Patent Ordinance 2000 and its Effects on Access to Medicine: An Analytical Study in the Light of the TRIPS agreement and Doha Declaration

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DECLARATION

I hereby declared that this dissertation is original and has never been presented in any university or institute of learning. I also declared that this dissertation has never been copied and any secondary information used has been duly acknowledged in this dissertation.

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August, 2022

DEDICAION

In the name of Allah, the Most Merciful and Benevolent. I dedicate this research to the Almighty Allah, the source of all knowledge, wisdom, and strength. I offer my sincerest gratitude for the blessings, guidance, and protection that enabled me to complete this work.

ACKNOWLEDGEMENT

- I am profoundly thankful to Dr. Naseem Razi for her insightful feedback, availabily, and encouragement, which have significantly contributed to the success of this research.
- I immensely appreciate the valuable guidance and support provided by Dr. Aziz Ur Rahman, my external supervisor, particularly in the selection of my research topic. His expertise has been instrumental in shaping this work.
- I am thankful to Dr. Warda Yasin, my internal examiner, and Dr. Shafqat Mahmood Khan, external examiner, for their insightful feedback and constructive suggestions, which have significantly contributed to the quality of this research.
- I pay my special thanks to my foreign evaluators Professor Graham Dutfield and GROSCLAUDE Laurent Pr, for their insightful feedback and suggestions, which have significantly contributed to this research. Your appreciation for this research work means a lot to me.
- I extend my gratitude to all my teachers and mentors who have contributed to my academic growth and development. Their collective wisdom and expertise have been invaluable to me.
- I extend my deepest gratitude to my beloved father, Zaka Ullah Butt, for his unwavering support, guidance, and love. His presence in my life has been a constant source of strength and motivation. Your wisdom and patience and have been invaluable to me.
- I dedicate this achievement to the loving memory of my mother, Rashida Butt, whose prayers, love, and sacrifices have been a guiding force in my life. Her memory motivates me to strive for excellence, and I am forever grateful for the time we shared.
- I am forever grateful to my beloved husband, Tanveer Ahmad Dar, for his unwavering support, love, and understanding throughout this journey. This achievement would not have been possible without him.
- To my precious children, Abdur Rehman, M.Musa and, Irha Fatima, thank you for being my source of joy, inspiration, and motivation. Your love and smiles have made every challenge worthwhile.

- I pay my heartfelt thanks to my beloved sister, Hafsa Butt, for her unconditional love, unwavering support, and constant motivation. Her presence has been a source of strength and inspiration.
- I also appreciate my brother-in-law, Asger Butt, for his encouragement and support which have been invaluable to me.
- I am grateful to my friends, Noreen Akhter and Sumara Zafer, for being a source of comfort, laughter, and inspiration. Your friendship has enriched my life and supported me throughout this journey.
- I am thankful to my family for their unwavering support and encouragement. Your love and belief in me have meant the world."
- I am grateful to everyone who has contributed to my journey, whether directly or indirectly. Your support and encouragement have meant the world to me.

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ABSTRACT

In order to create a balance between economic interest and public health is a complicated dilemma and at times it becomes an awful choice especially after the implementation of The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement). Before the implementation of the TRIPS agreement, there were more than 50 states which did not provide patent protection on pharmaceutical products as these states considered that patent protection of medicines will lead toward no competition; hence the prices of patented medicines will become high and unaffordable. This research describes the right to health and also asserts with evidence based arguments that the present patent system and its strict implementation affect the right to health. So, there is need to create a balance between the right of the inventors and the right of the users particularly when there is the matter of public health. It first provides the concept of right to health (as it directly linked with right to life) under the national and international law. It then further explores the intellectual property right, its importance and its global implementation under the umbrella of the WTO. This research provides the concept of state responsibility to provide the appropriate health facilities to its citizens. The TRIPS flexibilities enables the state authorities to take appropriate measures to protect public health and Doha Declaration on Public Health also reaffirms that whenever conflict arises between the implementation of Intellectual Property rights and public health, the TRIPS will be interpreted from public health perspective. The objective of this research is to suggest that the Patent Ordinance 2000 of Pakistan should be fully equipped with the TRIPS flexibilities to promote local industry and protect public health. This research adopts a comparative approach to examine the Indian Patent Law and how it incorporates and use the TRIPS flexibilities to ensure affordable health facilities to its citizens. Methodology has been applied for this research is primarily analytical and bears the qualitative aspect of the issue. It concludes that the Patent Law of Pakistan, as compared to India, could not incorporate the TRIPS flexibilities

according to the local needs. It suggests amendments in the Patent Ordinance 2000 to make it more convenient and useful for local industry and public health.

LITERATURE REVIEW

Gabriel J. Michael in his article *Catholic Thoughts and Intellectual Property: Learning from the Ethics* imposes an ethical obligation on the pharmaceutical companies to ensure an affordable access of life saving medicines. He mentions Gratian, a twelfth century canon lawyer, once wrote "feed the man dying of hunger because if you not fed him you have killed him". Michael asserts that pharmaceutical companies are responsible for the death of those poor people who died due to the non availability of essentials medicines in developing countries. He states that the law makers and police makers should incorporate this ethical obligation in a legal way and should bound the pharmaceutical companies to ensure the affordable access of life saving medicines.[1]

Lisa Forman and Jillian Clare Kohler compiled a very comprehensive book name as "Access to medicines as a human right: Implication for pharmaceutical industry responsibility". This book covered the entire current topic very broadly and provides a detailed discussion. The authors insist in the first chapter that right to health is very important right and recognized internationally and availability of medicines is the matter of great concern in developing countries particularly in Africa and Asia. Pharmaceutical industry makes a lot of development and reduced the mortality rate with improved quality of life but this improved quality of life is missing in developing and least developed countries. Patricia Illingworth in chapter 4 of this book which is titled as "A Corporate Social Responsibility and Right to Essential Medicines" asserts that it is the responsibility of pharmaceutical industry, who earns billion every year, to provide essential medicines in poor countries where millions of people died every year due to the lack of treatment facilities. Author put moral

[1] Michael, Gabriel J. Catholic Thoughts and Intellectual Property: Learning from the Ethics. Journal of Law and Religion25, no. 2(2009): 415-51.http://www.jstore.org/stable/20789489

obligation on the developed countries to provide full assistance to the developing countries to cope with health emergencies.[2] It is absolutely right that developing countries with their limited resources are not able to cope with health emergencies. Developed countries should not only help them in health sector but also provide technical assistance in starting their research and development program so that they can become the productive part of this global village.

James Love, director of Knowledge Economy International, has authored numerous articles and monographs on innovation and intellectual property rights. His work often focuses on the intersection of public health, access to knowledge, and the role of intellectual property in these areas. Love has analyzed the impact of TRIPS on developing countries, particularly in the context of public health emergencies and access to essential medicines. He has critiqued certain aspects of the TRIPS agreement and advocated for greater flexibility for developing countries to address their specific needs. Once he was asked ding an interview if the price of a drug is out of control, what should be done? He replied "The monopoly should be at risk, rather than the patients, when prices are too high. Intellectual property rights should be seen as a privilege, not a right, and the legal monopoly should be ended if prices are excessive"[3]

Christopher May and Susan Sell in a working paper name as *Forgetting History is Not an Option! Intellectual Property, Public Policy and Economic Development* narrates the historical development of Intellectual Property and effects

[2]Forman, Lisa, and Jillian Clare Kohler, eds. *Access to Medicines as a Human Right: Implications for PharmaceuticalIndustry Responsibility*. University of Toronto Press, 2012. http://www.jstor.org/stable/10.3138/j.ctt2ttns8

3 Plos Blogs, Talking Drug Prices, Pt 4 Drug pricing is out of control, what should be done? By James Love, https://yoursay.plos.org/2015/10/talking-drug-prices-pt-4-drug-pricing-is-out-of-control-what-should-be-done-by-james-love/ last accessed, 22August, 2022

of its global implementation. This paper discusses the TRIPS agreement and focus on the points that how to create a balance between private rights of inventers and public rights of users. It highlights that mere reproduction of the language of the TRIPS will not resolve the problems of developing countries so the writer discusses the range of possibilities that can facilitate the developing countries. Writer critically examines the history of IP and gives many examples when patent is granted but it did not result in social goods but hindered the way for new inventions. His narrative is that intellectual property rights are granted because inventors serve the humanity and a balance was created between the private rights and public rights. He asserted in his article that balance must be restored and the TRIPS plus provisions must be discouraged and banned. He indorses the Professor Cooper Dreyfuss who proposed that "Bill of Rights" must be incorporated in the TRIPS for users' interest. He argues that same level of protection of the IPRS by all countries irrespective of their development level is profoundly mistaken.[4]

Lawrence O. and Robert Archer in an article "The Duty of State to Assist Other States in need: Ethics, Human right and International Law" put a duty on a state to provide support to other states who do not have technical expertise or economic resources to preserve health and life of their citizens. Writer highlight the inequalities exist between developed and developing countries. Poor countries have unbalanced burden of premature death and diseases. He wrote that "average life expectancy in Africa is nearly 30 years shorter than in the America or The Europe". Least develop countries due to their limited resources and a lot of other issues use just between $1 and $25 per capita per year on health, on the other hand developed countries use between $500 and $5,000 per capita per year on health. The USA expenditure are

[4] Christopher May and Susan Sell, *Forgetting History is Not an Option! Intellectual Property, Public Policy and Economic Development,* DMIE working paper, May 2007.

highest than any other developed country and it is $5,000 per capita per year. If we talk about the health emergencies, we come to this conclusion that it affects developing countries more because of their poor health infrastructure and limited resources. Writer insists that the UDHR and the ICESCR placed an obligation on the state to cooperate individually and collectively to the maximum available resources to achieve the progressive realization of rights.[5]

Virginia A. Leary, JD in her article *"The Right to Health in International Human Right Law states"* that it is the responsibility of state to provide the proper health facilities to its citizens under the international law. She emphasizes that there is lack of enforcement by the international bodies to implement right to health. There is needed to make more efforts to create legal obligation on the state for the health of its citizens. She asserts that it is not sufficient to discuss the right to health for just legal perspective but a multi-disciplinary approach is required for the complete understanding of right to health. Writer discusses the WHO Report "Investing in Health". This report highlights the discrepancy exists between the developed and developing countries. Report of the UNICEF also highlights the health issues of children and these issues need attention.[6]

Eleanor D. Kinney in his article *"The International Human Right to Health What Does This Mean for Our Nation and World?"* talk about the right to health. He says that it is the duty of the state to provide the health facilities to its citizens. He insists that the countries are bound by the customary international law to provide

[5] Lawrence O. and Robert Archer, "Duty of States to Assist Other States in Need: Ethics, Human Rights and International Law," *Journal of Law and Ethics*, 35(2007):530, http://ssrn.com/abstract=1095769

[6] Leary VA, "The right to health in international human rights law". *Health and Human Rights*, Fall 1(1)(1994): 24-56. Available at https://pubmed.ncbi.nlm.nih.gov/10395710/ last assessed 14-06-2021

health facilities to its citizens whether that country accept right to health as constitutional right or not. He speaks about the United States of America that even the right to health is not a constitutional right but policy makers are bound by the customary international law to provide health care services to its residents. Writer confers the sources of international law that found a human right to health for all people. He provides a structure how right to health might be implemented internationally.[7]

Zhanna Mingaleva and Irina Mirshikh in his article "*Psychological Aspects of Intellectual Property Protection"* try to reveal the incentive behind the creative and scientific research activities and try to find out the reasons why people used pirated material instead of original product. A survey was conducted to gather information and the subject of the survey was professors, lecturers and researchers. The conclusion of the survey revealed that actual motive behind the creative and scientific research is to earn money and self- actualization. This research disclose that people used infringed material and pirated books because original products are costly and not easily available while on the other side pirated material is cheap and accessible. Proper legislation and enforcement procedure can make the situation better for the implementation of intellectual property rights.[8]

Director General of the World Health Organization in a report *"Addressing the global shortage of, and access to, medicines and vaccines"* asserts that the availability of medicine is the basic duty of a health care system. He also explains that availability means that medicine must be of good quality and affordable for general

[7]Eleanor D. Kinney, *The International Human Right to Health: What Does It Mean for Our Nation and World*, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=296394 last assessed 15-6-2021

[8] Zhanna Mingaleva and Irina Mirskikh, "Psychological Aspects of Intellectual Property Protection, "*Procedia-Social and behavioral Sciences*vol. 190, (2015): 220-226, www.sciencedirect.com last accessed 25 June 2021.

public. Reports highlighted that almost 90% people in developing economies have to bear their health expenditure without ant support from government. Ultimately the high prices of medicines directly hit the poor people.[9]

Khushbakht Hina and others in their article *"Intellectual Property Rights in Education of Pakistan: Review of Constitution, Current Status and expectation"* highlights that Intellectual Property Rights are very important for academics in Pakistan. They argue that Intellectual Property Rights and their protection are indispensable because these rights encourage inventions and creativity and also became the source of transfer of technology. Writers suggest constitutional amendment to incorporate the IPRs in it. The researcher conducted informal interviews with faculty members of different universities in Islamabad and concluded that faculty did not have much knowledge about IP and they suggest that there is need to arrange awareness programs by the university for students and faculty members.[10] The topic in which the present research is conducting is also an arcane area of patent law. Patent law is considered to be difficult subject among Intellectual property rights and there are few experts in Pakistan for patent law and only few studies has been conducted on the patent and the exorbitant prices of medicines.

M.Zaheer Abbas and Shamreeza Riaz explain in their article *"Flexibilities under TRIPS: Implication Gaps between Theory and Practice"* that The TRIPS agreement includes exceptions and flexibilities for low and middle income countries like compulsory licensing and parallel importation. Ultimate purpose of these

[9]Addressing the Global shortage of the and access to medicines and vaccines, Report by the Director General of the WHO, World Health Organization Executive Board 142nd session, 12 Jan. 2018,https://apps.who.int/gb/ebwha/pdf_files/EB142/B142_13-en.pdf. Assessed 19 July 2021.
[10] Hina Kushbakht et al. "Intellectual Property Rights in Education of Pakistan: Review of Constitution, Current Status and Expectations," July 2020, https://www.researchgate.net/publication/343254615_Intellectual_Property_Rights_in_Education_of_Pakistan_Review_of_Constitution_Current_Status_and_Expectations.

exceptions and flexibilities is to facilitate access towards affordable medicines. In this article writers highlight the implications which are faced by the third world countries who try to take benefit from these flexibilities. They assert that the current patent system favors the developed countries and suggest that developing countries should collaborate with each other while using compulsory licensing provisions. It might minimize the risk of losing foreign direct investment. Developed nations put a lot of pressure on developing countries for not to use flexibilities. The WTO and the WIPO must take appropriate measure to maintain a balance between the IPRs and public health and use of the TRIPS flexibilities must be ensured without any pressure by developed nations.[11]

A Samuel Oddi in his article *"The International Patent System and Third World Development: reality and myth?"* asserts that strong protection of patent system leads towards progress for developed countries but the scene is different for developing countries. He suggests that patent protection for developing countries have considerable social cost and international standards of patent protection may increase this cost. He suggests that developing countries should not go for international standards of patent protection because the patent systems of developing countries most of the time provide protection to the foreign inventions because there are no or little local inventions. [12] This article was written in 1987 before the TRIPS agreement when states have choice to enforce international standards of IP protection but now they are bound to enforce the global standards of intellectual property right if they want to enjoy trade relaxations. However, by using the TRIPS flexibilities and by

[11]M. Zaheer Abbas and Shamreeza Riaz, "Flexibilities under TRIPS: Implementation Gaps between Theory and Pracice," *Nordic Journal of Commercial Law*, (2013),http://ssrn.com/abstract=2367901.
[12]Oddi, A. Samuel. "The International Patent System and Third World Development: Reality or Myth?" *Duke Law Journal* 1987, no. 5 (1987): 831-78. Accessed August 2, 2021. doi:10.2307/1372691

creating balance between the rights of the produces and users of technology the developing countries can be benefitted from the existing the IPRs system.

Ellen 't Hoen in her Ph.d dissertation with the title of *"Practical Application of the Flexibilities of the Agreement on the Trade Related Aspects of Intellectual Property Rights"* asserts that during the HIV/AIDS crisis we came to learn that patent system especially for pharmaceutical sector is not properly balanced. She emphasizes that in developing countries almost 40 million people suffered with HIV/AIDS and 24.5 million were belong to sub-Saharan Africa. Access to life saving medicines was very limited; it was as low that only one patient among one thousand patients has access to ARVs medicines. Eight thousand people die every day in developing countries from HIV/AIDS. The effective treatment of HIV/AIDS through ARVs was available in developed countries in 1996 but these treatments were rarely available in developing countries because of the high prices. Generic ARVs by Indian companies had low price but patent on ARVs restrict the entry of generic ARVs. After the HIV/AIDS crisis, the international community realized the issue of access towards medicine. Doha Declaration, August 30 Decision and other global approaches were started like "Global fund to fight HIV/AIDS, United States President's Emergency plan for HIV Relief and UNITAID." All these efforts made it possible that in 2016, 19.5 million people among 36.7 had availability of ARVs. Author concluded that these numbers would not be possible without the entry of generic low cost ARVs medicines. She asked to use these strategies for other medicines of malaria, tuberculosis and cancer medicines.[13] Here, I will add my point of view that affordability of cancer medicines is not possible without national and international

[13]'t Hoen, Elisabeth,"Practical Application of the Flexibilities of Agreement on the Trade-Related Aspects of Intellectual Property Rights: Lesson beyond HIV for Access to new Essentials Medicines," PhD diss.(University of Groningen, the Netherland,2018),https://pure.rug.nl/ws/portalfiles/portal/55799433/Complete_thesis.pdf.

collaboration. Developed nation should help developing countries to provide health facilities to their citizens as international law also affirm this notion. Alma Ata Declaration explains the right to health as "worldwide social goal". Convention on the Right of the Child (CRC) also asked for international co-operation for the full realization of right to health.

Ellen 't Hoen in an article titled as *"TRIPS flexibilities and access to medicines: A European Approach"* states that the TRIPS flexibilities actually are the tools to manage the use of Intellectual Property and to improve the affordable access to quality medicines. The justifiable and legal use of these flexibilities is not confined to a specific community or area. Health and medicines are the concern for everybody everywhere in the world and is not limited to the poor and developing countries alone. High prices of new and patented medicines are a universal issue and it directly affects the economy of the country. Author asserts that the governments of the EU countries also felt pressure from the public to use the flexibilities under the TRIPS agreement like the compulsory licensing. Writer highlights that the provisions of the EU patent legislation regarding the protection of clinical trial data and the grant of exclusive market rights are the barrier to the effective use of compulsory licensing and in using other tools for the generic entry of medicine after their patent expire. [14]

K D Raju in his article *"Compulsory and Voluntary Licensing: A Legitimate way to Enhance Access to Essential Medicines in Developing Countries"* explains that the Compulsory licensing and voluntary license should be used as a tool to mitigate the effects of exclusive monopoly given to the patent holder. He argues that private right of the multinational pharmaceutical companies should not be preferred

[14] Hoen't EMT, "TRIPS flexibilities and access to medicines: A The European Approach," Health Action International, 2014, https://haiweb.org/wp-content/uploads/2019/06/HAI-TRIPS-Brochure-1.pdf .

over the public right of the poor people to access the essential medicines. He narrates the experience of developing countries how they used the Compulsory License provisions to help their people. He argues that due to the Compulsory licensing provisions and the apprehension to use these provisions compel the multinational pharmaceutical to enter into a strategic alliance with domestic pharmaceutical companies to manufacture the patented drug.[15] So it is also very important to incorporate these provisions in such a way that these tools should be workable when needed and grounds of granting compulsory license should be very broad and comprehensive as it effect the approach and dealing of multinational pharmaceutical companies. Appropriate use of the TRIPS flexibilities binds the multinational companies to issue voluntary license on reasonable terms and ensure affordability.

Asim Gulzar in his article *"Challenges and opportunities in the post TRIPS era for Pakistan-An overview of amended Patent Ordinance 2002"* take a detail analysis of the amendments takes place in the Patent Ordinance 2000. He discussed all provisions which were amended in 2002 and he argued that the amendment failed to take the full advantage of the TRIPS Flexibilities. Though a little change were made but law maker left a lot of room for misinterpretation and misunderstanding of poorly incorporated flexibilities. Terms are defined so broadly, the patentability criteria is not strict, compulsory licensing provisions are inadequately designed, provide only few grounds to issue compulsory license and some the TRIPS plus provisions are also added. He asserts that all these inadequate provisions have very negative effect on the country especially when it related to the health of the people and agriculture. Patents Ordinance 2000 need to be amended again to take full

[15]Raju K D, "Compulsory and Voluntary Licensing: A Legitimate way to Enhance Access to Essential Medicines in Developing Countries," Journal of Intellectual Property Rights, Vol 22, January 2017,23-31. http://docs.manupatra.in/newsline/articles/Upload/31AC60C2-ABCC-4799-A388-0F56ED7C9ECF.pdf.

advantage of the TRIPS Flexibilities and all stake holders should be invited to give their suggestion to make Patents Ordinance 2000 more effective and beneficial for the people of Pakistan.[16]

Carlos M. Correa in his article *"The TRIPS agreement and Access to Drugs in Developing Countries"* narrates that the Doha Declaration in 2001 and the Decision of 30 August in 2003 help the countries with no manufacturing capacity to issue compulsory license for importing drugs from other countries that have manufacturing capacity. In this way the countries may access to the patented medicines through compulsory license even without having manufacturing capacity. He asserts that the Decision of 30 August put pressure on the multinational pharmaceutical to lower the prices of patented medicines and issue voluntary license on reasonable terms and conditions. The author also put light on the problem of the FTAs which become a serious concern and due to which all the effort of Doha Declaration and Decision are in vain. Developed countries entered into the TRIPS plus negotiations through regional and bilateral agreement with developing countries and under these agreements the developing countries bound themselves not to use all flexibilities for getting some trade relaxations.[17] Practices of different countries showed that whenever conflict arises between the economic interest and the right to health the right to health is always compromised. Just international effort to ensure affordable drugs to the vulnerable people is not sufficient unless states efforts in this regard are not seriously involved. Ultimately, it is the very basic duty of state to provide the appropriate health facilities to its citizens by all means.

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[16] Gulzar Asim, "Challenges and Opportunities in the Post TRIPS Era for Pakistan--An Overview of Amended Patents Ordinance 2002," *SPO Discussion Paper Series: Understanding Pakistan Volume II*, 2014, https://spopk.org/wp-content/uploads/2019/11/dp_volume_ii.pdf.

[17] Correa M. Carlos, " TRIPS Agreement and Access to Drugs in Developing Countries" *International Journal of Human Rights*, 3(2005):25-38, https://sur.conectas.org/en/trips-agreement-access-drugs-developing-countries/.

Shamnad Basheer in his article *"'Exhausting' patent rights in India: Parallel Imports and TRIPS compliance"* he narrates that the amendment introduced in Indian patent law in 2005 attracted much attention of domestic and foreign pharmaceutical companies. Multinational pharmaceutical companies considered that their exclusive rights are compromised by incorporating new provisions particularly section 3(d) and 107A which deals with strict patentability criteria and parallel importation respectively. However, these provisions shows the commitment of Indian government that how the state is concerned about its duty to provide basic health facilities to its citizens[18]

Vijay Kumar Himanshu in his article "*Patent Monopoly and Doctrine of Exhaustion: Limits on Exclusive Right"* explain the right granted to the patentee and he also highlighted well that the exhaustion of patentee right after the first sale is not the limitation on the right of the patentee because the patentee is rewarded for his work after first sale now the buyer is authorized after paying the price to use gift or sold out the patented product as he wished except to reconstruct. The writer also suggested to rethink the doctrine of exhaustion and to incorporate the provisions of national exhaustion in the patent law of India to make it more compatible with article 6 of the TRIPS agreement.[19]

A study was conducted by the CIPIH to find out the impact of the TRIPS flexibilities on public health and to take into account the extent to which the developing countries incorporate these flexibilities to fulfill their public health needs. This study also tries to reveal the trade policies of developed and developing countries

[18] Shamnad Basheer and Mrinalini Kochupillai, " 'Exhausting' Patent Rights in India: Parallel Imports and TRIPS Compliance," Journal of Intellectual Property Rights, Vol 13(2008) p 486-497, http://docs.manupatra.in/newsline/articles/Upload/56BF7AA8-6A64-4630-AF64-5EC5BE9F4E6E.pdf

[19] Himanshu Vijay, "Patent monopoly and Doctrine of Exhaustion: Limits on exclusive rights", *Journal of Intellectual Property Rights*, vol 16 (2011) p 453-463, http://nopr.niscair.res.in/bitstream/123456789/13055/1/JIPR%2016(6)%20453-462.pdf

whether these policies give priority to public health concerns. This report concludes that appropriate use of the TRIPS flexibilities can promote access to affordable medicines. It also highlights that though developing countries incorporate one or more flexibilities in their national legislation but gape still exist between the incorporation of flexibilities and use of these flexibilities. Access to affordable medicine may become easier if the accurate incorporation of flexibilities and right usage are made together. Report also asserts that FTAs between developed and developing countries fail to take proper account of public health concerns and issues in developing countries.[20]

Kamini Shanmugaiah in his article *"The impact of TRIPS on access to medicines in developing countries: legal challenges faced by the pharmaceutical industry particularly in India"* narrates the impact of the TRIPS on developing countries with regard to access towards affordable medicine. He asserts that the TRIPS flexibilities particularly compulsory license and Bolar exception are very useful tools to control the abusive patent monopolies. He highlights that if the TRIPS flexibilities incorporated properly may help the developing countries to provide generic affordable medicines to its citizens. Author also discuss the data exclusivity provision and considered it as the TRIPS plus obligation for developing countries. He suggests for India a patent system in compliance with TRIPS and advised to avoid any TRIPS plus commitment.[21]

*CIPIH is a commission on intellectual property, innovation and public health. In May 2003 CIPIH was adopted with resolution WHA56.27at fifty sixth World Health Assembly. The objective of the commission was to highlight the linkage between intellectual property, innovation and public health.

[20] German Velasquez, Guidelines on patentability and access to medicines, South Centre: Research paper 61, March 2015, https://www.southcentre.int/wp-content/uploads/2015/03/RP61_Guidelines-on-Patentability-and-A2M_rev_EN.pdf

[21] Shanmugaiah Kamini, "The impact of TRIPS Agreement on access to medicines in developing countries: Legal challenges faced by the pharmaceutical industry particularly in India," *UUM Journal*

Oiasupo Ayodeji in his article *"Compulsory Patent Licensing and Local Drug Manufacturing Capacity in Africa"* explains the poor health conditions in Africa. He highlights that the disease burden is very high in Africa and country depend on the imported drugs to fulfill the need because drug industry in Africa is not capable to fulfill the demand as it does not have manufacturing capacity for most of the drugs. African countries have option to refuse to grant patent on pharmaceutical till 2021 and it is a time period for African countries to take full advantage to strengthen their pharmaceutical industry. Mutual collaboration of all African countries may help to gain this objective. He asserts that the African countries should pay more attention to their manufacturing capacity to take full advantage of the compulsory licensing provisions.[22]

Eduardo Urais and Shyama Ramani in their article *"Access to medicine after TRIPS: Is compulsory license an effective mechanism to lower drug prices? A review of existing evidence"* makes a detail analysis of prices of different drugs before and after the issuance of compulsory license. They reviewed literature gathered from different sources till 2018 and try to explain the price reduction made by the use of compulsory license. They include the cases of compulsory license just after the implementation of the TRIPS from 1995. 74 cases were reported from 1995 to 2018 but price data was not available for all countries and only for 24 cases data regarding the price was available. They discussed the 24 cases of compulsory license on 16 different drugs and the price information about 13 compulsory license cases was reported by the government sources. Results show that the mean prices of drugs were

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of Legal Studies, vol 3 (2012), p 51-76, http://e-journal.uum.edu.my/index.php/uumjls/article/view/4549

[22]Owoeye Olasupo, "Compulsory Patent Licensing and Local Drug Manufacturing Capacity in Africa" *Bull World Health Organ*, v.92(3) 2014: 214-219,https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3949597/.

reduced from 66.2% to 73.9% and it was concluded that the compulsory license is an effective tool to control the high prices of drugs. Authors also highlight that the compulsory license provisions can be effective only when the generic producers are available it might be the local manufacturing capacity or the use of provisions of Decision otherwise the just subsistence of compulsory license provision is not a solution. So writer advised that the developing countries should make serious efforts to develop their drug industry and incorporate provisions of Decision of 30 August in their patent law if they want to utilize the compulsory licensing provisions.[23]

Fredric M. Abbott and Rudolf V. Van Puymbroeck in their article *"Compulsory license for public health: A guide and model documents for the implementation of Doha Declaration Paragraph 6 Decision"* explain in detail the Doha Declaration and Decision on the paragraph 6 which highlight the issue of the countries with no or insufficient manufacturing capacity cannot use compulsory license flexibility in health emergencies. The 30thAugust decision makes the situation much better and allows the countries to issue a compulsory license for export of the drug into those countries that cannot manufacture the drugs. This article provides model document for the countries to incorporate the provisions of decision into their national legislation and it also provides model document for notification to the council of the TRIPS for importing and exporting countries. The authors provide the assistance to the developing countries and guide to implement Decision.[24]

[23]Urais and Ramani, "Access to medicines after TRIPS: Is compulsory license an effective mechanism to lower drug prices? A review of the existing evidence," *Journal of International Business Policy*, 3(10):1-18,https://www.researchgate.net/publication/344086685_Access_to_medicines_after_TRIPS_Is_compulsory_licensing_an_effective_mechanism_to_lower_drug_prices_A_review_of_the_exis.

[24]Abbott and Puymbroeck, Compulsory Licensing for Public Health: a Guide and Model Document for the Implementation of the Doha Declaration paragraph 6 Decision, the world bank working paper series,2005,

Javier Esparza in his article *"Indian patent law: working within The TRIPS agreement flexibilities to provide pharmaceutical patent protection while protecting public health"* give introduction to the Indian patent law and Indian pharmaceutical industry. He asserts that despite this fact that pharmaceutical companies spend a lot of efforts and money on the development of new drugs but only few new discoveries seen in the recent years. Due to high expenditures, it is frequently practiced by the pharmaceutical companies that they try to extend the life of their popular products to earn more money. Companies obtained new patents on same product after making minor changes. Author highlights that 2/3 of drugs approved for patent protection in USA is actually the result of the incremental changes of already approved drugs. He asserts that section 3(d) is a best way to deal and control the ever greening of patent system and he also narrates that section 3(d) shows the commitment of the Indian government to facilitate their citizens with proper health facilities.[25]

K D Raju in his article *"Compulsory V. voluntary licensing: A legitimate way to enhance access to essential medicines in developing countries"* elaborates the effectiveness of the compulsory license for developing countries and importance of Doha Declaration for countries having no or insufficient manufacturing capacity. He also highlights that after the Natco V Bayer case the multinational pharmaceutical companies now frequently issue voluntary license to domestic pharmaceutical companies to stay away from compulsory license. He also shares that in India Swiss Drug Company allow the local manufacturing of three patented medicines used to treat cancer. He claims that India compelled the multinational pharmaceutical

https://openknowledge.worldbank.org/bitstream/handle/10986/7269/334260rev0pub.pdf?sequence=1&isAllowed=y.

