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„A Critical Analysis of the Impacts of TRIPS in Developing Countries Regarding Patented Drugs– with Special Reference to Jordan. “

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Table of abbreviations

I	DE	Different ages
II	DRC	Drugs Registration Criteria
III	JFDA	Jordan Food and Drug Administration
IV	EC	European Commission
V	ECJ	The European Court of Justice
VI	EU	European Union
VII	FDI	Foreign Direct Investment
VIII	FTA	Free Trade Agreement
IX	GATT	General Agreement on Tariffs and Trade
X	GDP	Gross Domestic Product
XI	GSP	Generalized System of Preferences
XII	IO	International Organization
XIII	IP	Intellectual property

XIV	IPR	Intellectual property rights
XV	JEUAA	Jordan–European Association Agreement
XVI	JUSFTA	The Jordan-United States Free Trade Agreement
XVII	MENA	Middle East and North Africa
XVIII	MPIA	Multilateral Interim Appeal Arrangement
XIX	NGOs	Non governmental organization
XX	R&D	Research and Development
XXI	RBT	Rules Based Trading
XXII	TEU	Treaty on European Union
XXIII	TFEU	Treaty on the Functioning of the European Union
XXIV	TRIPS	Trade-Related Aspects of Intellectual Property Rights
XXV	UN	United Nations
XXVI	UPOV Convention	International Union for the Protection of New Varieties of Plants
XXVII	VGL	The Van Gend en Loos

XXVIII	WIPO	The World Intellectual Property Organization
XXIX	WTO	World Trade Organization

A Critical Analysis of the Impacts of TRIPS in Developing Countries Regarding Patented Drugs– with Special Reference to Jordan.

Abstract:

This thesis deals with the implementation, enforcement and development of intellectual property laws and regulations in the Hashemite Kingdom of Jordan. The thesis covers the development of intellectual property laws in the last decade and the preceding decade, in addition to the existing trade agreements between the Jordanian state and the United States of America, and the tangible effects of this agreement on Jordan in particular and its developing neighboring countries.

In addition to the trade agreements between the Jordanian state and the European Union and the role that these agreements have played, followed by the member states joining the World Trade Organization and what the European Union is doing to influence them.

This thesis clarifies the general nature of intellectual property laws in force in Jordan and the extent of their economic, political and social compatibility as well compared to the reality in which Jordan lives as a newly emerging developing country. This thesis argues that Jordanian intellectual property laws lack an economic fabric Regarding Patented Drugs, mainly because it is not compatible with the Jordanian culture and is not compatible with the stage of economic development in Jordan.

In addition, the thesis argues that intellectual property laws have had little economic impact on developing countries, and it specifically discusses the role that the TRIPS Agreement has played on these countries. Finally, the thesis disputes the legal perspective followed by the European Union countries to implement the TRIPS Agreement and the obligations it entailed, especially that the European Union countries were the first to call for the protection of intellectual property rights.

Abstrakt:

Diese Diplomarbeit befasst sich mit der Umsetzung, Durchsetzung und Weiterentwicklung von Gesetzen und Vorschriften zum Schutz des geistigen Eigentums im Haschemitischen Königreich Jordanien. Die Arbeit behandelt die Entwicklung der Gesetze zum geistigen Eigentum im letzten Jahrzehnt und im vorangegangenen Jahrzehnt, zusätzlich zu den bestehenden Handelsabkommen zwischen dem jordanischen Staat und den Vereinigten Staaten von Amerika, und die konkreten Auswirkungen dieses Abkommens auf Jordanien im Besonderen und seine Entwicklung Nachbarländer.

Neben den Handelsabkommen zwischen dem jordanischen Staat und der Europäischen Union und der Rolle, die diese Abkommen gespielt haben, folgte der Beitritt der Mitgliedstaaten zur Welthandelsorganisation und was die Europäische Union unternimmt, um sie zu beeinflussen.

Diese Arbeit verdeutlicht die allgemeine Natur der in Jordanien geltenden Gesetze zum Schutz des geistigen Eigentums und das Ausmaß ihrer wirtschaftlichen, politischen und sozialen Kompatibilität im Vergleich zu der Realität, in der Jordanien als aufstrebendes Entwicklungsland lebt. Diese Arbeit argumentiert, dass es den jordanischen Gesetzen zum geistigen Eigentum an einem wirtschaftlichen Gefüge in Bezug auf patentierte Arzneimittel fehlt, hauptsächlich weil es nicht mit der jordanischen Kultur und dem Stand der wirtschaftlichen Entwicklung in Jordanien vereinbar ist.

Darüber hinaus argumentiert die Dissertation, dass Gesetze zum Schutz des geistigen Eigentums wenig wirtschaftliche Auswirkungen auf Entwicklungsländer hatten, und sie diskutiert speziell die Rolle, die das TRIPS-Abkommen für diese Länder gespielt hat. Schließlich bestreitet die Dissertation die rechtliche Perspektive, die von den Ländern der Europäischen Union verfolgt wurde, um das TRIPS-Abkommen umzusetzen, und die damit verbundenen Verpflichtungen, insbesondere, dass die Länder der Europäischen Union die ersten waren, die den Schutz der Rechte des geistigen Eigentums forderten.

Chapter 1: Introduction

In current years, there has been significant advancement and improvement in intellectual property laws and regulations. The cause for this is the increase in the volume of trade and business operations, particularly in international activities.

The necessity for IP laws beyond national borders, as well as the improvement of national intellectual property laws, became apparent as a result of this. The Agreement on Trade-Related Aspects of Intellectual Property Rights (Agreement on TRIPS) is an example of such an endeavor.

The TRIPS agreement is the most controversial agreement of history because of its historic background and has drastic financial implications for developing countries. TRIPS agreement aims to provide Intellectual Property (hereinafter, IP) protection to the person who has some specific right in IP but due to such protections, it comes into conflict with the developing countries (DC) and least developing countries (LDCs) which have different prospects and issues contrary to TRIPS.

DC and LDCs showed their concern regarding the increasing demands of the developed countries for the extremely rigorous protections to be implemented by the DC and LDCs for IP protection. Such countries are also unsatisfied due to increased demands for IP protections excessive to that what they were promised in TRIPS negotiation rounds. The developed countries forced such countries to sign regional and bilateral agreements i.e., TRIPS-plus, in addition to TRIPS for the IP protections which has more harsh impact and stringent control for IP laws.

Most of the DCs claimed that such additional agreements overlook their native requirements, countrywide interests, technological capacities, institutional abilities, and public healthcare situations." Such raised issues ultimately led to the formulation of a set of development agendas at the WTO and other international forums.[1]

IP is the properties that are intangible in nature and relate to the idea, creative work, research, and inventions i.n. biotechnology inventions, brand music, artistic work, and writing of a person.[2]

[1] Peter K Yu, 'A Tale Of Two Development Agendas' (2009) 35 Ohio Northern University Law Review 511.
[2] Roberto Romandini, 'Flexibilities Under TRIPS: An Analysis Of The Proposal For Reforming Brazilian Patent Law' (2016) 15 John Marshall Review of Intellectual Property Law 150.

IPL admires such work of a person and grants them limited protection concerning their use and compels the others who utilize benefit from such invention to pay back such person in the shape of royalties. These royalties and taxes for the use of patented and copyright work seem justified but they cause severe financial burden and restraints on the DC and LDCs. For instance, in the area of patented drugs, IP law causes a drastic financial burden on the DC and restricts their access to such drugs, and ultimately, brings suffering patients.

The medicines of severe diseases i.e. Cancer, HIV/AIDS, and Hepatitis are already costly and through incentive payment, their availability becomes less as incentives raise the cost of medicine in the developing countries and make them completely inaccessible in the case of LDCs.[3]

Patented drugs are drugs that are essential life-saving drugs which access are inevitable for the patients and in case of their non-provision, they can cause drastic impacts on the health of patients. But these drugs are protected under the patents laws specifically under Intellectual Property Laws (IPL) which legally bounds the countries which are using or manufacturing generic medicine of such patented drugs to pay royalties or incentives to the original manufacturer of these drugs who holds all the patents rights regarding such medicines on account of his/her innovative work or research.

The countries that use this formula and rights for the creation of generic medicine pays incentive to the original manufacturers for that use.[4] Several factors contribute to the non-provision of the patented drugs to patients i.e. high prices, the inability of manufacturing generic medicine, corrupt government practices, improper and insufficient health-related legislation, and regulation, etc but these all are secondary factors that are generated due to barriers placed by the TRIPS Agreement in the shape of patent law.

IPL protects the patent rights of a manufacturer regarding patented drugs and restricts its access to the countries which are not in compliance with the provisions given under TRIPS Agreement as patent protections. After the implementation of the TRIPS Agreement, the developing countries have only the option to import generic medicine from the other countries if they do not have manufacturing abilities through compulsory licenses. But the cost of HIV-AIDs medicines was too high and caused around fifteen to twenty thousand US dollars per patient yearly.[5]

The LDC like South Africa (SA) was unable to bear that pressure. The conflict between IPL and healthcare was thoroughly raised in 1997 when the prevalence of the AIDs crisis in SA provoked

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[3] Carlos M Correa, *Intellectual Property Rights, The WTO And Developing Countries* (Zed Books 2000) 60-80.

