although it protects undisclosed data from commercial uses, which are unfair. Some countries have argued that the inventor who develops the test data makes huge investments and deserves a return for his investment through the protection of test data for at least a period of 5 years. This argument is in favor of protecting the investments rather than protecting the invention, which is the basic idea behind the TRIPS Agreement. Data exclusivity provisions act as a substitute for patents and take away the public domain products that should have been freely available, in turn having a significant impact on public health.

In some Free Trade Agreements, there is a stipulation of data exclusivity. Also, they have provisions that deal with patent linkages that would result in preventing the approval of new medicines by the Drug Regulatory Authorities if the drug for which consent is sought has already been patented. Another ill effect of data exclusivity is that it may hinder the use of compulsory licensing.

Some FTAs stipulate the time period of protection during which data exclusivity protection must be provided.

The United States FTA with Morocco in Article 15.10.1 stipulates that:

If a Party requires, as a condition of approving the marketing of a new pharmaceutical and agricultural chemical product,

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[109] Said Mohammed , *The Morning After: TRIPS-Plus, FTAs and Wikileaks - Fresh Insights on the Implementation and Enforcement of IP Protection in Developing Countries*, 2, TLS Research Paper Series, (2012).

a) the submission of safety and efficacy data, or

b) evidence of prior approval of the product in another territory that requires such information, the party shall not permit third parties not having the consent of the person providing the information to market a product on the basis of approval granted to the person submitting such information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the party. For purposes of this paragraph, a new product is one that contains a new chemical entity that has not been previously approved by the party.

The US Jordan Free Trade Agreement was entered between the U.S. and Jordan in 2000 and came into force in the year 2001. The US Jordan FTA was one of the first Bilateral Agreements that brought about TRIPS Plus provisions in Trade Agreements.[110] The U.S.-Jordan FTA makes an obligation on Jordan to provide for data exclusivity for a period that may extend up to 8 years.

Article 4.22 of the U.S.-Jordan FTA states that:

In accordance with Article 39.3 of TRIPS, each Party, when requiring, as a condition of approving the marketing of pharmaceuticals ..... that utilizes new chemical entities, the submission of undisclosed test or other data, or evidence of approval in any other country, the origination of which involves a considerable effort, shall protect any such information against unfair commercial use. In addition to this, each party shall preserve such information against disclosure, except wherein necessary to protect the public or unless steps are taken to ensure that such information is protected against unfair commercial use.[111]

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[110] Said Mohammed, *The Morning After: TRIPS-Plus, FTAs and Wikileaks - Fresh Insights on the Implementation and Enforcement of IP Protection in Developing Countries*, 2, TLS Research Paper Series, (2012).

[111] Footnotes 10 and 11 of the U.S.-Jordan FTA, which are related to Article 4.22 states that:

It is understood that protection for ―new chemical entities‖ shall also include protection for new uses for old chemical entities for a period of three years.

It is understood that, in situations where there is reliance on evidence of approval in another country, Jordan shall at a minimum protect such information against unfair commercial use for the same period of time the other country is protecting such information against unfair commercial use

The U.S.-Jordan FTA also includes protection of "new use" for chemical entities. Footnote 10 of article 4.22 states that: It is understood that protection for new chemical entities shall also include protection of new uses for old chemical entities for a period of three years.

According to an Oxfam report, data exclusivity provisions under the U.S.–Jordan Free Trade Agreement have resulted in delaying the introduction of generic drugs into the market while also increasing the costs of medicines as a result throughout the country. The report also indicates that the price of medicine has increased by up to 800% in Jordan after the implementation of the US-Jordan FTA in 2001.[112]

Data exclusivity protection which is stipulated in Free Trade Agreements beyond those levels prescribed under the TRIPS Agreement, restricts and limits the ability of states from using the flexibilities of TRIPS in accordance with their national needs and priorities.[113] Another detrimental effect of data exclusivity is evergreen patenting, which will provide extended patent protection to the drugs resulting in the entry of generics into the market getting prolonged. The generic manufacturer is left only with the option to repeat clinical trials and prove the safety and efficacy of the drugs, which would risk the health of the patients undergoing clinical trials. When data exclusivity protection is given to life-saving medicines treating deadly illnesses, it will delay access to affordable alternatives, putting the lives of millions of patients at risk of losing their lives. Guatemala, one of the poorest Latin American Countries, had to bow to the pressure put by the US and enact data exclusivity for pharmaceuticals affecting the already poor living conditions of their people.