[25] Esparza Javier, Indian Patent Law: Working within TRIPS Agreement flexibilities to provide pharmaceutical patent while protecting public health, accessed on 22 October 2021, https://www.law.fsu.edu/sites/g/files/upcbnu1581/files/JTLP/jtlp-v24-06-esparza.pdf

companies to cooperate with domestic companies so that the technology transfers in true sense. He also asserts that the fear of compulsory license forces the multinational pharmaceutical companies to control prices and to go for voluntary license. All these efforts resulted in the easy and affordable access of medicines to the vulnerable people of India.[26]

The WHO released its Global progress report of 2020 named as *"Accelerating access to hepatitis C diagnostics and treatment: overcoming barrier in low-and middle income countries"* and elaborated the progress towards achieving its goal of 2030 and substantial development in health sector. It was mentioned in the report that the data was collected and assembled in 2019 but as the COVID-19 pandemic spread worldwide and effect every department everywhere. This report also highlights the apprehension that the COVID-19 might reverse the efforts of a decade to progress in health sector. The reports assert that COVID-19 pandemic reminds the world that there is a dire need to invest efforts collectively for global health coverage to deal with emergencies.[27]

A report issued by the WHO *"Patent situation of key products for treatment of hepatitis C"* describes the role of the WHO and further explains that when state authorities asked for assistance to the WHO for equitable and affordable access to HCV treatment then the WHO team has to considered many aspects carefully. Access to new and affordable DAA is really a challenging task. Reports explain very clearly that before to suggest any strategy to the state authorities it is very important to know

[26] Raju K D, "Compulsory and Voluntary Licensing: A Legitimate way to Enhance Access to Essential Medicines in Developing Countries," *Journal of Intellectual Property Rights*, Vol 22, January 2017,23-31. http://docs.manupatra.in/newsline/articles/Upload/31AC60C2-ABCC-4799-A388-0F56ED7C9ECF.pdf.

[27] World Health Organization, Accelerating access to hepatitis C diagnostics and treatment, overcoming barrier in low and middle –income countries: Global progress report 2020, 27 January 2021, file:///C:/Users/user/Downloads/9789240019003-eng.pdf

clearly about the patent status of new the DAA in that jurisdiction. Report also clarify that this is not an easy task and it demands special knowledge and access to relevant department or their databases which are not available easily. This report provides information about the patent status of different HCV medicines whether patent is filed, rejected, withdrawn or granted. This report also identifies the secondary patent which resulted in delay of generic entry.[28]

Muhammad Umer et al. in their article *"Role of generic in the treatment of Hepatitis C infection"* highlights the importance of generic medicines that how these generic reduced the prices of DAA and enable many people in low and middle income countries to start treatment. He also discusses the practice adopted by the different countries for the entry of generic drugs some entered into bilateral agreement, some indulged in license territory regime, some reject the patent and some issued the compulsory license. He asserts that the entry of generic manufacturers results in intense competition and low price facilitate the patients of HCV. He explains the practice adopted by Pakistan that how the registration of the generic companies for Sofosbuvir facilitate the thousands of people in Pakistan to start their HCV treatment.[29]

Medicine San Frontieres in a report while highlighting the issue of HCV explains that worldwide 71 million people suffered with HCV infection. Report indicates that in 2015, 4 lac. 90 thousand people died from HCV infection. Report shows that though prices of HCV has fallen in recent years but still it is out of the

[28]World Health Organization, Patent status of key products for treatment of hepatitis C: Working Paper, June 2016, https://www.who.int/phi/implementation/ip_trade/sofosbuvir_report.pdf?ua=1 ,last accessed on 8th February 2022.

[29] Umer et al., "Role of generics in treatment of hepatitis C infections", Journal of Ayub Medical College, 4suppl, 28 (2016).890-894,https://www.researchgate.net/publication/354687406_ROLE_OF_GENERICS_IN_TREATMENT_OF_HEPATITIS_C_INFECTION last accessed on 27 January, 2022.

reach in many jurisdictions. It asserts that 2.1 million patients treated with new DAA and 68.9 million patients still waiting for access to safe and affordable treatment. Report also narrates the reasons for lack of access to DAA and concluded that there are many factors involved in delay access to HCV treatment including government non seriousness, patent barriers, regulatory complications and unaffordable high prices. Report suggests that countries should be active to use TRIPS flexibilities to ensure affordable treatment to their citizens.[30]

The WHO always promotes and provides best of its support for countries efforts to achieve equitable access to affordable HCV treatment. In the ambit HCV the efforts and role of the WHO is appreciate able. The WHO set the goal to eliminate the HCV till 2030 and to avail its goal it did a lot of efforts. The WHO provides assistance, guidance, set target country wise and then checks the response of all respective states. The WHO in its report *"Progress report on access to hepatitis C treatment: Focus on overcoming barriers in low and middle income countries"* reveals that countries where patents are not granted or applied the price of DAA are affordable due to generic entry and it also enables the manufacturers to export DAA in these countries. The WHO recommends the countries who granted patent and have high disease burden should go for compulsory license to reduce the price HCV treatment. The WHO also reveals clearly that the country that enables generic entry into their jurisdiction and start competition successfully reduces the prices of DAA.[31]

[30] Medecins Sans Frontierers, "Not even close", https://www.msf.org/sites/msf.org/files/hepc_issuebrief_hep_c_2017.pdf last accessed on 27 January, 2022.

[31] World Health Organization, Progress report on access to hepatitis C treatment: Focus on overcoming barriers in low and middle income countries, March 2018, p-viii, https://apps.who.int/iris/bitstream/handle/10665/260445/the WHO-CDS-HIV-18.4-eng.pdf

The Medicine Sans Frontieres (MSF) is an international association with objective to ensure access to medicine for all and worked on humanitarian grounds. The MSF is also known with the name of Doctors without borders. The MSF work a lot for HIV/AIDS patients and generic availability of anti-retroviral. The MSF is also working for low cost and effective treatment of HCV by DAA. In India with alliance of generic manufacturer and some NGOs filed the first patent opposition against Gilead's patent claim. After the one month from the patent opposition, Gilead signed with 11 Indian Generic companies a voluntary license for manufacturing and sale of Sofosbuvir, Ledipasvir and Velpatasvir. By the term of the voluntary agreement, the DAA can be sold in 101 countries only. The MSF articulates that this restriction by the Gilead is excluding many low and middle income countries which have millions of HCV patient. The MSF recommend Gilead and insisted on generic companies to reconsider their terms with Gilead and extent the geographical scope of license.[32]

Zaheer-ud-Din Baber et al. in their article *"The Pharmaceutical Industry, Intellectual Property Rights and Access to Medicines in Pakistan"* explain the structure of local pharmaceutical industry, its potential and compare it with other regional countries like India and Bangladesh. He articulates that drugs prices in Pakistan are higher than in India. He narrates that to be complied with the TRIPS agreement Pakistan strengthen its IP policies and law which might result in increasing foreign investment but it is also very important to evaluate the impact of this tightened

[32]Medicines Sans Frontiers, Access to Sofosbuvir, Ledipasvir and Velpatasvir: Analysis and recommendations on Gilead's license, March 2015, https://msfaccess.org/sites/default/files/the MSF_assets/HepC/Docs/HEPC_Analystics_GileadHepCLicense_ENG_2015.pdf , last accessed on 22 February 2022.

legislation on the access to medicine. He suggests that there is a dire need to check the impact of new IP regime on medicine with empirical studies.[33]

Zaidi, Ansari and Khan in their article *"The financial burden of cancer: Estimates from patients undergoing cancer care in a tertiary care hospital"* narrate the situation of developing countries particularly Pakistan that how the diagnosis of cancer badly effect the families emotionally and financially. A cross-sectional study was conducted in AKUH (Aga Khan University Hospital) Karachi. During the period of three months all the patients of breast cancer and head and neck cancer who visited the hospital and diagnosed were included in the data. During this period of three months 67 patients were examined and interviewed. In 94% cases the expenses are born by the families. The authors further highlight in this study that the financial burden to treat cancer is overshadowed the emotional burden. They narrate that in Pakistan the situation is worst as there is practice of single earning hand in a family. It was also observed in the study that all the patients of breast cancer were female and they depend on their male family member to bear the expenses of treatment. Study highlights that the situation become worse when the male member of the family diagnosed with cancer as they are, in 90% cases, sole earner of their family. It becomes very hard for them to continue their earning position during the cancer treatment. Every cancer case has its own pathetic story. It is very difficult to imagine the emotional trauma and financial hardships which families faced as they have to bear the burden themselves without any support from government. Authors suggest in concluding remarks that the government and non-government organizations should

[33]Baber Zaheer-ud-Din et al., the pharmaceutical industry, intellectual property rights and access to medicines in Pakistan, January 2013, https://www.researchgate.net/publication/304819584_The_Pharmacthe EUtical_Industry_Intellectual_Property_Rights_and_Access_to_Medicines_in_Pakistan ,last accessed on 24 February 2022.

come forward to provide financial support to the cancer patients and to help them to face this challenging situation.[34]

Sudip Choudhury in his article *"Intellectual Property Rights and Innovation: MNCs in Pharmaceutical Industry in India"* narrates that the aim behind the patent protection is to encourage investment for new researches and promote technological progress by transferring it in society which respect patent right. Aim of this study was to evaluate that after the patent protection in India MNCs enhance the budget of research and development activities and also to evaluate that the patent protection leads towards technological progress. Sudip concludes that even after patent protection the research and development and development activities are not increased in India by the MNCs. It also highlights that many of the patented drugs are not manufacture in India but imported from the other countries. So, it does not contribute to the technology development. Author argues that this hypothesis has approved failed in India that strong IP protection leads towards more research and development activities. He also insists that if these MNCs are conducting research and development outside the India and just importing the new patented drugs in country then India is just paying exorbitant prices of patented drugs without benefiting from technology transfer. He argues that the conventional thinking that developing countries should avoid to grant product patent proved true.[35]

Sudip Chaudhuri in another article *"Are medicine prices high and unaffordable after TRIPS? Evidence from pharmaceutical industry in India"* narrates that TRIPS is

[34] Zaidi et al., " The financial Burden of cancer: Estimates from patients undergoing cancer care in a tertiary care hospital", *International Journal for Equity in Health* 11, 60(2012), file:///C:/Users/user/Downloads/sThe_financial_burden_of_cancer_Estimates_from_pat%20(1).pdf , last accessed on 24 February.

[35]Sudip Chaudhuri, "Intellectual property rights and innovation: MNCs in pharmaceutical industry in India after TRIPS," Research Gate, November 2014, file:///C:/Users/user/Downloads/Sudip-ISID-WP-MNC-IPR-Nov-2014%20(1).pdf , last accessed on 25 Feb. 22.

considered as the most controversial agreement of the WTO especially by the generic pharmaceutical industry in India. History witnessed that during the AIDS pandemic when millions of people were dying because the prices of patented drugs were very high and unaffordable, Indian generic manufacturers were providing these medicines in very affordable prices and saved the lives of million people all around the world. After the TRIPS India started protecting product patent and now generic manufacturers cannot play their role to bring the price down. He claims in his research that the TRIPS affect the prices of medicines adversely. He asserts that the pharmaceutical companies have started selling their patented products at very high prices especially cancer medicines. Cancer has become a global health challenge and unaffordable prices make the situation more deteriorating. He finds out that the patent barriers and regulatory complication are the main reason for the high prices of cancer medicines. He concludes that the TRIPS flexibilities should be used and regulatory complications need to be simplified to make medicines affordable.[36]

Cancer has become the leading cause of death worldwide and it has become the source of attention for researchers, social activists and health personals from many years. P. Kanavos in his article *"The rising burden of cancer in developing countries"* which was written in 2006 asserts that till 2020 approximately 12 million people will die of cancer[37] and this prediction proves true as the report of the WHO shows the statistics that in 10 million people died of cancer in 2020.[38] Kanavos also mentioned

[36]Sudip Chaudhuri, "Are medicine prices high and unaffordable after TRIPS? Evidence from pharmaceutical industry in India," SSRN, December 2019, file:///C:/Users/user/Downloads/SSRN-id3767829.pdf , last accessed 26 February 2022.

[37] P. Kanavas, "The rising burden of cancer in the developing world", *Annals of Oncology*, 8,17 92006): p-15-23, available at https://reader.elsevier.com/reader/sd/pii/S0923753419414233?token=AF7808BBE14E9AFDB3C9874C9F872754E8F31C6417578E68536940AC60327EBC1AA61DCE1FEA7B27AAD48955A8552653&originRegion=the EU-west-1&originCreation=20220524033730

[38] Cancer, World Health Organization, February 2022, https://www.who.int/news-room/fact-sheets/detail/cancer , last accessed in 22 May 2022.

that developing countries have many policy issues regarding cancer treatment as there is inadequate health care system at national level with no preventive policies. He said that developing countries spend very less on health and that's the reason that cancer patient in developing countries either have no cancer treatment or the treatment is unaffordable for them. He claims that the international trade agreements also undermine the importance of affordable health care treatment. He said that as in 2002 international movement was started to combat the HIV infections particularly in low and middle income countries and this movement was succeeded to establish a Global AIDS and health fund. Cancer pandemic also needs that kind of concern on international level to reduce the miseries of cancer patient in developing countries.[39]

L. N Shulman et al. in their article *"Breast cancer in Developing countries: Opportunities for Improved Survival"* narrates that the breast cancer is the most common cause of death among women. He asserts that the survival rate of women diagnosis with breast cancer is remarkable in developed countries particularly in America as compare to 60 years ago and reason behind this improvement is early diagnosis, highly qualified surgery and use of new latest therapies gave extra ordinary results. He also highlights that there are increasing number of breast cancer in developing countries with high mortality rate as the treatment options are not available or affordable for people living in low and middle income countries. Women in low income countries are diagnosed late and this is the reason for more deaths. 78% women with breast cancer in South Africa are diagnosed at advance stage while in

[39] P. Kanavas, "The rising burden of cancer in the developing world", *Annals of Oncology*, 8,17 92006): p-15-23, available at https://reader.elsevier.com/reader/sd/pii/S0923753419414233?token=AF7808BBE14E9AFDB3C9874C9F872754E8F31C6417578E68536940AC60327EBC1AA61DCE1FEA7B27AAD48955A8552653&originRegion=the EU-west-1&originCreation=20220524033730

USA majority of breast cancer patient diagnose at stage I or II and only 5% [40]patient are of stage IV.

Philip, Mathew and John in their article *"Cancer cares: Challenges in the developing world"* discuss the challenges of developing countries while dealing with cancer. Information was collected by the young oncologist who attend annual meeting of American Society of Clinical Oncology and represent different jurisdiction of developing countries. There are number of challenges for the treatment of cancer including health care financing, awareness and delivery of appropriate treatment. Affordability of treatment is also a great challenge for the poor and at time cancer patients have to abandon their treatment due to financial constraints. Government support for cancer treatment is also inadequate so patient has to bear the cost of cancer treatment along with the miseries of cancer itself. The researchers suggest there is need to increase potential solution for making cancer treatment better. They highlight that during the HIV/AIDS crises developing countries faced the same challenges. At that time developed countries improved their diagnosis system and ensure the access towards new and effective therapies to treat HIV/AIDS while burden of disease was rising in developing world with high number of mortalities. Poor financial condition and inadequate health facilities was the main obstacles. However, international co-operation, training programs and significant role treatment activist ensure the availability of HIV/AIDS drug to the needy people. All the efforts led towards the successful treatment of millions of people and saved their lives. The researchers of this paper suggest that similar efforts needed to control cancer burden.

[40] L N Shulman et al., "Breast Cancer in developing countries: opportunities for improved survival", *Journal of Oncology*,595167(2010): 6, file:///C:/Users/user/Downloads/Breast_Cancer_in_Developing_Countries_Opportunitie.pdf last accessed on 24 May, 2020

International support, strong political will and full co-operation of pharmaceutical sector is needed to tackle cancer burden in developing countries.[41]

Cazap et al. in his article *"Structural Barrier to Diagnosis and Treatment of Cancer in Low- and Middle-Income Countries: The Urgent need for Scaling up"* asserts that there is dire need to scale up cancer treatment in developing countries to avoid high mortality rate. He also highlights that the improvement in technology decreases mortality rate for other diseases but for cancer mortality rate is increased in recent years. There might be many reasons for this increase including more exposure to the common risk factors and extra disclosure to carcinogens. There are different modes of treating cancer patients (surgery, radiation and systematic therapy or combination). In least developed countries these facilities are not available to the 90% of cancer patients. In low middle income countries though these treatments are available but limited to the urban areas and affordability is also a serious issue. He also highlights that there are only few oncologists in low and middle income countries and at times surgeon performed surgery and administered chemo therapy as well. While in high income countries the treatment for cancer is quite different and specialized oncologist performed chemotherapy. So, the author concludes that there is dire a need to train the oncologists and government should take appropriate measures to ensure the availability of affordable medicines.[42]

Saima Maliket al. in his article *"Survival analysis of breast cancer patient with different treatment: a multi central-central clinic pathological"* study tries to find out reasons for breast cancer in women. They collected data from different five

[41] Philip, Mathew and John, " Cancer care: Challenges in the developing world", *Cancer Research,, Statistics and treatment*, vol-1,1(2018)58-62, https://www.crstonline.com/article.asp?issn=2590-3233;year=2018;volume=1;issue=1;spage=58;epage=62;aulast=Philip

[42]Cazap et al., "Structural Barriers to Diagnosis and Treatment of cancer in Low AND Middle-Income Countries: The urgent need for Scale up", Journal of Clinical Oncology, vol. 34,1(2016) 14-20, https://ascopubs.org/doi/10.1200/JCO.2015.61.9189

hospitals in Islamabad and Rawalpindi between September 2014 to February 2018. Breast cancer was considered as the disease of western women but now the Asian women are equally affected by this disease. This study highlights that there are many reasons of breast cancer in Asian women late marriage, family history, abortions, late menopause and early menarche are main reasons to increase risk factor for breast cancer.[43]

Asim Yousaf in his article *"Cancer care in Pakistan"* discusses the current cancer status in Pakistan including the number of diagnosis facilities and cancer care centers in Pakistan. Author highlights that there is a short of data about cancer statistics in Pakistan. There is lack of trained oncologist in country and at time the surgeon after surgery start chemotherapy and many cancer patients never meet an oncologist during their whole treatment. Most of the cancer patient diagnosed at late stage in Pakistan. There are two main reasons for late diagnosis first is the lack of cancer awareness and second is the economic considerations. Patient in Pakistan are reluctant to visit doctor and avoid it as long as they can due to financial reasons. This is the reasons that in Pakistan doctor use symptomatic treatment instead of systematic diagnosis treatment, general physician most of the time unable to diagnosed cancer. In conclusion author insists that there is dire need to train our doctors, nurses and other medical staff and to increase the number of radiation machines and other equipment. He also insists that there should be more researches on cancer in Pakistan about the causes of cancer its treatment and other important information about cancer. He said that due to limited data about cancer further planning about cancer is very difficult.[44]

[43]Saima Malik et al. Survival analysis of breast cancer patient with different treatment: a multi-central clinic opathological study, file:///D:/cancer%20and%20pak/9232.pdf last accessed on 2nd May, 2022.
[44] Asim Yusuf, " Cancer Care in Pakistan", Japanese Journal of Clinical Oncology, vol 43:8(2013) p 771-775, https://academic.oup.com/jjco/article/43/8/771/894595 last accessed on 7 June 2022

Saira Saeed et al. in his article *"Cancer and how the patient see it; prevalence and perception of risk factors: a cross-sectional survey from a territory care center Karachi, Pakistan"* explains the causes, risk factors and myths about cancer. In this study, the author tries to investigate the cancer care in government hospitals and try to look into the common perception patient about the disease. 402 patients were examined with their due consent. They came to the conclusion that biomass exposure, smoking and smokeless tobacco (*gutka, mainpuri, bidi, naswar etc*) are the main risk factors for cancer. Many people aware of these factors but they use them continuously. Reason behind this use is easy availability and their cheap price. In Asia, burden of using smokeless tobacco is highest in the world and there are 100 million users are lived in Pakistan and India only. Breast cancer is most common type of cancer in women and head and neck is second more common among the people of Karachi. It was also observed during the study that cancer patient related to different factors with cancer like black magic, pollution and evil eye. In this way, they ignore the original causes of cancer.[45]

Hassan Irfan Khan in his article *"Pakistan recent trends in patent enforcement"* discusses different court cases won by the multinational pharmaceutical companies while enforcing their patent right. The author explains that the patent law of Pakistan provides protection to the intellectual property rights holder according to the international standards and now it is up to the right holder to claim remedy against the infringement through the court of law.[46]

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[45]Saira Saeed et al., " Cancer and how the patient see it; prevalence and perception of risk factors: a cross sectional survey from a tertiary care centre of Karachi, Pakistan," BMC Public Health, 19:360(2019) https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-019-6667-7 last accessed on 7th June 2022

[46]Hasan Irfan Khan, " Recent Trends in Patent Enforcement", United Trademark and Patent Services, 2008, http://www.buildingipvalue.com/08_AP/223-225UnitedTrademark.pdf last accessed 17 June, 2022.

Zaheer ud din Baber et.al. in their article *"The Pharmaceutical Industry, Intellectual Property Rights and access to medicines in Pakistan"* highlight the link between patent and public health and also explains the also explains the changes made by the Pakistan to comply with the TRIPS agreement. He asserts that the pharmaceutical industry in Pakistan has potential but industry needs government support to flourish and to utilize its full potential. He also suggests that policy makers while making IP laws should keep in mind the needs of local industry. The local industry mostly fulfils the needs of local people and provides medicines off-patented medicines on reasonable affordable prices. He suggests further empirical studies to evaluate the impact of new intellectual property legislation on public health. He also recommends that there is need to assess the effect of new the FTA signed between Pakistan and other countries on the right to health.[47]

M. Rehan Sarwar, Sadia Iftikhar and Anum Saqib in their article *"Availability of anticancer medicines in public and private sectors, and their affordability by low, middle and high-income class patient in Pakistan"* conducted a cross-sectional survey in 22 cancer hospitals including public and private sectors. They find out that oncologist in Pakistan treat cancer patient with conventional medicines (cisplatin, cyclophosphamide and etoposide). The authors assert that the oncologists are reluctant and avoid prescribing new patented cancer medicines due to the high prices of these medicines. They also find out in their research that the original branded cancer medicines are more easily available but these medicines are less affordable for low- and middle-income class. They also concluded that generic cancer medicines are

[47] Zaheer-ud-din Babar et al., " The Pharmaceutical Industry, Intellectual Property Rights and Access to medicines in Pakistan", *ResearchGate*, https://www.researchgate.net/publication/304819584_The_Pharmacthe EUtical_Industry_Intellectual_Property_Rights_and_Access_to_Medicines_in_Pakistan last accessed on 14 June, 2022

not easily available through these medicines are more affordable for low- and middle-income class. They suggest the government and drug regulatory authority to ensure availability and affordability of cancer medicines through their effective policies.[48]

Poul L.C. Torremans in his book *Intellectual Property Rights: Enhanced Edition of Copyright and Human Rights* explain the link between the human rights and IPRs. Chapter 5 of this book is edited by Estelle Derclaye titled as "Intellectual Property Right and Human Rights: Coinciding and cooperating" elaborates that human right and IPRs are conflict with each other and human right must overcome the other. The author insists that a balance is required to be maintained between these two rights. He puts an obligation on the legislature to create a balance and held the judiciary responsible to maintain this balance.[49]

THESIS STATEMENT

Patent Ordinance 2000 is not fully equipped with the TRIPS Flexibilities thereby affordable access to patented medicines is increasingly becoming an issue in Pakistan, hence, there is need to revamp Pakistan legal regime to overcome this problem.

OBJECTIVEIVES OF RESEARCH

The primary objective of this research is to evaluate the Patent Ordinance 2000 and to examine how far it ensures the affordable access to patented medicines in

[48]M. Rehan Sarwat et.al., "Availability of anticancer medicines in public and private sector, and their affordability by low, middle and high income class patients in Pakistan", BMC Cancer, vol18,14(2018). https://bmccancer.biomedcentral.com/track/pdf/10.1186/s12885-017-3980-3.pdf last accessed on 20 June, 2022

[49] Estelle Derclay, " Intellectual Property Rights and Human Rights: Coinciding and Cooperating," *Intellectual Property and Human Rights: Enhanced Edition of Copyright and Human Rights*, ed. Poul L.C. Torremans (The Netherlands: Kluwer Law International, 2008) 133-134.

Pakistan by using the TRIPS flexibilities. Further objectives of this research include as:

1. To trace the evolution of global protection of intellectual property rights generally and patent law particularly under the WTO regime.
2. To highlight the importance of right to health (as it interlinked with right to life) under the national and international law and to identify the conflict between patent and public health.
3. To analyse the existing statutory provisions of Indian patent law and patent law of Pakistan and identify the way in which India used the TRIPS flexibilities to promote local pharmaceutical industry and to ensure affordable access to patented medicines.
4. To highlight and identify the price difference between India and Pakistan for the same cancer medicines manufacture by same multinational pharmaceutical companies.
5. To highlight the very important fact that the patent office of Pakistan is frequently granting patent on new cancer drug without strict scrutiny, as made in India, which results in ever greening of patent and extent the patent life beyond 20 years.
6. To highlight the need of amendment in the existing patent law of Pakistan in order to make it more convenient and useful for local pharmaceutical industry and public health.

RESEARCH QUESTION

1. What is the nexus between patent law and access to medicine?
2. Are there adequate provisions in Pakistan Patent Ordinance 2000 to facilitate the affordable access to patented medicine?
3. Whether compulsory license provisions under the Patent Ordinance 2000 of Pakistan are sufficient and effective?
4. What is the impact of parallel import on the affordable access of patented medicines and how the patent law of Pakistan has addressed the issue?
5. How can we use access to HCV strategy to achieve desirable objectives in other fields such as access to cancer medicines?
6. Can Pakistan learn from the experience of the regional countries to revisit its patentability requirements like India?

METHODOLOGY

Doctrinal method of legal research shall be used as the provisions of Patents Ordinance 2000 of Pakistan and Patent Act, 1970 of India will also be taken into account and important case laws shedding light on the phenomenon of patent protection and public health will be discussed. Furthermore, the arguments are based on the findings of scholarly articles, law reviews, annual reports and different books related to the topic. Qualitative research methodology is employed to examine the patent system and its effects on affordable access of patented medicines.

THEORATICAL FRAMEWORK

During the review of literature, different theories about the justifications and effects of intellectual property rights were studied. Some important theories of intellectual property rights have been analyzed including labor theory, personality theory, utilitarian theory and social planning theory. The utilitarian theory on intellectual property rights as described by Mark A. Lemley in his article Faith-Based Intellectual Property[50] suggests that traditional justification for intellectual property rights has been utilitarian. Intellectual property rights cannot be justified as a moral end rather it should also be observed how intellectual property rights affect the world. While shaping intellectual property rights, the maximization of net social welfare should be maintained. Patent protection under the TRIPS agreement is unavoidable but for the sake of public health the TRIPS agreement must be interpreted from human right perspective so that rights of inventors and users are protected side by side. This notion is also reaffirmed in Doha Declaration 2003 on TRIPS agreement and Public Health. Law makers require maintaining an optimal balance between rights of inventers and right of the consumers. It is possible only by incorporating all the flexibilities of the TRIPS agreement into the Patent Ordinance 2000 of Pakistan so that access to affordable medicines would be ensured.

SIGNIFICANCE OF STUDY

Every state is under the legal obligation to protect right to health under the national and international law. Pakistan is also being the member of the WHO and other human rights convention and covenant is bound to promote right to health. For

[50]Lemley, Mark A., Faith-Based Intellectual Property (March 30, 2015). 62 UCLA L. REV. 1328 (2015), Stanford Public Law Working Paper No. 2587297, Available at SSRN: https://ssrn.com/abstract=2587297 or http://dx.doi.org/10.2139/ssrn.2587297

this purpose, state authorities are bound to make effective provisions of law and policies to ensure availability of adequate health facilities. This research will suggest that how Pakistan can ensure the availability of affordable medicines by keeping its laws within the TRIPS boundaries. In this way, state will be able to meet its obligations regarding to provide health facilities to its citizens. This research will suggest that integrated the proper use of the TRIPS flexibilities in patent law of Pakistan will provide the legal pathway to access affordable generic version of patent medicines.

This research will highlight that the use of parallel importation provisions, if properly incorporated as it is allowed under the TRIPS agreement, the patented medicines by the multinational pharmaceutical companies which are available in Pakistan but with the big price difference to India can be imported from India on affordable prices.

The TRIPS agreement provides very important tool, compulsory licensing, to undermine the patent abuses. The TRIPS agreement also allows the member states to determine the grounds for granting compulsory license according to their own needs and circumstances. Now, it is up to the states that how successfully it incorporates grounds of compulsory license to make it operative to ensure public health. Compulsory license should be used to balance the rights of users of technology and rights of producers of technology. Every law is a blend and balance of rights and duties but this balance is seems missing in the Patents Ordinance 2000 of Pakistan.

This research concludes that the patent law of Pakistan needs transformative changes to ensure that the benefit of new scientific progress should be enjoyed by all. This study highlights that objectives behind the patent monopolies is not just to allow

the importation of patented article by the multinational pharmaceutical companies but patent holder must ensure dissemination of technology and promote technology transfer through local production units. This study has analyzed the HCV situation in Pakistan and patent status availability and affordability of different HCV medication in Pakistan. Then, it furthers explores that the multiple strategies were adopted by the different state actors to control the prices of HCV medicines. This research suggests that the same strategy should be followed to control the prices of all medicines particularly cancer medicines.

This study concludes that transformative changes are required in the patent law of Pakistan to ensure the availability and affordability of medicines can be ensured for all. Amendment in the patent law of Pakistan will ensure that the benefits of scientific progress enjoyed by all as it was also aimed in the TRIPS agreement.

Affordable access of patented medicine is becoming an issue for all developing countries including Pakistan. Being the member of the WTO, Pakistan is bound to follow the minimum standards of the TRIPS agreement and patent, however, by incorporating the TRIPS flexibilities in the patent law of Pakistan will help to improve the existing situation and it will definitely ensure the access towards affordable medicines.

CHAPTERIZATION/ SCHEME OF RESEARCH

This research is consisted of five chapters. The Chapter One explains the concept of Intellectual Property Rights and how these rights emerged and implemented globally. All efforts to achieve the global implementation of the IPRs are discussed in detail. It also elaborates the importance of right to health under the national and international law. It determines the duty of state to provide the health facilities to its citizen under the international law. It also explores that the strict implementation of intellectual property rights results in the exorbitant prices of life saving medicines. The Chapter Two analyses the TRIPS flexibilities and Patent Ordinance 2000 of Pakistan and further investigates the extent to which these flexibilities are incorporated in the Patent Ordinance 2000 of Pakistan with a narrow or broad implementation of flexibilities is made. The Chapter Three sheds light on a comparative analysis of Patent Ordinance 2000 of Pakistan and Patent Act, 1970 of India. It highlights that the patent law of India fully equipped with the TRIPS flexibilities and maximum use of these flexibilities is obviously seen. It is also observed that the patentability criteria are also very strict under the Indian patent law to stop the ever greening of patent. The Chapter Four describes the availability and affordability of Hepatitis C Virus (HCV) medication in India and Pakistan. It further explains the patent status of HCV medicines in both jurisdictions and efforts made by the states to control the prices. This chapter explains that efforts by all the segments of state made it possible to control the price of hepatitis treatment in Pakistan. The Chapter Five discusses the availability and affordability of different anticancer medicines in India and Pakistan and patent status of these medicines in both territories has been investigated. It finds a huge prices difference in the cancer medicines in both jurisdictions. It also tries to find out the reason for the high prices in Pakistan and

much controlled prices in India for the same medicines by the same multinational pharmaceutical company.

ABBREVIATION

CDC	Centre for Disease Control
CRC	Convention on the Rights of the Child
DAA	Direct-Acting Antivirals
DNP	Delhi Network of Positive People
DSB	Dispute Settlement Body
FDC	Fixed-Dose Combination
FTA	Free Trade Agreement
GATT	General Agreement on Trade and Tariff
GATS	General Agreement on Trade and Services
HDI	Global Human Development Index
I-MAK	The Initiative for Medicines, Access and Knowledge
ICESCR	International Convention on Economic Social and Cultural Rights
IPAT	Intellectual Property Appellate Tribunal
IP	Intellectual Property
IPRs	Intellectual Property Rights
KEI	Knowledge Economy International
MNCs	Multinational Companies
MSF	Medicine San Frontiers
NHSF	National Hepatitis Strategic Framework
TAG	Technical Advisory Group
TRIPS	Trade Related Aspects of Intellectual Property Rights
TWG	Technical Working Group
UNO	United Nation Organization
USA	United States of America
WAC	Wholesale Acquisition Cost
WHO	World Health Organization

WTO	World Trade Organization

CHAPTER 1

INTELLECTUAL PROPERTY RIGHTS AND RIGHT TO HEALTH

Intellectual property rights (IPRs) and right to health, both rights are protected under the international law. Intellectual property rights are the rights of the inventors and researchers to promote further progress in science and technology. Right to health also interlinked with right to life. We cannot deviate the importance of these to rights. To create a balance between economic interest and public health is a complicated dilemma and at times it becomes an awful choice, especially after the implementation of the TRIPS agreement. Even though the TRIPS agreement provides a range of flexibilities to impose restrictions on intellectual property rights when it violate right to health but appropriate and wise use of these flexibilities is rare. Whenever conflict arises between right to health and IPRs most frequently the right to health is sacrificed. The purpose of this research is to suggest the state authorities to apply the human right approach to the international intellectual property regime. It would help the state authorities and state organs to monitor a balance between the right to health and IPRs.