[4] 'World Trade Organization TRIPS: Faqs Frequently Asked Questions About TRIPS In The WTO' (2019) <http://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm> accessed 28 October 2021.

[5] Jhanvi Tripathi, 'The TRIPS Agreement And Public Health: Understanding The Reform Agenda' (2021) <https://www.orfonline.org/research/the-trips-agreement-and-public-health/> accessed 31 October 2021.

its government to negotiate about the TRIPS impacts and find flexibility in the patent laws relating to patented drugs of HIV-AIDs. Subsequently, SA enacted the Medicines and Related Substances Act of 1997 to get generic medicine imports under compulsory licenses at low rates which was hardly hit by foreign medicine companies and this action was regarded as non-compliance with TRIPS by the US. The US threatened the SA for inflicting monetary sanctions in case of non-compliance. Resultantly, SA has to back off.[6]

I. Background:

The signing of the TRIPS agreement is an essential requirement for being a member of WTO. The ostensive reason for implementing such an obligation in the Uruguay Rounds was the infringement of IP laws which was causing a major indentation in the global trade and distorting the national trade of the USA.

The negotiation in the Uruguay Round of (General Agreement on Trade and Tariffs) GATT regarding IP laws was initiated by the USA which evidenced the total trade deficit of 60 billion US dollars to the US traders, ultimately resulting in the loss of 200000 jobs annually. These were the claims made by the US in the congress too and revealed the reason for such loss of infringement of IPs and piracy.

Similar figures were presented by Europe as a result of the survey held under counterfeiting EU directives. The result of 2000 studies done by the Center of Economics and Business Research on the same issue in Europe showed the result in the pharmaceutical sector that caused a loss of 292 million due to counterfeiting. The raised concerns regarding counterfeiting and piracy of IP laws resulted in the documentation of a new agreement called TRIPS.

The roots of the TRIPS Agreement are associated with the Marrakesh Agreement 1994 and the creation of the World Trade Organization (WTO). Before the TRIPS Agreement, various instruments and institutions were managing IP-related issues.

The General Agreement on Trade and Tariffs 1947 (GATT) had provisions relating to IPs. As a result of the Uruguay Round in 1986 and the Marrakesh Agreement in 1994, the trade-related aspects of IP were discussed and as a result of the several proposals regarding compulsory licensing and disputes settlement, TRIPS Agreement was created.[7]

The TRIPs Agreement initially from its creation has been a conflicting agreement and criticized by many countries due to its strict controls for IP laws but in the 20th century, when the HIV/AIDs crisis emerged it was severely criticized by the various scholars regarding health aspects. Medicines were not included in patentable goods prior to the implementation of the

[6] Ibid.
[7] Ibid.

TRIPS Agreement in 1990. Essential medications, for example, were unpatented in France and West Germany until 1967, and in Spain and Italy until 1992. However, when the WTO made it mandatory for member countries to implement the TRIPS Agreement and enact national legislation in accordance with its rules in the pharmaceutical and technology fields, a disagreement arose.[8]

This requirement also included adoption flexibility for developing nations until 2005 and LDCs until 2016. Even rich countries like the United States put pressure on member states to embrace the more severe TRIPS-plus Agreement. Because of the high level of IP control, drug prices in underdeveloped nations are higher, and medicine accessibility is limited due to high rates.

I.2 Overview of TRIPS Agreement

Intellectual Property Rights (hereinafter IPR) consist of copyrights, trademarks, undisclosed information i.e., secret data and secret formulas, patents, the layout of Integrated circuits, and industrial designs are covered under the Trade-Related Aspects of Intellectual Property Rights (TIPPS) Agreement which came into force in 1995 and known as the most comprehensive multinational treaty on IPR. TRIPS agreement covers all types of IP laws protections, therefore it is known as the first international agreement which provides all the protection in the field of IPRs.

The idea behind the presenting Trips Agreement was the protection of IPs because, with the increase in the use of products that consist of IPR i.e., patents, trademarks, copyrights, etc., the threat of use of these products without authority was increasing and if that threat increased the there was a danger to the proportion of trade order.[9]

To secure these services and goods, there was the need for a law that protected them internationally. Although there were several agreements were existed before TRIPS which were working with aim of IPs protections i.e., the Paris Convention for the Industrial property rights covering patents and trademarks, and Berne Convention relating to copyrights but the protections provided by these conventions were insufficient and related to selective areas of IP laws.

Therefore to fulfill that need an international agreement was drafted in the next Uruguay Round of GATT in 1986. With other agreements in this round TRIPS agreement was also discussed and

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[8] Junaid Subhan, 'Scrutinized: The TRIPS Agreement And Public Health' (*PubMed Central (PMC)*, 2006) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2323529/> accessed 2 June 2022.

[9] Justin Malbon and Charles Lawson, *Interpreting And Implementing The TRIPS Agreement* (E Elgar 2008).

passed in finally in 1994 in Morocco. Later on, along with the enforcement mechanism became part of the WTO agreement in 1995.[10]

I.3 Provisions of TRIPS Agreement

The provision of TRIPs related to patent and copyrights and patented drugs are discussed in this chapter because the subject of the research study is the impact of TRIPs related to patented drugs and to cover the subject. A brief overview to understand the key terms is discussed below:

Copyrights: Article 9-14

Copyright protection is related to procedures, expression, and operation methods.

The copyrights are discussed under articles 9-14 of the TRIPs. Article 9-21 is related to the Berne convention which is applicable as it is in TRIPs but the member states do not have any obligation regarding this. Article10 related to computer programs and data, whereas other articles related to rental rights, limitations, and other protections. The limitation period for copyright protection is the natural life of a person but in the case of artistic work it goes on even after the life of that person.

Patents: Article 27-34

Patents are the rights of a person if registered, not the creation, sale, and use of the other person, a similar thing which the owner has produced. The research and development, and innovation fall under the ambit of patent, therefore patented drugs are prohibited to be copied or made without the payment of royalties and other taxes.

Article 28 protects such rights. Article 29 deals with the manner in which the owner of the invention will disclose it for its registration. Article 31 details the circumstances that permit the use of patent products without the consent of the owner. Article 33 says the terms for patent protection are 20 years. article 34 deals with the burden of proof in case of conflict regarding patented drugs.[11]

Trademarks: 15-21

Article 15 states what includes in the definition of Trademarks i.e., names, letters, color combinations, article 16 deals with the rights of a person who is a trademark's owner. Article 17 deals with the fair usage policy as an exception to trademark use. Article 18 gives the period for

[10] Mart Leesti, 'Historical Background, General Provisions And Basic Principles Of The TRIPS Agreement And Transitional Arrangements' (1998) 3 Journal of Intellectual Property Rights 68-73.
[11] Duncan Matthews, *Globalising Intellectual Property Rights* (Taylor and Francis 2013).

registration of trademarks which is seven years, whereas article 18 talks about termination of trademarks in case of non-usage for the period of three years after registration.[12]

Industrial Designs: 25-26:
TRIPS Articles 25-26 define the basic standards for design registration regulations in member states.

Layout Designs of Integrated Circuits:
Articles 35-38 of TRIPS establish minimal standards for layout design, i.e. topographies of integrated circuits, and national regulations.[13]

II. Research Objective

The reason for this study is to evaluate the impacts of the TRIPS agreement on developing countries and with specific reference to Jordan who recently joined the TRIPS-plus agreement. For that purpose, all the social, legal, economic, political impacts will be discussed in detail.

The reason for conducting this study is to find out the conflict between developing and developed nations regarding TRIPS agreement, to find out the reasons why developing countries have a conflict with strict TRIPs applications and what are the impacts of such strict rules on the developing countries, especially in Jordan. These impacts will be explored and examined relating to the issue of patented drugs to summarize the topic and narrow down its scope.

II.2 Research Questions

What are the patented drugs and why are they essential for patients?

What are the Intellectual Property Laws and how does the TRIPS Agreement cover these laws?

What are the social impacts of the TRIPS Agreement concerning patented drugs?

What are the legal impacts of the TRIPS Agreement and how do they impact the member states?

What are the economic implications of TRIPS and TRIPS-plus for Jordan?

Whether the TRIPS agreement caused any health crisis for Jordan or not?

What is the possible solution to overcome the healthcare barriers if any caused by the TRIPS Agreement?

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[12] TRIPS Agreement 1994. Art 18.
[13] Peter K Yu, 'TRIPS And Its Discontent' (2006) 19 Marquette Intellectual Property Law Review 369.

II.3 Research Methodology

The qualitative research methodology will be adopted for my research thesis, and I will gather my data from all online libraries and other relevant resources to discuss the subject matter. One of the most common methods of obtaining qualitative research data is through journals and reports, which allow access to rich data that can be analyzed in a variety of ways. This research includes all published materials of patented drugs by WHO as well as "grey literature", which is mainly working in the legal and social domain.