4.2.3 TEST DATA REQUIREMENTS

Article 16.4 of the US-Singapore FTA says that-

If a Party requires the submission of any information concerning the safety and efficacy of a pharmaceutical product prior to permitting the marketing of such product,

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[112] Oxfam. *All Costs, no Benefits: How TRIPS-plus Intellectual Property Rules in the US–Jordan FTA Affect Access to Medicines. Oxford*, Oxfam Briefing Note, (2007).

[113] Said Mohammed, *Public health related TRIPS-plus provisions in bilateral trade agreements, A policy guide for negotiators and implementers in the WHO Eastern Mediterranean Region*, WHO, (2010).

the party shall not allow third-parties that do not have the consent of the party providing the information to market the same or a similar product on the basis of the approval granted to the party submitting such information for a period of at least five years from the date of approval for a pharmaceutical product and ten years from the date of approval for an agricultural chemical product.

This means that the earlier test data which are submitted by the drug manufacturing company in the first place cannot be relied on by the generic manufacturers, and this situation even exists in cases where a drug is not patented. The generic manufacturer will have to conduct clinical trials to get approval for marketing the drugs that have already been done and thus will have to incur enormous costs for the same. Not only that, since the generic manufacturers also are to conduct clinical trials, making the generic drugs also becomes expensive. Conducting clinical trials for drugs that are already tested and approved is unethical. Such a clinical trial would result in the generic manufacturing company incurring large amounts to conduct the clinical trial. The whole idea of the production of generic drugs is to reduce the price of medicines. In this case, the generic versions also become expensive.

4.2.4 PATENT LINKAGE

Patent linkage is referred to as "the practice of linking the granting of ... any regulatory approval for a generic medicinal product to the status of a patent for the originator reference product".[114]Patent Linkage is not explicitly mentioned in the TRIPS Agreement. However, many countries such as the US, Canada, and Japan, as a part of the FTAs concluded by them, recognize Patent linkage.

The E.U. does not allow Patent Linkage requirements in their FTAs as it is considered an anti-competitive instrument by the European Commission. According to the European Commission, the patent linkage would delay the entry of generics and biosimilars into the market. In the U.S., the concept of Patent linkage is statutorily provided under the Drug

[114] European Commission, European Commission Pharmaceutical Sector Inquiry Final Report 2009, http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf (last visited 13 May 2021).

Price Competition and Patent Restoration Act, 1984 (The Hatch-Waxman Act 1984). A patent linkage prohibits the drug regulatory authority of a country from approving a drug if there is a patent in effect for that drug, even if it is a frivolous one.

KORUS FTA is a bilateral trade agreement negotiated in the year 2007 between the U.S. and Korea and came into force in the year 2012. Provision on Patent linkage was included in the KORUS FTA.

Article 18.9.5 of the KORUS FTA states that:

when a non-originator manufacturer of a pharmaceutical product applies for marketing approval, the relevant patent owner must be notified of the identity of the person who makes such request. The government must have measures implemented to prevent such other persons from marketing a product without the consent or acquiescence of the patent owner during the term of a patent notified to the approving authority as covering that product or its approved method of use".

With Patent Linkage, it is ignored that the rights conferred by patents are private, and the legal concerns around patents are entirely a separate issue. They are not concerned with the safety and efficacy of drugs. Patent linkages oblige the public authorities to enforce private intellectual property rights which do not have any knowledge in areas relating to patents.[115]Patent linkage refers to the application of a conditional relationship between the granting of marketing approval for a patent status of the originator reference product and the generic product.[116] The patent linkage system creates an exclusive right that prevents the marketing approval of a pharmaceutical product which can be used to deter generic competition.