First chapter will put in plain words the economical debate about the IPRs and ethical debate about the right to health. Ethical justification about intellectual property and obligations of State to provide appropriate health facilities to its citizens will

be the part of our discussion. By explaining the scope of right to health this research will describe the impact of IPRs on the right to health. We will discuss the duty of state to stop the TRIPS flexibilities from being misused which ultimately influence the right to health. This research will provide the legal grounds to the nations of the world to repudiate the unjustified protection of the IPRs (TRIPS Plus provisions) especially when the fundamental right to health is threatened.

International treaties which deal with right to health will be examined and what kind of duties these treaties impose on the Sovereign states will be observed. International institutions dealing with right to health, how these institutions bind the state to implement their recommendations and all related experiences will be thrashed out. International treaties which dealing with intellectual property rights will be discussed and international institutions dealing intellectual property rights, how these institutions work, how these institutions implement their decisions and all other related matter will be hammered out.

1.1. Intellectual Property Rights

We are living in the era of ever widening rights. IPRs are also one of the rights which emerged as the result of progress in science and technology. IPRs are the monopolies given to the creators and innovators for the creation of their intellect. Purpose of these monopolies is to give confidence to the creators and inventors that they can utilize their invention as they think appropriate. Any other person is not allowed to interfere with their rights. No one can create, sell or use the invention without the due permission of creator and inventor. These protections create competition; enhanced

confidence and the way of further research and development remain continued by getting adequate profit from the invention in the market. If these protections are not provided in the society, then there might be little investment for further research because the risk of loss will prohibit the inventers to waste money, time and skills.

We can bifurcate the intellectual property rights into two categories

- Copyrights and right related to copyrights
- Industrial property

1.1.1. Copyright and right related to copyright

The original work of the author of the books and the author of the literary and artistic works is protected under the copyright law. Copyright includes writing, music, poetry, novels, software codes and architecture work. Ideas, facts or methods are not protected under the copyright and the protection is given to the expression. No one can sell, reproduced or published the protected material without the due permission of copyright owner. Life time protection is given under the copyright law plus 50 years protection after the death of the author is also given to the heir of the author.[51]

1.1.2. Industrial property

Industrial property can be further divided into two categories, one is trade mark and the other is the patent. Trademarks are distinctive symbols that are used by the producer of a product to make it different from the other products hence the recognition of product would be easy for the consumer. Trademarks are the marks of recognition. These marks help the consumer to identify the product which they want to use. The aim

[51] Richard Wincor and Irving Mandell, *COPYRIGHT, PATENTS AND TRADEMARK: The Protection of Intellectual and Industrial Property*, First Edition (New York: Oceana Publications, 1980)10.

of protecting these distinctive signs is to ensure the quality of product and the fair competition. The second type of industrial property is patent and the term of patent is 20 years. It provides protection to new inventions, new technologies and designs. Patent holder has full control on his invention he can sell it, can give license to other person or can transfer his right. No other person is allowed to make, sell or import the patented products without the permission of patent holder.[52] Patent is protection for a new and functional invention given by the government for a limited period of time. Exclusive rights are given to the inventor of invention and all other persons are prevented to use, sell or manufacture the invention without the prior permission of inventor.

1.2. Historical Development of IPRs

History of IPRs shows that it was not easy to put in force and implement intellectual property rights on national and international level. The current global system of intellectual property rights is the result of many disagreements and disputes. Ownership of ideas and knowledge was a new concept; it was not easy to accept this new notion so a lot of objections were raised by the different secrets of society. A large number of debates were made and a lot of arguments were given on national and international level for the justification of intellectual property rights. The history of intellectual property rights is disputed, contested and constantly evolving. History of intellectual property right can be bifurcated in three periods.

[52]Sahai Bisarya, "Significance of Intellectual Property Rights in Current Era," mondaq, December,2020, https://www.mondaq.com/india/trademark/1020686/significance-of-intellectual-property-rights-in-current-era, last accessed on 11 February, 2020.

- Territorial Period
- International Period
- Global Period

1.2.1. Territorial Period

The very first protection given to the IPRs was based on the principle of territoriality. Different subject matters of IPRs were start protected in different areas at different times. The first patent was granted in 1421 by Italy (Florence), and three years' monopoly was given. Patent was granted to an architect named Filippo Brunelleschi for developing a crane machine that was used for the transporting marbles from mountain. In England the first patent was granted by Henry IV to Flemish glassmaker, named John of Uthynam and 20 years monopoly was given.[53]

Patent system was recognized in different territories at different period of time. The Venetian Act was promulgated in 1474. This Act was considered as the basis of contemporary international patent system. In 1623 England introduced the Statute of Monopolies. USA commenced its patent law in 1790.France enacted its patent law in 1791. Patent system of that time was very simple and short and not complicated like today's patent system.[54]

Trademarks are the brand names that ensure the quality of product. History of the trademarks is very old and it is not easy to trace when first sign was used as trademarks. In ancient times people were used to make marks on goods manufactured by them.

[53]Matt Kwong, "Six significant moments in patent history,"Rthe EUters, Nov.2014, https://www.rthe EUters.com/article/us-moments-patent-idUSKBN0IN1Y120141104,last accessed on 9th July2021.
[54] W. R. Cornish, *Intellectual Property: Patents, Copyrights, Trade Marks and Allied Rights*, First edition. (London: Sweet and Maxwell Publisher, 1981) 80.

Roman used to mark the name of the maker on the back of the tiles and bricks. Lamps made of clay also bear any particular identification marks on it. Trademarks are used and protected socially however after some period of time they got legal protection. [55]

In 1803 France enacted Factory Manufacture and Workplace Act in which it was considered as crime to use the seal of someone without authorization. In 1957 France promulgated Manufacture and Good Marks Act and a complete trademark system was introduced. In 1862 England enacted its Merchandise Mark Act. In 1874 Germany provided its first trademark law. It was subsequently replaced by the Trademark Protection Law of 1894. The first trademark law of USA was introduced in 1870 name as Federal Trademark Act 1870. It was abolished in 1879 and a new law was enacted to provide protection to trademark 1881.[56]

Protection of copyright was needed after the invention of printing press. Before the invention of printing presses, it was very difficult to copy the work of other manually because this process may constitute many mistakes. Printing presses make it possible to prepare multiple copies of a work in no time and without any mistake. The Statute of Anne 1709 was considered to be the first law deal with copy right. Purpose of this Acts was to protect author's work from piracy. USA adopted its first copyright law in 1790.[57]

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[55] Dr. Peter Drahos, "The Universality of Intellectual Property rights: origin and development*," Queen Mary Intellectual Property Research Institut*, (London: Queen Marry and Westfiel College, 1998), https://www.wipo.int/edocs/mdocs/tk/en/wipo_unhchr_ip_pnl_98/wipo_unhchr_ip_pnl_98_1.pdf, last accessed on 9th July 2021.

[56] Anamika Ghandi, " Historical Development of Trademark Law," Legal Bites, Dec. 2020 https://www.legalbites.in/historical-development-of-trademark-law/. Last assessed on 9th July 2021.

[57] Charul Tripathi, "Historical Development of Law of Copyright," Mondaq, August 2020, https://www.mondaq.com/india/copyright/978858/historical-development-of-law-of-copyright, Assessed on 10th July 2021.

During the territorial period protection is limited to the state which granted it other states are not bound to take action against infringements and the holder of intellectual property rights cannot enjoy the protection in other territories. Owners of intellectual property rights faced the problems of piracy and free riding in other countries and they cannot take action against the violations. In order to overcome these problems, the protection of IPRs entered into the next phase of protection which was known as the international period.

1.2.2. International Period

In nineteenth century, Sovereign States realized that serious efforts needed to protect IPRs. It was not sufficient to provide protection of the IPRs in a particular territory while the violations were continued in other territory. UK found that the work of its writers and researches is pirated in other countries without any authorization. America also copied the work of UK's creators without giving royalty to the authors. In 1838 and 1844 two Acts were enacted that gave protection to the work which was not published in UK. The concept of reciprocity was given in these statutes. Work of the foreigners would be protected in UK if the other States also protect the work of UK's author in their state. Under the Act of 1844 a number of bilateral agreements signed by the UK government with different European countries.[58]

Copyright practice of USA was totally different from UK. Copyright Act 1790 of USA just gives protection to the resident and citizens of USA and not to the foreigner. This practice was continued in USA for a long time. After the World War II the USA

[58] William Cornish, *Intellectual Property: Patents, Copyright, Trade Marks and Allied rights* , Sixth Edition (London : Sweet and Maxwell Limited, 2007)

changed its strategy for international copyright. It was not or just copyright but other areas of IP were also start protected by the bilateral agreements among the different states of Europe. In 1883 almost 69 international bilateral agreements were taken place dealing with the protection of trademarks. These agreements were operated on the basis of reciprocity. States started to protect the IPRs of their writers and researchers in foreign jurisdiction on reciprocal basis.[59]

Most of the developing countries developed their IPRs system under the colonial administration. During this period, they are not equipped with research activities and institutional infrastructure. These States inherent the intellectual property laws as being the part of colonial system. In 1856 United India also acquired its first patent law under the British colonial rule. It was a time when many developed countries were not enacted proper patent legislation. Developing countries became the part of international IP regime in nineteenth century by the creation of Paris (1883) and Berne (1886) conventions. Purpose of these two conventions is to ensure the protection of IPRs in distant jurisdiction.[60]

Article 19 of Berne Convention also called as colonial clause asserted The European powers to implement these rules in their respective colonies. These conventions (Paris and Berne) replace the week system of The European countries to implement the IPRs in other jurisdiction through the bilateral agreements. Article 19 of Berne

[59] Stuart Banner, *American Property: A History of How, Why and What We Own*, First Edition (London: Harvard University Press, 2011) 26-28.
[60] Carolyn Deere, The Implementation Game, (New York: Oxford University Press, 2009) 31-34.

Convention also called as colonial clause and it asserted The European powers to implement these rules in their respective colonies.[61]

Many colonial administered areas got independence after the Second World War. After independence these countries re-examined their laws including intellectual property law. India also constituted a committee to review the patent law of India. The committee concluded that existing system of patenting is not suitable for India and it did not encourage the research and invention in Indians. So India revised its patent law according to the need of its national interest and poor people. It was not only the case of India but many others countries were also relaxed the area of pharmaceutical patents after independence.[62]

In post-colonial era developing counties responded to the system of international IPRs in different way. Developing nation postponed to join the international intellectual property conventions. They apprehended that international Intellectual property system provides too much protection and as newly independent states it would burden their system.[63]

In 1893 the International Bureau were created to implemented Paris and Berne conventions. The WIPO was created in 1967 and it replaced the power and function of International Bureau. By the creation of the WIPO all sovereign states start protecting some basic principle of intellectual property and especially the provisions related to the national treatment. During this period states were not under the uniform system of

[61] Carolyn Deere, The Implementation Game, (New York: Oxford University Press, 2009) 41-42
[62] Peter Drahos, "Negotiating Intellectual Property Rights: Between Coercion and Dialogue," *Global Intellectual Property Rights Knowledge, Access and Development*, ed. Peter Drahos and Ruth Mayne (New York: Palgrave Macmillan,2002), 161-182.
[63] Carolyn Deere, The Implementation Game, (New York: Oxford University Press, 2009) 31-34.

intellectual property rights. States had a lot of discretion to implement their intellectual property system according to their convenience. Some states provide protection to the patent on the basis of 'first to invent and other on the basis of 'first to file'. During this period many developing and even some developed countries did not provide protection for pharmaceutical.[64]

Developing countries had been demanded some reforms in international intellectual property system especially in the area of patent and copyright. Developing countries asked for reforms in compulsory licensing provisions to make it more practical and more convenient. Developed countries especially USA were not ready to relax the rules of compulsory licensing. A controversy aroused between developed and developing countries. This controversy led the USA to change the forum of implementing international IP standards.[65]

In 1980 the WIPO, UNCTAD and UNESCO was the forum to implement the international intellectual property rules. The USA deal with a serious issue because developing countries always disagreed with its proposal related to more strict IP provisions. The WIPO was not controlled by the USA and developing countries always resist the proposal of more strict rules of intellectual property protection. The USA started to argue that international intellectual property system must be discussed the

[64] Dr. Peter Drahos, "The Universality of Intellectual Property rights: origin and development*," Queen Mary Intellectual Property Research Institut*, (London: Queen Marry and Westfiel College, 1998), https://www.wipo.int/edocs/mdocs/tk/en/wipo_unhchr_ip_pnl_98/wipo_unhchr_ip_pnl_98_1.pdf, Last accessed on 9th July 2021

[65] Peter Drahos, "Negotiating Intellectual Property Rights: Between Coercion and Dialogue," *Global Intellectual Property Rights Knowledge, Access and Development*, ed. Peter Drahos and Ruth Mayne (New York: Palgrave Macmillan,2002), 161-182.

multinational trade negotiations under the GATT. Intellectual property rights became the subject of GATT and the world is forcefully entered into the global era of IP protection.[66]

1.2.3. Global Period

During the international period the developed countries and their multinational corporations were not satisfied with the protection of IPRs. Forty-nine out of ninety-eight developing countries that were the member of Paris Convention did not provide patent on pharmaceutical products. Exceptions which were discarded by the developed countries twenty or more years before were still in use by the developing countries. Many Conventions of the WIPO were not acceded by most of the developing countries. Movement started by the developing countries for adding more relaxing provisions of Paris Convention between 1981 to 1983.[67]

Free riding problems were not abolished during international period. America has a lot of reservations because the film and pharmaceutical industry was the backbone of is economy and strong IP protection was the real need to protect its industry. Paris and Berne Conventions were no more western clubs because a lot of developing countries become its member. The principle of one vote one state was practiced and developed countries could not control the process to implement the laws of their own choice.[68]

Developed countries realized that it was difficult to strengthen the enforcement of IPRs through the Paris and Berne Convention. Meanwhile during this period the USA

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[66] Debort J. Halbert, *Intellectual Property in the Information Age: The Politics of Expending Ownership Rights*, First Edition. (London: Deborah Charles Publications) 21-23.
[67] Carolyn Deere, The Implementation Game, (New York: Oxford University Press, 2009) 47.
[68] Dr. Peter Drahos, "The Universality of Intellectual Property rights: origin and development*," Queen Mary Intellectual Property Research Institut*, (London: Queen Marry and Westfiel College, 1998), https://www.wipo.int/edocs/mdocs/tk/en/wipo_unhchr_ip_pnl_98/wipo_unhchr_ip_pnl_98_1.pdf , last accessed on 9th July 2021.

take some domestic measure to implement IPRs. Power under Section 337 of the Tariff and Trade Act of 1930 was made active. This section gave power to USA authorities to seizure and destroys the pirated material. USA started to take action against the infringements however the scope of section 337 was limited to the violation within the territory and on the border of USA and not in the market of other countries. [69]

Section 301 of Trade and Tariff Act was also amended in 1984 and it empowered the office of United States Trade Representative (USTR) to take action in other countries against the IP infringements. Countries who did not implement IP policies would not be provided with trade privileges by USA. A pressure was built on developing countries to follow IP.[70] USA adopted another strategy to control the cross border enforcement of IP rights through the bilateral trade agreements. It was proved as a much unbeaten strategy by USA government to minimize the IP violations.[71]

The America with the support of other developed countries including The Europe, Japan and Canada succeeded to incorporate IPRs as a subject in multinational trade negotiations held at Punta del Estate in September 1986. After a lot of discussion and debate, the Uruguay Round of Multinational Trade Negotiations was finalized in Marrakech. Final Act was signed by more than hundred countries. Act includes multiple agreement as part of it i.e. agreement establishing the WTO (World Trade Organization)

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[69] Michael L. Doane, " TRIPS and International Intellectual Property Protection in an age of Advancing Technology," *American University International Law Review*, vol.9, 2(1994):9, http://digitalcommons.wcl.american.edu/auilr, last assessed on 4th July 2021.

[70]Sell, Susan K. "Intellectual Property Protection and Antitrust in the Developing World: Crisis, Coercion, and Choice." *International Organization* 49, 2 (1995): 315-49. http://www.jstor.org/stable/2706974 , last accessed July 7th, 2021.

[71] Duncan Matthew, *Globalizing Intellectual Property Rights the TRIPs Agreement*, first edition. (Newyark: Taylor & Francis e-library, 2003) 14-15, http://wto.tpo.ir/uploads/Globalizing%20Intellectual%20Property%20Rights.pdf , last assessed July 5th 2021.

and the TRIPS agreement (Trade Related Aspects of Intellectual Property Rights). All countries that were the members of WTO are bound to follow the TRIPS agreement. Trade and international intellectual property system was combined under one umbrella. All state that want to enjoy the trade relaxation and tariff concession have to implement the TRIPS agreement.

After the TRIPS agreement a new period of global implementation of intellectual property rights was started. States have no choice to avoid the TRIPS agreement if they want to enjoy the trade relaxations under the international trading system. Through trade connection the TRIPS agreement get in touch with all states that are members of the multilateral trading system. States are under obligation to implement a uniform and expanded set of IPRs protection being the part of multilateral trading system. It was not the end of the story but the just beginning. After the global implementation of the TRIPS agreement FTAs (free trade agreement) are emerged as a new tool of implementing more strict IP rules.[72]

1.3. Intellectual Property Rights under the International Law

IPRs became an important part of international discussion. It would not be wrong to say that no international debate completing at the present time without discussing the IPRs. There are the following international documents which deals with the intellectual property rights.

[72] Dr. Peter Drahos, "The Universality of Intellectual Property rights: origin and development*," Queen Mary Intellectual Property Research Institut*, (London: Queen Marry and Westfiel College, 1998), https://www.wipo.int/edocs/mdocs/tk/en/wipo_unhchr_ip_pnl_98/wipo_unhchr_ip_pnl_98_1.pdf , last accessed on 9th July 2021.

1.3.1. Paris Convention for the Protection of Industrial Property

Paris Convention for the protection of industrial property was first adopted in 1883 and revised several times. Paris Convention was amended last time in Sep. 1979. It is the one of the first intellectual property treaties.[73] Currently 177 states are the members of the Paris Convention. In April 2004, Pakistan also deposited its instrument of accession to Paris Convention and it came into force in July 2004.[74] Paris Convention was the first international treaty that gives a priority right to the applicant who does apply in one jurisdiction and claim the same right in other jurisdictions. It also gave the provisions of national treatment that is the same treatment for citizens and others.[75] It makes the procedure much easier for the inventers and protection of industrial property in different jurisdictions is not a complicated issue now. Applicant enjoys the same benefits from the same original date when he applied in first jurisdiction.

1.3.2. Berne Convention for the Protection of Literary and Artistic Work

Berne Convention was first adopted in 1886 and last revised in 1971. Initially 8 countries became its member and now 177 countries adopted it.[76] On 30 July, 1969 Pakistan also set down its instrument of accession to the Bern Convention 1886 as revised in Stockholm (14 July 1967).[77] Basically Berne Convention provides protection

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[73]WIPO Database of Intellectual Property, "Paris Convention for the protection of Industrial property," http://admin.theiguides.org/Media/Documents/WIPO%20Paris%20Convention.pdf, last accessed 1 July, 2021.

[74] WIPO IP Portal, "WIPO-Administered treaties," https://wipolex.wipo.int/en/treaties/ShowResults?search_what=C&treaty_id=2, last accessed 1st July 2021.

[75]Wolfgang E. Siebeck et all, Strengthening Protection of Intellectual Property in Developing countries, World Bank Discussion Papers, 1990, https://documents1.worldbank.org/curated/es/658721468739497745/pdf/multi0page.pdf, last accessed 30 June, 2021.

[76]The Editors of Encyclopaedia, "Berne Convention," Encyclopaedia Britannica, Apr. 2018, https://www.britannica.com/topic/copyright, last accessed on 2nd July 2021.

[77]WIPO, Bern Notification no.13, https://www.wipo.int/treaties/en/notifications/berne/treaty_berne_13.html, last assessed 1st July 2021.

to the literary and artistic work not only in the native land of the author but in other countries as well. Berne Convention provides the protection for life plus 50 years after the death of the author.[78]

1.3.3. Madrid Agreement Concerning the International Registration of Marks

There are 108 contracting parties to Madrid Union (marks) assembly and Pakistan is also one of them. It facilitates the international registration of marks by filling a single application. It make possible to protect a mark in all other countries by international registration.[79] Madrid system facilitates trademark owner and make the system much easy. It is not an easy task to file application in different countries, using different languages, observe different procedures and deposit multiple different fees. International registration make it more easy by one application by using simple language and just paying one fee one can enjoy the protection.[80]

1.3.4. WIPO Convention

In July, 1967 the draft of World Intellectual Property Organization (WIPO) Convention was signed and in 1970 it enforced. International Bureau which was established under the Paris and Berne Conventions replaced by the through the WIPO Convention. The WIPO ensures the protection of IP right and look at the administrative

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[78]J.H.Reichman, "Universal Minimum Standards of Intellectual Property Protection under TRIPS Component of the WTO Agreement," *Faculty Scholarship*, vol. 29(1995): 01,https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1617&context=faculty_scholarship, last accessed on 2nd July 2021.

[79] WIPO, IP Portal, "WIPO-Administered treaties," https://wipolex.wipo.int/en/treaties/ShowResults?search_what=B&bo_id=20, last assessed 2nd July 2021.

[80] WIPO, IP Portal, "Summary of the Madrid Agreement Concerning the International registration of Marks (1891) and Protocol relating to the Agreement (1989)," https://www.wipo.int/treaties/en/registration/madrid/summary_madrid_marks.html, last accessed 2nd July 2021.

activities of IP unions created under different treaties.[81] There are 193 contracting parties to the WIPO Convention and Pakistan is also one of them. Pakistan joins the WIPO Convention in Oct, 1976.[82]

1.3.5. The TRIPS agreement

The World Trade Organization (WTO) was emerged in 1995 as a multilateral trading system with its three pillars, General Agreement on Trade and Tariff (GATT), General Agreement on Trade and Services (GATS) and Trade Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS agreement provides the minimum standards for the protection of the IPRs.[83]

Before the TRIPS agreement developing countries are not bound to implement the intellectual property rights. Some developing countries provided the partial enforcement to intellectual property right and others were not. Before the TRIPS agreement IPRs are governed by the Paris and Berne Conventions. These conventions had not effective enforcement mechanism that was the main reason to attach IPRs with the WTO. The WTO's dispute settlement mechanism and threat of trade sanctions bound the developing countries to change the existing IP legislation to meet the TRIPS agreement standards. The TRIPS provide the minimum standards for enforcing IPRs. State may make more

[81]WIPO, " Summary of the Convention establishing World Intellectual Property Organization (WIPO Convention)(1967)," https://www.wipo.int/treaties/en/convention/summary_wipo_convention.html , last accessed 2nd July 2021.
[82]WIPO IP, Portal, "WIPO-Administered Treaties," https://wipolex.wipo.int/en/treaties/ShowResults?search_what=C&treaty_id=1, last accessed 2nd July 2021.
[83]Ben Wills, "The Arguments For and Against the TRIPS Agreement," E-International Relation, Dec. 2013, https://www.e-ir.info/2013/12/23/the-arguments-for-and-against-the-trips-agreement/, last accessed on 8thJuly 2021.

extensive provisions to protect and enforce IPRS however developing countries cannot provide IPRs protection less then provided under the TRIPS agreement.[84]

1.4. Right to Health

Right to health is fundamental right of every human being irrespective of his religion, region and race. It is the basic right of every human being to be provided with appropriate health facilities whenever he needs for himself or for those to whom he cares and loves. Age, gender, race, territory, religion and political affiliation should not be a barrier to access the indispensable right of having health facilities. Every right has a simultaneous duty; hence it is the responsibility of state to provide proper health facilities to its citizens. In my opinion the right to health and the right to life are interlinked. We cannot deviate the dependency of these two rights. Life means you are able to perform your duties, take a good care of your family and become a productive part of society but if you are suffered with a disease and treatment is not available to you or affordable for you; definitely you cannot perform your duties. It is not the end that you cannot perform your duties but this is just the beginning of story that has a long tragic way. Your family suffered by your illness and you will become a burden for your family and the society. Life without appropriate health facilities is just breath in and breath out and nothing more. In short, we can say that security of life or enjoyment of life cannot be completed without a good health. Good health ensures a decent and dignified life.

Mostly, we believe that right to health means availability of health care services or the construction of new hospitals. But, in reality, it is a much wider concept instead of

[84]Peter K.Yu, "The Objectiveives and Principles of the TRIPS Agreement," *Houston Law Review*, 46:4(2009) 979-1046, https://scholarship.law.tamu.edu/facscholar/457/,, last accessed on 8th July, 2021,

just constructing hospitals. Right to health is an inclusive right. It includes many important factors which are very important to maintain health. Right to health includes right to safe water, right to safe food, right to adequate sanitation, right to healthy environment and gender equality.[85]

Right to health include right to appropriate health facilities and these facilities should be available to all citizens without any discrimination. It includes the treatment of a disease and prevention and control of diseases when it is the matter of epidemics or pandemics. Right to health is incomplete without the availability and affordability of medicines. The WHO issues periodical lists of essentials medicines and it is the obligation of state to ensure the availability of these essentials medicines in the country.[86] Just availability of essential medicines is not enough and it must be accomplished with affordability concern. Affordability of medicine and health care services are as important as availability of medicines. In my opinion, non affordability of medicines create more vulnerable situation. It creates discrimination in society which results in restlessness and agitation. In order to maintain peace in the society, it is indispensable to provide equality and justice not only in health sector but in all domains of life.

1.5. Right to Health under International Law

Right to health is the internationally recognized right. Many of international agreements provide protection to the right to health. Internationally, the World Health Organization is specialized agency of UN which deals with health concerns of all around

[85]World Health Organization, *The Right to Health: fact sheet 31*, p-3, available at https://www.ohchr.org/documents/publications/factsheet31.pdf , last accessed 4th June 2021.
[86]*ibid.*

the world. It deals with the health issues from pregnancy to the old age. Right to heath has become the part of international human right law and many international declarations and treaties which provide right to health. Some of the important documents are discussed here.

1.5.1. World Health Organization

The World Health organization is a specialized agency of United Nation. It works to promote health facilities worldwide. It has it's headquarter in Geneva with six regional offices, 150 country offices and 194 member states. The WHO plays an important role in improving the health system of poor countries and helps them to be prepared for health threats. The goal of the WTO is to provide basic health facilities to everyone and everywhere in the world.

A conference was organized in San Francisco to set up the United Nations in April 1945. Brazil and China recommended that an international organization should be established which deal with health issues all around the world. Secretary General invoked a conference to establish an international health organization. A committee of technical expert met and prepared proposals for the constitution of international health organization. These proposals were presented in international health conference which was conducted in 1946 at New York. The Proposals which were presented in the conference resulted in the adoption of the Constitution of the World Health Organization in July 1946. It was signed by the 51 states which were the member of UN and 10 states which were not the member of UN.[87]

[87]History of the WHO, World Health Organization, https://www.who.int/about/who-we-are/history, last accessed on 17th August 2021.

Right to health is a basic human right and this right was earliest uttered in 1946 in the constitution of the WHO. It narrates that "the enjoyment of the highest attainable standard of health is one of the fundamental right of every human being". The preamble of the WHO constitution explains health as

> "a state of complete physical, mental and social well being and not merely the absence of disease or infirmity".[88]

The World Health Assembly is the governing body of the World Health Organization. It consisted of 194 Member States. Representative of all member states met every year to decide the goal and policies of the organization. Then tasks are assigned to the member states to reach the goals and implement the policies. The WHO also issued the recommendations at time with the delegation of experts to assist the countries how to deal with situation when global health is at risk.[89]

1.5.2. Universal Declaration of Human Rights

After the Second World War, the Universal Declaration of Human Rights was adopted by the UNO. The purpose of this declaration was to acknowledge the rights of every human being anywhere in the world. The UDHR also recognized the right to health as basic right of everyone. Article 25 of Universal Declaration of Human Rights narrates the right to health as that

> Everyone has the right to a standard of living adequate for the health and well-being of themselves and of their family, including food, clothing, and housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control. Motherhood and childhood are

[88] Elearnor and D. Kinney, *The International Human Right to Health: What Does This Mean For Our Nation and World?*https://mckinneylaw.iu.edu/ilr/pdf/vol34p1457.pdf , last assessed on 25 May, 2021.
[89]the WHO and the WHA- an explainer, World Health Organization, https://medium.com/who/who-and-the-wha-an-explainer-80cc26f47e4b, last accessed on 17 August 2021.

> entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection.[90]

The article 25 of the UDHR explains that the adequate standards of living include health facilities and it further widens the scope of right to health by adding these facilities for a person and his family too. It explains that in case of sickness and appropriate medical services should be available. Wording which is used in subsection 2 of article 25 is the "special care and assistance and social protection." Interpretation of these words cannot be completed without incorporating the right to health in it. Human rights are interdependent. Enjoyment of one's right depends on many other rights. So, when we talk about human right, we are directly or indirectly talking about right to health.

1.5.3. International Covenant on Economic Social and Cultural Rights

The International Covenant on Economic Social and Cultural Rights adopted in 1966 also recognized the right to health as a fundamental human right. Pakistan is the state party to the International Covenant on Economic Social and Cultural Rights and became signatory to it in 2004. Ratification of convention was made on 2008.[91] After the adoption of the ICESCR, it has become the source for explaining the social, economic and cultural rights of a man. Many national and internal constitutions and instruments incorporated these rights in their provisions. Courts are also taking help from the definition of the ICESCR while interpreting social, economic and cultural rights.[92]The ICESCR in article 12 narrates the right to health as;

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[90]United Nation, *Universal Declaration of Human Rights*,https://www.un.org/en/about-us/universal-declaration-of-human-rights , last accessed 2nd June 2021.
[91] Available at indicators.ohchr.org
[92]Danwood Chirwa, The Right to Health in International Law: Its Implication for the Obligation of State and Non-State Actors in Ensuring Access to Essentials Medicines,

1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

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:

(a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;

(b) The improvement of all aspects of environmental and industrial hygiene;

(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;

(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.[93]

This article considers the right to health as a basic component for living a life with dignity. This covenant sets the responsibility of state to provide health facilities to its citizen. It covers all the areas which can affect the health. It bounds the state parties to recognise the physical and mental health as the basic right of everyone and also demands to take appropriate measures for the full realization of right to health. It puts the obligation to provide health facilities from the inception of child till he arrives in this world. This section widens the area of right to health by including healthy and hygienic environment in it as the unhealthy environment may become the reason for ill health. It also includes in health facilities avoidance and treatment of diseases and all medical services (availability of hospitals, doctor and medicines) as a part of health facilities.

1.5.4. Convention on the Rights of the Child

The Covenant on the Right of the Child adopted in November 1989 by the General Assembly of the UNO also discussed the right to health. Pakistan is the state party to the Convention on the Right of the Child and became signatory to it in 1990 and

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https://open.uct.ac.za/bitstream/handle/11427/18181/article_2003_chirwa_d_m.pdf;sequence=1last , last accessed on 8th June 2021.

[93]United Nation Human Right, *International Covenant on Economic Social and Cultural Rights,* https://www.ohchr.org/sites/default/files/cescr.pdf , last assessed on 3rd June 2021.

the ratification and accession to convention was also made in the same year.[94]The CRC elaborated right to health in the article 24 as that

> 1. State parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. State parties shall strive to ensure that no child is deprived of his or her right of access to such health services.
>
> 2. States Parties shall pursue full implementation of this right and, in particular, shall take appropriate measures:
>
> (a) To diminish infant and child mortality;
>
> (b) To ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care;
>
> (c) To combat disease and malnutrition, including within the framework of primary health care, though, inter alia, the application of readily available technology and through the provision of adequate nutritious foods and clean drinking-water, taking into consideration the dangers and risks of environmental pollution.