In order to complete this research thesis, I will rely on information gathered from a variety of primary sources (books and statutes) and secondary sources such as online journals, scholar's thesis work, numerous websites, and any other accessible resources. All of the resources gathered will be reviewed with my supervisor in order to facilitate a more productive discussion.

III. Significance of Topic

Medicine is a curative commodity that should not be patented as the lives of many people are dependent on the availability of medicines. If as a result of the monopoly of drug companies the prices of the drugs increases it will directly impact the lives of patients in DC and make them inaccessible.

Nothing could be more important than the life of a person, and if that is suffering due to the non-affordability of medicines then it is in clear conflict with human rights. As access to medicine falls under the rights to life, therefore, it is much more important than securing private rights over the rights of the masses. Therefore, this thesis suggests it will be significant in bringing a possible solution to the barrier put by the TRIPS Agreement in the availability of medicines in the DC, especially in Jordan after the acceptance of TRIPS-plus.

Even the patients are not able to meet the cost of generic medicines, in this situation, there is a need for the plausible solution of this problem whether through bringing amendments in the current TRIPS Agreement or through the country-wise adjustment in Jordan for the provision of less costly drugs.

Chapter 2: Literature Review:

In this literature review section, we will investigate the existing literature on the question of patent drugs and implied constraints put by the TRIPs Agreement on the access to such drugs.

Although TRIPS Agreement protects the IP rights, it indirectly places strict constraints on the access of patented products and medications.

We will discuss the effect on the World Trade Organization (hereinafter WTO) after the TRIPs agreement authentication.

I. Results of the TRIPS Agreement:

The WTO makes rules for global trading between nations. As it holds the world trade. The countries that take its membership, TRIPS come into a package deal of that membership.[14]

The member countries have to accept all the multinational agreements accepted by the WTO, for example, in 2000 Jordan became a member of WTO and accepted the TRIPS agreement, and implemented its provision into its national law.

The purpose of TRIPS is to implement a uniform set of rules for the protection of intellectual property rights in order to achieve global harmony and more stability in international trade relations between countries[15], but when I look critically at the effect of the TRIPS agreement, it leads to strict and unnecessary strict control of intellectual property protection, which ultimately became the reason for restricting access to essential and life-saving medicines in developing countries.[16]

II. Barriers in Access to life-Saving Drugs:

Patented drugs are drugs that are essential life-saving drugs which access are inevitable for the patients and in case of their non-provision, they can cause drastic impacts on the health of patients. But these drugs are protected under the patents laws specifically under Intellectual

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[14]Sudip Chaudhuri, *The WTO And India's Pharmaceuticals Industry: Patent Protection, TRIPS and Developing Countries* (Oxford University Press 2005) 39-128.
[15]Peter K. Yu, '*The Objectives and Principles of the TRIPs Agreement*' (2009) 46 Houston Law Review 981.
[16]Antony Taubman, Hannu Wager and Jayashree Watal, *A Handbook On The WTO TRIPS Agreement* (Cambridge University Press 2012) 124.

Property Laws (IPL) which legally bounds the countries which are using or manufacturing generic medicine of such patented drugs to pay royalties or incentives to the original manufacturer of these drugs who holds all the patents rights regarding such medicines on account of his/her innovative work or research.[17]

The situation of medical facilities and healthcare in third world countries is already miserable, many factors contribute to the situation of the public health crisis in developing countries particularly socio-economic factors i.e., poor infrastructure, transportation,[18] poor roads in access for medical facilities especially in rural areas, improper sanitation systems are the major causes of the spread of diseases in developing countries.

In such conditions the outbreak of viral diseases is normal, AIDs, Malaria, Dengue fever, HIV are the disease outbreak as the result of such situations. Political negligence and corruption make the healthcare situation in such countries worsen. The role of Pharmaceutical companies has also changed in the current age and they are more tend to profit-making rather than social welfare.

The research and development by these companies are done for profit-making and competitive marketing, which overall impacts the situation of healthcare.[19] Thus the implementation of TRIPS provisions for compulsory licensing has a more severe impact and increases the cost of medication which ultimately hinders the access of poor patients to life-saving or essential medicines.

This situation creates a socio-legal battle relating to humanitarian laws which say access to medicine is a fundamental right of a person under the International Covenant on Economic, Social, and Cultural Rights (ICESCR) 1966 and on contrary the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1995, which protects the private rights of individuals and grants them a temporary monopoly over their the innovation.[20]

Strong control of TRIPs agreement makes the prices of medicine higher and thus hinders its access to the people who are in most of its needs, on the other hand, there is a continuous demand for strict IP control to preserve the patented work and paying royalties for its use.

Both notions contest with each other as on side humanitarian laws work for human rights whereas TRIPS agreement works for the personal rights of the individual with certain exception of the use of patent right without the permission of the relevant person.

The stringent controls for IP protection mentioned under TRIPS Agreement make it hard for the developing and LDCs to access low-cost medicine. In the current era where the deadliest virus

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[17] Brayan C Mercurio, 'T*RIPS, Patents, And Access To Life-Saving Drugs In The Developing World*' (2004) 8-12.
[18] Ibid.
[19] Ibid.
[20] Holger Hestermeyer, *Human Rights And The WTO* (TPB 2011) 211-219.

i.e. , Ebloba and COVID-19 are enveloping swiftly, and non-communicable diseases i.e AIDs, Hepatitis, and Cancer are prevailing, then the implementation of patent law will make the situation of LDcs miserable.[21]

From the research regarding AIDs, it is proved that 15 out of 49 adults and around 78000 children in Kenya are affected by the Ebola virus, and due to high prices, medicine is unaffordable, which enhances the chances of them in the next few years.[22]

The current situation of COVID-19 has the deadliest impact on the lives of people. Million people have already died as a result of this virus.

Now that the discovery of the anti-COVID-19 medicine has been done, soon the medicine companies will use the TRIPS Agreement as an instrument to hold the medicine and make a lion's share out of the profit.[23] Although on May 2021, the LDC i.e. Fiji, India, Egypt and Indonesia, Pakistan, Maldives, Mozambique, Mongolia, Namibia, South Africa, Vanuatu has submitted a proposal for the waiving certain provisions of the TRIPS Agreement in the wake of the COVID-19 crisis for a flexible period till present the threat is novel and research is being done, but soon after that, there is apprehension for the COVID-19 to fall in the same category of previous IP laws which will worsen the situation.[24]

[21] Marion Motari, Jean-Baptiste Nikiema and Ossy M. J. Kasilo, 'The Role Of Intellectual Property Rights On Access To Medicines In The WHO African Region: 25 Years After The TRIPS Agreement', BMC Public Health (2021) 11.
[22] Graham Dutfield, Literature Survey On Intellectual Property Rights And Sustainable Human Development (UNCTAD 2003) 17-18.
[23] Joe Chen, 'Balancing Intellectual Property Rights And Public Health To Cope With The COVID-19 Pandemic' [2021] eRepository 27-30.
[24] John Zarocostas, 'What Next For A COVID-19 Intellectual Property Waiver?' (2021) 397 The Lancet 1871-1872.

III. Compulsory Licensing and Production of Generic Medicines:

In this section, we will discuss the flexibilities TRIPS Agreement offers for the manufacturing and importing of generic medicine under compulsory licensing which is mentioned under 31 of the TRIPS Agreement. Although the drugs companies are bound under this Agreement to provide medicine rights in case of urgency that term is ambiguous as a proper definition of urgency is not given as to what would cause urgency and what would be its scale?.

The issue for patented drugs arises as a result of the violation of patent right in the field of information technology (IT). Most of the companies used reversed technology and by making identical software caused a fraction in prices of the product in the market, to stop this piracy and violation strong IPR controls were implemented under the TRIPS agreement.

The same was then applied to the pharmaceuticals sector. Thus, due to research and development the companies invest in research therefore, they claim their share from their products, but on the contrary, generic medicines are low-cost medicine manufactured domestically by using the same formula of patented drugs. These generic medicines are low-cost for the patients but for their manufacturing compulsory license has to be obtained.[25]

Regarding the pharmaceutical sector, TRIPs give the least protections for making a balance between granting access to essential medicines and protecting invention rights for producing new medicines.[26] As contrary to its objective as mentioned under article 7 to provide a global system of intellectual property protection.

TRIPs do not provide a global system and the member may themselves recognize the other member's patent right not automatically as they are not the same for each member state. Similarly, non-discrimination measures are mentioned under articles 3 and 4 of TRIPs agreement under which instruction is given for non-discrimination and to provide the same standard of protection as provided to their nationals.[27]

IV. Compulsory License Under Article 31:

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[25] Ellen F. M 't Hoen, Pascale Boulet and Brook K Baker, *Data Exclusivity Exceptions And Compulsory Licensing To Promote Generic Medicines In The European Union: A Proposal For Greater Coherence In European Pharmaceutical Legislation* (2017) 1-9.