Patent linkages are seen to have a negative effect on Countries by extending the ability of generic drugs to enter the market, and the detrimental impact of patent linkage has also been established in countries with the widespread presence of HIV, for instance, in

[115] Report of the United Nation's Secretary-General's High-level panel on Access to Medicine, p26, (2016)

[116] Son K-B, Lee T-J, *The trends and constructive ambiguity in international agreements on intellectual property and pharmaceutical affairs*, Glob Public Health, 1169, (2018).

Ukraine.[117] The simplest way to achieve a balance in the Patent linkage is by not incorporating them in the FTAs, as the E.U. does. This will help save a country's national health care system and the economy as patent linkage results in delaying generic entry into the market and increasing the cost of medicines.[118]

4.2.5 RESTRICTIONS ON THE USE OF COMPULSORY LICENSES.

The TRIPS Agreement recognizes the use of compulsory licensing, and Article 31 of the TRIPS Agreement provides conditions in which compulsory licensing can be granted. It also gives the discretion to the member states to decide on the grounds on which such compulsory licensing can be granted. Even then, the choice that the States may avail to use compulsory licensing can be, to a great extent, limited by FTAs entered between them. Despite the Doha declaration, which affirms the rights of the countries to use compulsory licenses, the U.S. is trying to limit the scope of compulsory licensing through the FTAs.

Article 31 of the TRIPS Agreement does not put any limitation on the countries as to the grounds for providing compulsory licensing or why non-commercial governmental use may be adopted. It is left to the nations to decide on the matter. Some FTAs, such as the FTA of the U.S. with Jordan, Singapore, and Australia, restrict this freedom available to the government and confines it to cases of anti-competitive practices, non-commercial public use, or national emergency, or other circumstances of extreme urgency.[119]

The U.S.-Jordan FTA provides those grounds on which compulsory licensing can be granted by Jordan and thus limits the capacity of the State in issuing compulsory licensing.

Article 4.20 of the FTA states that:

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[117] UNDP, *The State of Ukrainian National Legislation: Opportunities to use TRIPS Flexibilities,* Available at http://www.undp.org.ua/images/stories/ IPRandAEM_Kyiv/BackgroundPaperFinal_ENG.doc, last accessed on February 20,2021.

[118] Laurenza Eugenia, *The Scope of Patent Linkage in the US-South Korea Free Trade Agreement and the Potential Effects on International Trade Agreements,* 6 EUR. J. Risk REG. 439 (2015).

[119] Correa M,Germán Velásquez, *Access To Medicines: Experiences With Compulsory Licenses And Government Use – The Case Of Hepatitis C,* Research paper 85, South centre April (2019).

Neither party shall permit the use of subject matter of a patent without the authorization of the right holder except in the following situations:

a. to remedy a practice determined after the judicial/administrative process to be anti-competitive;

b. in case of public non-commercial use or a national emergency or other circumstance of extreme urgency, provided that such use is limited by government entities or legal entities acting under the authority of any government; or

c. on the ground of failure to meet working requirements provided that importation shall constitute working.

After 2005, when the transitional period provided under the TRIPS agreement expired, the negative effect of restricting compulsory licenses increased because, at that time, the generic manufacturers had to rely on voluntary and compulsory licenses.[120]

4.2.6 REDUCTION OF TRANSITIONAL PERIODS.

A transitional period under the TRIPS Agreement was provided in order to give the countries a period to make changes to their system to cope with the more substantial Intellectual Property rights contained in the TRIPS Agreement. A transitional period of one year was provided to the developed countries[121], developing countries[122] were given a 4-year transitional period, and the Least Developed Countries were given a transitional period of 10 years under the TRIPS Agreement.

Annex VII.3 of the E.U.–Jordan Association Agreement states that:

Jordan undertakes to provide for adequate and effective protection of patents for chemicals and pharmaceuticals in line with Articles 27 to 34 of the WTO Agreement on Trade-

[120] Mercurio Bryan, *TRIPS Plus provisions in FTAs: Recent Trends*. Regional Trade Agreements And The WTO Legal System, 215, 232,(2006).

[121] Article 65.1, TRIPS Agreement.

[122] Article 65.2, TRIPS Agreement.

Related Aspects of Intellectual Property Rights, by the end of the third year from the entry into force of this Agreement or from its accession to the WTO, whichever is the earliest.