The CRC describes right to health from the perspective of preventive health care services and curative health care services. It bounds the member states to provide the health facilities to children including treatment facilities, to control child mortality rate, to avoid malnutrition in children and to ensure the availability of healthy food, safe drinking water and pollution free environment. Sub-section 4 of section 24 places an obligation on all state parties to co-operate with each other to achieve the objectives of this section in the following words.

> "States Parties undertake to promote and encourage international co-operation with a view to achieve progressively the full realisation of the right recognized in the present article. In this regard, particular account shall be taken of the needs of developing countries."[95]

[94]Indicators.ohchr.org.
[95] United Nation Human Right: Office of the High Commissioner, *Convention on the Right of the Child*, available at https://www.ohchr.org/sites/default/files/crc.pdf , last assessed on 5th June 2021.

This subsection bounds developed countries to provide their assistance in health sector to enable developing countries to ensure public health. Developing countries with limited resources should also be assisted with facilities to deal with their obligation in health sector. It is realised in this section that without international co-operation and assistance, it is not possible to achieve universal health objectives.

1.5.5. Alma Ata Declaration

The Alma Ata declaration is also a significant publication adopted at international conference on primary health care in 1978 by the WHO and the UNICEF. This declaration discusses right to health as basic human right and put a responsibility on the state to provide appropriate health facilities to its citizens.

The Conference strongly reaffirms that health, which is a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity, is a fundamental human right and that the attainment of the highest possible level of health is a most important world-wide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector. The existing gross inequality in the health status of the people, particularly between developed and developing countries as well as within countries, is politically, socially, and economically unacceptable and is, therefore, of common concern to all countries. Governments have a responsibility for the health of their people which can be fulfilled only by the provision of adequate health and social measures.[96]

[96]World Health Organization, *Declaration of Alma Ata*, https://cdn.who.int/media/docs/default-source/documents/almaata-declaration-en.pdf?sfvrsn=7b3c2167_2 , last assessed on 6th June 2021.

The Alma Ata Declaration also explains right to health not only as physical health but as a "complete physical, mental and social well-being". It widens the scope of right to health and declared it as a "worldwide social goal" and this worldwide goal needs worldwide efforts and contributions to achieve its objectives. The declaration also asserts that equality in health facilities worldwide is very important and discrimination among the nations is not adequate. This declaration highlights the inequalities that exist between developed and developing countries regarding health facilities and often in same jurisdiction inequality exists between different economic and social groups. It also acknowledged that this goal cannot be achieved only with the efforts of health sectors but "other social and economic sectors" should also come forward and play their part to achieve the health objectives. All the signatories of declaration affirm that this inequality is not acceptable. So, governments are held responsible to take appropriate measures to provide the health facilities to its citizens.

1.5.6. International Convention on the Elimination of All Form of Racial Discrimination

The International Convention on the Elimination of All Form of Racial Discrimination was adopted in 1978. Pakistan is also state party to the Convention. It became signatory to it in 2008 and ratification/accession was made in 2010. The Convention protect in article 5(e) (IV) the right to health as

"States Parties undertake to prohibit and eliminate racial discrimination in the enjoyment of the right to public health, medical care, social security and social services."[97]

1.5.7. Convention on the Elimination of All Form of Discrimination against Women

Convention on the Elimination of All Form of Discrimination against Women (1979) also narrates the right of women and their right to appropriate health facilities without any discrimination. Pakistan is also state party to the Convention and ratification/accession was made in 1996. Article 12 of the convention explains right to health in the following words

> 1. States Parties shall take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning.
>
> 2.States Parties shall ensure to women appropriate services in connection with pregnancy, confinement and the post-natal period, granting free services where necessary, as well as adequate nutrition during pregnancy and lactation.[98]

1.6. Intellectual Property Rights and Right to Health in Pakistan

Pakistan is the member of the WTO and it puts an obligation on state to provide minimum standards of protection for IPRs. Pakistan in order to fulfill its obligations as the member of the WTO introduced new laws and also made amendments in existing laws. Pakistan is also member of the WHO and many other international human rights conventions who protect right to health as discussed above. Practical glimpse about the IPRs and right to health are presented here.

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[97]United Nations Human Right, Office of the High Commissioner, *International Convention on the Elimination of All Form of Racial Discrimination*, https://www.ohchr.org/sites/default/files/cerd.pdf , last assessed on 6th June 2021.

[98]UN Women, *Convention on the Elimination of All Form of Discrimination against Women,* https://www.un.org/womenwatch/daw/cedaw/text/econvention.htm#article12 , last accessed on 8th June 2021.

1.6.1. Intellectual Property Rights in Pakistan

In Pakistan, laws related to intellectual property rights include trademark laws, patent laws and copyright laws. These laws protect the original work of authors and inventers from unauthorized used by the third party. Pakistan is a member of the WTO and bound to protect higher standards of protection for the IPRs as prescribed by the TRIPS agreement. In Pakistan there are following laws available to protect different kinds of IPRs.[99]

- Patent Ordinance 2000/ Patent Rules 2003
- Trademarks Ordinance 2001/ Trademarks Rules 2003
- Copyright Ordinance 1962/ Copyright Rules 1967
- The Custom Act 1969
- Pakistan Electronics, Media Regulatory Authority (Amendment) Act 2007
- Pakistan Penal Code (Act XLV of 1860)
- Competition Act No. (XIX of 2010)
- The Drug Act (XXXI of 1976)
- Press, Newspaper, News Agencies and the Books Registration Ordinance (2000)

In order to comply with the TRIPS requirement Pakistan legal regime of the IPRS was revised and multiple amendments have been made to make it more the TRIPS compliance. Pakistan was remained on the priority watch list of USA till 2014 as it was considered by the USA IPRs that implementation in Pakistan were not adequate and effective.

[99]G. M. Chaudhry, *The Intellectual Property, Intellectual Property Laws in Pakistan and International Treaties on IPRs*, First Edition (Lahore: Federal Law House, 2005) 67.

1.6.2. Intellectual Property Organization of Pakistan

The office of Intellectual Property Organization of Pakistan was established in 2005. The objective of the organization is to put Pakistan on the map of the world with its strong IP enforcement infrastructure. The IPO Pakistan initially worked under the Cabinet Division but in 2016 it was transferred under the Commerce Division. The objective behind this transfer is to make organization more efficient in IP management. In 2012 the Intellectual Property Organization of Pakistan Act was introduced to run the function of the IPO Pakistan efficiently.[100] Under the Act, the IPO Pakistan is assigned with the following major tasks

- To manage all IP offices in Pakistan
- To create awareness in public about the IPRS
- To administer and coordinate with all system of government to implement the IPRs
- To coordinate with government for strengthening the IPRs
- To advise the Federal Government on IP policies
- To ensure adequate enforcement of IPRs by enforcement agencies (police, Pakistan custom and FIA)[101]

1.6.3. Intellectual Property Tribunals in Pakistan

Keeping in view the importance of emerging IPRs, the Federal Government established IP tribunal in Pakistan. Initially, three tribunals have been established in Sind, Punjab and Islamabad Capital Territory. The IP tribunals ensure the specialized judiciary

[100]Intellectual Property Organization of Pakistan, IPO, https://ipo.gov.pk/Introduction , last accessed on 8TH August, 2022.
[101]Intellectual Property Organization Act 2012, https://ipo.gov.pk/system/files/IPO-Act-2012.pdf , last accessed on 8th August, 2022.

who has completed understanding of IP laws and IP rights. Judges of district and session courts, high courts or the attorney who fulfilled the criteria are appointed as the judge of IP tribunals.[102] In 2015 the registrar of copyright was appointed as the judge of IP tribunal and it is appreciated to appoint a person who has a better understanding of the IPRs. In order to exercise its powers, the tribunals have civil and criminal jurisdiction to adjudicate IP related cases. After the establishment of IP tribunals, all the cases related to IPRs will be tried by the tribunals and all the cases in other courts also transferred to the IP tribunals. The objective of these tribunals is to protect the IPRs and to provide speedy justice against the IP violations. The establishment of tribunal reveals the continuous commitment of country to enhance the protection of IPRs, create awareness in public and provide confidence to the IPRs holder that will leads towards economic growth.[103]

1.7. Right to Health in Pakistan

Pakistan is a low middle income country with GDP of 5110 USD International per capita (2018). Health spending is USD International 160.6 per capita. The share of health spending made from out of pocket is 66.5 % and it is highest in the region. Mortality rate of children under the age of five per 1000 live birth is 69.3 Pakistan, 36.6 India, and 30.2 Bangladesh and Pakistan has high mortality rate in the region. Beds in hospital per 1000 are 0.6 Pakistan, 0.7 India and 0.8 Bangladesh and Pakistan has more pathetic situation in the region. Breast cancer is the most common cause of death among

[102]G. M. Chaudhry, *Guid to Intellectual Property Law*, First Edition. (Lahore: CPI Publications, 2008).
[103]Seema S Mansoor, " IP Tribunals established" LEXOLOGY, 1 February, 2016, https://www.lexology.com/commentary/intellectual-property/pakistan/vellani-vellani/ip-tribunals-established , last accessed on 8th July 2022.

women and more than 15% of the all deaths occur in Pakistan alone. One doctor is available for 1000 people and one nurse is available for 2000 people in Pakistan.[104]

Pakistan's health indicators are seen as worst among the other regional countries. The Global Human Development Index (HDI) report 2019 clearly places Pakistan way behind India and Bangladesh and even the average of the entire South Asia. Pakistan stands at 152 positions among the 189 countries in the providing insufficient health facilities.[105]So, it would not be wrong to say that health facilities in Pakistan are not adequate. Right to health is recognized internationally and many covenant and declarations are provided right to health to everyone everywhere in the world. Pakistan is the member and signatory of almost all these declaration and covenant. It is an international obligation to provide health facilities to its citizens. Health is the provincial subject but practice is that both the federal and the provincial governments take part in health sector. Pakistani health system has inadequate facilities and there is lack of proper infrastructure. There is a dire need to upgrade the health system in Pakistan on priority basis.[106]

It is the responsibility of government of Pakistan to make progressive policies to reduce the health suffering of its people. Country like Pakistan where the poverty rate is very high and 66.5% health expenditure made from out of pocket state must include

[104]OECD/the WHO (2020), *Health at a Glance: Asia/Pacific 2018: Measuring Progress towards Universal Health Coverage*, OECDPublishing, Paris, https://www.oecd-ilibrary.org/docserver/health_glance_ap-2018-en.pdf?expires=1634647392&id=id&accname=guest&checksum=5EC9DD948CB4BB78280D6BF9E3AB0BD1 , last accessed on 2nd July 2022.
[105]Mehtab Haider, *Human Development Index 2019: Pakistan ranks lower then all South Asian Countries*, The News, 13 December, 2019,https://www.thenews.com.pk/print/582826-human-development-index-2019-pakistan-ranks-lower-than-all-south-asian-countries, last accessed on 4th August, 2021.
[106]Danish Lagari, Where is My Right to Health? " Counting the Law," March 2020, https://courtingthelaw.com/2020/03/17/commentary/where-is-my-right-to-health/, last accessed on 16th August 2021.

appropriate health policies in its priority. Burden of poor health became the cause of poverty. Good health is the primary assets of poor people because with good health they are in a position to perform their duties and responsibilities as a family member and as a citizen. Government should take some urgent steps and assistance could be taken from the private health sector. With the cooperation and involvement of the of private health sector, the situation would become more convenient and expedient which ultimately help the poor people to assess their basic right to health.

1.7.1. Right to Health in the Constitution of Islamic Republic of Pakistan 1973

Right to health gets much importance in the current era. Many states especially democracies in developed and developing world incorporated right to health in their constitutions, it means these rights can be pleaded in the courts. Worldwide 109 states incorporated right to health in their constitutions.[107]

The Constitution of Pakistan 1973 does not recognize the right to health as the fundamental right. Amendment procedure of the Constitution of 1973 is rigid and it is a barrier to incorporate human rights in the Constitution. Article 4 and 9 of the Constitution of Pakistan related to the right to life. At the outset the interpretation of right to life was limited to the vegetative life but after the 80's the progressive definition was given to the right to life. Judiciary is the guard of the constitution. It is the duty of the judges to

[107]Elearnor and D. Kinney, *The International Human Right to Health: What Does This Mean For Our Nation and World?* https://mckinneylaw.iu.edu/ilr/pdf/vol34p1457.pdf, last accessed on 25 May, 2021.

interpret the law and the constitution. Judiciary in Pakistan performed its role well and it widens the scope of right to life.[108]

Judiciary expands the area of already existed constitutional rights. Right to life is attached with all other right which affects the quality of human life. Courts in Pakistan play empathic role and give a liberal interpretation of right to life. Liberal interpretation of right to life provides the poor citizen a way out from the corrupt government functionaries and address the public issues.[109]Constitution of Pakistan deals with right to life under article 9 and this article while interpretation covers the right to health. The right to health is mentioned under the article 38 but being the part of principal of policy the state is not answerable for the violation because the enforcement of principal of policy is subject to the available resources of state.[110] State authorities cannot exonerate from their liability to enforce fundamental right only on the ground of lack of resources. Right to health is not provided under the fundamental rights but right to life under article 9 cover the right to health in it. Right to life means it includes all ancillary rights which are necessary for the enjoyment of life. Concept of enjoying life cannot be completed without good health. Good health ensured dignified life.

In Chest Foundation case the High Court of Pakistan decided that smoking is very harmful for human beings. Smoke which is the result of the smoking affect the active smoker and it also made the other people passive smoker who sit near the person who

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[108] Tahir Perwaiz and Dr Aman Ullah, " Expanding Litrature of Human Right to Life in Pakistan",file:///D:/chapter%201/right%202%20health/rit%202%20health%20in%20cons.%201973/22_v32_2018%20dr%20amanullah.pdf , last accessed on 13th August 202.

[109] Shoukat Mahmood, The Constitution of Pakistan, Second Edition (Lahore: Pakistan Law Times Publication, 2003) 87-89.

[110]Inayatullah Khan, "The Right to Health," International The News, May 10, 2020, https://www.thenews.com.pk/print/656415-the-right-to-health, last access on 17th August, 2020.

smoke. Passive smoker involuntarily inhale the smoke which affect his health very much. High Court issued directions to the Pakistan Broadcasting Corporation and maintained right to heath that no advertisement should be made which present the smoker as hero and encourage the smoking among the young people.[111]

High Court of Sind decided that it is the obligation of govt. authorities to provide appropriate health facilities to the general public in govt. hospitals. High court explains the scope of article 9 and explains term life as "Health care includes the meaning of the term "life" and not restricted to the mere the vegetative and animal life or mere existence from conception to death but it (life) includes all such amenities and facilities which a person born in a free country is entitled to enjoy with dignity." Court also highlight that normal procedure is that all the organ of government should work independently and avoid interference but when fundamental right are violated then it means an abnormal situation arise so in an abnormal situation court can quit the normal procedure and interfere.[112]

In Anjum Irfan case court observed that polluted water of Ravi River becoming the source of different diseases which ultimately affect the health of public at large. Relevant authorities were directed to perform their duties according to the law to make environment pollution free. Safe and pollution free environment guarantee the good health of citizens. Right to life under the article 9 of the constitution of Islamic republic

[111] *Pakistan Chest Foundation v Government of Pakistan* 1997 CLC 1379
[112] Aamir Latif Ali Zardari Vs. Province of Sind and others, 2019 CLC 224, accessed on 16th August.https://www.pakistanlawsite.com/Login/TopicPage.

of Pakistan does not explain the word "life" but court explain that life includes the right to health.[113]

1.8. Confrontation between the Right to Health and the Intellectual Property Rights

Many developing and even some developed countries did not provide protection for pharmaceutical patents before the TRIPS agreement. Research and development (R&D) cost for pharmaceutical invention is very high. According to an estimate the approximate cost of a new drug is $800 million in America. Cost of a new drug is so high because only few chemical substances succeeded to come in the market. Only 1% chemical compositions are applied for trial on human beings.[114] Several studies are conducted to demonstrate the importance of patent on medicines. Patents are very significant for pharmaceutical industry otherwise there would be only few investments in R&D of pharmaceutical industry. Pharmaceutical patents are very imperative for the continuation of new and advance medicines of new and old diseases. Without the patent protection there would be apprehension that cost of R&D could not be retrieved hence pharmaceutical companies would invest a lesser amount.

[113]Anjum Irfan Vs Lahore Development Authority through the Director General PLD 2002 Lahore 555, Assessed on 16 August 2021, https://www.pakistanlawsite.com/Login/TopicPage.
[114]Abdulkadir Civan, Access to Medicines and Intellectual Property Rights, 29 June 2015, http://citeseerx.ist.psu.edu/viewdoc/download;jsessionid=4155DC9C09186E5638629826010D402A?doi=10.1.1.488.4924&rep=rep1&type=pdf, last accessed on 19 July 2021.

Almost 600,000 children in developing countries were died before they turn to 5 years.[115] Reasons for these deaths in most cases are affordability and non availability of medicines. Patents became debatable when millions of people in Africa were dying with AIDS. Pharmaceutical companies were not ready to sell the antiretroviral drugs on affordable prices. History witnessed that thousands people were dying daily but Pharmaceutical companies were not ready to compromised their profit. Strong patent protection stops the way for affordable low cost generic option.[116]

Almost 2 billion people have lack of access to the basic medicine in developing countries. Availability of medicine is a key to an effective health care system. Availability of medicine means that medicines must be of good quality (safe to use) and its price must be affordable. High prices of new medicines burdens the health care system all around the world especially developing economies. There is a dire need to increase the access to essentials medicines. In developing countries, 90%poeple bear their health expenditure of their own without any assistance from government. High prices of patented medicines burden the poor people.[117]

Right to appropriate health facilities is basic right of every human being irrespective of his religion, region and race. Right to health is essential to access to medicine. Access to medicine is indispensable to control the disease and epidemics. The reports of the World Health Organization have revealed that 1.4 million people die from

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[115] Siva Thambistty, " Improving Access to Patented Medicines: Are Human Rights Getting in the Way?," LSE Legal Study Working Paper NO.3/2018,file:///C:/Users/user/Downloads/SSRN-id3130703.pdf, last accessed on 10 August 2021.

[116] ibid

[117]Addressing the Global shortage of and access to medicines and vaccines, Report by the Director General of the WHO, World Health Organization Executive Board 142nd session, 12 Jan. 2018,https://apps.who.int/gb/ebwha/pdf_files/EB142/B142_13-en.pdf , last accessed 19 July 2021.

tuberculosis[118], 680,000 people die with HIV/AIDS[119] and 409,000 death accord due to malaria in 2019.[120] These diseases are curable but people in poor countries have no access to medicine or if medicines are available but not affordable for them. All international human rights documents and treaties recognized the right to health and also realized the link between right to health and economic resources. Affordability of medicines is very significant issue to the health facilities.[121]

The TRIPS agreement resulted with a lot of changes regarding the implementation of IPRs. All countries being the member of WTO changed their standards of implementing intellectual property. These new minimum standards of enforcing IPRs create a direct conflict between right to health and intellectual property. Patent standards under the TRIPS agreement provide the monopoly to the patent holder for a particular period. During this period patent holder can charge the price of his own choice. Patent protection of medicine makes the prices of new medicines very high.[122] Consumption of medicine is directly linked with its price. Affordable prices of medicines would help to save the lives of people who died every year due to the non availability of medicines. High prices of medicines limit its use and poor people deprived from the treatment which is available but not affordable for them.

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[118]World Health Organization, Tuberculosis,https://www.who.int/news-room/fact-sheets/detail/tuberculosis, last accessed on 14 Oct, 2020.
[119]World Health Organization, HIV/AIDS, https://www.who.int/news-room/fact-sheets/detail/hiv-aids,ssed , last accessed 14 July, 2021.
[120]World Health Organization, Malaria, https://www.who.int/news-room/fact-sheets/detail/hiv-aids , last accessed on Its April, 2021.
[121] Anuradha Chadha, "Intellectual Property Rights Vis-a Vis Right to Health: A Critique," Nov, 2014, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2529105 , last accessed on August 2021.
[122]Christopher May and Susan K. Sell, *Intellectual Property Rights: A Critical History*, First Indian Edition (New Delhi: Lynne Rienner Publishers, 2008)

Millions of people in developing countries have lack of access to the medicines. Due to the intense patent protection prices of medicines become very high then its actual production cost. Strong patent protection leads towards the disability of government to provide the appropriate health facilities to its citizens.[123] It is the duty of state to ensure the access towards medicines but state is bound to ensure patent protection on one hand and to ensure availability of medicine on another hand. Obligations imposed by the TRIPS agreement handicap the Government to perform its other duties. Sovereignty of state became affective when external factors interfere with the power of Government.

In order to solve this issue and for controlling patent abuse Doha declaration on the TRIPS agreement and public health was passed by World Trade Organization and World Health Organization. Doha Declaration was passed in 2001 at Doha, Qatar, it makes the situation clearer that the TRIPS agreement should be interpreted by the member state in such a manner that it must not be inconsistent with the right to health and it must ensure the availability of medicines to those people who need it. Permission was given to the member states to use TRIPS flexibilities and issue compulsory license in public health crises. Freedom was given to the member states to determine the grounds to issue compulsory license. Doha declaration on Public Health decided to give priority to human right when it conflict with economic interest. It guide the member countries how to use and interpret the TRIPS exception while dealing with health emergencies.[124]

[123]Sandy A. Johnson, *Challenges in Health and Development*, (New York: Springer, 2011) 169-171.

[124]Chuan-feng Wu, "Raising the right to health concerns within the framework of intellectual property law," July 2010, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1578865 , last accessed on 13 August 2021

Compulsory licensing provisions allow the government to manufacture the drugs without the due permission of the patent holder when emergency situation arises. The TRIPS agreement prohibits the exportation of patented medicines and country that issue compulsory license cannot export the medicine and permission is given to manufacture for domestic use only. The TRIPS agreement did not allowed the member countries to help the poor countries that do not have manufacturing capacity.[125]

The countries that do not have manufacturing capacity faced problem because they cannot take benefit from compulsory licensing provisions. Decision of 2003 allowed the importation of patented drugs under the compulsory licensing for the countries that do not have manufacturing capacity. A developed country may issue compulsory license manufacture generic drugs and export in the country that need these drug but do not have manufacturing capacity.[126]

The Decision of 2003 gives permission to export the patented drugs under the Compulsory license to the country that do not have manufacturing capacity. A detailed procedure is also provided to avail the provisions. Two compulsory licenses will be issued, one in the country that will export the medicine and second in the country that will import the medicine because it does not have manufacturing capacity. Some requirement needs to be fulfilled before the compulsory license for export purposes is issued for instance notification must be given to the TRIPS Council. The compulsory license must be issued for least developed country or the country that do not have

[125] Anuradha Chadha, "Intellectual Property Rights Vis-a Vis Right to Health: A Critique," Nov, 2014, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2529105 , last accessed on 13 August 2021.
[126]Chuan-feng Wu, "Raising the right to health concerns within the framework of intellectual property law," July 2010, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1578865, last accessed on 13 August 2021.

manufacturing capacity. Drugs exported for the low income country must not be export to the high income country.[127]

Decision of 2003 relax the provision of compulsory licensing and facilitate the poor people to access the essential medicines. Use of these provisions can facilitate the many countries to take advantage of the TRIPS flexibilities. Relaxation provided Decision of 2003 is effective only for the countries that incorporated these provisions in their national legislation. To date in the European countries only Canada and in our region only India have incorporated the provision Decision of 2003 in their national legislation.[128]

The TRIPS agreement which was adopted through the WTO on the urge of developed countries is not satisfactory for them. This is the reason that more stringent roles are adopted by the developing countries through free trade agreement with developed countries also known as the TRIPS Plus provisions. Free trade agreements restrict the developing countries to use the TRIPS flexibilities. Without using compulsory licensing and parallel importation provisions, the entry of generic drugs become more difficult. Developed countries and multinational pharmaceutical companies put pressure on the developing countries to incorporate strict patent provisions in their domestic law than those provided under the TRIPS. These strict rules of patent protection paralyze the sovereign states to cope with health emergences. It is the duty of state to create a balance between two contradicting rights i.e. public right of right to health and private right of patent holder. There must be a balance between the right to health and IPRs. It is

[127] Anuradha Chadha, "Intellectual Property Rights Vis-a Vis Right to Health: A Critique," Nov, 2014, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2529105, last accessed on 13 August 2021.
[128] *ibid*.

observed from the practices of states that whenever inconsistency arrived between these two rights priority is given to the IPRs. Main reason for this priority is the link of IP rights with trade relaxation under the umbrella of the WTO.

1.9. Duty of State to Provide Health Services to Its Citizens

It would not be wrong to say that right to health is relatively a new concept in the era of rights. Before the eighteen century, health of people fell outside the range of state responsibility. The concept of welfare state emerged and it was considered that state has the responsibility to provide health facilities to its citizens. All the international instruments and treaties put responsibility on the state in the health sectors. Under the customary international law, states are bound to follow weather they ratified it or not.

There are many factors which play an important role to maintain one's health, like environment in which we live, family history, society and one's own habits. It is not the only state which can ensure the health of its citizens but many other factors are also very important. In order to continue good health depends upon many factors like safe and clean water, safe and pollution free air, healthy food, proper sheltering or housing, key information about good health, and safe and healthy working environment. State needs a lot of resources to provide all such facilities to its citizens. Keeping in view the all, the best definition for right to health is provided by the WHO "to the highest attainable standard of physical and mental health" instead of absolute right to be healthy.[129] In this research, we will confine our discussion to the right to health care (provisions of medical

[129]Danwood Chirwa, The Right to Health in International Law: Its Implication for the Obligation of State and Non-State Actors in Ensuring Access to Essentials Medicines,https://open.uct.ac.za/bitstream/handle/11427/18181/article_2003_chirwa_d_m.pdf;sequence=1last , last accessed on 8th June 2021.

services) and not about the pre-condition of good health (environment, safe water, sanitation and food etc). We will discuss curative health care services and not the preventive health care services. Our area of research will be comprised of availability of medicines as the basic component for the right to health. In this research, we will discuss the state responsibility to provide health facilities to its citizen including treatment facilities, ensure availability of medicines and these medicines must be affordable. If a medicine is not affordable for patients, its availability is of no use. Usage of a medicine is linked with its price. This research will confine to health facilities, availability and affordability of medicines.

It is responsibility of state to utilize its available resources fully to provide health facilities to its citizens. States must take necessary steps in right direction without any delay. Though states are bound by their available resources but some responsibilities cannot be ignored or compromised and right to health is also one of those responsibilities that should be cared at most. It is obligation of state to provide health facilities to its citizens without any discrimination. It is also the obligation of state authorities to make proper legislation for emergency situation and proper health plans for protecting right to health. State should also guarantee the availability of essentials medicines to its citizens at affordable rate. State cannot excuse from its responsibility just because of the limited resources. State must take the necessary steps to guarantee right to health, even with limited resources.[130]

[130]World Health Organization, *The Right to Health: fact sheet 31*, https://www.ohchr.org/documents/publications/factsheet31.pdf , last accessed 4th June, 2021.

Developing countries must be more vigilant and active in making appropriate legislation for emergency situation in health sector. In case of any natural disaster, pandemic or contagion disease developing economy are under more threat then the developed economy due to their limited resources. Developing countries don't have appropriate infrastructure in health sector, there is lack of availability of essential medicines and there is lack of medical and paramedical staff, which resultantly may cause more casualties. We can see in case of influenza pandemic that its medication and vaccination was very costly and it was not affordable by the most of the developing countries.[131]

It is the duty of state to respect and protect the right related to the health of its citizens and fulfill its duties to maintain the right. Duties to respect means that state should not involve in any act which directly or indirectly affect the right to health. It is the duty of state to provide health care facilities, standard drugs and there should be no discrimination to the health care services. State is the guardian of all rights so it is also the duty of state to protect right to health and the third party should not be allowed to interfere in decision related to the health of its citizens. Proper legislation is the key duty of state to make laws and take appropriate measures for the private sector (pharmaceutical companies, private hospitals, labs etc) so that they cannot interfere with the health of its citizens. Women and children are equally provided health facilities.[132]

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[131] Anbrasi Edward et al., " Review of Strategies to Strengthen the Performance of Health Organizations", *Improving Health Services Delivery in Developing Countries: From Evidence to Action*, ed. David H. Peters et al. (Washington, DC: The World Bank, 2009) https://openknowledge.worldbank.org/bitstream/handle/10986/12335/48790.pdf?sequence=1&isAllowed=y , last accessed on 12 March 2020.

[132]World Health Organization, *The Right to Health: fact sheet 31*, https://www.ohchr.org/documents/publications/factsheet31.pdf , last accessed 4th June, 2021.

1.10. Duty of Sovereign State to Provide Assistance to Other Sovereign States in Health Sector

It is the duty of state to provide the health services to its citizens. If a state is unable to provide health facilities to its inhabitants for any reasons like due to emergency situation or poor financial conditions or lack of technical expertise than who will be responsible? Whether these states will be help out or will they be left with their fortunes? The answer to this question is that it will be the duty of international community to help them and provide assistance to state that do not have sufficient resources or have lack of technical expertise to come up with health emergencies. [133]

There is a great difference between the health infrastructure of developed and developing countries. Developing countries have to face a lot of challenges and their governments are unable to provide all health facilities to citizens. Lower income countries spend on health just below USD 200 per person per year and high income countries spend USD 3450 per person per year. So countries with adequate resources should come forward and help those who do not have appropriate resources.[134]

Article 21 of the Universal Declaration of Human Rights evokes the social security as the basic human right and it claims that for its realization efforts must be made by the national and international community. Article 21 of UDHR explains as

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[133] Lawrence O. and Robert Archer, "Duty of States to Assist Other States in Need: Ethics, Human Rights and International Law," *Journal of Law and Ethics*, 35(2007):530, http://ssrn.com/abstract=1095769 , last accessed on 5th June 2021.

[134]OECD/the WHO (2018), *Health at a Glance: Asia/Pacific 2018: Measuring Progress towards Universal Health Coverage*, OECD Publishing, Paris, *https://doi.org/10.1787/health_glance_ap-2018-en* , last accessed on 16 August 2020.

> Everyone, as a member of society, has the right to social security and is entitled to realization, through national effort and international co-operation and in accordance with the organization and resources of each State, of the economic, social and cultural rights indispensable for his dignity and the free development of his personality.[135]

It asserts that every individual being the part of the society is entitled to "social security". Interpretation of these words cannot be completed without incorporating the right to health in it. Social security is a very wide terms and includes so many right in it i.e. protection of life, security for property, protection from illness and treatment in case of bad health are all constitute "social security". Human rights are interdependent. Enjoyment of one right depends on many other rights. So, when we talk about human right in other words we are directly or indirectly talking about right to health.

International Convention on Economic, Social and Cultural Rights reaffirms the motto of United Nation to protect and promote the human rights, freedom and respect of individuals. The ICESCR place a responsibility on individuals to help other individuals and assist his community. It also puts an obligation on a state to help other states who need economic and technical support. The ICESCR determines the responsibility in the following words

> Realizing that the individual, having duties to other individuals and to the community to which he belongs.....Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures.[136]

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[135]United Nation, *Universal Declaration of Human Rights*,https://www.un.org/en/about-us/universal-declaration-of-human-rights , last accessed 2nd June 2021.
[136]United Nation Human Right, *International Covenant on Economic Social and Cultural Rights*, https://www.ohchr.org/en/professionalinterest/pages/cescr.aspx , last assessed on 3rd June 2021.