[26] Simon A. Fitzpatrick, *Prospects Of The Further Copyrights Harmonization* (2003) 215.

[27] Charitini Stavropoulou and Tommaso Valletti, 'Compulsory Licensing And Access To Drugs' (2014) 16 The European Journal of Health Economic 83-94.

This section relates to compulsory licensing for the manufacturing and importation of low-cost or generic drugs. Article 27-31 deals with patented commodities and their use and incentives paid to the person who has this right exclusively for the use of his product. TRIPs Agreement binds the member states to provide patent protection to the inventors in patented goods or products.[28] Likewise, Article 28 deals with patented goods and confers some rights on the inventor of patented goods and gives the right to exclude any other person to use, sell, or make the products of the same nature, without the permission of the right holder or owner and to pay incentive for such use.[29]

Article 31 deals with compulsory licensing, under which the member states can grant a compulsory license for patented goods or processes to the parties, (whether government or Pharmaceutical companies) upon fulfilling certain conditions. In this section, an exception is kept to use patented goods without the permission of the patent holder in certain circumstances.

Usually, for such permission the situation must be discussed with the patent holder, and obtaining his consent is compulsory, but if the situation of urgency arises, the member state (government) is forced to grant a compulsory license to the parties without the consent of the right holder.

Concerning pharmaceuticals, this right is granted to the other states to manufacture generic or low-cost medicine of patented drugs, so that access to essential medicines can be made possible. [30] But for that process, certain guidelines are mentioned to be followed. TRIPs agreement by keeping the balance protects the rights of the patent holder and gives guidelines for manufacturing under certain circumstances.

Article 31 states that:

a) The authorization must be considered on individual merits.
b) This use can only be done with the permission of the patent holder but in case of urgency, that permission is not required and the state can allow for compulsory licensing.
c) The period and scope of such use will be limited to the purpose for which that is obtained.
d) Non-exclusive use of such a patent.
e) Such use will be non-assignable.
f) Such use shall be authorized for the domestic market only.
g) The period for use shall be ceased after the purpose for which it was used.

[28] TRIPS Agreement 1994, Art 27.
[29] TRIPS Agreement 1994. Art 28.
[30] Beatrice Stirner and Harry Thangaraj, 'Learning From Practice: Compulsory Licensing Cases And Access To Medicines' (2013) 2 Pharmaceutical Patent Analyst 195-213.

h) The right holder shall be paid with the adequate incentive for the use of patented goods as per the economic value of such authorization.
i) Any decision regarding the legal validity of use will be subject to judicial review.
j) Remuneration provided shall be subject to judicial review.
k) The members have an exception to the condition mentioned under sub-clauses (b) and (f) where the purpose of such authorization is the judicial review or process is anti-competitive.[31]

This whole subsection (f) is relevant for discussion because it puts the barrier to access to medicine, and allows its production only in the domestic market of the state to whom the license is granted. Thus, all the countries do not possess the relevant technology and equipment for manufacturing generic medicines. In this situation, the lack of technology and infrastructure hinders the access of patients to medicines. This article makes limitations and circumscribes the production to the domestic market, thus also banning the import of such drugs under compulsory license from any other country at low rates, which has the technology and infrastructure, and production capabilities of such generic medicines.[32]

Similarly, it also hinders a country from exporting generic medicine to the country in need of public health care and is incapable of manufacturing such medicines in the domestic market. Thus, the purpose of this provision is to protect the rights of the patent holder and restrict the import and export of generic medicine produced under compulsory license but as the result of such restriction, the countries which do not have adequate technology for manufacturing medicines cannot take the benefit of this clause.[33]

Similarly, sub-clause (h) is also controversial in this section, as it takes about adequate remuneration to the patent holder, as per the economic value of authorization. The parties never get agreed on what is adequate remuneration, and what is the economic value of authorization. Thus, create conflict and cause barriers in the access of cheap medicine for the patients.[34]

After the Doha Declaration 2001, the issue of emergency is also discussed but still, that term is ambiguous, as it is also contrary to the assertion of TRIPs agreement for creating uniformity in the terms and standards for each state.[35]

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[31] TRIPS Agreement 1994. Art 31.
[32] Tú Thanh Nguyen, *Competition Law, Technology Transfer And The TRIPS Agreement* (Edward Elgar 2010).
[33] Ann Marie Effingham, 'TRIPS Agreement Article 31 (B): The Need For Revision' (2016) 46 Seton Hall Law Review 883.
[34] Sandra Bartelt, *Compulsory Licenses Pursuant To TRIPS Article 31 In The Light Of The Doha Declaration On The TRIPS Agreement And Public Health* (2003) 283.
[35] H. Sun, 'The Road To Doha And Beyond: Some Reflections On The TRIPS Agreement And Public Health' (2004) 15 European Journal of International Law 123-150.

The emergency word is not defined and what would be the condition of emergency or extreme urgency will be decided by the country or member state itself, each state has its standard for declaration of emergency. Due to these barriers, the process of production of low-cost medicine is hindered and the states are unable to take benefit of this section into its true spirit.

Chapter 3: Implications of TRIPS-plus on Jordan's Healthcare System

In this chapter, I will discuss the TRIPs plus agreement, its implication for Jordan concerning patented drugs. In this chapter, a detailed discussion is presented regarding the question of whether TRIPS-plus brought some fruitful changes in the trade and economic development of Jordan as a result of imposing strong patent protections and stringent control in the pharmaceutical sector, or it merely increased the cost of patented drugs in Jordan.

To investigate the impacts of TRIPS-plus on Jordan, secondary research is adopted. A qualitative study is adopted in this regard, and already available data from various resources, websites, online journals will be consulted.

Various books are consulted to investigate this question, and already available data of interviews conducted by previous scholars on similar issues is used. As my research thesis is on the impacts of TRIPS agreement on developing countries related to patented drugs, which already have been discussed in previous chapters, therefore, in this chapter I will deal with the impacts of TRIPS and TRIPs-plus regarding Jordan.

TRIPS imposed restrictions upon the countries for the strict protection of patents and other IP rights. To soften the implication put up by the TRIPs agreement in 2001 Doha declaration was held on public health issues in which the remedy of compulsory licensing was suggested which is discussed in the previous chapter in detail.

But that controls were not enough by the developed countries and continuous demand for doing more was noticed by the United States (US) for the strong and rigorous TRIPS implications which are known as TRIPS-plus. TRIPs–plus are the rules which are imposed by the US through various modes i.eBilateral agreements or regional free trade agreements (FTAs), on developing countries.

As evidenced from previous practices, the US imposed TRIPs plus rules on developing countries as a result of concessions given to countries that are newly in accession with WTO. The US also through various trade sanctions, reduction in foreign aids and assistance, and by offering technical assistance programs to developing countries impose pressure on them for signing FTAs for strict IP rules.[36]

[36] Marion Motari (n 21)

It is already discussed that the IP protection imposed by the TRIPs has a drastic implication in the public health sector of developing countries, as its rule restricts the production of low-cost medicines. Thus, in such conditions, the implementation of TRIPS-plus rules for IP protection will make the situation of public health more pathetic by making the cost of essential medicines higher than before.

The restriction imposed by generic medicine exportation, or exportation in case of an emergency situation, is not able to meet the needs of a country that has a higher level of suffering.[37]

Jordan became a member of WTO in 2000 and as a condition for its accession to WTO, Jordan accepted the TRIPs plus agreement and implemented it into its national legislation regarding patents. Soon after it acceded to WTO, US and Jordan signed a regional agreement of FTA.

This FTA was done to bring new technologies and increase the availability of generic and patented medicines and ultimately will bring Foreign Direct Investment (FDIs) in the country. The reason for choosing Jordan for this specific analysis is the Jordan-US FTA.

Jordan is the world's fourth country and first Arab developing country which accepted the TRIPS-plus agreement.[38] Therefore, investigating the impacts of TRIPs-plus on Jordan will be a practical example of TRIPs plus implications, and how far it is beneficial for the developing countries or it just costs increasing agreement.[39]

I. An Overview of Jordan's Healthcare System:

Jordan is a developing country with a lower income level. The population of Jordan is six million and with a per capita income of 2450$ probably. The public healthcare system of Jordan is poor, which has more drastic impacts on poor people as compared to its overall population.

In a health survey of 2004 of Jordan World Bank (WB) stated:

"Poor people are at more health risk as compared to rich people, as they can afford the medication. Such conditions lead to an increased mortality rate in infant children, malnutrition, higher disability, and infertility risk."[40]

According to the National Poverty Alleviation strategy:

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[37] Robert M Sherwood, 'The TRIPS Agreement: Implications For Developing Countries' (1996) 37 The Journal of Law and Technology 491.
[38] J.H Reichman, 'The TRIPS Agreement Comes Of Age: Conflict Or Cooperation With The Developing Countries' (2000) case western reserve journal of international law 441.
[39] Tú Thanh Nguyen, *Competition Law, Technology Transfer And The TRIPS Agreement* (Edward Elgar 2010 .
[40] World Bank, Jordan Poverty Assessment: Executive Summary (2004)1 27.