This provision in the EU-Jordan Association Agreement does not recognize the privileges that are given to Jordan under the TRIPS Agreement and state that it should provide for the protection of patents of chemicals and pharmaceuticals within three years, which would be two years before the period provided under TRIPS Agreement for Jordan. The reduction of transitional periods may have an adverse effect on these countries because it would reduce the time available for them to prepare themselves for more robust Intellectual Property Protection provided under the TRIPS Agreement.

4.2.7 RESTRICTIONS ON PARALLEL IMPORTING

Parallel importing of medicines helps those countries which have a weak developing capacity and rely on export activities. Parallel importing increases the availability and accessibility of drugs and thus reduces the price of medicines. It will also bolster the generic production of drugs. When a restriction is imposed on parallel importing, the generic manufacturers will not be allowed to export the medicines overseas, which will be cheaper than the ones available for them in the market. This restriction imposed on parallel will result in increasing the cost of drugs.

Article 6 of the TRIPS Agreement states that:

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4, nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

This article is the result of a compromise made between countries supporting a system of international exhaustion and parallel imports and national exhaustion at the Uruguay round. Article 6 TRIPS Agreement leaves WTO member countries a choice to adopt between national, regional, or international exhaustion regimes. The neutral wording in article 6 of

the TRIPS Agreement was accepted by the U.S., which permits them to induce other countries to adopt measures that restrict parallel importing.[123]

Parallel importing takes place without the consent of the patent holder. It involves the import and resale in a country of a patented product that is put on the market of the country that exports in a legitimate manner by the titleholder. Since the patent holder will already be rewarded for the invention through the first sale of the product, the right of the inventor gets exhausted there.[124]

Also, unlike flexibilities like compulsory licensing that requires the member to prove that such flexibility has been adopted due to some medical emergencies, parallel importing does not require such a condition. The developing countries can resort to parallel importing without being questioned by the other WTO members.

The FTA of the U.S. with Morocco in Article 15(9)(4) and the FTA of the U.S. with Australia in Article 17(9)(4) restricts parallel importation.

Article 15(9)(4) of the US-Morocco FTA states that:

Each party shall provide that the exclusive right of the patent owner to prevent the importation of a patented product or a product that results from the patented process without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory.

Article 17(9)(4) of the U.S.- Australia FTA states that:

Each party shall provide that the exclusive right of the patent owner to prevent importation of a patented product or a product that results from a patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on importation by contract or other means.

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[123] Bonadio, E. *Parallel Imports in a Global Market: Should a Generalised International Exhaustion be the Next Step?*. European Intellectual Property Review, 33(3), pp. 153-161, (2011).

[124] Correa M, *Public health and intellectual property rights*, 2(3), Global Social Policy, 261, 269, (2002).

4.3 ELI LILLY V. CANADA (ICSID Case No.: UNCT/14/2)

Free Trade Agreements with investment provisions and Bilateral Investment Treaties widen the enforcement of IPRs by incorporating them as a covered investment. The rules and regulations that interfere with patent and data-protection rights might conflict with the investor protections under the Agreement and make countries subject to investor-state disputes for their public health policies.

Eli Lilly v. Canada was an investment dispute under the investment chapter of NAFTA in 2012. The dispute was filed by Eli Lilly, a U.S. pharmaceutical company, against Canada. Eli Lilly was the manufacturer of two successful drugs, Strattera and Zyprexa, that successfully treated attention-deficit hyperactivity disorder (ADHD) and schizophrenia which were patented. The court revoked these patents after being challenged by generic manufacturers. The patents were challenged on the grounds of their utility based on the promise utility doctrine under the Canadian patent law. This dispute was the first Investment State arbitration that dealt with patent rights as an investment. The decision to be taken by the Arbitral Tribunal was whether the Canadian government complied with the standards of treatment envisaged under international law.

The arbitral tribunal here decided the case in favor of the State. It held that Canada's decision to revoke the patents was not in violation of the fair and equitable treatment standard. According to Article 40(1) of UNCITRAL Rules, Eli Lilly was liable to bear the cost of Arbitration along with Canada's Arbitration and legal fees. Even though the decision was in favor of the Canadian government, the tribunal did not consider the frivolity in the claims made by Eli Lilly.