States who are ratified the ICESCR are under a legal duty to help other states for the realization of the rights provided under the ICESCR and right to health also protected under the ICESCR but this obligation is subject to the available resources of a state. If resources available then states that are parties to the ICESCR are required to take steps individually and collectively to provide economic and technical assistance in the health sector to the states that are poor or have less expertise in health sector.[137]

Alma Ata Declaration of the WHO on health care also highlights the inequalities exist between the developed and developing states in health sector. It explains as "The existing gross inequality in the health status of the people particularly between developed and developing countries as well as within countries is politically, socially and economically unacceptable and is, therefore, of common concern to all countries"[138]

After examining the international instruments, we can understand that it is the duty of the state to provide proper health facilities to its citizen. Primary duty of state is to provide proper health facilities to its citizens and secondary duty (subject to its resources) is belong to other sovereign states to provide help and assistance to the deprived states that cannot help their citizens.[139]

The basic principle of human right law is equality and non-discrimination. It is very important to note that peace and harmony in the world cannot be maintained without protecting dignity of man and equality among the human beings. Different statute and

[137] Lawrence O. and Robert Archer, "Duty of States to Assist Other States in Need: Ethics, Human Rights and International Law," *Journal of Law and Ethics*, 35(2007):530, http://ssrn.com/abstract=1095769, last accessed 13 July 2021.
[138]World Health Organization, *Declaration of Alma Ata*, https://www.who.int/teams/social-determinants-of-health/declaration-of-alma-ata , last accessed on 6th June 2021.
[139] Lawrence O. and Robert Archer, "Duty of States to Assist Other States in Need: Ethics, Human Rights and International Law," *Journal of Law and Ethics*, 35(2007):530, http://ssrn.com/abstract=1095769, last accessed on 21 July, 2021.

treaties of international law contain provisions related to the non-discrimination and inequality. Preamble of the Universal declaration of human rights also explain the concept of equality as

> Recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world.[140]

1.11. Conclusion

After a lot of discussion above while concluding this chapter, it is observed that right to health and intellectual property rights both are very important and recognized on national and international level. National and international laws bound the state to protect these two rights. Now it is very keen duty of state to protect and ensure enforceability of these two rights. There is actually a dire need to create a balance between these two rights. Protection of invention is very significant for further innovation and progress of science and technology nevertheless right to health should not be compromised for economic benefits. Right to health is compromised in developing and least developed countries to gain some economic benefits and to please develop nation by strict implementation (not using TRIPS flexibilities). It is the recognize duty of the state to provide appropriate health facilities to its citizens and it is also a recognize duty of other states, that have sufficient resources, to provide assistance to state who need their help. The countries with sufficient resources, developed countries, can provide assistance in many ways like by donating medicines, building health infrastructure, provide technical assistance and expertise in health sector etc. But foremost among all these, I think, is to

[140]United Nation, *Universal Declaration of Human Rights*,https://www.un.org/en/about-us/universal-declaration-of-human-rights , last accessed 2nd June 2021.

allow them to make laws according to their own needs keeping themselves within the ambit of TRIPS agreement. Developing countries should be allowed to use all the TRIPS flexibilities to maximum extent for the purpose of public health. Interference of developed countries in the affairs of developing countries makes the situation deteriorating. Too much interference leads towards the compromised Sovereignty of state. Sovereignty of state demands that state should be independent to take decision for the benefit of its people. So balance of these two rights is very important according to the need of each state without any interference from other states or any non-state actors.

CHAPTER 2

PATENT ORDINANCE 2000, TRIPS FLEXIBILITIES AND DOHA DECLARATION ON PUBLIC HEALTH

The TRIPS agreement affects the public health and affordability of medicines hence its implementation has become the matter of great concern globally. In this chapter we will focus on the provisions related to the public health under the TRIPS agreement and side by side the provision of Pakistan Patent Ordinance 2000 of Pakistan has been analyzed. Accordingly, this chapter narrates the TRIPS flexibilities and then moves how the Pakistan Patent Ordinance 2000 incorporated these flexibilities and the content analysis has been made between the two. We will analyze that is the Patent law of Pakistan utilized all the flexibility provided by the TRIPS in appropriate manner or it just a piece of paper without effective and forceful provisions. This chapter will also shed light on the response of developed countries when developing countries use these flexibilities and how they pressurize them to enter into TRIPS Plus provisions and affect the public health. In this chapter we will also reveal that the patent law of Pakistan is adequately equipped with the relaxations provided by the Doha Declaration on Public Health and Decision of 2003.

2.1. Introduction

Global implementation of the TRIPS agreement, particularly inception of pharmaceutical patents makes the choice very hard for developing countries including Pakistan. Trade relaxations and the implementation of the TRIPS agreement are connected to opt together and choice to adhere to one is no more available. Pakistan became the member of WTO in 1st January 1995 and being a developing country 5 years relaxation (transitional period) was given. Pakistan was bound to confirm all its IP legislation in accordance with the TRIPS agreement till the first January 2001. Pharmaceutical patents resulted in the high prices of medicines. International reports and index revealed that health facilities in Pakistan are worst in the region and the one third of the population in Pakistan living beyond the line of poverty. Government support in health sector is also really inadequate and insufficient and most of the health expenses are made by the people from their own pockets.

Use of the TRIPS flexibility can make the situation much healthier. The TRIPS flexibilities can ensure the easy access to affordable medicines. An overview of developing countries' IP legislation revealed that only little flexibilities are incorporated but not implemented whenever needed and some developing countries are not incorporated these flexibilities into their IP legislation. Developing countries are not adequately incorporating the TRIPS flexibilities and if incorporate the proper usage of these flexibilities is not practically seen. There might be many reasons for this non usage like lack of political will or lack of technical expertise. The gap between the TRIPS flexibilities and their use should be filled so that the poor people may have access to the

affordable patented medicines. In this chapter we will reveal that the patent law of Pakistan incorporated the TRIPS flexibilities or not and we will also explore that these TRIPS flexibilities are practically implementable or just a formality is fulfilled without using technical expertise by the legislature.

Proper usage of these flexibilities is very important it will enable the state authorities to cover the gray area that is created after the implementation of the TRIPS agreement. Doha Declaration on Public Health also makes it clear that the purpose of the TRIPS flexibilities is to help the poor countries with limited resources to deal with health emergencies. It is also clearly stated in the Doha Declaration on Public Health that whenever economic interest conflict with the obligation of state to provide health facilitate to its citizens, health concerns will prevail over the economic interests. Decision of 2003 is also very important in this perspective to facilitate the developing economies to deal with their health issues.

2.2. Historical development of the Patent Ordinance 2000

During the international period of intellectual property protection developing countries respond differently. Most of the developing countries were reluctant to adopt the international standards of IP protection into their national legislation because they think that international standards of IP protection will limit their use of new technologies. United India was introduced with its first patent law in 1856 under the British colonial rule. It was the time when many developed and the European countries are not equipped with patent law. Colonial system just introduced laws in their colonies but they failed to

create an IP culture or technical expertise. After the decolonization, the India and Pakistan respond to their IP laws differently.[141]

Patent law of Pakistan can be traced back to the 19th century when under the British colonial rule, The Patents and Designs Act 1911 was adopted. After independence, the same act was continued with little modification. After being the member of the WTO and under the TRIPS requirements Pakistan was bound to introduce the new Patent system which would comply with the minimum standards of patent protection as provided under the TRIPS agreement. [142] The Patents and Designs Act 1911 was amended in 1997 to comply with international standards and subsequently it was repealed and two new acts were introduced. The Designs Ordinance 2000 and The Patents Ordinance 2000 as the new laws provide designs and patent protection in the country according to the global standards.[143]

Patents Ordinance 2000 was amended four times, first in 2002, second in 2007, in 2010 and last in 2016. Patent in Pakistan is dealt under the Patents Ordinance 2000 along with the Patent rules 2003.[144] The Patents Ordinance 2000 is failed to incorporate the TRIPS flexibilities in it as it was evident from the subsequent amendments. In 2000 when the Patents Ordinance was promulgated the local pharmaceutical industry showed its reservation that the Patents Ordinance failed to make full use of flexibilities given under

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[141] Carolyn Deere, The Implementation Game, (New York: Oxford University Press, 2009) 35.
[142]Zuberi M A, "Intellectual Property Rights Day: TRIPS Agreement and its implication for Pakistan," Business Recorder, April 26 2005, https://fp.brecorder.com/2005/04/20050426239010/, last accessed on 22 July 2021.
[143] Gulzar Asim, "Challenges and Opportunities in the Post TRIPS Era for Pakistan--An Overview of Amended Patents Ordinance 2002," *SPO Discussion Paper Series: Understanding Pakistan Volume II*, 2014, https://spopk.org/wp-content/uploads/2019/11/dp_volume_ii.pdf, last accessed on 22nd July 2021.
[144]Sheikh Maira, "Understanding and Developing Pakistan's Intellectual property Law Framework," Research Society of International Law Pakistan, Oct. 2014, https://rsilpak.org/wp-content/uploads/2019/01/Understanding-and-Developing-Pakistan%E2%80%99s-Intellectual-Property-Law-Framework.pdf , last accessed on 22nd July 2021.

the TRIPS agreement. The economic co-ordination committee from the cabinet conducted a meeting in which a detailed discussion was made on the Patents Ordinance 2000 and some amendments were proposed and 'promulgated as Patents Amendment Ordinance 2002.[145] First amendment was made in 2002 and certain changes were made regarding the definition of invention, novelty, patentable inventions, environment and patent linkage etc. The other amendments which were made in 2007, 2010 and 2016 were very nominal and no major or substantial change was made.[146]

2.3. Historical Development of the TRIPS agreement

Developments in science and technology have transformed the business sector. Now most of the businesses depend on the technology and technology-based industry. USA has become from the net users to the net producer of technology. This change required the strong protection of IPRs. It was estimated that USA suffered the loss of 60 billion dollars per year due to piracy and other type of violations accord in different countries. In 1980, the USA noticed this problem and took some immediate actions on national and international level to overcome the problem of piracy and all.[147]

In 1970, an "Anti-counterfeiting Coalition" was made by the 100 multinational corporations to put a pressure on their national governments for making appropriate provisions and policies to control the trade of counterfeited goods on national and international level. Trade of counterfeited goods became an important matter of

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[145] Gulzar Asim, "Challenges and Opportunities in the Post TRIPS Era for Pakistan--An Overview of Amended Patents Ordinance 2002," *SPO Discussion Paper Series: Understanding Pakistan Volume II*, 2014, https://spopk.org/wp-content/uploads/2019/11/dp_volume_ii.pdf , last accessed on 22nd July 2021.
[146] *Ibid.*
[147] Michael L. Doane, " TRIPS and International Intellectual Property Protection in an age of Advancing Technology," *American University International Law Review*, vol.9,2(1994):4, http://digitalcommons.wcl.american.edu/auilr , last accessed on 4th July 2021.

discussion during the Tokyo Round of the GATT. All these efforts resulted to draft an agreement "Agreement on Measures to Discourage the Importation of counterfeit Goods". This agreement failed to create consensus between states. In 1982, during the ministerial meeting of the GATT, the issue was raised again which was not addressed in Tokyo Round. Representatives of different developed countries introduced the innovative edition of "anti-counterfeiting code". Representative of USA insisted to negotiate again on the revised version of "anti-counterfeiting code". Developing countries particularly India and Brazil still resisted the adoption of code on the GATT forum. Their stance was that the WIPO is the appropriate forum to discuss the issues and implementation problems of IPRs.[148]

In 1982 regardless the feeling of doubt which developing countries had the GATT's Director General was asked to conduct meetings with director General of WIPO to negotiate that how these two institutions would play their part to control the trade of counterfeit goods. In 1984 Council of the GATT constituted a group of specialists included the member from the WIPO and the GATT. They were advised to submit their report to the council of the GATT. The report suggested that both institutions (GATT and WIPO) would work together to control counterfeiting issues. Developing nations raised objections on the report. They again argued that IP issues would be the part of the WIPO because they could control the matter in the WIPO because the decisions are made by voting and they took benefit from being more in numbers.[149]

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[148] Duncan Matthew, *Globalizing Intellectual Property Rights the TRIPs Agreement*, first edition. (New York: Taylor & Francis e-library, 2003) 9-11,http://wto.tpo.ir/uploads/Globalizing%20Intellectual%20Property%20Rights.pdf , last accessed 5th July.
[149]Ibid.

Developed countries realized that it was not easy to strengthen the enforcement of IPRs through the WIPO. Meanwhile during this period, the USA took some domestic measure to implement IPRs. Power under Section 337 of the Tariff and Trade Act of 1930 was made active. This section gave power to USA authorities to seizure and destroys the pirated material. Scope of section 337 was limited to the violation within the territory and on the border of USA and not in the market of other countries. [150]

Section 301 of Trade and Tariff Act was also amended and it empowered the office of United States Trade Representative (USTR) to take action in other countries against the IP infringements. Countries who did not implement IP policies would not be provided with trade privileges by USA. A pressure was built on developing countries to follow IP.[151] USA adopted another strategy to control the cross-border enforcement of IP rights through the bilateral trade agreement. It was proved as a much unbeaten strategy by the USA government to minimize the IP violations.[152]

Despite the resistance from the developing countries on July 1986, proposal was presented by the representatives of Swiss and Colombia to include IPRs for negotiation in

[150] Michael L. Doane, " TRIPS and International Intellectual Property Protection in an age of Advancing Technology," *American University International Law Review*, vol.9,2(1994):9, http://digitalcommons.wcl.american.edu/auilr , last accessed on 4th July 2021.
[151]Sell, Susan K. "Intellectual Property Protection and Antitrust in the Developing World: Crisis, Coercion, and Choice." *International Organization* 49, no. 2 (1995): 315-49, http://www.jstor.org/stable/2706974, last accessed on 5th July 2021.
[152] Duncan Matthew, *Globalizing Intellectual Property Rights the TRIPs Agreement*, first edition. (Newyark: Taylor & Francis e-library, 2003) 14-15,http://wto.tpo.ir/uploads/Globalizing%20Intellectual%20Property%20Rights.pdf, last accessed on 5th July 2021.

ministerial declaration. The proposal was submitted to Punta del Este Ministerial Conference and accepted with no considerable modifications.[153]

After a plenty of efforts by the developed nations and lots of confrontation by the developing countries, IPRs had become the part of trade negotiations. United States declared that the purpose of incorporating the TRIPS in trade negotiation was

> to reduce the distortion and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade, the negotiations shall aim to clarify GATT provisions and elaborate as appropriate new rules and disciplines[154]

2.4. Flexibilities under the TRIPS agreement and the Patent Ordinance 2000 of Pakistan

The TRIPS agreement provides a range of flexibilities for the member states so that they can perform their obligations properly. TRIPS flexibilities are some of the policy options which are available to the WTO member countries. Purpose of these relaxations is to allow the WTO member countries to implement their obligation properly. State authorities can use these flexibilities in diverse ways including adoption of public health policies and other national development priorities. Flexibilities provided under the TRIPS agreement allow members countries to exploit creative solutions into their national legislation and practice

[153] Duncan Matthew, *Globalizing Intellectual Property Rights and the TRIPs Agreement*, first edition. (New York: Taylor & Francis e-library, 2003) 17, http://wto.tpo.ir/uploads/Globalizing%20Intellectual%20Property%20Rights.pdf, last accessed on 5th July 2021.

[154] U.S. Framework Proposal to GATT Concerning Intellectual Property Rights,4 Int'I Trdae Rep. (BNA) 1371 (Nov. 4,1987) "quoted in"Duncan Matthew, *Globalizing Intellectual Property Rights the TRIPs Agreement*, first edition. (Newyark: Taylor & Francis e-library, 2003) 17.

concept according to their national need especially in those areas which are not explicitly define by the TRIPS agreement.

Without the proper use of these flexibilities there is apprehension that the Sovereign States would not perform their obligation towards their citizens. Flexibilities provided under the TRIPS agreement cover the certain areas which deal with the pharmaceutical patents and the policies of government related to the patenting system. It provides certain discretions to the states to explain the patentability criteria and to exclude the certain subjects from the patentability. It also provides the liberty to the state authorities to determine the grounds of compulsory licensing and to allow parallel imports. If the developing countries incorporate all these flexibilities in their patent legislation, resultantly it would definitely increase the access to affordable medicines.

2.5. Principal of Exhaustion

Literal meaning of exhaustion is the state of being exhaust and worn out. Under the principle of exhaustion, the patent holder when sold his product in the market then his right over that product is exhausted. The second owner who purchases the product from the patent holder (first owner) has right to gift, donate or sold the product to anybody he wants. Patent holder after first sale cannot control the movement or use of product because this cause restraint in trade and free competition.

In common law countries, the doctrine of exhaustion is also considered as the implied license between the buyer and the seller. The sale of patented product gives an implied license to the buyer that he may exercise all the rights against the purchased product. This doctrine of exhaustion is known as the “doctrine of the first sale” in United States. The doctrine of exhaustion is also use in European Countries, initially this doctrine is limited

to a particular territory but European Court of Justice (ECJ) extends the implementation of this doctrine to the entire common market and this is known as regional exhaustion.[155]

Principle of exhaustion has three kinds national exhaustion, regional exhaustion and international exhaustion. The European communities (EC) practice regional exhaustion but some other countries go for national or international exhaustion. The principal of international exhaustion is also known as the parallel importation. Prohibition of parallel importation may be considered as bar on international competition. Parallel imports do not affect the right of the patent holder to get the reward of his invention as he gets benefits after the first sale of the patented article but it ensures the patent invention "to the mutual advantage of the producers and users of the technological knowledge" (article 7 of TRIPS)[156]

Patent law of Japan does not provide the express provision about parallel importation. In BBS Wheels Case the Japanese Supreme Court opens the door for parallel importation. Supreme Court addressed the very important issue in an interesting way. There was a substantial difference of price in the market of Japan and Germany for same product which was patented in Japan and Germany. Court held that it is not the violation of patent to parallel import the auto parts from Germany and would not be considered as the violation of Japanese patent.[157]

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[155] Correa Carlos, "Pro-competitive Measures under TRIPS to Promote Technology Diffusion in Developing countries" *Global Intellectual Property Rights Knowledge, Access and Development*, ed. Peter Drahos and Ruth Mayne (New York: Palgrave Macmillan, 2002), 44.
[156] Correa Carlos, "Pro-competitive Measures under TRIPS to Promote Technology Diffusion in Developing countries" *Global Intellectual Property Rights Knowledge, Access and Development*, ed. Peter Drahos and Ruth Mayne (New York: Palgrave Macmillan, 2002), 45.
[157] BBS KRAFTFAHRZTHE EUGTECHNIK AG V RACIMEX JAPAN KK; JAP AUTO PRODUCTS KK,Case No H-7 (O) 1988, dated 1 July 1997,

2.5.1. Principal of Exhaustion under the TRIPS agreement

The TRIPS agreement under Article 6 also provides the principle of exhaustion. It allows the member states to adopt the principle of exhaustion which in other words known as parallel importation. Article 6 of the TRIPS agreement narrate as

"For the purpose of dispute settlement this agreement, subject to the provision of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."[158]

Interpretation of Article 6 ensures that states are free to incorporate the exhaustion principle in the national legislation. It is the discretion of state to adopt the principle of national or international exhaustion. The principle of international exhaustion is also known as parallel importation. Countries having provisions of parallel importation are allowed to import the product from other countries where the product placed in the market legitimately. If the patented products are being sold on low prices in some countries by the patent holder or any other authorized person then it can be parallel import. [159]

Article 28 of the TRIPS agreement defines the rights of the patent holder. It provides the right to prevent third party from importation but it has a foot note on this right as "like

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https://law.unimelb.edu.au/__data/assets/pdf_file/0005/1679999/Hays.pdf , last accessed 11 September,2021.

[158] Trade Related Aspects of Intellectual Property Rights, https://www.wto.org/english/docs_e/legal_e/27-trips.pdf, last accessed on 2nd September 2021.

[159] Baker Brook, " A Full Description of WTO TRIPS Flexibilities Available to ARIPO Member States and a Critique of ARIPO's Comparative Study Analyzing and Making Recommendations Concerning Those Flexibilities," March 2019, https://www.bu.edu/gdp/files/2020/05/ARIPO-Member-States-obligations-and-flexibilities-under-the-WTO-TRIPS-Agreement-March-2019.pdf , last accessed on 5th June 2021.

all other rights conferred under this Agreement regarding the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6." It means that the foot notes 6 defines that the right of patent holder to prevent others from importation is subject to the article 6 of the TRIPS agreement which deals with exhaustion. So, it is clear that the TRIPS agreement does not prevent the member state from incorporating parallel important provisions.[160]

Doha declaration on the TRIPS agreement and public health reaffirms the TRIPS and allow the exhaustion in the following wording "The effect of the provisions in the TRIPS agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge,"[161]

Developing countries should incorporate the explicit provisions of parallel importation in their national legislation. It can be used as an effective tool to ensure access to affordable patented medicines. Patented medicines still have different prices in different markets so countries having explicit parallel importing provisions can take benefit from substantial difference in prices. This flexibility of parallel importation is provided under the TRIPS agreement cannot automatically be considered as the part of national legislation but the countries have to legislate these provisions into their national legislative system.[162]

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[160]Zhaung Wei, "Facilitating Patent Related Flexibility in the TRIPS Agreement," Intellectual Property Rights and Climate Change: Interpreting TRIPS, (New York, Cambridge University Press, 2017) 275-277.
[161] Doha WTO Ministerial 2001, Declaration on the TRIPS agreement and public health, https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm last accessed on 25th October 2021.
[162]F Sisule and OH Cecilia, " The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines," Commission on Intellectual Property Rights, Innovation and Public Health(CIPIH), 2005, https://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf , last accessed on 2 September 2021.

2.5.2. Principal of Exhaustion under the Patents Ordinance 2000

Patents Ordinance 2000 of Pakistan defines the right of the patent holder in Article 30. In 2002 first amendment of Patents Ordnance 2000 was introduced and Article 30 was also amended. Three new provisions were introduced in it 30(1)(a), 30(1)(b) and 30(5)(a) respectively. Article 30(1)(a) describes the right of the patentee against its invention when it is a product and narrates that the patentee has right "of making, using, offering for sale, selling, or importing for these purposes that product;". It also provides same right to the patentee when the process is patented as "Where the subject matter of a patent is a process, the holder of a valid patent may prevent third parties not having the owner's consent from the act of using the process, and from the acts of using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process."[163]

Right are provided that the patent holder has all right related to the patented products but the limitation is also attached with these rights. As the Article 30(5) (a) narrates as "The rights under the patent shall not extend to-(a) Acts in respect of articles which have been put on the market anywhere in the world by the owner of the patent or with his consent or by an authorized person or in any other legitimate manner such as compulsory licenses;"[164]

This new provision introduced the principle of exhaustion which was allowed in the TRIPS agreement under article 6 and 28(a). However the provision of exhaustion as elaborated under the Patents Ordinance 2000 of Pakistan has very restricted and limited

[163]Patent Ordinance 2000, https://ipo.gov.pk/system/files/%28112%29PatentsOrdinance2000_Amendmentsfinal_0.pdf ,accessed 10 July 2021.
[164]Ibid.

scope.[165] It dost not explain anything clearly about the exhaustion whether it allowed national exhaustion or international exhaustion. Actually, the term of exhaustion, parallel importation or even the word importation is not used and just in few words without any explicit term the right is granted and a lot of room is left for interpretation. The language of law demonstrates the intention of legislature so the language should be forceful and cover all the relevant interpretation so that the language should not be misinterpreted. Parallel importation can be used as a very important tool to access affordable medicine so this tool should be utilized to the maximum extent within the legitimate boundaries of the TRIPS agreement.

2.6. Patentability Criteria

The TRIPS agreement defines the criteria for patentability in a very broad perspective and left the states with option to deal the patent law according to their national needs. Once the criteria are fixed for patent protection and requirements are fulfilled, the patent have to be granted. So, there is need to set the strict conditions for patentability and utilize the discretion provided by the TRIPS. The member states may make variations in patent law by defining different terms in broad or narrow manner as the novelty and invention is not define by the TRIPS and the states may define terms according to the way suits to their economic social and cultural requirements. The states which are technologically advanced and have strong national innovative production system would encourage broad and relaxed patentability standards to foster competition. Alternatively, the states which are very week in research and depend upon the imported technologies to

[165] Zahid Nasir, "A Study of Health-Related Flexibilities in International IP Framework and Patent Law in Pakistan" Master's Thesis,(Graduate School of Seoul National University, 2017) http://www.clt.re.kr/V1/data/file/Thesis/000000146436_20181115164505.pdf , last accessed on 9th June,2021.

fulfill domestic needs should opt narrow and strict patentability conditions to minimize the foreign monopolies. [166]

It is also very imperative to have more exceptions in the patent law to encourage local industry. Some jurisdictions also provide provisions for the revocation of patent for certain prescribed reasons i.e. a patent might be revoked if obtained fraudulently; or obtained by the person who is not the really inventor; or patent specification is not adequately disclosed; or for any other reasons. The purpose behind the protection of patent is twofold, one is to give economic benefit to inventor as incentive for future inventions and the second is to benefit the society to enjoy invention and equally equipped with the knowledge of the invention. Proficient patent systems always keep balance between the rights of the patent producers and patent users.[167]

2.6.1. Patentability Criteria under the TRIPS agreement

Article 27 (1) of the TRIPS agreement deals with the patentable subject matter and provide details when patent will be granted. Article 27 (1) narrates as Patentable Subject Matter as

> patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application

Article 27 provides a very general definition of invention that it would be new, involve an inventive step and are capable of industrial application. The TRIPS agreement

[166]Saad Mohammad, Public health related TRIPS-Plus provisions in bilateral trade agreement: A policy guide, WTO Regional office, p 136,https://applications.emro.who.int/dsaf/dsa1081.pdf , last accessed on 8 October 2021.
[167]Reichman J. H, "From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement," *Journal of International Law and Politics* 29.(1996) 11-93, https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1073&context=faculty_scholarship , last accessed on 5th June, 2021.

does not provide any definition of novelty, inventive step or industrial application. It means member states are free to define what is patentable and what would not be the subject of patent protection.[168]

Article 27 prohibits to discriminating any field of technology from patentability but it does not define the field of technology. This is the reason that some countries exclude the computer programs, business methods and abstract ideas from patent protection. When any particular term is not defined by the law then it is the matter of interpretation how to interpret the term. The countries who do not give patent protection to any field of technology they make a very wise justification for that denial. They actually do not discriminate any 'field of technology' but make a difference between invention and discovery and provide protection to the inventions and not to discoveries. Discovery means to find something that already exists in the nature and invention means to create something new with your own ideas and efforts.[169]

Every technology has a diverse and exclusive aspect. States are allowed to adopt different rules of patent protection for different kind of technologies. Pharmaceutical patent have a direct link with the health of people and with the responsibility of states so the policy makers have a strong reason to adopt different rules for pharmaceutical

[168] Watal Jayashree, "Developing Countries and the Protection of Intellectual Property Rights: Current issues in WTO," *WTO Law and Developing Countries*, ed. Berman George and Mavroidis Petros (New York, Cambridge University Press, 2007) 146.
[169]Baker Brook, " A Full Description of WTO TRIPS Flexibilities Available to ARIPO Member States and a Critique of ARIPO's Comparative Study Analyzing and Making Recommendations Concerning Those Flexibilities," March 2019, https://www.bu.edu/gdp/files/2020/05/ARIPO-Member-States-obligations-and-flexibilities-under-the-WTO-TRIPS-Agreement-March-2019.pdf , last accessed on 9th June 2021.

sector.[170]This Article give much relaxation to the member states that they can exclude the certain subject matter from the patentability.

Article 27(2) of the TRIPS agreement also allowed the members to exclude from patentability the invention which prevent public order and adversely affect the health of human beings. Articles 27 of the TRIPS agreement leave the states with discretion to exclude a wide range of subject matter from patentability. States are bound to protect pharmaceutical patents but they have choice to go for a system in which it would be effortless or tough to get patents on known medicines. Stoppage of secondary patent by the strict patentability criteria can also make the situation, regarding access to medicine, much better. Patent Act, 1970 of India and Argentina incorporated strict criteria of patent protection for new medicines and Brazil and East Africa also suggested it for their patent law reforms.[171]

2.6.2. Patentability Criteria under Patents Ordinance 2000 of Pakistan

Patent Ordinance 2000 is not fully equipped with the flexibilities provided under the TRIPS agreement. Though a detail amendment in 2002 was introduced in Patent Ordinance but even after amendment the wise use of TRIPS flexibilities is not seen. Patent Ordinance 2000 u/s 2(c) explains the term invention as

> Any new and useful product, including chemical products, art, process, method or manner of manufacture, machine, apparatus or other article; substance or article or product produced by manufacture and includes any new and useful improvement of any of them and an alleged invention[172]

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[170]Max Planck Institute, Declaration on Patent Protection: Regulatory Sovereignty under TRIPS, 2014, https://www.mpg.de/8132986/Patent-Declaration.pdf , last accessed on 7 September 2021.
[171]Ibid.
[172] Pakistan Patent Ordinance 2000: A Memorandum on Pakistan's new Patent Ordinance, 2000, http://www.pakistanlaw.com/memorandum_newpatent_law.php , assessed on 10th September,

After amendment in 2002 the definition of patentable invention is given under section 7 as

> any invention is patent able, if it is new, involve an inventive step and capable of industrial application.[173]

Before the amendment of Patents Ordinance 2000, the scope of invention was very broad and it include the 'alleged invention" after amendment the scope of invention was narrow down but it is still wider than the required by the TRIPS agreement. It includes the inventive step and industrial application in the definition of invention but fail to properly define these terms. Developing countries can take benefit by explaining these terms according to their need and use in its favor. Industrial application is term which needs much elaboration and many significant fundamentals may cover under the definition which can help local industry to take benefit from foreign inventions and flourish.

The TRIPS agreement provides the minimum standards of patent protection keeping in view the issues and concerns of developing countries. Wider definition of invention might lead to provide patent on new chemical entities (NCE) mixed up in new drugs and secondary patent on new combination of already existing NCE and on new uses of already existing NCE. Broad definition will open the way for secondary patent and patent monopoly will be enjoyed for more than 20 years.[174] If a country adopts the broad standards of patentability, then those provided under the TRIPS agreement it would help the pharmaceutical companies to misuse the whole patent system as the Pakistani

[173]The Patent Office, Patent Ordinance 2000, accessed 10 July 2021, https://ipo.gov.pk/system/files/%28112%29PatentsOrdinance2000_Amendmentsfinal_0.pdf.
[174] Gulzar Asim, "Challenges and Opportunities in the Post TRIPS Era for Pakistan--An Overview of Amended Patents Ordinance 2002," *SPO Discussion Paper Series: Understanding Pakistan Volume II*, 2014, https://spopk.org/wp-content/uploads/2019/11/dp_volume_ii.pdf, last accessed on 20 April, 2021.

pharmaceutical industry is not researching oriented and patent office grant patent to the foreign patent holders. So, the country like Pakistan must go for strict patentability criteria to minimize the foreign patent monopolies.

2.7. General Exceptions

Every right has some limitations and patent rights are also not exception to this general rule. It is said that exceptions in any system make that system strong and efficient in performance. Patent law systems all around the world provide exceptions however the content of these exceptions is different as according to the need of their system. The objective of incorporating these exceptions in the patent system is to encourage the transfer of technology, to control anticompetitive practices or to solve the health-related issues. These exceptions include, as per the practices of different countries, the use of invention for two purposes first is the experimental use and second is to get regulatory approval for the in time entry of generic drugs in the market as soon as the patent expires.