"The poverty in Jordan is increasing and can be between 15-30%." [41]

There is no healthcare financing system by the government, and such people are paying for healthcare expenses from their own pockets, thus causing an increased burden for them in affording medicines, and only 60% of the Jordan population which has health insurance, are insured on their expenses.[42]

Unlike the African countries, Jordan has a low HIV/AIDs spread ratio, but the prevalence of other Non-Communicable Diseases (NCDs) are the major reason for death and disability in people. Similarly, Cardiovascular diseases and cancer is the major reason for deaths in Jordan,[43] But this does not end here, the increasing threat of Diabetes is also alarming for the countries because according to an estimation, the number of Diabetic patients will reach up to 680000 in 2030.[44]

II. Implications of TRIPS-plus for Jordan:

The situation of healthcare is already drastic in Jordan, and Jordan mainly relied on generic medicines. But after Jordan acceded to WTO and enforced the TRIPs agreement into its national legislation the cost of medicine is highly increased, thus making it inaccessible for poor people.

In such a situation, signing an FTA with the US resultantly impose more stringent and robust restriction on the use of patented drugs and other IP laws.[45] This FTA is considered a part of the wider US-Middle East Trade Program, through which the US wants to create a Free Trade Zone (FTZ) in the Middle East and North Africa (MENA) Region. Therefore, similar to Jordan, the US has entered into an FTA with Morocco, Bahrain, and Oman, and imposed a higher level of IPR protection, (previously, the USA concluded an FTA with Israel, and entered negotiations (now stalled) with the United Arab Emirates in 2005. The USA has also entered into trade and investment framework agreements with Algeria, Egypt, Kuwait, Qatar, Saudi Arabia, Tunisia, and Yemen, and is working on accession to the World Trade Organization with Lebanon, Algeria, and Yemen).

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[41] Ministry of Social Development, 'Poverty Alleviation For A Stronger Jordan: A Comprehensive National Survey, Amman' (2002) 14-15.
[42] Ministry of Health, 'National Health Strategy 2006-2010, Amman' (2006) 52-53.
[43] Charles T Collins-Chase, 'The Case Against TRIPS-Plus Protection In Developing Countries Facing AIDS Epidemics' (2008) 29 University of Pennsylvania Journal of International Law 763.
[44] 'Cardiovascular Diseases' (2008) <http://emro.who.int/ncd-Regionalsituation-jor-Back.htm.> accessed 23 June 2022.
[45]Patricia M. Danzon and Michael F. Furukawa, 'Prices And Availability Of Pharmaceuticals: Evidence From Nine Countries' (2003) 22 Health Affairs 536.

The imposition of TRIPs plus rule was the precondition for Jordan's accession to WTO. Through that following rules were implemented into Jordan national laws:

Box 1: Health-related TRIPS-plus rules and obligations in Jordan's IP code

Patent Law No. 32 (1999) and Patent Law No. 71 (2001)[*]

- Forbids parallel importation without patent holder's prior consent.

Unfair Competition Law and Trade Secrets Law No. 15 (2000)[**]

- Introduces five years of data exclusivity that commences on the medicine's date of registration in Jordan[21]

US-Jordan FTA (2001)

- Patent linkage (notification only)[22]
- An additional three years of data exclusivity (beyond five years) for new uses of already known chemical entities
- Compulsory licensing permitted only to remedy an anti-competitive practice, in case of public non-commercial use, or in the case of national emergency or other situations of extreme urgency.
- Patent extension for unreasonable curtailment of patent term as a result of a delay in the marketing approval process
- *Best efforts* to accede to or ratify the Patent Cooperation Treaty (PCT)[**]

Source[46]

Presently, US officials and the United States Trade Representative (USTR) applauded the Jordan–US Free Trade Agreement (FTA) as an achievement, praising it as an instance of a country where "globalization has profited" its economy, citing "increased economic growth generally, and in particular, benefits for Jordan's pharmaceutical and biomedical technology industries" (Ryan and Shanebrook, 2004, p. 1). Furthermore, according to this line of reasoning, the increasing presence of international pharmaceutical firms in Jordan, as well as increased accessibility and availability of pharmaceuticals to all Jordanians at cheaper prices, are evidence of these benefits. Moreover, it has been asserted that the Jordan–US Free Trade Agreement (hereinafter JUSFTA) has enhanced the potential of local enterprises to manufacture generic

[46] Rohit Malpani, 'All Costs, No Benefits: How The US-Jordan Free Trade Agreement Affects Access To Medicines' (2009) 6 Journal of Generic Medicines: The Business Journal for the Generic Medicines Sector.

pharmaceuticals and engage in new, innovative research and development in conjunction with big multinational pharmaceutical firms.

"Since the passage of the FTA, the Jordanian drug sector has begun to produce its own unique medications" and has increased "access to new medicines" at cheap costs, according to a recent letter from Congressman James Moran to the American Congress.[47]

If we analyze the provisions of JUSFTA, it imposes harsh restrictions and gives less patent flexibility to developing countries which hinder access to medicines, by making their prices skyrocketing. Article 17-23 deals with the TRIPs-plus restriction regarding patented drugs.

Another part of the JUSFTA is the concerns regarding the use of compulsory licensing and parallel importation. Even though TRIPS restricted such use to specific situations, TRIPS was nonetheless flexible enough to ensure that the poor continued to have access to affordable, life-saving drugs.

To use an example, article 31 of TRIPS delegated the interpretation of national health emergencies to the member states themselves, while also granting them the authority to "take actions essential to protect public health and nutrition" in an emergency.

Despite objections from the Pharmaceutical Research and Manufacturers of America (PhRMA) and other MPM to such concessions, the Doha Round's Declaration on Public Health, which took place in the shadow of the September 11th attacks in the United States and the ensuing Anthrax threat saga, reinforced these flexibilities and asserted that the TRIPS "Agreement can and should be interpreted and implemented in a manner supportive of WTO members' purpose of safeguarding public health.[48]

The United States Trade Representative attempted to reduce and weaken such flexibilities by narrowing the circumstances under which compulsory licensing and parallel imports are permitted.

Because of this, article 20 of the Jordan–US Free Trade Agreement (FTA) permits compulsory licensing only under the following circumstances: to remedy an anti-competitive practice; in cases of public non-commercial use; in cases involving a national emergency or other situation requiring extreme urgency; and on the basis of failure to meet working requirements. Furthermore, Article 20 included a blueprint for the conditions that would allow for the employment of such safeguards to be implemented. As a result, it is in violation of the spirit of

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[47] Hamed El-Said and Mohammed El-Said, 'TRIPS-Plus Implications For Access To Medicines In Developing Countries: Lessons From Jordan–United States Free Trade Agreement' (2007) 10 The Journal of World Intellectual Property 438-475.

[48] Mohammed El-Said, 'The Road From Trips-Minus, To Trips, To Trips-Plus' (2005) 8 The Journal of World Intellectual Property 53.

the Doha Declaration on TRIPS and Public Health, which emphasizes that member states should have "the freedom to select the basis on which such licenses are given."[49]

Chapter 4: Data Analysis

In continuation of the question discussed in the previous chapter, in this chapter, I will analyze the existing data regarding the impact of TRIPs-plus on Jordan. In this regard, I will investigate the question of how TRIPs-plus increase the price of generic medicines, specifically due to the "Data Exclusivity Rule" (hereinafter DER or DE), and what will be the effect if Jordan was not a part of TRIPs-plus.

I. Generic Medicine Competition and TRIPs-plus:

As a result of JUSFTA the generic medicines competition has been reduced. Due to solid protections given under the TRIPs-plus rules, more ways are available to pharmaceutical companies to reduce generic medicine competition.[50]

Most of the medicine companies have not registered their patents for medicines which they newly launched in Jordan, instead, they relied on the TRIPs plus provisions for the protection of patents rights. Because TRIPs plus rules give intense protection to such companies through DER.

This could be evidence from the figures that after the JUSFTA, most of the multinational companies (MNCs) brought their new medicine to the Jordan market but they didn't register them into the patent office.

As per the analysis of Oxfam, around 108 new medicines were launched by MNCs in the pharmaceutical sector but they were not registered, and between 2002 and 2006 there was no generic medicine were launched in the market which is equal to or having same formula which is used in above mentioned newly launched medicines, which clearly shows that JUSFTA and TRIPs-plus rules causing hindrance into generic medicine competition.[51]

The 108 medicines issued by the MNCs has a monopolistic rule in Jordan regarding those medicines which indirectly result in high prices of medicines.[52]

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[49] Ibid.
[50] 'Jordan Trade Announcement' (*Georgewbush-whitehouse.archives.gov*, 2022) <https://georgewbush-whitehouse.archives.gov/news/releases/2001/12/20011207-5.html> accessed 26 April 2022.
[51] Ryan B Abbott and others, 'The Price Of Medicines In Jordan: The Cost Of Trade-Based Intellectual Property' (2012) 9 Journal of Generic Medicines: The Business Journal for the Generic Medicines Sector 75-85.
[52] Ibid.