Eli Lilly v. Canada is not the only case wherein pharmaceutical companies used international investment agreements to attack decisions to alter patent protections of medicines for public health objectives. Still, there are cases such as Novartis-Colombia, and Gilead-Ukraine ISDS claims. These arbitrations demonstrate that the governments face a crisis in the domestic policy space created by the chilling effect that the investor-state Arbitration has on the domestic health measures. This also shows the extraordinary power

that is vested with the corporations even to challenge the national sovereignty over I.P. policy and public health and to promote private Arbitration of public interest.[125]

4.4 NOVARTIS V. COLUMBIA

In 2014, a group of public health organizations of Columbia requested the government of Columbia to declare Glivec (also known as Imantib) as medicine of public interest and issue compulsory licensing on the same. This drug was considered a magic bullet to treat leukemia, and WHO added it to the list of Essential Medicines in 2015. In 2015, the Columbian government decided to declare a blood cancer drug Glivec, a medicine of public interest, as the high price of the medicine made it unsustainable for the Columbian public health budget. Declaring this as medicine of public interest would bring down the cost of the drug by the introduction of generics into the market.[126]

This was vehemently opposed by Novartis, the company that had the patent over Glivec. This was because Novartis had been making a considerable profit from this drug, and the revenue accounted for 10% of the company's total revenue. It threatened to sue Columbia in the International Arbitration Tribunal, and the claim that was made was that the Columbian government had violated its Bilateral Investment Treaty with Switzerland. Novartis also argued that issuing a compulsory license for the drug and reducing the drug's price would amount to the expropriation of the patent on Glivec and that Columbia violated the company's legitimate expectations.

The threat to initiate arbitration was not only made by Novartis but also by the U.S. government and Switzerland governments. Even though the drug's price was reduced to 44%, the government did not dare to overthrow the monopoly of Novartis and issue a compulsory license. Pharmaceutical companies such as Novartis have been using a large amount of their financial resources to avoid the use of compulsory licenses around the world. Actions like these by the pharmaceutical companies ensure that they gain massive

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[125] Baker Brook , Geddes Katrina, *The Incredible Shrinking Victory: Eli Lilly v. Canada, Success, Judicial Reversal, and Continuing Threats from Pharmaceutical ISDS*, 9, Loyola University Chicago Law Journal, (2017).

[126] Novartis V. Columbia: How Big Pharma sabotaged the struggle for affordable cancer treatment, Available at https://10isdsstories.org/cases/case2/, last accessed on 24.08.21.

profits from manufacturing these medicines, eventually making the lives of millions in dire need of medicines miserable.[127]

4.5 CONCLUSION

One of the significant justification put forth for more robust global patent protection through TRIPS and TRIPS-plus provisions is that increased IPR Protection would incentivize the development of life-saving drugs.[128] It can be seen from today's patent systems that it is, to a large extent, based on the market dynamics of industrialized countries.[129] The patent system comprising of the TRIPS and TRIPS-plus provisions to a great deal is designed for the pharmaceutical companies to recover the cost incurred by them on developing the drug, marketing the drug, and also to help them gain profit.

Little or no concern is shown on how the patent system or these provisions would affect the lives of millions of people by denying their access to medicine. The TRIPS-plus provisions in the regional and bilateral trade agreements are said to strike a wrong balance between the interest of the patent holders and the interest of the general public.[130] One of the problems that are attributed to the TRIPS-plus provisions in the Free Trade Agreements is that it creates an obstacle to the developing countries to fully use the flexibilities that came about with the Doha Declaration on the TRIPS Agreement and Public Health.

Since the majority of the population in the least developing countries live below the poverty line, even a slight increase in the price of medicines would result in them being inaccessible to them. The past decades have seen the revolutionary development of life-saving drugs. With the TRIPS-plus patent protections that these medicines have, it becomes financially unsustainable, and often, people are saddled with demanding out-of-pocket expenses.

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[127] Ibid.

[128] Outterson K. *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5(1), Yale Journal of Health Policy, Law and Ethics, ,193, (2005).