2.7.1. Exception for Research and Experimental Use

Experimental use of the patented invention can be used as an important tool to encourage the further inventions. Experimental use of the patented invention would increase the inventions depend upon the ‘inventing around’ or will improve the efficiency of existing invention. It will also help to evaluate the competency and novelty of invention. In America the patented invention can be used for scientific experimentation

even without the permission of the patent holder. The Europe widen this right and experimentation of invention is permitted even for commercial purposes.[175]

2.7.2. Bolar Exception

Bolar exception allows the use of patented invention by the third party before the expiry of patent right. The use of the patented invention before expiry is the violation of patent if the country does not have Bolar exception provisions. The objective of this exception is to obtain the marketing approval of the drug (generic) immediately after the patent expires. Bolar exception helps the immediate entry of the generic medicines in the market after the patent expires and a competition started between the generic manufacturer and the brand owner which ensure the that the people will have access to the low-cost medicines.[176]

Bolar exception was introduced first time in America. Roche Products, Inc. V. Bolar pharmaceutical Co. was a historical case related to the use of the invention for the regulatory approval. Bolar was the manufacturer of the generic drugs and the Roche was a research based pharmaceutical company. Roche get patent on the active ingredient of its brand name medicine Dalman. Bolar used the patented active ingredient for experimentation to check the bioequivalence of his generic drugs to obtain FDA approval. Bolar also claims that the public policy demand that generic drugs must enter in the market immediately patent expires so that the competition of price started between the branded and generic drugs. The Court of Appeal for the Federal Circuit (CAFC)

[175] Correa Carlos, "Pro-competitive Measures under TRIPS to Promote Technology Diffusion in Developing countries" *Global Intellectual Property Rights Knowledge, Access and Development*, ed. Peter Drahos and Ruth Mayne(New York:Palgrave Macmillan,2002), 47.
[176] Carolyn Deere, The Implementation Game, (New York: Oxford University Press, 2009) 100.

rejected Bolar's claim and decided that the use of invention by the Bolar was for the business purposes and not for the experimental purposes.[177]

This case was decided in 1983 and in the very next year in 1984 the Congress passed the law "Hatch-Waxman" and allowed the use of patented invention, before the patent expires, for regulatory approval so that the generic medicine enter the market in time. The Act define as

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention…… solely for uses reasonably related to the development and submission of information under a Federal law, which regulates the manufacture, use, or sale of drugs or veterinary biological products.[178]

The European Communities complained against Canada in the WTO dispute settlement body (DSB) that the section 55.2(1) deals with the regulatory approval exceptions and section 55.2(2) deals with the stockpiling exception[179] were challenged. The panel decided that the provisions of Canadian Patent Act which provide regulatory review exception are not inconsistent with Article 27.1 and this exception covered by the Article 30 of the TRIPS hence justified. The panel also decided that the stockpiling provision are inconsistent with Article 28.1 and exceptions under Article 30 of the TRIPS does not cover stockpiling exception because it is a substantial reduction of the exclusive right conferred to the patent holder.[180]

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[177] Roche Products, Inc. V. Bolar pharmaceutical Co. 733 F. 2d 858(Fed.Cir. 04/23/1983), https://unctad.org/ippcaselaw/sites/default/files/ippcaselaw/2020-12/Roche%20v.%20Bolar%20Pharmacthe EUtical%20.pdf , last accessed 11th September 2021.

[178] Ibid.

[179]Stockpiling exception permit the generic drug manufacturer to manufacture and compile the patented articles before a certain period of patent expiry but goods prepared or manufactured cannot be sold in the market before the patent expire.

[180]World Trade Organization, WTO Dispute Settlement Board: One Page Case Summaries 1995-2020, https://www.wto.org/english/res_e/booksp_e/dispu_settl_1995_2020_e.pdf , last accessed 13th September 2021.

2.7.3. General Exception under the TRIPS agreement

Article 30 of the TRIPS agreement provides the general exceptions and allows the member states to give certain exceptions against the monopoly right of the patent holder. These exceptions may include use of patent for research, teaching, experimentation to improve and experimentation to get regulatory approvals. However, it must be ensured that such exceptions should not affect the full exploitation of patent and legitimate right of the patent holder. Article 30 provides as

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.[181]

2.7.4. General Exception under the Patents Ordinance of Pakistan 2000

Original draft of the Pakistan Patents Ordinance 2000 does not have Bolar exception in it but after the first amendment in 2002 the three new provisions were added article 30(5)c,30(5) e and 30(5) f respectively. Section 30(5) c narrates "act done only for experimental purposes relating to the patented invention". Article 30(5) e provides the Bolar exception in the following words namely "acts, including tests, necessary for the approval of a product for its commercialization after the expiration of the patent"[182]

[181] Trade Related Aspects of Intellectual Property Rights, https://www.wto.org/english/docs_e/legal_e/27-trips.pdf ,last accessed on 2nd September 2021.
[182]Patent Ordinance 2000, https://ipo.gov.pk/system/files/%28112%29PatentsOrdinance2000_Amendmentsfinal_0.pdf , last accessed 10 July 2021.

Article 30(5) f provides exception on the right conferred on the patent for teaching purposes, language of article 30(5) f is as "acts done for teaching purposes in educational or research institutions."[183]

Inception of Bolar exception in the patent law of Pakistan is very important and it will help the generic manufacturers to compete the patent holder in the market as soon as its patent expires. Pre-testing will help the generic drug manufacturer to save time and entered the generic drugs in the marketing immediately patent expires.

Only few developing countries utilize the Bolar exception in their patent legislation. Patent law of Pakistan utilizes the exception on the right conferred on the patent as provided by the article 30 of the TRIPS agreement but the use of exception is very restricted and limited. Article 30 of the TRIPS agreement does not explain the scope of the exceptions so the countries have freedom to utilize this provision to the maximum extent. Paragraph 5(a) of the Doha Declaration on Public Health also narrates the aim and objectives of the TRIPS agreement is to ensure the access to medicines and the transfer of technology so countries should interpret the provision of Agreement maximum to facilitate its people specially for the availability of affordable medicines.[184]

[183]Ibid.
[184] Gulzar Asim, "Challenges and Opportunities in the Post TRIPS Era for Pakistan--An Overview of Amended Patents Ordinance 2002," *SPO Discussion Paper Series: Understanding Pakistan Volume II*, 2014, https://spopk.org/wp-content/uploads/2019/11/dp_volume_ii.pdf , last accessed on 13 June 2021.

2.8. Use of Patent without Authorization of the Patent holder/ Compulsory License

Law provides the facility to use the invention without the authorization of the right holder in certain circumstances, such use recognizes as government use and compulsory license. Government use and compulsory licensing are very important flexibilities for the developed and developing countries to mitigate the effects of exclusive patent monopolies. This key flexibility can be used as an important tool to access affordable generic medicines. Doha Declaration on Public Health reaffirms that these provisions should be utilized to minimize the sufferings of people living with poor health conditions. States are independent and free to determine the grounds of granting compulsory licensing so it is the discretion of states how to incorporate these provisions and make them to facilitate their citizen to maximum extent.[185]

Government uses or the compulsory license grant the government right to authorize third party to manufacture the patented drug without the authorization of the right holder in circumstances of extreme urgency. However, there are certain conditions need to be fulfilled before granting the compulsory licensing for instance the use of compulsory licensing provisions will be for public use and before granting the compulsory licensing to the third-party efforts must be made to get a voluntary license from the patent holder. If the efforts to get the voluntary license fail on reasonable terms and conditions and within a reasonable time, the government will be authorized to issue a compulsory license

[185]F Sisule and OH Cecilia, " The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines," Commission on Intellectual Property Rights, Innovation and Public Health(CIPIH), 2005, https://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf , last accessed on 2 September 2021.

for public use. Reasonable time will be decided by the state authorities and the TRIPS is silent about the term what is reasonable time.[186]

The argument behind the patent protection is to encourage the creativity and innovation. However, the patent protection does not give authority to the multinational pharmaceutical companies to exploit the right of general public. Private right of patent holder should not be preferred over the public health protection. Compulsory license provisions under the TRIPS agreement can be used as a very important tool to handle the misuse of patent system. It is also very important to incorporate compulsory license provision in such a way that it should be workable when needed. Unfortunately, many developing countries though have compulsory licensing provision but the grounds of granting compulsory licensing are too narrow that these provisions are not workable.[187]

2.8.1. Compulsory Licensing under the TRIPS agreement

Now we will discuss the provisions of compulsory licensing under the TRIPS agreement and explore how the TRIPS agreement provides important provisions to protect the rights of patent holder and also left the member states with liberty to decide the certain matters according to the need of their people. Article 31 explains the Compulsory Licensing provisions as;

> Other use without the authorization of the right holder: Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: (a) authorization of such use shall be considered on its individual merits; (b) such use may only be permitted if,

[186] Carolyn Deere, The Implementation Game, (New York: Oxford University Press, 2009) 81-82.
[187] Raju K D, "Compulsory and Voluntary Licensing: A Legitimate way to Enhance Access to Essential Medicines in Developing Countries," *Journal of Intellectual Property Rights*, Vol 22, January 2017, 23-31. http://docs.manupatra.in/newsline/articles/Upload/31AC60C2-ABCC-4799-A388-0F56ED7C9ECF.pdf , last accessed on 5th August 2021.

> prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of national emergency or other circumstances of extreme urgency or in cases of public non commercial use.[188]

The TRIPS agreement provides facility to the Member States to manufacture the patented goods for domestic market without the authorization of right holder, whenever needed in health emergencies. Certain limitations are also attached with such use, however the grounds for granting compulsory license are not provided by the TRIPS and the States are free to determine the grounds of compulsory licensing according to the need of their people. Certain conditions are needed to be fulfilled before the issuance of the compulsory licensing. First of all, article 31 (a) explains that each case of granting compulsory license will be considered individually because everyone has different circumstances and different reasons to issue compulsory license.[189]

Article 31 (b) put a prior obligation that the Member states must made some efforts to get a voluntary license on reasonable terms and conditions and within reasonable time before the issuance of the Compulsory License. If all the efforts fail to get a voluntary license on 'reasonable commercial term' within a reasonable time, the Member state will be authorized to issue compulsory license. This condition is also having limitation that 'in case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use' and 'to correct anti-competitive practice' 31(k) the prior obligation of negotiation with right holder can be waived. State

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[188] Patent Ordinance 2000, https://ipo.gov.pk/system/files/%28112%29PatentsOrdinance2000_Amendmentsfinal_0.pdf , last accessed 10 July 2021.

[189]Baker Brook, " A Full Description of WTO TRIPS Flexibilities Available to ARIPO Member States and a Critique of ARIPO's Comparative Study Analyzing and Making Recommendations Concerning Those Flexibilities," March 2019, https://www.bu.edu/gdp/files/2020/05/ARIPO-Member-States-obligations-and-flexibilities-under-the-WTO-TRIPS-Agreement-March-2019.pdf , last accessed 8th July 2021.

parties can issue compulsory license and will notify the patent holder about the issuance of compulsory license as soon as possible. [190]

The TRIPS does not provide any particular duration for the use of compulsory license; however, the use of compulsory license would be confined to that particular purpose for which it is issued (3(c)). The use of Compulsory License shall be stopped when the cause is over or cure and the issuance authority will protect the interest of the licensee (31(g)). The use of patented product under the compulsory license shall be non-exclusive (31(d)), non-assignable (31(e)) and the supply of patented product shall be limited to the domestic market (31(f)). According to the financial value of the invention the compensation shall be given to the patent holder (31(h). The decision of issuing compulsory license and to determine the amount of compensation is open to judicial review by the higher authority (31(i)).

2.8.2. Doha Declaration on Public Health

The TRIPS agreement is silent about the grounds of granting compulsory license and States are free to decide the grounds keeping in view the needs and health concerns of their citizens. A disagreement was existed between developed and developing countries about the circumstances when the compulsory license will be issued and that it is available just for 'essential medicines' or otherwise, all these questions are answered in Doha Declaration on Public Health. A ministerial conference held in Doha an agreement was concluded between all the members of World Trade Organization (WTO) and the conflicts between the TRIPS agreement and the health concerns of developing countries

[190] Abbott and Puymbroeck, Compulsory Licensing for Public Health: a Guid and Model Document for the Implementation of the Doha Declaration paragraph 6 Decision, the world bank working paper series,2005, https://openknowledge.worldbank.org/bitstream/handle/10986/7269/334260rev0pub.pdf?sequence=1&isAllowed=y, last accessed 24th August 2021.

are addressed in the Doha Declaration.[191] Doha declaration on the TRIPS agreement and public health confirms that the members countries are free to determine the ground of compulsory license and in paragraph 5(b) it states as "Each member state has right to grant compulsory license and freedom to determine the grounds upon which such licenses are granted"[192]

2.8.3. Doha Declaration on Public Health and the interpretation of Article 31

Doha Declaration on Public Health makes a very clear interpretation of the article 31 of the TRIPS agreement and makes it very clear that "the TRIPS agreement doesn't and shouldn't prevent Members from taking measures to protect public health". It also reaffirms that "

> the TRIPS agreement can and should be interpreted and implemented in a manner supportive of the WTO Members." The Doha Declaration on Public Health allows the Members to use flexibility of The TRIPS agreement to avoid the side effect of the exclusive patent monopoly on the access to medicines. States are free to use "the right to grant the compulsory license and the freedom to determine the grounds upon which such licenses are granted the right to determine what constitute a national emergency or other circumstances of extreme emergency.[193]

Doha Declaration on Public Health recognized that it is "the right of the WTO Members to use, to the full, the provisions in The TRIPS agreement, which provide flexibility for this purpose." It is the right of member states "to protect public health and,

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[191] Niesporek Anna, "Compulsory Licensing of Pharmacuetical Products & Access to Essential Medicines in Developing Countries," Master thesis,(Linköping University, Ekonomiska institutionen,2005) http://www.diva-portal.org/smash/get/diva2:21332/FULLTEXT01.pdf , last accessed on 4th August 2021.
[192] Doha WTO Ministerial 2001, Declaration on the TRIPS agreement and public health, https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm , last accessed 16 August 2021.
[193] World Trade Organization, Declaration on the TRIPS Agreement and Public Health, 14 Nov. 2001, https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm , last accessed on 5th July 2021

in particular, to promote access to medicines for all."[194] Doha Declaration on Public Health recognizes the issue that the developing and least developed countries faced in the health sector. It asserts that the protection of IPRs are important but its effect on the prices of medicines needs to be controlled and it is possible just by using the flexibilities provided under the TRIPS agreement.

Doha Declaration on Public Health in paragraph 6 recognized a very important issue which is related to the Member states that does not have manufacturing capacity. The countries with no manufacturing capacity or with little manufacturing capacity cannot take benefit from the compulsory licensing provisions. The council for TRIPS was advised to find some solution to solve this problem and submit a report during the 2002 in the General Council. It was not an easy task to find the solution, however after the very hard negotiation, the developed and developing countries come to an option acceptable for all. On 30th August 2003 the problem was resolved and the WTO announced that the restriction on the export of patented medicines was abolished and countries with no manufacturing capacity can import the patented medicine from the other country.[195]

A complete procedure is provided for compulsory license issued under the Decision of 2003 for export purposes. Both countries will issue the compulsory license one for the export purpose and the other for the import purpose. Importing country must be the one who is a least developed country or do not have the manufacturing capacity. The importing country will notify to the Council for TRIPS about its intention to issue a compulsory license for importing patented. It will confirm the Council for TRIPS that it

[194] Ibid.
[195] Carolyn Deere, The Implementation Game, (New York: Oxford University Press, 2009) 146.

has no manufacturing capacity and will inform about the name of the medicine and the approximate quantity of medicine. The importing country will not pay the remuneration to the patent holder for compulsory license but the country who will export the medicine will pay the remuneration to the patent holder for manufacturing the drugs.[196]

The exporting country will also notify to the Council for TRIPS about its intention to issue a compulsory license for export to the country that do not have manufacturing capacity. The exporting country will provide detail information to the Council for the TRIPS about the licensee, goods (medicines), its size, details about the country where the goods will export and all other relevant information. The exporter country will export only particular amount of goods that would be sufficient to fulfill the need of importing country. The product must be specially packed by using different colors and signs so that it can be differentiate from other products but such packing should not affect the price. After the product is dispatched then the licensee will mention about it on the particular website or on the WTO website about the size and the distinguish feature of the product.[197]

2.8.4. Patents Ordinance 2000 of Pakistan and Compulsory licensing provisions

Patents Ordinance 2000 also provides the compulsory license provisions under section 58 and 59. In 2002 the Patents Ordinance was amended and two new provisions were added 58(iii) and 58(iv). The compulsory licensing regime under the patent

[196] Songeeta Shashikant, " The Doha Declaration on TRIPS and Public Health: An Impetus for Access to Medicines", *Access to Knowledge in the age of Intellectual Property*, ed. Gaelle Krikorian and Amy Kapczynski (NEW York: Zone Book: 2010)

[197] Abbott and Puymbroeck, Compulsory Licensing for Public Health: A Guid and Model Document for the Implementation of the Doha Declaration paragraph 6 Decision, the world bank working paper series,2005, https://openknowledge.worldbank.org/bitstream/handle/10986/7269/334260rev0pub.pdf?sequence=1&isAllowed=y , 24th August, 2021.

ordinance 2000 is very week and poorly worded and even after amendment in 2002 it is fail to equip with the strong and effectively workable compulsory licensing grounds.[198] Here we will discuss and analyze the provisions of compulsory license in Patents Ordinance 2000 and will suggest that how these provisions can be made more effective and workable within the boundaries of TRIPS. The article 58 describe as

Exploitation by a Government agency or third Person: - (1) Subject to sub-section (2), where

I. the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or
II. the federal government has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the federal government is satisfied that the exploitation of the invention in accordance with this sub-section would remedy such practices; or
III. the patent holder refuses to grant a license to a third party on reasonable commercial terms and conditions; or
IV. where patent has not been exploited in a manner which contributes to the promotion of technological innovation and to the transfer and dissemination of technology,[199]

Compulsory licensing provisions are very important for both developed and developing countries and several studies are conducted which ensure the very effective results of using compulsory license to access medicines and to create an atmosphere of competition. Using the compulsory licensing provisions or even by having the adequate compulsory licensing provisions build a pressure on the multinational companies which help to increase the availability and affordability of medicines in the country. Compulsory license provisions under the Patents Ordinance 2000 are not enough to

[198] Gulzar Asim, "Challenges and Opportunities in the Post TRIPS Era for Pakistan--An Overview of Amended Patents Ordinance 2002," *SPO Discussion Paper Series: Understanding Pakistan Volume II*, 2014, https://spopk.org/wp-content/uploads/2019/11/dp_volume_ii.pdf , 13 June 2021.
[199] Patent Ordinance 2000, https://ipo.gov.pk/system/files/%28112%29PatentsOrdinance2000_Amendmentsfinal_0.pdf , accessed 10 July 2021.

fabricate a pressure on multinational pharmaceutical companies or create an environment for competition and encourage the technology transfer.[200]

Under the Patents Ordinance 2000 four grounds are provided when the Federal Government have right to grant the compulsory license and authorized the government agency or the third person to manufacture the patented product without the permission from the right holder. The use of patented invention is subject to the adequate remuneration which would be paid to the patent owner. The Federal Government shall decide the amount of remuneration according to the economic value of the invention used under the compulsory license.

The grounds of granting compulsory license are very narrow and limited and can only be active as describe in 58(1) when the public interest so requires or to control anti-competitive practice or patent holder refuse to give license or when the patent invention is not exploited properly. The word public interest is not defined and explained. Public interest needs to be explained properly what it includes and what not. The term public interest is so wide that it might be misused against the public if not explained properly. There is need to clarify that the patent invention should not impede the public health and it must be used as an instrument to protect and ensure public health. Country like Pakistan where one third of population is living beyond the line of poverty and 66.5% health expenditure are made from the citizens' pockets, the prices are the main issue to access medicines. High prices are the very main obstacle to access medicines. It must include in the compulsory licensing ground that the multinational pharmaceutical

[200] Niesporek Anna, "Compulsory Licensing of Pharmacuetical Products & Access to Essential Medicines in Developing Countries," Master thesis,(Linköping University, Ekonomiska institutionen,2005) http://www.diva-portal.org/smash/get/diva2:21332/FULLTEXT01.pdf , 17th March 2021.

companies should provide the medicine on affordable prices for the poor people of Pakistan to avoid the consequences of compulsory license.

Second ground of granting compulsory license is when the patent holder practices the patent in an 'anti-competitive' way. Anti-competitive practice is not elaborated, what practices by the patent holder will be considered as anti-competitive and no procedure is provided that how the federal government will act and control anticompetitive practices. It must be clearly incorporated as a ground for the issuance of compulsory license that if the patent holder or his licensee abuse the patent right to restrain trade or use it in way to restrict competition in the market then compulsory license would be issued to remedy such use.

The third ground for granting compulsory license under the Patent Ordinance 2000 is that if the licensee fails to get license from the patent holder on the reasonable terms and conditions then the Federal government may issue compulsory license. 'Reasonable commercial terms and conditions' needs to be explained because one thing which is reasonable from one side might be unreasonable from another side and there is apprehension that this term might be misused while interpreting. It must be strongly worded that the objective of giving patent right is to encourage inventions and alongside to support the local industry to equipped with new technologies and the inventions should work in Pakistan on commercial terms and conditions so that the local industry flourish and competitive environment grow. License by the patent holder to different licensees will help to generate competition which will resultantly lower the prices of product and it should not slowly base on the imported goods.

The fourth ground of granting compulsory license is, if the patent holder fails to 'exploit in a manner which contributes to the promotion of technological innovation'. No particular time period is prescribed for the patent holder during which he should exploit the invention. Duration should be fixed after which it will be considered that the invention is not exploited within reasonable time. It must be clearly stated in the law that the patent right must contribute to the promotion of technological innovation and it must become a reason to transfer technology and dissemination of knowledge. Balance of rights should be of great concern while incorporating the provisions of patent law and this balance clearly worded that the patent must become the reason of dissemination of technology and it should not only base on importation of patented products. Importations of patented products impede the way for dissemination of technology while the local production of patented products will actually lead towards the technology transfer and dissemination of technology.

Article 59 also provides the ground to grant compulsory license by the controller on the request of any person on the reason of non-working, again the non-working is not explained. In the next chapter, we will narrate how non-working provisions are explained under the Patent Act,1970 of Indian and patents Ordinance 2000 of Pakistan should also have such explicit provisions. No rules and regulations are provided about the practical application of section 58 this is the reason that the compulsory license provisions are a waste of time and inactive. There is a dire need to review the compulsory licensing provisions and explain administrative process to make it more help full and convenient to make the availability of medicines easier.

Under the patent law the government use and the compulsory license have almost the same effects. There is only a little difference between these two flexibilities. The former is for private and non-commercial purposes and the latter is for private and commercial purposes. Under the patent law of Pakistan, the grounds for public and non-commercial purposes are wide so that the government may take the necessary step to fulfill its obligations regarding the right to health. The grounds for compulsory license for private and commercial purposes only one ground is provided which is the "non-working" of patent and the term "non-working" include what is not yet explained.

Most developing countries have provisions to grant compulsory license just for domestic market and not for import or export purposes. Decision of 2003 is not operative in the countries which did not amend their laws and implement the Decision through the proper legislation. Doha Declaration and implementation Decision of 2003 are the result of strong battle between the developed and developing countries hence there is need to implement these flexibilities into the national legal system otherwise all the efforts will become useless. It is also very important to allow the use of compulsory license under the Decision of 2003 for commercial purposes because the use of license just for government use or non commercial purpose will limit its use and impede to generate competition.[201]

Compulsory licensing provisions of Pakistan's patent law did not take benefit from the Doha Declaration and the Decision of 2003. It allows the member countries that they may incorporate provisions in their national legislation for issuing compulsory license and import drugs from other country if they do not have manufacturing capacity

[201] Correa M. Carlos, " TRIPS Agreement and Access to Drugs in Developing Countries" *International Journal of Human Rights*, 3(2005):25-38, https://sur.conectas.org/en/trips-agreement-access-drugs-developing-countries/ , last accessed on 19th September 2021.

or on the other hand the member countries may make provisions in their national legislation to issue a compulsory license for export purposes to the country that do not have manufacturing capacity.

It is not sufficient just to have provisions in the national legislation unless these provisions have persuasive and forceful grounds. So, it is the need of the hour that the Pakistan should incorporate conclusive provisions in its national legislation to avoid doubts. Few grounds of granting compulsory license will limit its use and it will become difficult to avail compulsory license. This is not only the case of Pakistan but most of the developing countries have very limited provisions related to the TRIPS Flexibilities.

2.9. Use of the TRIPS Flexibilities and the Response of Developed Countries

Patent protection provides exclusive monopoly over the invention and reduces competition which leads towards the high prices of medicines. Competition in the market and generic medicines lowers the price. Before the implementation of the TRIPS agreement countries had choice to give patent on pharmaceutical or not and almost fifty countries did not provide patent protection for pharmaceutical. It is claimed that with the implementation of the TRIPS agreement the prices of patented medicines became so high that it is not affordable for many who direly need these medicines. However, the TRIPS provides multiple ways to access the drugs and these ways known as the TRIPS

Flexibilities and compulsory license is very important tool of them.[202]

Working of patent system is also controlled by the bilateral and regional trade agreements. Developed countries negotiate many trade agreements in which developing states ensures to withdraw their rights to use TRIPS flexibilities and promise to add strict provisions then required by the TRIPS. These agreements put obligation on the developing countries to extend the term of patent to compensate the delay for regulatory approvals. These agreements also include provisions to provide patent for new use of already existing chemical entities. This practice is frequently exercised by the pharmaceutical companies to avoid competition they get patent for the different aspect of the same drug. In addition to this, the companies get the secondary patent on different formulation, compositions and dosages. [203]

It is a precondition for all medicines whether original or generic on to get regulatory approval to enter in the market. The system related to the patent and regulatory approval is totally different from each other. Both systems deal under different laws, different criteria and different institutional structure. It is beneficial for the multinational pharmaceutical companies to create a link between these two institutions and the regulatory authority keep the patent status of a drug in mind before giving the market approval to any drug. This coordination known as "linkage" and it help the patent holder

[202]Urais and Ramani, "Access to medicines after TRIPS: Is compulsory license an effective mechanism to `lower drug prices? A review of the existing evidence," *Journal of International Business Policy*, 3(10):1-18, https://www.researchgate.net/publication/344086685_Access_to_medicines_after_TRIPS_Is_compulsory_licensing_an_effective_mechanism_to_lower_drug_prices_A_review_of_the_exis , last accessed 24 September 2021.

[203]Shedlen et al., "Patent, trade and medicine: past present and future," *Review of International Political Economy*, 27(1) 75-97, http://eprints.lse.ac.uk/100032/ , last accessed 23rd September 2021.

to ‘extend the period of exclusivity”. Developed countries put pressure on the developing countries through trade agreement to favor their pharmaceutical companies and asked to add the provisions related to the “linkage”.[204]

Developed countries also have great concern about how the developing countries deal with their data exclusivity provisions. The TRIPS agreement under article 39.3 bound the state to protect data from “unfair commercial use” but so far, the “unfair commercial use” is not explained that which use would be unfair. It is also silent about that the state authorities can use data for generic producer without disclosing to them. So, states are free to interpret the provision with their own feasibility. Pharmaceutical companies submit the clinical trial data to the regulatory body to reveal the efficiency of a drug to get the market approval. It is very important to note that whether the health authorities allow the generic producers to use same data for regulatory approval after the term of patent expires. By doing so, state authorities will help the generic producers to save their time, cost and energies to collect the same clinical trial data again. Developed countries through trade agreement take away these flexibilities provided by the TRIPS agreement.[205]

Free trade agreement between the USA and Jordan also include two provisions which deal with the data exclusivity. The aim of these provisions is to squeeze and limit the flexibility provided by the TRIPS. Almost all FTAs of USA with other countries cover data exclusivity provisions. USA also used another tactic to challenge the provisions of law in the WTO dispute settlement body that these provisions are violating

[204]Ibid.
[205]Saad Mohammad, Public health related TRIPS-Plus provisions in bilateral trade agreement: A policy guide, WTO Regional office, p 136, https://applications.emro.who.int/dsaf/dsa1081.pdf , last accessed on 8 October 2021.

TRIPS. USA complained in the WTO Dispute settlement body against the data exclusivity provision of Argentina in 2000 but Argentina was strict with its interpretation so USA dropped its case against Argentina in 2002.[206]The report of Oxfam international reveals that the free trade agreement between USA and Jordan and specially the data exclusivity provisions hit very hard, as these provisions became the reason for high prices of medicine as no generic competitor is available. Due to these FTAs, the Jordan cannot take benefit from the TRIPS Flexibilities.[207]

Parallel imports also facilitate the entry of low-cost generic drugs in the country as seen in Kenya parallel importation reduced the cost of antiretroviral drugs. USA is the supporter of national exhaustion and FTAs between USA and Morocco bound the exhaustion to the national level. Bolar exception also facilitates the entry of generic drugs in the market immediately after the patent expires. USA in many FTAs with regional countries limits the use of early working exception as in the case of Morocco. USA includes through FTAs 'new use of the known product' in patent protection as the USA's FTAs with Morocco and Oman have the provisions of new use.[208] USA limits the use of TRIPS flexibilities through the FTAs and pressurize the developing countries by using different tactics i.e. WTO dispute settlement process, special 301 reporter and by the diplomatic threats.

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[206]WTO, DS196: Argentina- certain measures on the protection of patent and test data,https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds196_e.htm , last accessed 10th October 2021.
[207]Oxfam Briefing Papers, All cost, no benefit: how TRIPS-plus intellectual property rules in the USA-Jordan FTA affected access to medicines, 2007,https://oxfamilibrary.openrepository.com/bitstream/handle/10546/114080/bp102-all-costs-no-benefits-trips-210307-en.pdf%3Bjsessionid%3D08975082 , last accessed 23rd September 2021.
[208]Ibid.

2.10. Conclusion

The TRIPS agreement is the most controversial component of the WTO and with the implementation of the TRIPS it seems that the health will be compromised over the trade. During the Uruguay Round of GATT negotiations, a lot of disagreement was existed between the developed and developing countries and even within the developed countries. Most contentious issue was the protection of the pharmaceutical by the patent because the patent protection enables the patent holders to charge high prices for his product as no other competitor subsist. Patent holders earn profit much higher than the actual cost or the research cost of the drug. It was quite evident during the AIDS crises when millions of people were dying in Africa because they can't afford the high cost of the patented drugs. AIDS crises highlight the controversy between patent and health. It is true that other factors are also involve in access to medicines i.e. health facilities, infrastructure, administrative control and professional support but it is also true that price of a drug is also very important to determine that how many will die due to the non-availability of medicines in the upcoming years. Flexibilities provided under the TRIPS agreement compensate the worst effects of the TRIPS agreement and the proper and wise use of these flexibilities make the situation much batter for the developing countries like Pakistan. Pakistan incorporated the flexibilities in its national legislation but the grounds for availing the flexibilities are very narrow and restricted. Restricted ground will limit its use and at times make these flexibilities useless. There is a dire need to incorporate more ground and in this regard, Pakistan may take help from the regional countries that how they are using and implementing flexibilities in their national legislation. India and Brazil

are using these flexibilities very rightly and try to utilize the patent system for the benefit of its people.

Effects of the TRIPS on public health rise as a serious concern on the international level. Developing countries succeeded in the adoption of Doha Declaration on the TRIPS agreement and public health. Doha Declaration clearly states that whenever conflict arises regarding the implementation of the TRIPS and right to health then right to health will prevail over IPRs. Declaration clearly elaborates that the TRIPS agreement should not interfere with the right of a State to provide the health facilities to its citizen. Decision of 2003 also allows the countries to issue compulsory license for importation of drug. Patents Ordinance of Pakistan do not provide this flexibility and compulsory licensing provisions become useless for those medicines which cannot manufacture by local pharmaceutical industry. It is very important to include the Decision of 2003 into the patent law of Pakistan as the local pharmaceutical industry cannot manufacture the cancer medicines. It means Pakistan cannot issue compulsory license for cancer and other medicines for which it does not have manufacturing capacity. There is dire need to include the Decision into the patent law of Pakistan to make compulsory license provisions effective and workable.

CHAPTER 3

PATENT ORDINANCE 2000 OF PAKISTAN AND PATENT ACT, 1970 OF INDIA: A COMPARATIVE STUDY

In this chapter, the provision Patents Act, 1970 of India will be analyzed and compare with the Patents Ordinance 2000 of Pakistan. It will be observed that how Indian patent law successfully incorporate TRIPS flexibilities and how Pakistan can learn from India to make its patent law provisions more progressive and beneficial for its people and for its local pharmaceutical industry within the boundaries of the TRIPS.

3.1. Introduction

Global implementation of intellectual property rights through the TRIPS agreement posed serious challenges for both developed and developing countries particularly in the area of public health and developing countries due to their hard economic conditions are suffered more. The TRIPS agreement is equipped with flexibilities to facilitate the developing countries and to mitigate the consequence of patent monopolies. The sensible use of TRIPS flexibilities is very vital for public health because the TRIPS provides flexibilities in general and left the state with discretion to add in it according to their individual needs. Every state has its own requirement and responsibilities which become the strong reason to set its priorities. Implementation and interpretation of the TRIPS agreement also reflects state priorities. State can interpret the TRIPS agreement in either way so as to facilitate the public health or to promote trade by

waiving health related flexibilities, however, the wise use of law is one in which a balance is created between these two conflicting interests.