There are several reasons for the non-filing of the patent by MNCs in the Jordan market. The first reason is that Jordan is not a signatory of the Patent Cooperation Treaty (PCT), due to which the process of patent registration becomes tough, laborious, and expensive.

The second reason is DER because most of the MNCs have a monopoly over patented drugs, which is enough to hinder the generic completion for five years after the original manufacturer launched a medicine.

Till five years after the first making of such patented drugs, no generic medicine can be brought into the market. As a result of EDR protection offered by JUSFTA. For instance, out of twenty-one MNCs, only three have registered themselves, the main reason for not bothering to register a patent is DER.

II. Data Exclusion Rule and Issues of Patent Protection:

DER is the rule which hinders generic medicine competition by creating a monopoly through exclusive rights in the market, even if there is no patent registered.

If a company has done a clinical trial of medicine, it has a monopoly over this medicine for five years or more, even without registering its patent rights. As a result of this clinical trial, the other companies making generic medicine are prohibited from making such medicines.[53]

Thus, TRIPs-plus rules are more strict provisions than TRIPs agreement which only protect the "undisclosed data" and forbids it from its "unfair commercial use" under article 39 of the TRIPs agreement. TRIPs agreement, in fact, gives redress to the member states through generic medicines but TRIPS-plus makes additional rules of market monopoly for a specific period and ED, which undermines the perfect competition and generic medicine, and only promotes monopoly of the manufacturer for a limited period.[54]

As a result of TRIPs-plus, it is evident that most MNCs started to claim their patent rights on the manufacturing of new medicines for 8-10 years and with the help of ED, even if their claims regarding medicine and its clinical trial is not true they have a monopoly in the market for at least five years.

29 DER has weakened the perfect competition rule by allowing monopoly over drugs even without patent protection. Therefore, most of the MNCs rely on the ED for the protection of medicines, and by submission of clinical trials obtain the ED rights.

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[53] Rohit Malpani (n 46).

[54] Carlos M Correa, 'Unfair Competition Under The TRIPS Agreement: Protection Of Data Submitted For The Registration Of Pharmaceuticals' (2002) 3 Chicago journal of international law 69.

According to the research of Oxfam (2007), almost 103 medicines are newly launched in the Jordan market which has no registered patent rights, almost 79% of them have no generic competition in the market, due to ED.

Oxfam interviewed the generic medicine producers in Jordan who were irritated by the ED protections which cause obstacles in the way of generic medicines production, if the ED law has not existed in Jordan generic medicines can be launched as a competition of original medicines launched by MNCs, thus resulting in reduction of prices.[55]

If the consequences of EDR are analyzed, I can say that EDR has a direct link with increased price, and lives of poor people are at the will of pharmaceutical companies, who due to their monopoly can fix the prices, and if they are unaffordable by the poor people, it would result into their death, which is a serious issue.

For instance, If I compare the situation of Patented drugs and generic medicines with any other Arab country which has not adopted TRIPs-plus rules, for instance, Egypt, the situation can be unblemished. In Egypt, the prices of medicines are low and generic medicines of patented drugs are available in the Egyptian market as Egypt has no obligation of ED and TRIPs-plus rules.

The reason for choosing Egypt for this data analysis section is that: first, Egypt is a neighboring Arab country that has not adopted TRIPs-plus rules or any FTA with the US. Second, my research is based on secondary data, therefore, ample data was available for this comparison, and third, Egypt has almost the same diseases in issues i.e., Heart and cancer which is a major reason for deaths in Egypt too.[56]

Thus, as a result of the comparison of best-selling drugs of heart and diabetes in Jordan and Egypt, a clear distinct result can be noticed. In Jordan as a result of EPR, the prices of patented or original drugs are higher and no generic medicines are available in the market whereas in Egypt, the prices are controlled and due to the availability of generic medicines, the prices are low and perfect competition exists.

[55] Carlos M Correa, *Data Exclusivity For Pharmaceuticals: TRIPS Standards And Industry'S Demands In Free Trade Agreements* (Edward Elgar Publishing 2010) chapter 21.
[56] Rohit Malpani (n 46).

The below-given Table 2 is giving a comparative analysis of the situation of medicines prices of both countries.

Country (company)	Active Pharmaceutical Ingredient (dosage)	Medical use	Price per Unit (in Jordanian dinars at prevailing exchange rate)	Jordan price compared to Egyptian price
Egypt (local generics manufacturer)	Metformin (850 mg)	Anti-diabetic	.02	800%
Jordan (Merck)	Metformin (500 mg)		.16	
Egypt (local generics manufacturer)	Atenolol (100 mg)	Anti-hypertensive	.03	367%
Jordan (Kleva)	Atenolol (100 mg)		.11	
Egypt (local generics manufacturer)	Rosiglitazone maleate (4 mg)	Anti-diabetic	.40	167%
Jordan (Glaxo SmithKline)	Rosiglitazone maleate (2 mg)		.67	
Egypt (local generics manufacturer)	Simvastatin (20 mg)	Anti-hyperlipidemic	.452	498%
Jordan (Merck)	Simvastatin (20 mg)		2.25	
Egypt (local generics manufacturer)	Ramipril	Anti-hypertensive	.14	557%
Jordan (Sanofi-Aventis)	Ramipril		.78	

Sources : (Jordan and Egypt Ministry of Health)[57]

Thus, from this Table results, I can assert that, if the TRIPs-plus is not implicated in Jordan the prices of medicine could be low due to generic competition. Similarly, if TRIPS-plus provisions are imposed in Egypt that will hinder the generic medicine production by providing EDR to the original manufacturers of drugs.

The grips of Trips-plus in Jordan are that strict, it has dwindled its generic competition. Another conflict that arose as a result of JUSFTA and TRIPS-plus is the additional three-year DER in case any new use of already existing medicine is discovered.[58]

Under article 4 of JUSFTA, the pharmaceutical companies can file an additional three-year monopoly, where the formulation, process, and dosage of the already existing drug is discovered.

There is a conflict between the Jordan government and MNCs on this issue because they consider it part of the same process and DER must be present for the already new patented drugs only, but drugs companies, on the other hand, claimed that in each discovery new process, formulas and indications are used, and through lobbying and litigation process are insisted to include new formulation or change of dosage of the drug under the EDR[59].

Even though the definition of these processor formulations is narrow and not the conflict over this issue is not sorted out, still, it is evidenced that twenty-five drug companies have additional three years of different ages (DE) over the new use discovery of medicines. It is proven from research and data sheets, that after the accession of Jordan with WTO and JUSFTA, the prices of medicines in Jordan have increased. As per estimation, the prices of therapeutic drugs have increased from 0-20%.[60]

There are several reasons which also increases the prices of medicines in Jordan i.e., inflation, new economic standards, currency change, or political factors, but the main factor which is solely enough to enhance the prices is the non-existence of generic medicine competition and monopoly of MNCs over original drugs due to EDR and somehow the patent protection.

Although TRIPs plus rule have increased the prices of medicines, it is an undeniable fact, most of the original medicines have captured Jordan's market due to their improved formulas and use.

[57] Ibid.
[58] Carlos M Correa (n 55).
[59] Carlos M Correa (n 54).
[60] Intercontinental Medical Statistics (IMS) Annual reports 2002-2006.

Table 2: Market share of medicines with no generic equivalent (2002-2006)

	2002	2003	2004	2005	2006 (first two quarters)
Market Share (%)	3.0	5.3	7.2	9.1	9.4
Sales (US$) in thousands	2964	6192	9217	13,699	14,296

Source[61]

For instance, as a result of interviews of doctors in Jordan, they asserted that the new medicines are used in the treatment of blood and tumors, and their use in this treatment is high, but there are alternatives of these high-cost drugs available, as generic medicines.

Generic medicines are not available sometimes due to a lack of technological capabilities and patent protections, and generic competition is also blocked due to TRIPs-plus rules.

III. US Claims and Situation of Jordan Drug Industry:

The US claimed the JUSFTA as a success for Jordan, a guarantee of economic growth, and a source of Foreign Direct Investment (FDI).

The US representative flaunted the JUSFTA as a reason for the increased growth of the Jordan pharmaceutical industry and claimed that JUSFTA has brought a positive impact on the Jordan medicine market, through FDI, Research and Development (R&D), and launching of new and effective medicines by medicine companies.[62]

But after analysis of existing data and facts, these claims prove to be wrong, as the first reason is the FDI as claimed by the USA. Facts and figures show that there is no increase in the FDI in the local drugs industry as a result of JUSFTA.