[129] Tvedt M, *One Worldwide Patent System: What's in It for Developing Countries*?, 31(2) Third World Quarterly, 277, (2010).

[130] Watkins Kevin, *The Threat to Developing Countries*' UNDP Human Development Report Office Occasional Paper, 10–2 (2005)

Several Latin American negotiators negotiating FTAs with the U.S. have expressed their fear of having to agree to the TRIPS-plus provisions if they want to get concessions on the goods and agriculture from the USA. [131] The countries that enter into these FTAs has no other option but to accept the demands made by the U.S. Clearly, the TRIPS-plus provisions in these FTAs are designed to best suit the interest of the U.S. These TRIPS-plus provisions are identical to the domestic laws of the U.S. TRIPS-plus provisions in the U.S. bilateral and multilateral Free Trade Agreements include "limiting the potential exclusions from patentability, requiring the grant of patents for 'new uses' of known compounds, requiring the extension of patent terms under certain conditions, preventing parallel importation, limiting the ground on which compulsory licenses can be granted, and permitting the prosecution of non-violation nullification or impairment claims."

This being the case, any country that agrees to enter into a Free Trade Agreement with the U.S. is bound by this term, which clearly limits or eradicates the flexibility provisions provided in the TRIPS Agreement and Doha Declaration. The Doha Declaration is a hard-fought bargain made by the developing countries, LDCs, NGOs, and activists to address public health concerns and enhance access to medicines. Also, the TRIPS flexibilities had the role of helping the developing countries adapt to the higher standards of IP protection. In reality, countries face extremely difficult or even impossible to implement TRIPS flexibilities that get robbed by the stronger IP protections brought about with the FTAs. The countries seeking stronger IP protection should not lose sight of the fact of real-world consequences for millions of patients around the world.

Similar is the case of the proposed EU-India FTA. The TRIPS Plus provisions in protecting the Intellectual property that is proposed by the EU, if implemented, will severely affect the generic industry of India. Not only the Indian generic manufacturers get affected by such a move of the EU, but millions of patients globally depend on India for affordable drugs. The EU has also proposed border regulations in the FTA, which has already been proved to affect the generic industry of India. In 2008 and 2009, the European customs officials detained more than 20 ships containing generic drugs from India based on the fictional patent violation. India criticized this seizing of medicines in the name of fictional patent

[131] David Vivas-Eugui, *Regional and bilateral agreements and a TRIPS-plus world: the Free Trade Area of the Americas (FTAA*), TRIPS Issues Papers 1, (2003)

violations for violating the principles of the TRIPS Agreement. These kinds of border measures result in interfering with legitimate trade and threaten access to medicine.

Also, the RCEP (Regional Comprehensive Economic Partnership), which was initiated in 2012, is a proposed FTA between the ten ASEAN member states and its six FTA partners has brought in concerns that this proposed FTA would restrict the access of affordable medicines to the people of countries that are part of the FTA. A number of IP enforcement provisions are submitted by Japan that goes beyond the TRIPS Agreement principles that would have a detrimental effect on access to medicine. Many of the conditions that are being negotiated are similar to that of the TPP (Trans-Pacific Partnership) Agreement which is considered the worst trade deal for access to medicine ever.[132]

TRIPS Agreement and TRIPS-Plus provisions have a significant impact on the regulation of public health and pharmaceutical patent protection. These provisions would result in prolonging the monopoly terms granted to pharmaceutical patents and would delay the entrance of generics into the market at an earlier stage.[133] This also would result in the medicines being expensive to the general public and can hinder the access to treatment to the people, especially the poorer sections of the society.

The delay in accessing affordable medicines may mean the difference between life and death to those fighting deadly diseases. The trade policies of these FTAs threaten to cause harm to the interests of comparatively weaker populations. The developed countries that hold patents use these higher-level IP protections and prevent developing countries from implementing TRIPS Flexibilities.

The right to health and the right to benefit from scientific progress is envisaged under the UDHR (Universal Declaration of Human Rights). Still, their enforceability and accountability mechanisms are weaker when compared to the Intellectual Property protections.[134] The developed and the developing countries should not only be utilizing the

[132] Davies B, East Asia Head of MSF Access Campaign.