As in previous chapter we analyze, the TRIPS agreement and compare the flexibilities provided under it with Patents Ordinance 2000 of Pakistan and concluded that though the patent law of Pakistan incorporate flexibilities but not in a persuasive manner. Only few grounds were provided to avail these flexibilities and this limited and narrow approach makes the flexibilities useless. Now, in this chapter, we will compare patent law of Pakistan with the patent law of India and find out that how the Indian legislature incorporates the TRIPS flexibilities in its patent law. It will also examine that Indian legislature adopted a broad or narrow approach and did it prefer patent over right to health or a balance between these two conflicting interests is maintained. Especially the most controversial provision 3(d) will be analyzed and investigated and we will also conclude by examining that whether Pakistan can learn a lesson from the Indian patent law or not?

3.2. India and Pakistan

Pakistan and India both got independence from the British colonial rule in 1947. Pakistan and India are actually cut from the same geographic and cultural cloth as being the part of United India for centuries. Religion was the main reason for the separation of two nations but they still share so many things as they spent a lot of time together. They share the same culture for instance folk tales of Heer and Ranja, Sheeri and Farhad, Sassi and Panu equally popular between the people of both countries. Many festivals are still celebrated among the people of both sides like Basakhi as an agricultural festival and

Basant is celebrated at the end of winter seasons. Mughals ruled sub-continent for a long time and left the both sides with cultural heritage such as Badshahi Masjid in Lahore and Taj Mahal in Agra. Hockey is the national game of Pakistan and India but cricket is very popular among the people of both sides.

Pakistan and India share a long border of 3323 kilometers.[209] This is one of the dangerous borders in the whole world and it is said that it is visible from the space during night view as 150,000 flood lights fixed by India to sure clear visibility at night.[210] Gross national income of Pakistan per capita in international dollars (2018) is 5110 and gross national income of India per capita in international dollar (2018) is 6630. Health spending in USD international per capita is 253.3 (2017) in India and health spending in USA international per capita is (2017) 160.6 in Pakistan.[211]

3.3. History of Patent Law in Pakistan and India

United India was introduced with its first patent law in 1856 under the British colonial rule. It was the time when many developed and the European countries are not equipped with patent law. This law was reformed in different times and finally The Patents and Designs Act of 1911 was adopted. The Colonial system just introduced patent laws in their colonies but they failed to create an IP culture and technical expertise among the local people.[212] After the decolonization the India and Pakistan respond to their IP laws differently. After independence India took the matter of patentability very seriously.

[209] India – Pakistan Border, ,https://en.wikipedia.org/wiki/India%E2%80%93Pakistan_border, last accessed on 21 October 2021
[210].ibid
[211]OECD/the WHO (2020), Health at a Glance: Asia/Pacific 2020: Measuring Progress Towards Universal Health Coverage, OECDPublishing, Paris,https://doi.org/10.1787/26b007cd-en, last accessed on 19 October 2021.
[212] Carolyn Deere,The Implementation Game, (New York: Oxford University Press, 2009) 35.

India as a newly independent state formed two expert's committees to take advice that how to reform the patent system in India according to their need. In order to make the patent system more effective the first committee was set up (in 1949) to suggest that how to use the patent system in national interest. Under the supervision of Justice Tek Chand committee suggest amendment to control the misuses of patent system and very next year in 1950 the amendment was made to control the misuses though incorporating provision related to the working of patent and compulsory licensing.[213]

The second committee was structured to think about the efficiency of existing patent system under the supervision of Justice N. Rajagopala Ayyangar. Ayyangar report was considered as source for new patent regime of India.[214] This report suggests some revolutionary changes in the patent law to upgrade it and to encourage the local industry. The committee suggest that existing patent system of India has failed to encourage inventions and public was also unable to take technical or industrial expertise. Committee also highlight 80 to 90 % of patent protected owned by the foreigners and they enjoyed the monopoly over the local markets.[215] The Ayyangar report resulted to introduce a bill in the parliament in 1965 and finally India was successfully introduced Patent Act 1970.[216]

Patents law of Pakistan is also traced back to the 19th century when under the British colonial rule, The Patents and Designs Act 1911 was adopted. After

[213] Vijaypriya L R, "A critical of access to medicine in the light of Indian Patent (Amendment) Act", LLB thesis, (School of Law, Christ, Bengalura, 2018), http://ssrn.com/abstract=3554639 , last accessed 24th October 2021.
[214] Unni V.K., Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Context of Public Policy and Health, *Global Business and Development Law Journal,* 25(2012): 323, https://scholarlycommons.pacific.edu/globe/vol25/iss1/12 , accessed on 24th October 2021.
[215] ibid
[216] ibid

independence, Pakistan was continued the same act with little modification. After being the member of the WTO and under the TRIPS requirements, Pakistan was bound to introduce the new Patent system which would comply with the minimum standards of patent protection as provided under the TRIPS agreement. [217] The Patents and Designs Act 1911 was amended in 1997 to comply with international standards and subsequently it was repealed and two new Acts was introduced. The Designs Ordinance 2000 and The Patents Ordinance 2000, as the new laws provide designs and patent protection in the country according to the global standards.[218]

3.4. Patents Act, 1970 of India, Use of TRIPS Flexibilities and Lesson for Pakistan

At the time of independence, the Indian drug industry is dependent upon the multinational companies and most of the drugs were imported to fulfill the domestic needs. After independence India immediately started to tone up its patent law and in 1970 India successfully introduced its patent law which was designed to fulfill local needs and to promote the local drug manufacturing. The Patents Act 1970 did not provide patent protection to the pharmaceutical products, this decision was made consciously to support the local drug industry and this decision lead the Indian drug industry on the top as the producer of low cost generic drugs globally. Before the implementation of the TRIPS

[217] Zuberi M A, "Intellectual Property Rights Day: TRIPS Agreement and its implication for Pakistan," Business Recorder, April 26 2005, https://fp.brecorder.com/2005/04/20050426239010/ , last accessed on 26th October 2021.
[218] Gulzar Asim, "Challenges and Opportunities in the Post TRIPS Era for Pakistan--An Overview of Amended Patents Ordinance 2002," *SPO Discussion Paper Series: Understanding Pakistan Volume II*, 2014, https://spopk.org/wp-content/uploads/2019/11/dp_volume_ii.pdf , 13 June 2021.

agreement till 2005 India was the leading exporter of generic drugs to the developing countries.[219]

It was the matter of great concern for developing countries who imported generic drugs from India that what will happen after 2005 when India starts protecting the pharmaceutical products. India was already aware of this fact that pharmaceutical protection will affect its generic industry and will increase the health expenditure of country. So it incorporated all safeguards related to the public health in its patent law and uses the TRIPS flexibilities to the maximum extent to facilitate its pharmaceutical industry and to ensure the affordable medicines to its people.[220]

Representative of India Dr. Sengupta during a discussion at Geneva on a social forum explained the health system in his country and share that access to affordable medicines is a matter of great concern for the people of India and NGOs are also very active in this regard. This is the reason that the prices are affordable in India "10 percent or less then the global process". He told that Indian generic antiretroviral reduced the cost of treatment 40 times then the original brands. He also suggested that the India should keep on resisting the TRIPS plus provisions in its patent law to ensure the affordable medicines in India and other importing countries.[221]

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[219]Rama Sarma, *Intellectual Property Laws*, First Edition. (New Delhi: Wadhwa and Company Law Publishers, 2009) .

[220]'t Hoen, Elisabeth,"Practical Application of the Flexibilities of Agreement on the Trade-Related Aspects of Intellectual Property Rights: Lesson beyond HIV for Access to new Essentials Medicines," PhD diss.(University of Groningen, the Netherland,2018),https://pure.rug.nl/ws/portalfiles/portal/55799433/Complete_thesis.pdf , last accessed on 11 August 2021.

[221] United Nation, Office of the HIGH commissioner, Access to Medicines in the context of the Right to Health, 2015, https://www.ohchr.org/Documents/Issues/SForum/SForum2015/OHCHR_2015 Access_medicines_EN_WEB.pdf , last accessed on 22 October 2021.

Unlike Pakistan, Patents Act, 1970 of Indian is well equipped with the TRIPS flexibilities and the objective here is to elaborate the extent of variation in the implementation of TRIPS flexibilities between the laws of both countries.

3.5. Patentability Criteria

Pharmaceutical companies now spend a lot of money on research and development of new drugs (new molecular entities) but despite expenditures only few new inventions occur. The strategy adopted by the multinational pharmaceutical companies is that they always try to extend the life of their popular patented drugs in order to earn more millions each year. Pharmaceutical companies make incremental changes and got new patent on already existing drugs and in this way extend the life of the patent beyond twenty years. All this process is known as the ever greening of patents.[222]

Pharmaceutical firms tried to obtained secondary patent to extend the period of exclusive monopoly. This practice is counter argued by the human rights activists that getting patent on alternative molecules forms, uses or formulations are not primary, less novel and missing inventive step. Secondary patents restrict competition and patients are denied to get benefit from generic entry. In secondary patent there is no or less research investment so patent protection should not be given. Developing countries should add some specific policies to restrict secondary patent and it will help in time entry of generic medicines.[223]

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[222] Esparza Javier, Indian Patent Law: Working within TRIPS Agreement flexibilities to provide pharmaceutical patent while protecting public health, https://www.law.fsu.edu/sites/g/files/upcbnu1581/files/JTLP/jtlp-v24-06-esparza.pdf , last accessed on 22 October 2021.

[223] Sampat, Bhaven N. and Shadlen, Kenneth C., Secondary Pharmaceutical Patenting: A Global Perspective (January 2017). NBER Working Paper No. w23114, Available at SSRN: https://ssrn.com/abstract=2907917

Globally one third of global population have no access to essentials medicines and this figure increased in some developing countries by reaching the half of the population. Ever greening of patent prolongs the life of patent and access to affordable generic medicines delayed. It is a great challenge for the developing countries to set strict criteria for patentability that would not contradict with the TRIPS but stop the way of ever greening of patent. It is very important for developing countries to strict with the principle of "one product and one patent" because multiple patents can be obtained on any invention by changing minor "combination or new clinical indications".[224]

Article 27.1 of the TRIPS agreement puts obligation on all the WTO member states to provide the patent protection for pharmaceutical products. TRIPS agreement set the standard of patentability as novelty, inventive step and industrial application. These three requirements are not further explained by the TRIPS so a room is left for the member countries to explain these terms according to their own system and need in a narrow or broader perspective.[225]

It is the beauty of Indian patent law that it takes full advantage from all the flexibilities and the room left by the TRIPS agreement competently filled by the Indian legislature. Indian patent law explains invention under article 2(j) as "invention means a new product and process involving an inventive step and capable of industrial

[224] Velasquez German, Guidelines on patentability and access to medicines, South Centre, March 2015, https://www.southcentre.int/wp-content/uploads/2015/03/RP61_Guidelines-on-Patentability-and-A2M_rev_EN.pdf , last accessed on 15 October 2021.
[225] F Sisule and OH Cecilia, " The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines," Commission on Intellectual Property Rights, Innovation and Public Health(CIPIH), 2005, https://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf ,last accessed on 2 September 2021.

application".[226] It also explains clearly the inventive step and industrial application. Inventive step is explain under article 2(ja)[227] as "inventive step means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art;"[228] The Patent Act 1970 elaborates inventive step as that it must be technically advance then the existing knowledge of the relevant field and it must not be an art which is expected from the skilled worker. The person seeking patent protection must create something new which never exist before so discoveries are not inventions and invention must have financial benefits. Industrial application of invention indicates that invention should not be a just intellectual activity but it must be useful for industry. Industry means an economic activity for some profit purposes so it is also very important for an invention to get protection under patent that it must have some economic benefits for the industry.

3.5.1. Section 3(d) of Indian Patent Act 1970

India starts protecting pharmaceutical products in 2005 after making amendment in its Patent Act, 1970 but it provides strict conditions for patentability. Patent Act, 1970 explains well the term invention and also makes comprehensive interpretation of inventive step and industrial application. It also elaborates in detail under section 3 a list of the substance that will not be considered as invention. Section 3(d) is very important

[226] The Patents Act, 1970, https://www.advocatekhoj.com/library/bareacts/patents/index.php?Title=Patents%20Act,%201970 , accessed on 22 October 2021,
[227] Inserted by the Patents (amdt) Act, 2005, w.e.f. 1-1-2005
[228] The Patents Act, 1970, https://www.advocatekhoj.com/library/bareacts/patents/index.php?Title=Patents%20Act,%201970 ,accessed on 22 October 2021.

and it exclude so many things from patentability and stop the way for ever greening of patent by restricting the criteria to obtained a patent.

Section 3(d) explain explicitly that "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. *Explanation:* For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;"[229]

Ultimate objective of section 3(d) is to stop the way for ever greening of patent and this section actually reflects the intention and seriousness of India about its commitment to ensure the availability of affordable medicines to its citizens. The world "efficiency" in section 3(d) is not defined by the law and it became a matter of controversy among the critics, however the Indian court define the term "efficiency" and the validity of section 3(d) in Novartis Case.[230]

[229] The Patents Act, 1970, https://www.advocatekhoj.com/library/bareacts/patents/index.php?Title=Patents%20Act,%201970 ,accessed on 22 October 2021.
[230] Novartis Ag v. Union of India, (2013) 6 SCC 1, https://www.supremecourtcases.com/index2.php?option=com_content&itemid=99999999&do_pdf=1&id=43380 , last accessed on 28 October 2021.

3.5.2. Novartis V. Union of India (2013)

Novartis file a patent for a salt Imatinib Masylate in beta crystalline form used to treat cancer and it was actually an improvement on Imatinib free base which was already patent so Novartis was refused to grant patent under section 3(d). Novartis challenge the section 3(d) on three grounds. The first ground is that the section 3(d) is unconstitutional because it violates the Indian Constitution Article 14 which deals with the equality before law. Section 3(d) is discriminate pharmaceutical sector from other sector of technology. Second ground was that the section 3(d) violates the Article 27(1) of the TRIPS and India failed to fulfill its obligation under TRIPS. Third ground was about the complexity exist in section 3(d) that it is arbitrary to the ingenious concept that the discovery will be considered as invention if the substance enhances the known efficiency.[231]

The case was well defended by the Assistant controller of patent and designs and brilliant arguments were given to up held the validity of section 3(d). It was argued that the India is a developing country with poor population and under the constitution of India it is the duty of State to provide appropriate health facilities to its citizens and access to affordable medicines is a way to achieve good health. The justification for section 3(d) is to control the "ever greening of patent" and to encourage the generic producers to enter market in time and provide low-cost medicine to the poor people. It was also further elaborated that the objective of section 3(d) is not to discriminate pharmaceutical sector but just a differentiation is made with other sector of technology because its effect on the

[231] Shanmugaiah Kamini, "The impact of TRIPS Agreement on access to medicines in developing countries: Legal challenges faced by the pharmaceutical industry particularly in India," *UUM Journal of Legal Studies,* vol 3 (2012), 51-76, http://e-journal.uum.edu.my/index.php/uumjls/article/view/4549 , last accessed on 24th October 2021.

society is very strong because it effects the health of public at large.[232] In this case the supreme court of India set the limitations of patentability and also upheld the validity of section 3(d).

3.5.3. Amendment needed in the Patent Ordinance 2000

Patents Ordinance 2000 of Pakistan explains invention under section 2(i) as "any new and useful product and process, in any field of technology and any new and useful improvement of either of them;" It broaden the way of granting patent protection by allowing the 'useful improvement' of patented product and process is also patentable and it enables the pharmaceutical companies to get patent on incremental changes and prolong the life of patent beyond 20 years so it will delay the entry of low cost generic drugs in the market. As we can see that in case of Imatinib for which India refused to grant the patent u/s 3(d) Pakistan grant patent for Imatinib and create problem for cancer patient due to high prices of medicines. Pakistan must incorporate provisions like 3(d) on Indian Patent Act 1970 to narrow down the area of patentability and avoid frivolous patent.

The country like Pakistan where the prices of medicines hit the poor people very hard, even the middle income families cannot afford the high prices of medicines. There is no sustainability in the drug prices and it might be raised suddenly. During the 2018 to 2019 the prices of medicines raised many times and the prices of 500 medicines or more

[232] Esparza Javier, Indian Patent Law: Working within the TRIPS Agreement flexibilities to provide pharmaceutical patent protection while protecting public health, https://www.law.fsu.edu/sites/g/files/upcbnu1581/files/JTLP/jtlp-v24-06-esparza.pdf , last accessed on 23 October 2021.

raised 200% which was the highest in the history.[233] It is direly needed for the country like Pakistan to adopt strict patentability criteria because being a developing countries strong implementation of intellectual property stander will lead towards the unaffordable drug practices as it is already practiced in Pakistan.

Some countries grant patent protection on new use of a product or process as the America also grant patent on new use of a product or process but it is required by the law that such use must be novel and non-obvious. In America there is greet competition in the market and billions of dollars spend by the multinational pharmaceutical companies on the research and development of new product so the broader definition would encourage the inventor and increase competition in the market.[234]

Pakistan has a large population and stands on sixth number in world ranking but has no contribution in global pharmaceutical research. Local pharmaceutical industry is not conducting research because research need huge amount and local industry cannot bear these expenses as one single molecule needed more than 1 million dollar to develop this heavy amount is not affordable for private sector without the government support.[235] To encourage local industry and to create a culture of research and development it is very desirable to have strict patentability criteria to minimize the foreign patent and their monopolies in the market. Government support in funding the research, creating

[233] Transparency International, Speaking out for affordable medicines in Pakistan, https://www.transparency.org/en/blog/speaking-out-for-affordable-medicines-in-pakistan , last accessed on 25 October 2021.

[234] F Sisule and OH Cecilia, " The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines," Commission on Intellectual Property Rights, Innovation and Public Health(CIPIH), 2005, https://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf ,last accessed on 2 September 2021.

[235] Zaheer Farhan, Research in pharmaceutical sector: Pakistani companies lag behind their Indian, Chinese counterparts, The Expess Tribune, https://tribune.com.pk/story/231549/research-in-pharmacthe EUtical-sector-pakistani-companies-lag-behind-their-indian-chinese-counterparts , last accessed 14 August 2021

awareness in universities on research and provide such legislation which support research culture is also indispensable to motivate local pharmaceutical industry.

A study is conducted by CIPIH revealed that most developing countries provide three conditions for patentability as provided by the TRIPS agreement without further explicit provisions, even the countries who recently adopted or amended patent law. Reports highlight that the 55% of law which adopted or amended recently did not provide specific provisions according to their needs.[236] Pakistan adopted its new Patent Ordinance 2000 and amended many time but even after amendments it fails to utilize all health related provisions according to the need of its people. Pakistan should explains further about the new uses of known product to strict patent grant and it will help to promote access towards affordable medicines and to create a competitive environment.

3.6. Principal of Exhaustion

Patent holder gets some exclusive rights over the patented product including right to make, to use, to sell and to import the product. Doctrine of exhaustion puts some limitations on the rights of the patent holder. This doctrine establishes a principal that patented items when sold; the patent holder's right over the product is also terminated. Now buyer has the right to use the product himself, gift to his love one, donate it or resale it to any person he wants without the permission of the patent holder. The rationale behind this principal is that the patentee is already been rewarded by the first sale and

[236] F Sisule and OH Cecilia, " The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines," Commission on Intellectual Property Rights, Innovation and Public Health(CIPIH), 2005, https://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf , last accessed 2nd September 2021.

now any restriction on the use or on the resale will be the considered as violation of the rights of the buyer.

Exhaustion has three kinds i.e. national exhaustion, regional exhaustion and international exhaustion. National exhaustion is limited within the territory of a state which granted patent right. It might be the resale of patented article in remote areas in which the patent holder or its distributer never provides their services. Regional exhaustion allows the importation of patented goods within a particular region. International exhaustion permits the importation of patented goods from anywhere in the world. The Patent Act 1970 of India provides provision for international exhaustion however it is silent about the national exhaustion.[237]

International exhaustion also named as parallel importation and this principle is incorporated in Indian patent law after amendment in 2002. A legitimate parallel importation is allowed in India and section 47 and 107(A) deals with parallel importation provisions. Exclusive rights given to the patent holder are subject to certain conditions and parallel importation is also one of those conditions which are provided to lessen the effects of patent monopolies. Doha Declaration and the TRIPS agreement allowed the parallel imports with objective to facilitate the availability of medicines.[238]

The article 47 of the Indian patent law narrates that the rights of the patent holder are subject to some conditions and while narrating those condition when patent holder

[237] Shamnad Basheer and Mrinalini Kochupillai, " 'Exhausting' Patent Rights in India: Parallel Imports and TRIPS Compliance," Journal of Intellectual Property Rights, Vol 13(2008) p 486-497, http://docs.manupatra.in/newsline/articles/Upload/56BF7AA8-6A64-4630-AF64-5EC5BE9F4E6E.pdf , last accessed on 23 October 2021.

[238] Himanshu Vijay, "Patent monopoly and Doctrine of Exhaustion: Limits on exclusive rights", *Journal of Intellectual Property Rights*, vol 16 (2011) p 453-463, http://nopr.niscair.res.in/bitstream/123456789/13055/1/JIPR%2016(6)%20453-462.pdf , last accessed on 21 October 2021.

cannot claim his right it explain that "any machine, apparatus or other article in respect of which the patent is granted or any article made by using a process in respect of which the patent is granted, may be imported or made by or on behalf of the government for the purpose merely of its own use;".[239] It further narrate that "in the case of a patent in respect of any medicines or drug, the medicine or drug may be imported by the government for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the government or other dispensary, hospital or medical institution which the Central Government may, having regard to the public service that such dispensary, hospital or medical institution renders, specify in this behalf by notification in the Official Gazette."[240]

Section 47 describes that the government has authority to import any patented machine or apparatus but for its own use and it also authorize the government to import any patented drug or medicine for its own use or distribution in any hospital or dispensary by notifying its name in the official Gazette. Section 47 allows parallel importation and it did not provide the list of circumstances under which the government would be able to utilize these provisions like national emergency or situation of extreme urgency but it just allow the government to import, use and distribute for its own use by itself or by the third party. So the government has wider

power for parallel importation and it is not restricted to any particular circumstances.[241]

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[239] The Patents Act, 1970, https://www.advocatekhoj.com/library/bareacts/patents/index.php?Title=Patents%20Act,%201970 , last accessed on 22 October 2021,
[240] ibid
[241] Himanshu Vijay, "Patent monopoly and Doctrine of Exhaustion: Limits on exclusive rights", *Journal of Intellectual Property Rights*, vol 16 (2011) p 453-463,

Section 107A (b) also deals with parallel importation but in this section any person is allowed to import patented products "merely of its own use" and condition of importation by government as imposed in section 47 is not seen here. Under the said section "importation of patented products by any person from a person [who is duly authorized under the law to produce and sell or distribute the product], shall not be considered as an infringement of patent right."[242] This section allows any person to import the patented products from the other country and the only condition attached with such parallel imports is that the importation must be by the person who is duly authorized by the patentee to produce, sell or distribute the product. Import from the authorized dealer is allowed under the law by using clear wording without creating any uncertainty and ambiguity. It also suggests some creative ways to interpret these provisions to ensure the availability of low-cost medicines.

3.6.1. Amendment needed in the Patent Ordinance 2000

It would not be wrong to say that the Patent Law of Pakistan poorly incorporated flexibilities provided by the TRIPS agreement and this practice is keep on with Doctrine of Exhaustion. Unlike India the Patents Ordinance 2000 provides very restrictive and narrow provisions for exhaustion without explaining anything clearly. In 2002, first amendment of Patents Ordnance 2000 was introduced and the principal of exhaustion was incorporated. The original draft of patents Ordinance 2000 did not contain provisions about the exhaustion however after amendment the effective use of this principal is still missing. Right are provided to the patentee that the patent holder has all right related to

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http://nopr.niscair.res.in/bitstream/123456789/13055/1/JIPR%2016(6)%20453-462.pdf , last accessed 26 October 2021.

[242] The Patents Act, 1970, https://www.advocatekhoj.com/library/bareacts/patents/index.php?Title=Patents%20Act,%201970 , last accessed 22 October 2021,

the patented products but the limitation is also attached with these rights. As the Article 30(5) (a) narrates as "The rights under the patent shall not extend to-(a) Acts in respect of articles which have been put on the market anywhere in the world by the owner of the patent or with his consent or by an authorized person or in any other legitimate manner such as compulsory licenses;"[243]

This new provision introduced the principle of exhaustion which was allowed in the TRIPS agreement under article 6 and 28(a). However, the provision of exhaustion as elaborated under the Pakistani patent law has very restricted and limited scope.[244] It dost not explain anything clearly about the exhaustion whether it allowed national exhaustion or international exhaustion. Actually, the term of exhaustion, parallel importation or even the word importation is not used and just in few words without any explicit terms the right is granted and a lot of room is left for interpretation. The language of law demonstrates the intention of legislature so the language should be forceful and cover all the relevant interpretation so that the language should not be misinterpreted. Parallel importation can be used as a very effectives tool to access affordable medicine so this tool should be utilized to the maximum extent within the legitimate boundaries of the TRIPS agreement. In Pakistan comprehensive and detailed provisions of exhaustion should be introduced by allowing government to import patented medicines or aprontous for using in government hospitals. It will help to control the high prices of patented

[243] The Patent Office, Patent Ordinance 2000, https://ipo.gov.pk/system/files/%28112%29PatentsOrdinance2000_Amendmentsfinal_0.pdf , last accessed 10 July 2021.
[244] Zahid Nasir, "A Study of Health-Related Flexibilities in International IP Framework and Patent Law in Pakistan" Master's Thesis,(Graduate School of Seoul National University, 2017) http://www.clt.re.kr/V1/data/file/Thesis/000000146436_20181115164505.pdf , last accessed on 24 October 2021.

medicines in Pakistan by the multination pharmaceutical companies who are selling the same medicines in very low price in India and other neighboring countries.

3.7. Compulsory License

Patent protection encourages creativity and work as incentive for further research and innovation. However, patent doesn't mean that the multinational pharmaceutical companies are free to abuse and misuse the right of public at large to have free access to affordable medicines. Public right to health cannot be compromised for the private right of intellectual property holder. The TRIPS agreement provides the provisions of compulsory license though this term is not used and just a procedure is provided that enables the state to use patent without the authorization of the patent holder. Adequate remuneration will be paid to the patent holder which will be fixed by the government. Compulsory license is an effective tool to control the abusive patent monopolies and to address the extreme urgency and national emergencies requirements.

Section 84 of the Patents Act, 1970 of India is deals with the compulsory license. Section 84 provides a detail procedure for compulsory licensing without leaving any ambiguity or uncertainty and all relevant terms are explained really well by utilizing TRIPS discretion provided to each member state. Section 84 (1) allow to grant compulsory license as

> (1) At any time after the expiration of the three year from the date of the [grant] of a patent, any person interested may make an application to the Controller for the grant of compulsory license on patent on any of the following grounds, namely: - (a) that the reasonable requirement of the public with respect to the patented invention have not been satisfied, or (b) that the patented invention is available to the public at a

reasonable affordable prices, or (c) that the patented invention is not worked in the territory of India.[245]

Three grounds are provided for the grant of the compulsory license, first ground can be invoked when the patented invention fail to fulfill the "requirement of public", second ground become active when the invention is not available to the general public on affordable prices and the third ground is become relevant when the patented invention is not worked in India. The Controller may issue a compulsory license on the request of any interested person after the three years from the grant of compulsory license if satisfied that the circumstances under section 84(1) exist.[246]

To remove any uncertainty and for widening the range of circumstances to issue compulsory license the Patent Act further explain in detail under section 83 the conditions which will be considered as the non-working of patent system. It also elaborated in detail under section 84(7) when the requirement of public will be considered as not fulfilled.

3.7.1. Working of Patent Invention in India

Section 83 explains in detail the conditions which if not fulfill would deem as non-working of patent and may become a reason to issue compulsory license. Section 83(a) states that the patent protection is given to encourage invention on one hand and to ensure the invention should work on commercial scale in India on other hand. It elaborates clearly the objective of granting patent protection is to give incentive to the patentee and

[245] The Patents Act, 1970, https://www.advocatekhoj.com/library/bareacts/patents/index.php?Title=Patents%20Act,%201970 , last accessed on 22 October 2021.
[246] Patil Harsha, "Compulsory Licensing under the Indian Patent Act, "*Journal of Information dissemination and Technology*," vol 9, 3(2019), 125-128, https://media.proquest.com/media/hms/PFT/1/TJ6EC?_s=jh39jNF3a3DMo6%2Ba3F27EKUSeyQ%3D , last accessed 28 October 2021.

invention to the public to use and exploit fully. An invention if fail to work commercially within a reasonable time then it will be considered that the requirement to work in India is not fulfilled and it is a valid ground of granting compulsory license. Section 83(b) further elaborates that the patent is not granted just to enjoy monopoly by the patent holder or that he has exclusive control over the market but the objective behind this protection is to assure the transfer of technology and this objective is demolished by the importation of patented products. It means that if a patentee relay on the importation and local production of the invention is not started then it will be considered as patent is not working in India and it will be a valid ground for granting compulsory license. It is really very useful provision and would be very effective if implemented because local production actually results in transfer of technology and create job opportunity for local community.

Article 7 of the TRIPS agreement which deals with Objectives states as "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations." While explaining the working of patent invention section 83(c) used the same wording by using same comas and full stop. If patent protection is not contributing to the transfer of technology or dissemination of technology or the promotion of technological innovation, it means that patent is not working in India. Patent protection is given for the mutual benefits of the producers and users of technological invention and a balance is created between rights and obligations which must be maintain by the patentee.

Section 83(d) makes it clear that the patent protection should not impede the right to health but it should help to promote public health and welfare. Section 83(e) further endorse that the patent protection do not in any way handicap the government to perform its duties to protect public health. Section 83(f) narrates patent holder or any person deriving title from him should not misuse his rights and by no way he is allowed to restrain trade or create any hurdle in international transfer of technology. Section 83(g) is claiming that the patentee must ensure that the patented invention must be available to the public on affordable prices. This provision as per my opinion is very important and significant for poor countries where it is difficult for people to bear their household expenditures and high prices of medicine makes the situation more deteriorating. If innovation and particularly pharmaceutical products are not affordable for general public then it means that these inventions do not doing well to them. By this way the objective of invention to serve for the mutual benefit of the producers and users stop working.

3.7.2. Requirement of Public

Patent Act, 1970 under section 84(a) describes the ground of granting compulsory license and state that if patent fail to fulfill the requirements of public compulsory license may issue, if requested by any interested person. It did not leave the term “public” unexplained and explains the term in a very impressive way. Section 84(7) narrates the conditions in the absence of which it will be deemed that the requirement of the “public” is not fulfilled. The first condition is that if the patentee refused to grant a license to any interested person on reasonable terms and conditions then it will be considered as the demand of public is not fulfilled. The second condition is that if due to the patentee any trade or industry or the development and establishment of any new trade or industry in

India are prejudice. Third condition describes as if the patent holder unable to fulfill the demand of patented articles adequately with reasonable terms. The fourth condition deals that if the patent holder fails to develop "a market for export of the patented article manufactured in India" then it will be considered that the requirement of public is not fulfilled. The last condition describes that if the patentee imposed conditions to grant a license for the purchase, hire or use of patented products which affect the development of any industry in India then it will be considered as the requirement of public is not fulfill and it is also a ground for granting compulsory license.

Grounds of granting compulsory license are not provided by the TRIPS agreement and states are free to decide the grounds according to their needs and requirement of their people. Doha Declaration on The TRIPS agreement and Public Health also asserts expressly in paragraph 5(a) that "Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."[247] Patent Act, 1970 of India utilizes this flexibility to the greatest extant. It covers all the aspects very well; maximum grounds are added and India efficiently try to reduce the consequences of exclusive patent monopoly.

3.7.3. Natco Vs Bayer

In 2012 India utilize the flexibility of compulsory license to strike balance between the economic interests of the inventor and the interest of the public at large. India has a largest pharmaceutical industry but 65% of its population has lack of access to essential medicines. The reason behind this lack of access is mainly the high prices of medicines.