US officials claimed that particularly, in the field of licensing, clinical data outsourcing, and appointment of scientific officers indicates the access to medicines. [63] However factual realities

[61] Rohit Malpani (n 46).
[62] Ruth Lopert and Deborah Gleeson, 'The High Price Of “Free” Trade: U.S. Trade Agreements And Access To Medicines' (2013) 41 Journal of Law, Medicine & Ethics 199-223.
[63] CAFTA And Access To Medicines' (*United States Trade Representative*, 2022) <https://ustr.gov/> accessed 26 April 2022.

are different from 1995-2000 there was no FDI in the drug industry of Jordan, even the claim of FDI as a result of JUSFTA, there was no FDI was done.

Similarly, regarding the claims of license outsourcing, the generic medicine producers claimed that there were neither enough licensing agreements signed by the pharmaceutical companies to them, nor the technology transferred by these multinational drug companies.

As a result of this, the new medicines are not manufactured locally, instead they are imported. According to the Jordanian Association of Pharmaceutical Manufacturers (JAPM), the licensing agreements which are effective in Jordan are signed before 1999.

The medicine companies only share little knowledge about medicines with local manufacturers which consists of packing of lifestyle drugs, and license agreements for the manufacturing of medicine are not allowed. The MNCs in the pharmaceutical sector are more inclined in capturing the local market and making profits instead of transmitting knowledge and bringing FDI.

Another issue found in this regard is the false claim of R&D in the local market. The foreign companies are more diverted towards making profits and there is research-based evidence that local drug manufacturing companies are least involved in the R&D and not even inventing new medicines into the market.

The US claimed that as a result of JUSFTA, there is an increase in the R&D and invention of local medicines, but the results are different. Since the signing of JUSFTA in 2001, there is no single locally manufactured drug that is patented.[64]

The facts show that local drug companies only invest 0.1% of their revenues in R&D processes.[65]

Several factors hinder the manufacturing capabilities of local manufacturers i.e., lack of capital to invest in R&D, expensive clinical trials to overcome EDR, no FDI in the last ten years since the signing of JUSFTA, lack of infrastructure for manufacturing, lack of expertise, etc.

The next claim was regarding innovations, as the US representative claimed that due to JUSFTA, there is an increase in innovation in the pharmaceutical sector, new medicines are launched in the Jordan market which will bring innovation.

A US representative claimed that 65 new medicines are brought in the Jordan local market. But the fact is that these medicines are sold out in the US and only 9 medicines were available in the Jordan local market. The top five medicine companies (Pfizer, BSM, Merck, Genzyme Roche, and Genentech) of the US claimed that 33% of their 88 newly launched products are registered. But in fact, most of these medicines were not launched in Jordan. The prices of such newly launched medicines are also skyrocketing that a common person cannot afford these medicines.

[64] Jordanian Food and Drug Agency (JFDA) Annual Statistic Reports 2006.
[65] Hanan Sboul, 'Jordanian Association Of Pharmaceutical Manufacturers' (2005).

For instance, if a civil servant has to buy one unit of a drug named "Fludara" used in Leukemia, he has to work for 266 days to afford that medicine. Although these newly produced medicines are effective in the treatment, they still have an extremely high cost which makes them unavailable for the poor people who cannot have access to such medicine due to their finances.[66]

From the above mentioned facts and data, it is obvious that the healthcare sector of developing countries, particularly of Jordan is under peril of IPRs, due to their excessively harsh level of protection awarded.

The main reason for this protection seems to be to increase the profit of pharmaceutical companies and to ignore the situation of the health crisis. As it is evident from the TRIPs-plus rules which have a strong interference in the relaxation of emergencies granted under 31(f) of TRIPs agreement.

In the developing world, there is more threat of the spread of communicable diseases. In Asian, Latin American, and MENA regions there is more threat of diseases therefore, they are considered as profitable markets for foreign investors.

But the situation of Jordan is a lesson for the other countries not to accept any FTAs without properly understanding their implication for them. As with time, the US will push more countries for the signing of FTAs or TRIPs plus which will undermine the ability of local manufacturers and thus, will make the medicines highly expensive or inaccessible for the poor. For example, in Jordan,

Around 40% of its population is not benefited from the National healthcare insurance, and they have to pay the expenses of medication out of their pocket causing them an extreme burden for the payment of medical costs. This increase in the prices of medicine will ultimately, undermine the abilities of the Ministry of Health (MOH) budget, and will cause pressure on it, thus in case of extreme cost, it would ultimately become impossible for them to grant any subsidiary in the cost of medicines or treatment. The figures show that almost 25% of the health budget in Jordan is used in buying medicines, which is hampering the healthcare program of the country.[67]

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[66] Rohit Malpani (n 46).

[67] Vanessa Kerry and Kelley Lee, 'TRIPS, The Doha Declaration And Paragraph 6 Decision: What Are The Remaining Steps For Protecting Access To Medicines?' (2007) 3 Globalization and Health 1-12.

CHAPTER 5: Conclusion

Concerning the scope and nature of the TRIPS Contract's compulsion to protect data from unfair commercial use, I reviewed and analyzed the various draughts of Article 39.3 TRIPS, as well as the numerous proposals, advanced during negotiations.

The analysis determined that the article's historical evolution during the Uruguay Round does not support the claim that protection against unfair commercial use requires DE. In addition, my argument is supported by textual analysis and interpretation of the provisions of TRIPS Article 39.3 in accordance with treaty interpretation rules.

Contrary to what the JFDA has done in the past, the obligation to protect TD does not apply to all data provided to the organization by drug originators.

Certain criteria must be met by protecting data. The data must be requested by the regulator and must pertain to a product containing a novel chemical entity (or, under the JUSFTA, a novel application of an existing chemical entity) as its active molecule.

Furthermore, the data must be confidential (undisclosed) and the result of considerable effort. Similarly, the nature of the obligations imposed by the relevant article of the JUSFTA could be argued in the same way.

This agreement modifies the protection conditions of several TRIPS articles. The JUSFTA extends protection against unfair commercial use and disclosure to data relating to new uses for existing chemical entities, as well as data submitted to foreign health regulatory authorities when relying on a foreign marketing authorization issued based on such data.

Although these changes may have serious consequences for Jordanian public health, for example, increasing drug prices and erecting barriers to generic competition for mostly off-patent medicines.[68]

I demonstrated that the JUSFTA does not transform these obligations from unfair commercial use and disclosure protection to data exclusivity. Furthermore, the JFDA's practice of relying on originators' data without their consent may not be considered data protection. Of course, this is not an unethical practice, nor is it a commercial use.

Indeed, when the safety and efficacy of generic drugs are established without conducting a material examination of the originators' data, or when the evaluation is based on a reference

[68] Kenneth C. Shadlen, Bhaven N. Sampat and Amy Kapczynski, 'Patents, Trade And Medicines: Past, Present And Future' (2019) 27 Review of International Political Economy 75-97.

product's foreign marketing authorization, it may not be considered a use of data. Even a generic manufacturer's indirect reliance on an originator's data does not constitute use in this scenario, as they lack access to the data, let alone the ability to use it.

In addition, the pharmaceutical industry in Jordan and the Free Trade Agreement between Jordan and the United States are being compared. Jordan, which signed a TRIPS free trade agreement with the United States in 2001, is being compared with the United States.

Despite the fact that Jordan's pharmaceutical industry is flourishing, the country's total domestic output has increased from $77 million in 1990 to nearly $230 million in 2000. However, Jordan's manufacturing output continues to lag behind that of more industrialized countries, such as Australia, despite recent improvements.

As of 2005, Jordan's pharmaceutical exports totaled $202 million, accounting for roughly one-sixth of all Australian pharmaceutical exports in that same year. The pharmaceutical sector in Jordan also has "limited capital resources and poor research and development capacity," which means that the country's ability to innovate and develop new pharmaceutical products is limited.

Similar to the other free trade agreements discussed in this section, Jordan's free trade agreement with the United States provides the same intellectual property protection protections.

This includes linking Jordanian pharmaceutical export licensing to US regulatory standards, as well as increasing protection for pharmaceuticals that have already been patented but are being used in new ways. In 1995, the Jordanian Industrial Development Bank published a study that concluded strengthening intellectual property rights would be detrimental to domestic production by reducing investment and output, decreasing domestic production and thus employment levels, increasing drug imports while decreasing exports, and rising pharmaceutical prices.[69]

The pharmaceutical sector in Jordan has achieved results that are significantly closer to those predicted by the 1995 IDB research, despite projections of increased trade from the United States. As early as 2003, two years after the signing of the Free Trade Agreement between the United States and Jordan, a Jordanian pharmaceutical company defined the country's development approach as "branded generic," with producers "looking for the formula on the internet... and then making it.

[69] Hamed El-Said and Mohammed El-Said, 'TRIPS-Plus Implications For Access To Medicines In Developing Countries: Lessons From Jordan–United States Free Trade Agreement' (2007) 10 The Journal of World Intellectual Property 438-475.

Even though some people copy the formula exactly, the vast majority of people make minor modifications and resell it under a different brand name.[70]

Producing companies will use this technique until the drugs' patent protection expires, indicating that there is no significant investment in research and development of innovative potential in the industry. Because pharmaceutical companies almost exclusively develop drugs that have lost their patent protection after twenty years, the availability of new medications is significantly reduced.