[133] Said Mohammed, *The Morning After: TRIPS-Plus, FTAs and Wikileaks - Fresh Insights on the Implementation and Enforcement of IP Protection in Developing Countries*, 2, TLS Research Paper Series (2012).

[134] Report of the United Nations Secretary-General's High-level panel on Access to Medicine, p20, (2016).

flexibilities available under the TRIPS Agreement, but they also have an obligation to facilitate the utilization by the countries from a public health perspective.[135]

The governments entering in Free Trade Agreements should ensure that they do not curtail their primary rights to health and access to medicine. Patents and IP rights should not stand in the way of manufacturers developing affordable generic life-saving drugs.

The world will ultimately become a difficult place to live in for the people of the developing countries if the countries such as the U.S., which is a developed country and has a responsibility to ensure global welfare, resort to practices that ultimately affect the public health of the people around the globe.[136] Many developing countries are struggling with the already incorporated TRIPS Agreement into their national laws. With TRIPS Plus obligations, these countries are overburdened in protecting the healthcare needs of their people.

These TRIPS-Plus provisions in the FTAs are not mere threats but are concrete barriers that impede the right to health and access to medicine. When Nations enter into FTAs with little or no preparation without taking into account the consequences it will have, they will likely be burdened with obligations that will erode their capacity to use TRIPS flexibilities, ultimately failing to protect the right to health of their people. The trade benefits that arise from these FTAs should not impede the public health rights of the people. Ultimately, it is to be understood that all these I.P. protection, be it under the TRIPS Agreement or the TRIPS-plus provisions in the FTAs, are at the expense of the primary rights of the citizens to access medicine and their right to health

CHAPTER 5

[135] Musungu Sisule, Cecilia, *The Use Of Flexibilities In Trips By Developing Countries: Can They Promote Access To Medicines?,* 35,South Centre (2006)

[136] Supra note 5.

CONCLUSION, SUGGESTIONS, AND RECOMMENDATIONS

5.1 INTRODUCTION

"Bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries."[137]

The developing countries are forced to accept the TRIPS-plus obligations put forth by the wealthier nations during the bilateral negotiations. Countries that have already incorporated TRIPS-plus obligations in their IP regime have had worrying consequences. Ultimately, the lives of the people and their basic rights should not be sacrificed for the trade gains of the countries.

The present patent system itself is flawed as major health needs are unmet even after more than 25 years of the TRIPS Agreement coming into force. The present patent system is used to incentivize the research and development of drugs, keeping the prices of drugs high and also investing in R&D for unimportant medicines. There is a dearth of investments when addressing the public health needs of the poor.

The lack of R&D means that very few drugs are in the market to treat the diseases that affect the poor. If at all available, the exorbitant prices of these medicines keep them away from the reach of the disadvantaged. This creates an imbalance between the needs of the people and the availability of medicines which results in the death of millions. Innovations and R&D is pointless if the medicines remain inaccessible to the needy. Thus, the dearth of innovation and R&D is not the only issue.

Also, studies show that there is very little invention happening because of the patent system. The pharmaceutical industry fails to identify the public health needs and sets wrong research priorities. The present R&D is concentrated in areas that have high demand. Due to their poverty, the poor people's public health demands are often unanswered as they fail to come

[137] Recommendation no: 4.26, Public Health, Innovation and Intellectual Property Rights Report of the Commission on Intellectual Property Rights, Innovation and Public Health April, 2006.

up with effective demand. The research activities are profit-oriented and are in the interest of the market rather than the global health needs.

The World health statistics every year show remarkable progress in areas such as the Average life expectancy, maternal mortality rate, infant mortality rates, etc. But assuming that this impressive statistic is a universal one is wrong on so many levels. Millions of people, particularly those belonging to the underprivileged population, die every year due to diseases that could be preventable or treatable. The link between poverty and health is a strong one. This is also a vicious cycle as poverty is one of the main contributors to ill health, ill-health in people reinforces poverty.

People belonging to the Low- and Middle-Income countries suffer the most, carrying a disproportionate burden of disease. Eliminating these gaps between the developed countries and LMICs remains a difficult task because R&D done by the pharmaceutical companies does not focus on the diseases that affect mainly the LMICs. Also, the TRIPS Agreement, along with the TRIPS-plus provisions of FTAs, let alone eliminates these gaps between the countries but widens them.

Eventually, if the trend continues wherein the LMICs lack access to medicine, there will be a genocide by denial to access to medicine on the people belonging to LMICs. Their inaccessibility to medicine is a violation of their human right to health, and the basic right to life is denied to these people.

Access to medicine is an area that requires much attention, and the problems that this creates should be addressed on an international level. The WHO, along with other international organizations, have constantly been taking efforts to ensure access to medicine, especially to the people belonging to the LMICs.

No development can be said to be there if the health conditions of the people remain poor. A country can enter into FTAs to get trade concessions and can increase its trade through various activities. If all these are done by sacrificing access to medicine to the people of that country, the government ultimately fails.

5.2 SUGGESTIONS AND RECOMMENDATIONS

- Countries entering into FTAs should prioritize the public health of their people. Countries entering into FTAs should make sure that TRIPS-plus provisions incorporated through these FTAs will not affect their public health to the extent that the trade concession that these countries get will not be disadvantageous to the public health of the people. Priority should be given to accessing medicine, and any provision that impedes this right to access to medicine should be avoided.

- Most often, negotiators from LMICs are not aware of the consequences the TRIPS-plus provisions that they negotiate will have. The negotiators of the LMICs should be made properly aware of the consequences the TRIPS-plus provisions will have on the public health of a country.

- Provisions such as the extension of patent duration, restrictions on parallel importing, restrictions on compulsory licensing, etc., would have grave consequences on countries' public health systems. The TRIPS Agreement itself contains ambiguities. Much of it remains unclear about the flexibilities that are available and its interpretation.

- How the TRIPS Agreement is interpreted and how it can be positively used as a means to increase the public health scenario of countries and how it can protect and promote access to medicine is of much importance. The provisions of the agreement should be used in such a way that it can incentivize the inventor of a new drug and also remove the barriers in accessing medicines.

- As stated in the Doha Declaration, "The TRIPS Agreement does not and should not prevent the countries from taking measures to protect public health, and can and should be interpreted in a way that supports the rights of countries to protect public health and in particular, promote access to medicine for all."

- This is an important step that should be taken by all the countries, especially the developed ones. The developed countries should not threaten the developing countries on their right to access medicine and enhance their public health. The Doha declaration should guide the interpretation of the TRIPS Agreement in such a way that the Agreement is taken forward and interpreted and implemented in a more health-friendly way to ensure access to medicine.

- The affirmations made by the Doha declaration can also be used to shut away from the scare tactics and threats of trade sanctions that the developed countries put on the developing countries when entering into the FTAs. It should be mandated that the TRIPS-plus provisions should not be put forth as recommendations in trade negotiations as it will impede the right to health of the people belonging to the countries on which these obligations are put forth.

- The governments have a significant role in ensuring access to medicine for their people. One of the main reasons people find it difficult to access medicine is the non-availability of proper health insurance. Very often, people belonging to the LMICs have to pay the health and medical expenses out-of-pocket. The governments of these countries should ensure that their people have proper medical insurance and their health needs are met.

- The pharmaceutical industries should invest in R & D of drugs that are essential to meet the public health needs of the population rather than investing in the interest of the market. This results in suffering and loss of lives of people due to neglected diseases.

- As a matter of public policy, governments should find the best viable means to incentivize research. Alternatives to the patent system should be used to incentivize the inventions due to the existing flaws in the patent system. Nevertheless, the government has a duty to balance the social interest as well as the economic interest. Thus, it is imperative to switch to an alternative system to incentivize the inventor and further the cause of public health and access to medicine.

- The role of governments and NGOs in sensitizing people about the importance of access to medicine and the right to health is inevitable. Most often, these rights are blatantly violated by the big pharmaceutical companies and even by the governments. It is a fact that these people may not even realize that their rights are being violated. The people should be educated about their fundamental right to health and their right to access medicine.

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