As a result, despite numerous promises made during the FTA negotiations that foreign countries would actively invest in expanding domestic capacity, no international pharmaceutical company has sought to establish facilities in Jordan, preferring instead to export pharmaceutical products or license the manufacture of pharmaceutical products.

The adoption of TRIPS-plus laws into Jordan's intellectual property system has resulted in a reduction in access to medicine:

- TRIPS rules, specifically data exclusivity, have prevented generic competition for 79 percent of drugs launched by 21 multinational pharmaceutical companies since 2001. Additional expenditures on medicines with no generic competitor ranged from $6.2 million to $23.03 million as a result of data exclusivity enforcement.

- Since 2001, foreign pharmaceutical companies have made almost no foreign direct investment (FDI) in Jordan to synthesize or manufacture medicines in collaboration with local generics companies, jeopardizing public health.

- Foreign pharmaceutical companies have invested exclusively in expanding scientific operations in Jordan, where aggressive sales tactics are used to encourage the use of expensive patented medicines over less expensive generics.

- Since the FTA's passage, stricter intellectual property rules have discouraged Jordanian companies from conducting pharmaceutical research and development, and these companies have produced no new medicines.

[70] Ryan B Abbott and others (n 51).

- Jordan's new product launches account for a relatively small percentage of total product launches in the United States and European Union. Numerous new medicines introduced in Jordan are prohibitively expensive and therefore unaffordable for the average citizen. In the United States, few, if any, of these newly released medications have been purchased.

The conclusion of the thesis regarding the nature and scope of the obligation to protect TD from unfair commercial use is based on an examination of the various versions of the TRIPS Agreement's Article 39.3 text as well as the various proposals advanced during negotiations.

Furthermore, the treaty interpretation rules support my case. I came to the same conclusion when it came to the relevant article of the JUSFTA. The JUSFTA made some changes to the TRIPS article's conditions of protection for TD.

These changes included broadening protection against unfair commercial use and disclosure of data relating to new uses for existing chemical entities, as well as data submitted to foreign health regulatory authorities when relying on foreign marketing authorizations issued on the basis of such data.

Despite the fact that these changes have the potential to significantly impact Jordan's access to medicine, I demonstrated that the JUSFTA does not change Jordan's obligations, which range from protection against unfair commercial use and disclosure to data exclusivity.

As a result, this thesis strongly suggests that the JFDA incorporate into the "Drugs Registration Criteria" the definitions of what constitutes a new chemical entity and new uses for existing entities discussed in Chapter Four of this thesis (DRC). Furthermore, I recommend that the JFDA stop assuming that data submitted by sponsors of new drug applications meet protection requirements.

Recommendations

Medicine access is a critical element of an individual's fundamental right to health. Though, TRIPS-plus provisions in the US-Jordan Free Trade Agreement and subsequent US-developing country free trade agreements threaten to erode poor people's access to medicine. Oxfam makes the following recommendations to help alleviate the burden of the US TRIPS-plus agenda and its impact on medicine access:

- Jordan should refuse to ratify the PCT because TRIPS does not require it, and the FTA's "best efforts" provision may not be enough to compel ratification. If Jordan ratifies the PCT, it is likely that the Jordan Patent Authority will face a significant increase in patent applications, thereby reducing generic competition.[71]

- The free trade agreement between the United States and Jordan replicates TRIPS patentability definition requirements. In order to comply with TRIPS obligations, Jordan's intellectual property law should be amended to severely restrict the patentability of medicines. Jordan, in particular, should consider a more restrictive patentability definition.

- Jordan may enact exceptions to mitigate the impact of data exclusivity, such as requiring an originator drug company to relinquish data exclusivity if the company fails to submit a marketing authorization application in Jordan within one year of global marketing authorization. Jordan could also expressly waive data exclusivity in the event of a compulsory license or a government use order.

- Allow parallel importation: Jordan could significantly reduce its financial burdens associated with medicine by repealing its prohibitions on parallel imports, which were not prohibited under the FTA.

As a result, I strongly recommend that the JFDA incorporate the chapter's definitions of what constitutes a new chemical entity and new uses for existing entities into the "Drugs Registration Criteria" (DRC). Additionally, it is recommended that the JFDA abandon its current practice of presuming that data submitted by sponsors of new drug applications satisfy all conditions and

[71] Rohit Malpani (n 46).

requirements for protection; instead, sponsors should be required to demonstrate that their data satisfies all conditions and requirements for protection. Additionally, specific reasonable exceptions to and legitimate grounds for revoking protection under Jordanian law must be included.

I strongly advocate for the following reforms:

I. Permits registration of drugs manufactured or imported pursuant to compulsory licenses or obtained through parallel importation based on the data provided by the originators.

II. Allow the registration of a generic drug based on the originator's data when the originator's product is sold at an unreasonable price, the originator engages in anticompetitive behavior involving the data directly or indirectly, the originator discontinues marketing its products locally, and the quantities provided are insufficient to meet local demand.

III. If, however, the originators' data is inadvertently used, the producer of the generic should compensate the originators fairly. Payments may be made on a cost-sharing basis. However, such compensation should not be paid in instances of wrongdoing by the originator, such as anti-competitive behavior or an unjustifiable lack of, or insufficient, commercialization.

IV. Additionally, I propose that the duration of protection for data relating to patented products be linked to and limited by the duration of the patent. This restriction is necessary to ensure that the early working exception to patent rights is invoked promptly. This exception was created to allow generic versions of patented medicines to be marketed immediately after the patent on the patented medicine expires. If data protection is extended beyond the patent's expiration date, the purpose of this exception may be defeated by an unnecessarily long delay in the entry of generics.

Furthermore, this thesis recommends that the JFDA include the following circumstances as grounds for revoking data protection in the Jordanian DRC: 344

I. If a product is not marketed in Jordan within six months of its local registration date, or if the product is marketed in insufficient quantities to meet reasonable local demand, or if the product is sold at unreasonably high prices.

II. If a product is unavailable in the local market for an uninterrupted six-month period without reasonable cause, or if the same period is the result of multiple shorter durations during the term of protection.

III. If a pharmaceutical product's registration application is abandoned prior to or following the JFDA's issuance of a sanitary approval for its marketing. Apart from preventing abuses of data protection, such as "evergreening," these proposed measures should strike a balance between the public interest and the originator's interests. By increasing competition in the pharmaceutical market, the measures are intended to alleviate some of the economic burden associated with data protection. The majority of the preceding recommendations regarding Jordan's protection of test data are applicable to all developing countries, regardless of developmental stage or income level.

As I have demonstrated, however, establishing this ground does not always result in the transfer of advanced technology and reductions in drug prices. Due to the legal ambiguity created by Article 27.1 of the TRIPS Agreement's nondiscrimination clause, the legitimacy of including this ground in the law remains unclear. Additionally, this ground could constitute a violation of the JUSFTA.

I have demonstrated that compelling a patentee to pursue its patent locally does not always result in lower-priced medicines. This concern is particularly acute in Jordan's case, given the country's size. Additionally, mandatory local work may prevent the transfer of advanced technologies, as owners would vigorously protect their know-how, which is required to operate patented technology, in order to prevent diffusion. Concerning the legal ambiguity under TRIPS, it has been argued that enacting this ground would violate Article 27.1 TRIPS' non-discrimination clause, which states that patents and patent rights shall be available and exercisable regardless of whether products are imported or manufactured locally. In Jordan's case, including the ground of

non-working locally in the Patents Law violates the JUSFTA, which states that importation constitutes work.

As such, I recommend that Jordan define the circumstances in which a patentee's importation does not constitute working the patent. I specifically recommend amending Jordan's Patents Law's Article 22 to include the following provision.

a. A patent is considered unworked and may be redressed in the described circumstances by the competent authority by issuing a compulsory license.

My recommendation may help resolve the issue of high-priced medicines by making them available under compulsory licenses manufactured by a local firm or through importation.

To be sure, this solution falls short because it ignores the issue of advanced technology access. To address the issue of compulsory licensing for unworked technologies, this study discovered that establishing "the public interest" as a ground for compulsory licensing may enable such access.

If a patentee refuses to work and license its patented technology on reasonable commercial terms to a local firm and it is in the public interest to have this technology worked locally, it is in the public interest to establish such an outright refusal as a ground for compulsory licensing. This thesis demonstrates that enacting the public interest ground remains a legitimate measure for Jordan to pursue, as permitted by the TRIPS Agreement and the JUSFTA, particularly in the area of public health.

Compulsory licensing in the public interest is one of the measures permitted by Jordan under Article 8 of the TRIPS Agreement and Article 5 of the Paris Convention (incorporated by reference into TRIPS Article 2) to advance the public interest in the local pharmaceutical sector, which is critical to the country's socio-economic and technological development. Numerous WTO members have included this ground in their legislation. Finally, as recognized in the Doha Declaration, Article 31 of the agreement does not limit WTO members' ability to act in the public interest.

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