[247] Doha WTO Ministerial 2001, Declaration on the TRIPS agreement and public health, https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm , last accessed on 23 June 2021.

Indian patent law provides detail provisions, in compliance with TRIPS agreement, of compulsory license. To favor a domestic pharmaceutical company named as Natco India issued its first compulsory license in 2012.[248]

Buyer corporation is an international pharmaceutical company. It invented Sorafenib (Carboxy substituted diphenyl ureas) brand name is Nexavar to treat cancer. Sorafenib is effective to treat kidney and liver cancer of stage 4 and it extend life for 4 to 5 years. Bayer charge for one month treatment with Rs.280,428 and per year treatment cost is 33,65,136. Natco filed an application in 2011 u/s 84(1) of the Indian Patent Act. Natco offer to sell the Nexavar at the rate of Rs 8,800 for per month treatment.[249] Controller decided that Bayer had failed to fulfill the reasonable requirement of public and failed to ensure the working of patent in India or manufacture the drug within the territory of India. Despite of all the price of drug is unaffordable for the poor people of India. Judgment also highlighted that due to the high price of the Nexavar only 2% of cancer patient could continue treatment and rest of the 98% remain untreated. Buyer provided many justifications including that the quantity required by the India do not economically suitable for starting manufacturing in India. Controller rejected all the argument of Bayer and granted the compulsory license. [250]

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[248] Gautam, Savita; Dasgupta, Meghna (2013) : Compulsory licensing: India's maiden experience, ARTNeT Working Paper Series, No. 137, Asia-Pacific Research and Training Network on Trade (ARTNeT), Bangkok,https://www.econstor.the EU/bitstream/10419/103872/1/774037490.pdf , last accessed 28 October 2021.

[249] Raju K D, "Compulsory and Voluntary Licensing: A Legitimate way to Enhance Access to Essential Medicines in Developing Countries," *Journal of Intellectual Property Rights*, Vol 22, January 2017,23-31. http://docs.manupatra.in/newsline/articles/Upload/31AC60C2-ABCC-4799-A388-0F56ED7C9ECF.pdf, last accessed on 28 October 2021.

[250] BusinessLine, India first compulsory license granted to Natco for Bayer's cancer drug, November 14,2017, https://www.thehindubusinessline.com/companies/Indias-first-compulsory-licence-granted-to-Natco-for-Bayers-

7% royalty fixed for buyer which was highest in the world. Bayer decided to go far appeal to the IPAT (Intellectual Property Appellate Tribunal) against the decision of Controller. Bayer argued that the requirement of obtaining voluntary license must be fulfilled u/s 84(6)(iv) before the compulsory granted but this requirement was not fulfilled by the Natco. The IPAT rejected this point as letter by the Natco to Bayer for license and reply of refusal by the Bayer is sufficient to fulfill the requirement of law. The IPAB decided a substantial issue that the section 84 provides three grounds for granting of compulsory license however if any one of the three grounds is satisfied then requirement will be fulfilled to grant compulsory license. The IPAB narrated that affordability of medicines is an important issue and cannot be separated from public interest. The TRIPS agreement under article 8(1) also authorizes the member countries to take necessary steps to protect public interest. IPAB disagreed with the controller on this point and clarify that importing of drug is justified if manufacturing in India is not possible. Bayer was not satisfied with the decision and moved its case to Bombay High Court. Bombay High Court reiterated the decision of IPAB and Supreme Court of India also declined to interfere in the decision of the Bombay High Court.[251]

3.7.4. Compulsory License for Export of Pharmaceutical Products

The TRIPS agreement provides provisions for compulsory license but just to supply for domestic market. It causes serious issue for least developed and developing countries with no manufacturing capacity because these countries cannot take benefit from the

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cancerdrug/article20408026.ece?__cf_chl_captcha_tk__=69.dgYnjjnUnUvWHsYoSIQIpnTL7Z7Eg4eM.tOzuI9Y-1637039552-0-gaNycGzNCL0 , last accessed 29th October 2021.

[251] Raju K D, "Compulsory and Voluntary Licensing: A Legitimate way to Enhance Access to Essential Medicines in Developing Countries," *Journal of Intellectual Property Rights,* Vol 22, January 2017,23-31.http://docs.manupatra.in/newsline/articles/Upload/31AC60C2-ABCC-4799-A388-0F56ED7C9ECF.pdf , last accessed on 25 June 2021.

compulsory license and the problem of access to medicines remains unanswered. Doha declaration on The TRIPS agreement and public health in paragraph 6 recognizes this matter and directed the council for TRIPS to provide expeditious solution for this issue. It states as "We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS agreement. 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."[252] On 30 August 2003 the General Council announced its Implementation Decision of 2003 which allow the least developed and developing countries with no manufacturing capacity to issue a compulsory license for import purpose to fulfill the needs of its people.[253]

Section 92(A) of Indian Patent Act 1970 deals with the compulsory license of patented pharmaceutical products for export purpose in exceptional situations. This provision was incorporated in 2005 by an amendment in the Act. Section 92(A) narrates as

> Compulsory license shall be available for manufacture and export of patented pharmaceutical product to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems [254]

[252] Doha WTO Ministerial 2001, Declaration on the TRIPS agreement and public health, https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm , last accessed 18 June 2021.
[253] WTO, General Council, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health,2003, https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm , last accessed 21 June 2021.
[254] The Patents Act, 1970, https://www.advocatekhoj.com/library/bareacts/patents/index.php?Title=Patents%20Act,%201970 , last accessed on 22 October 2021.

Before the implementation of The TRIPS agreement till 2005 India was the leading exporter of generic drugs to the developing countries.[255] It was the matter of great concern for developing countries who imported generic drugs from India that what will happen after 2005 when India start protecting the pharmaceutical products. India was already aware of this fact that pharmaceutical protection will affect its generic industry and will increase the health expenditure of country.[256] So it incorporated provisions for the importation of patented product to facilitate countries with insufficient or no manufacturing capacity. The objective of this provision was twofold first to help the country who do not manufacture patented product for the need of their people and second to facilitate its generic drug industry and to ensure the affordable medicines to the all deserving people.

3.7.5. Amendment needed in the Patent Ordinance 2000

Section 58 and 59 of the Patent Ordinance 2000 provides provisions for compulsory licensing. In 2002 an amendment was made in the Patent Ordinance 2000 and two new provisions were added 58(iii) and 58(iv). Even after amendment the Patent Ordinance 1970 has very limited and restricted grounds for issuance of the compulsory license. Section 58 provides four grounds when the Federal Government my issue a compulsory license and allow the government agency or any other person to exploit invention. Exploitation shall be limited to that particular purpose for which it is issued

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[255] Unni V.K., Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Context of Public Policy and Health, *Global Business and Development Law Journal*, 25(2012): 323, https://scholarlycommons.pacific.edu/globe/vol25/iss1/12.

[256] 't Hoen, Elisabeth,"Practical Application of the Flexibilities of Agreement on the Trade-Related Aspects of Intellectual Property Rights: Lesson beyond HIV for Access to new Essentials Medicines," PhD diss.(University of Groningen, the Netherland,2018),https://pure.rug.nl/ws/portalfiles/portal/55799433/Complete_thesis.pdf , last accessed 17 March 2021.

and the owner of the patented invention shall be paid adequate remuneration which will be determined by the Federal Government according to the economic value of the authorization.

First ground of granting compulsory license is when "the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires".[257] Under this ground there are certain terms which need elaboration and explanation such as what constitute "public interest" and what includes "national security". Second ground can be invoked when the practice by "owner of the patent or his licensee is anti-competitive" then the Federal Government is authorized to issue compulsory license to cure such practice. Here the term anti-competitive must be explained properly. Third ground is that when "the patent holder refused to grant a license to a third party on reasonable commercial terms and conditions". Fourth ground related to circumstances "where patent has not been exploited in a manner which contributes to the promotion of technological innovation and to the transfer and dissemination of technology,"[258]

The compulsory licensing regime under the patent ordinance 2000 was very week and poorly worded and even after amendment in 2002 it failed to equip with the strong and effectively workable compulsory licensing provisions.[259] Pakistan can learn from the regional countries like India and use the patent system a in such a way to facilitate its

[257]Patent Ordinance 2000, https://ipo.gov.pk/system/files/%28112%29PatentsOrdinance2000_Amendmentsfinal_0.pdf , last accessed 10 July 2021.
[258] Ibid.
[259] Gulzar Asim, "Challenges and Opportunities in the Post TRIPS Era for Pakistan--An Overview of Amended Patents Ordinance 2002," *SPO Discussion Paper Series: Understanding Pakistan Volume II*, 2014, https://spopk.org/wp-content/uploads/2019/11/dp_volume_ii.pdf , last accessed 12 June 2021.

people. Before the implementation of the TRIPS agreement the countries are free to adopt a patent system suitable for their national interest and fulfill the need of their people. Now the situation is quite different and nation of the world have to adopt minimum standards of IP protection provided by the TRIPS agreement to enjoy trade benefits as being the member of WTO. The TRIPS agreement leaves some options for member countries to add some provisions according to their national needs. Doha Declaration on the TRIPS agreement and public health also be aware of the gravity of subject matter and asserts in paragraph 3

> We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effect on prices[260]

Doha declaration on the TRIPS agreement and public health also endorse that the members countries are free to determine the grounds of granting compulsory license and in paragraph 5(b) it states as "Each member state has right to grant compulsory license and freedom to determine the grounds upon which such licenses are granted"[261]

Patent Ordinance 2000 of Pakistan provides four grounds for granting of compulsory license which are already explain above. The patent Act of India also provides four grounds for granting of compulsory license i.e. patent invention should fulfill the requirement of public, prices of invention must be affordable and patent invention must work in the territory of India. It explains the term "public" and "working of patented invention" in detail. It explains that the requirement of public will not be completed without satisfying mention conditions and five conditions are provided under

[260] Doha WTO Ministerial 2001, Declaration on the TRIPS agreement and public health, https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm , last accessed 24th June 2021.
[261] ibid

this heading. It further elaborated what is meant by the working of patent and seven conditions are added which if not fulfilled will be considered as patent is not working. In this way Patent Act 1970 provides fifteen grounds for granting of compulsory license. It tries to minimize the possible misuses of patent monopoly and try to ensure a balance between the mutual right of producers and users of technology.

Compulsory license provisions are very important for developing and even for developed countries. These provisions really help to control the exclusive monopoly of patent holder. Effective and forceful provisions of patent law help the government authority to negotiate successfully with the multinational pharmaceutical companies regarding the price concerns. It is very important to learn from the experiences of other countries and improve the national legislation to promote knowledge and to ensure affordable medicine. Like India, Pakistan should also incorporate more grounds for granting compulsory license to make it workable and practical. After the examination of the patent law of India and Pakistan, it is realized that Patents Ordinance 2000 of Pakistan should incorporated at least following grounds for granting of compulsory license.

3.7.5.1. Affordability of Invention

Affordability of invention is a matter of great concern which should not be ignored. If the price of an invention is high and the general public cannot afford it then it will be considered that the poor people cannot enjoy it, utilize it and take benefit from it. Country like Pakistan where more than one third of its population living beyond the line of poverty and where more than 65% of health expenditures are paid out of the pockets of its citizens, affordability is a great problem. Health spending of Pakistan is USD

International 160.6 per capita which is less than India.[262] Like India the patent law of Pakistan must incorporate the affordability as ground of granting compulsory license. It must be worded clearly that the invention must be affordable for the general public otherwise government will be authorized to issue compulsory license to make it affordable for its people.

After the HIV/AIDS crises the patents of medicines were highlighted and its effects on the high prices of patented medicines were also criticized. Doha Declaration on The TRIPS agreement and public health also recognized it in paragraph 1 as "We recognized the gravity of the public health problems afflicting many developing and least developed countries".[263] Nations of the world are realizing this problem more than before however the effective measures are seen internationally (collectively) but there is lack of implementation domestically. It is not only for Pakistan but all countries with limited resources must add affordability provision as a ground of granting compulsory license.

3.7.5.2. Social and Economic Benefit

Patent protection is provided to encourage invention and to secure that the invention should work with in the territory to give social and economic benefit to the public.[264] It must be incorporated as a ground to grant compulsory license that the protection of patent right should ensure the promotion of innovation and transfer of technology and it (patent) must be used for the mutual benefit of users and producers of invention. Patent system

[262]OECD/the WHO (2020), *Health at a Glance: Asia/Pacific 2018: Measuring Progress towards Universal Health Coverage*, OECDPublishing, Paris, https://www.oecd-ilibrary.org/docserver/health_glance_ap-2018-en.pdf?expires=1634647392&id=id&accname=guest&checksum=5EC9DD948CB4BB78280D6BF9E3AB0BD1 , last accessed 29th October 2021.

[263] Doha WTO Ministerial 2001, Declaration on the TRIPS agreement and public health, https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm , last accessed 24 June 2021.

[264] Birgittee Andersen, "The Rationales for Intellectual Property Rights Revisited," *Intellectual Property Rights: An Overview*, ed. Veena (India: The Icfai University Press, 2006) 9.

can promote social and economic welfare if a balance between the rights and obligations is created through proper legislation as we can see in Patent Act 1970, of India.

3.7.5.3. Promote Public Health

Pharmaceutical patents are the matter of great controversy because it resulted in the high prices of medicines. After the implementation of TRIPS all the member countries are bound to protect pharmaceutical patents. Like India, Pakistani patent law should also have this provision as a ground of invoking compulsory license that patent system should promote public health and do not impede the public health or the availability of medicines. It must not create hurdle for government to provide health facilities to its citizens. Duty of government should not impede by the patent protection and patent should act as an instrument to protect public health.

3.7.5.4. Local Manufacturing of Patent Invention

Patent Act, 1970 provides a very useful provision which explain the conditions when it will be considered that the patent is not working in India and compulsory license might be issued. This provision describes as the patent "are not granted merely to enable patentee to enjoy a monopoly for the importation of the patented article". This is a very useful provision especially the country like Pakistan where more than 80% patent are registered by the foreigners and the research and development activities by the local pharmaceutical companies are almost absent. We must incorporate this provision in the patent law that the multinational companies after getting patent must start producing patented product locally. Local production is actually a key to transfer of technology and dissemination of technology because the disclosure of patent invention in papers which

are kept in patent office store room cannot transfer technology in the country like Pakistan where research culture is not develop yet.

3.7.5.5. Develop Export Market

Indian patent law provides that the compulsory license will be granted if the reasonable requirement of public is not satisfied and it further explains that if "a market for export of the patented article manufactured in India is not being supplied or developed" then it will be considered that requirement of pubic is not fulfilled and compulsory license might be issued. It is obligatory in India for the patent holder to avoid compulsory license to develop a market for export of the patented article. If this provision is added and implemented in Pakistani patent law then it will lead towards the development of new market and can enhance the opportunities of job for many jobless people so ultimately a way to progress will be started. This is actually a way to balance the rights of producers and users of technology. Otherwise, countries with no manufacturing capacity and with limited research and development activities cannot take benefit from patent system and patent system would actually become a burden for them.

3.7.6. Compulsory License for Import and Export Purpose under the Decision of 2003 and the Patent Ordinance 2000

The TRIPS agreement allows the compulsory license just to supply for the domestic market. This creates a serious problem for countries with insufficient and no manufacturing capacity as they cannot take benefit from the compulsory license flexibility. After much efforts by the developing countries and international organizations it is allowed to issue compulsory license for export in countries with no or insufficient manufacturing capacity. This relaxation provided by the general council's Decision

which was announced on 30th August 2003. This relaxation is not available automatically. Countries who want to import or export the patented drugs under compulsory license must have to incorporate this flexibility into their national legislation. Compulsory license provisions of patent law of Pakistan do not have this flexibility we must incorporate it in our national legislation.

3.8. Aptox Rwanda Deal

The "Aptox Rwanda Deal" refers to an agreement between the Canadian generic drug maker Apotex and the Rwandan government to supply Apotex's AIDS medication Apo Triavir to Rwanda. This deal was significant because it marked the completion of a legal process that allowed Apotex to bypass patent restrictions and provide affordable medication to Rwanda. In 2007, Rwanda sought a compulsory license to produce generic HIV/AIDS medication due to the high cost of patented drugs. Canada notified the Council for TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) about this compulsory license in October 2007. Apotex subsequently secured a contract with the Rwandan government in 2008, allowing them to supply Apo Triavir. In September 2008, Apotex announced that it would be shipping seven million antiretroviral pills to Rwanda, enough to treat 21,000 patients.[265]

Canada was the first who issued a compulsory license for export. But after that no other successful case has seen yet. Developing countries willingness and response from

[265] Matthew Rimmer, Race Against Time: The Export of Essential Medicines to Rwanda, *Public Health Ethics*, July 2008: 1(2) 89–103, https://doi.org/10.1093/phe/phn011

developed countries is very important. It is also duty of developed countries to cooperate so that flexibility would become a reality.[266]

3.9. Conclusion

We are lining in the era of technology and innovation so patent law is getting special importance among other laws. It is very important to legislate patent law vigilantly according to the needs of each state. Every state is progressing towards achieving new goals and benchmark with different speed. Some states are making progress very speedily and others are not so. Patent law can play a significant role to determine the speed of progress if enacted according to the need of each state. Every state has its own requirement and demands, that is way the TRIPS left with some room that could be filled by the states according to the local needs. Pakistan's patent law also needs to be revamped to encourage local industry and to create a culture of research and development. There is dire need to have strict patentability criteria to minimize foreign monopoly as the patent system of Pakistan protecting 80% to 85% foreign patent. Most of the technologies are imported in Pakistan instead of manufacturing. Pakistan facing the same situation as India faced in 1960 after which India formed a committee which observed that 70% to 80% patent is from the foreigners and they are occupying the local markets. Committee suggested some changes and in 1970 India introduced new patent regime according to needs of its own people in which industry flourished and public health became affordable. It is pathetic that a very important issue which is solved by India in 1970 we are still waiting for that and concern authorities are not realising the

[266] Amollo, R.. Revisiting the TRIPS regime: Rwanda-Canadian ARV drug deal tests the WTO General Council decision, *African Journal of International and Comparative Law*, 2009: 17(2), 240-269.

issue. So there is dire need to make appropriate changes in patent law of Pakistan to make in more compatible to public health and local industry.

CHAPTER 4

AVAILABILITY AND AFFORDABILITY OF HEPATITIS C MEDICINES IN PAKISTAN AND INDIA

It is the primary duty of state to provide health facilities to its citizens as in the chapter one we elaborated and establish this duty against the state and in certain circumstances against the whole world under the international law. Availability and affordability of medicines is the key component of health facilities. It will be examined in this chapter that what is the situation regarding the availability and affordability of Hepatitis C Virus infection and its treatment in Pakistan and India. Hepatitis C affects the whole world and Pakistan has the highest HCV burden worldwide.

4.1. Introduction

Development in science and technology improved the living standards all around the world and this development led to the introduction of new rights and obligations, IPRs are also one of the newly emerging rights. Patent protection is the most controversial among the other IPRs due to its negative effects on the prices of medicines. Monopoly rights under the patent prohibit the entry of generic drugs and patent holder is free to charge high price under the allege claim of R&D charges. Millions of people in developing and under developed countries have lack of access towards the lifesaving medicines and most prominent reason is non affordability. International organizations i.e. WTO and the WHO tried to maintain a balance between IPRs and right to health. The TRIPS agreement also provides different tools for the member countries to use and

mitigate the consequences of exclusive patent monopolies. However, developing and least developed countries are failed to use these tools effectively to control the patent misuses. There are many reasons for this failure and most dominant reason is the lack of expertise and technical knowledge about how to deal with IPRs keeping in view their national needs. It would not be wrong to say that intellectual property and particularly patent is an arcane field of law and only few experts are found in developing and least developed countries. This is the reason that developing countries remain unsuccessful to use TRIPS flexibilities for the benefit of their people. Some developing countries are not incorporate these tools/flexibilities at all and others are though incorporate but have very week and poor ground for using these tools which make it useless at all. Even some countries incorporate TRIPS flexibilities very effectively but usage of these flexibilities is really missing and the reason for this non usage might be the pressure by the developed countries. It is the duty of a state to ensure access to affordable medicines to its citizen and for the fulfillment of this obligation state must utilize its entire available means. Proper legislation and then the implementation of law is need of the hour. In this chapter we will examine the practice of multinational pharmaceutical companies and the agencies, side by side strategy adopted by the state authorities how they ensured the availability and affordability of hepatitis C medicines in Pakistan and India.

4.2. Hepatitis C

Hepatitis is a viral disease which effect liver. Liver is an important organ of human body and perform multiple key functions e.g. filters our blood, help nutrients to be

processed and fight against infections.[267]Infectious virus caused liver inflammation and leads towards a number of health issues. Chronic hepatitis C leads towards liver cirrhosis, liver cancer and other liver related serious issues which cause many premature deaths.[268]the WHO revealed in its report issued in 2015 that there are 71 million people suffered with HCV worldwide and 399000 deaths accord from liver cancer, liver cirrhosis and hepatocellular carcinoma.[269] The WHO declared hepatitis as a public health threat and designed a Global Health Sector Strategy (GHSS) to eradicate hepatitis (up to 90% reduction in incidents and 65% reduction in mortality) till 2030.[270] The WHO estimate that if the member states take proper measures including diagnosis at proper time, vaccination, ensure availability of medicines and by educating people then 4.5 million deaths can be avoided till 2030.[271] Currently 58 million people are suffered with chronic HCV and every year 1.5 million new infections crop up. 290,000 people lost their life due to HCV in 2019. Antiviral medicines are very effective and can cure 95% patients if diagnosis at right time.[272]

4.3. Treatment for hepatitis C

HCV infection at time doesn't require a treatment for a person with strong immune system but chronic HCV needs treatment to cure the disease. The treatment

[267] Center for Disease Control and Prevention, What is viral hepatitis?, https://www.cdc.gov/hepatitis/index.htm , last accessed on 11 Dec, 2021
[268] World Health Organization, Hepatitis, 2021, https://www.who.int/health-topics/hepatitis#tab=tab_1 , last accessed on 14 December 2021.
[269] World Health Organization, Guidelines for the case and treatment of persons diagnosis with chronic hepatitis C virus infection, July 2018, file:///D:/chapter%204/hep%20c/9789241550345-eng.pdf , last accessed 15 December 2021.
[270] Ibid
[271] World Health Organization, Hepatitis, , https://www.who.int/health-topics/hepatitis#tab=tab_1 , last accessed on 14 December 2021.
[272] World Health Organization, Hepatitis C, https://www.who.int/news-room/fact-sheets/detail/hepatitis-c , 27 July 2021

recommended by the WHO to heal HCV is also the direct-acting antiviral (DAAs). DAAs are the most effective and safe treatment to cure HCV and can be used for all people above the age of twelve years. A patient of HCV may be needed 12 to 24 months treatment to cure; however the treatment may be prolonged depending upon the patient individual health and the existence or non-existence of cirrhosis. Treatment of the HCV through DAAs is very costly in high and upper-middle income countries but comparatively the cost is much affordable in low- and middle-income countries due to the availability of generic.[273]

World Health Organization (the WHO) adopted its first Global Health Sector Strategy for Viral Hepatitis 2016-2021. The WHO provides guidelines and assistance for the member countries to control and treat HCV. Number of people treated with DAAs in 2015 to 2021 was increased dramatically from 122000 in 2015 to 2.6 million in 2018. There are many reasons for this increase and the reduction in the treatment cost is one of them.[274]

The treatment cost of hepatitis by DAA reduced since 2015. There are two main reasons for this price reduction. The first reason is that the entry of generic DAAs increased competition and reduced the price. In some territories the patents were not granted or applied for DAAs and due to the lack of patent protection generic manufacturers are allowed to produce without license. The generic manufacturers are free to produce for domestic market and also for export in countries where patent is not

[273] ibid
[274] World Health Organization, Accelerating access to hepatitis C diagnostics and treatment, overcoming barrier in low and middle –income countries: Global progress report 2020, , vii, file:///C:/Users/user/Downloads/9789240019003-eng.pdf , last accessed 27 January 2021.

granted or applied. The second reason is that the voluntary licenses are granted to 100 or more countries which enable the purchase of DAAs from the licensees.[275]

The availability of DAAs is increased in recent years but still millions of people who are diagnosis with HCV have not yet started treatment (38%) and the reason in most of the cases is affordability. Prices are very high for HCV treatment in upper middle-income countries e.g. China, Brazil, Colombia, Kazakhstan, Turkey and Mexico. Approximately 14 million patients of HCV are living in these countries. These countries are not party to the voluntary license and patents are also granted in most of the territories and for this reason the entry of generic drugs is illegal and prices are high.[276]

4.4. Treatment options for HCV

Options available for DAAs are increased and improve with the passage of time. Interferon injections were used to treat hepatitis C and treatment last for 6 to 12 months. The treatment through interferon has its side effect because the treatment is long so it affects the body and many side effects observed. The common side effect is as the swelling at the injection site, pain in whole body, fever, nausea, vomiting, sleeping problems, diarrhea, lack of appetite and lack of white blood cells.[277] Now new treatment

[275] World Health Organization, Progress report on access to hepatitis C treatment: Focus on overcoming barriers in low and middle income countries, March 2018, viii, https://apps.who.int/iris/bitstream/handle/10665/260445/the WHO-CDS-HIV-18.4-eng.pdf , last accessed 24 January 2021.
[276] World Health Organization, Progress report on access to hepatitis C treatment: Focus on overcoming barriers in low and middle income countries, March 2018, ix, https://apps.who.int/iris/bitstream/handle/10665/260445/the WHO-CDS-HIV-18.4-eng.pdf , last accessed on 24th January 2021.
[277] Susan J. Bliss, Interferon for hepatitis C: Understanding long term side effects, February 2019, https://www.healthli/ne.com/health/hepatitis-c/interferons-long-term-effects , last accessed on 21 January 2021.

through the direct-acting antiviral (DAAs) has revolutionized the treatment of hepatitis C. Three pangenotypic regimens are considered as most effective for all six HCV genotypes

1. Sofosbuvir / velpatasvir
2. Sofosbuvir / velpatasvir / voxilaprevier
3. Glecaprevir /pibrentasvir

Access is limited for these drugs in low- and middle-income countries. Sofosbuvir/velpatasvir registered only in three countries (low and middle income). No access program is introduced for low- and middle-income countries by the originator of glecaprevir/pibrentasvir.[278]

4.5. Strategies to control the high prices of DAA

The introduction of DAA has revolutionaries the HCV treatment as the cure rate is more than 90 % but the prices was very high and unaffordable for many all around the world. To determine the price of a drug is a complicated issue and a confidential business. Manufacturing company set a wholesale acquisition cost (WAC) when launches its product however that cost is not true estimate of the expenditure. However, a lot of negotiations are involved between the manufacturer of drug and users of drug (through the health insurance companies) by different means including Pharmacy Benefit Managers (PBMs). After all efforts the medicines became available for general public in public pharmacies. The Sofosbuvir was first approved in USA by FDA in December 2013 and the initial price introduced was 84000$ for 12 weeks treatment which was

[278] World Health Organization, Progress report on access to hepatitis C treatment: Focus on overcoming barriers in low and middle income countries, March 2018, viii, https://apps.who.int/iris/bitstream/handle/10665/260445/the WHO-CDS-HIV-18.4-eng.pdf , last accessed 24th January 2021.

1000$ for 1 pill. High prices of effective DAA was a major concern as the most of the patients who needs treatment belong to low and middle-income countries. It is the joint responsibility of different actors to ensure availability and affordability of medicines to the needy patient and this joint responsibility is shared by the state, pharmaceutical companies, international agencies and NGOs (non-governmental organization). In this way, different strategies adopted and mechanism used to control the high prices of DAA and availability of generics also tried to ensure the affordability. Now we will have glimpse on the different means and tools which are used to control the prices of DAA.

4.5.1. Negotiate the price reductions with pharmaceutical companies

State authorities used to negotiate with the pharmaceutical companies regarding the price of a drug and try to come up with the most affordable one. Pharmaceutical companies develop a strategy for reducing price keeping in view different well research and transparent estimation regarding the capacity of government or people to pay the price of drug. France successfully negotiated with Gilead for Sofosbuvir 12-week treatment at 61,000 $ and Spain agreed with Gilead for same treatment at 28,000 $.[279]

4.5.2. Voluntary License Agreement

Voluntary license agreement is also very important tool to make drug affordable by creating competition among the generic manufacturers. The patent holder grants a voluntary license to other pharmaceutical companies to manufacture the drug and supply in the market according to the terms and conditions mention in the agreement.

[279] Umer et al., "Role of generics in treatment of hepatitis C infections", Journal of Ayub Medical College, 4suppl, 28 (2016).890-894,https://www.researchgate.net/publication/354687406_ROLE_OF_GENERICS_IN_TREATMENT_OF_HEPATITIS_C_INFECTION , last accessed 27 January, 2022.

Gilead signed a voluntary license agreement with 11 Indian pharmaceutical companies for generic Sofosbuvir. According to the terms of the license the Indian companies can sell generic Sofosbuvir to only those 101 countries whose names were given in the license agreement. 7% royalty were fixed which Indian companies would pay to Gilead on the sale of generic Sofosbuvir. Gilead have the credit to be the first who grant the voluntary license and the make this agreement public and the copy of agreement is also publicly available.[280]

Voluntary license agreement makes a strong business sense. Involvement of generic manufacturers can scale up production rapidly as they are well equipped with the local regulatory requirements and have connection with network of developing countries and local markets. Voluntary license give benefit to the patent holder in the form of royalty and benefit the society by scaling up the production and affordability through competition. Data from the WHO reveal clearly that the prices of DAA are more affordable in the countries where generic competition is well-built. Medicine patent pool can also play very important role in this regard if more and more companies sing voluntary license with Medicine Patent Pool.

4.5.3. Market Segmentation

Pharmaceutical companies set different price policies for different economies keeping in view the market size and economic conditions of the countries. This strategy reveals the sound business sense and ensures the availability of medicines. Pharmaceutical companies also offered different prices in public and private sector for middle income

[280] Edward et al., "access to hepatitis C medicines", Bulletin of the World Health Organization, 93(11): 799-805, https://accesstomedicinefoundation.org/media/atmf/Access-to-Hep-C_the WHO_DE-TP-JI.pdf , last accessed 28 January, 2022.

countries in which they seem great economic value. Gilead used this approach of market segmentation for its patented product Sofosbuvir. It charged $ 84,000 for a course of treatment with Sofosbuvir in USA and charged $ 900 for same treat in Egypt. This huge difference was based on the market size and per capita income of respective countries.[281]

4.5.4. Patent rejection

Patent for pharmaceutical is a major barrier for access to affordable medicines. Patent monopolies enable the patent holder to charge high prices as there is no competition available. Egypt provides the cheapest medicine of HCV treatment and it ensure the access to affordable treatment by rejecting patent application of Gilead and BMS also withdraw its application. In this way, the Egypt enabled the local industry to manufacture and supply the Sofosbuvir. In 2017, Egypt provided treatment to the more than one million people in government hospitals.[282] Patent application of Gilead is also rejected by the China and now multiple Chinese pharmaceutical companies manufacturing generic Sofosbuvir.[283]

Patent oppositions for DAA had been filed and won in many states on different grounds. Sofosbuvir was challenged on the ground that it is not the inventive enough and is already in public domain according to the law of some jurisdictions. In 2013 the patent on Sofosbuvir was first time challenged in India by DNP+ (Dehli Network of Positive People) and I-MAK (The Initiative for Medicines, Access and Knowledge). After India

[281] Edward et al., "access to hepatitis C medicines", Bulletin of the World Health Organization, 93(11): 799-805, https://accesstomedicinefoundation.org/media/atmf/Access-to-Hep-C_the WHO_DE-TP-JI.pdf , last accessed 28 January 2022.
[282] Medecins Sans Frontierers, "Not even close", https://www.msf.org/sites/msf.org/files/hepc_issuebrief_hep_c_2017.pdf , last accessed 27 January 2022.
[283] Umer et al., "Role of generics in treatment of hepatitis C infections", Journal of Ayub Medical College, 4suppl, 28 (2016).890-894, https://www.researchgate.net/publication/354687406_ROLE_OF_GENERICS_IN_TREATMENT_OF_HEPATITIS_C_INFECTION , last accessed 27 January 2022.

many, countries filed patent oppositions against the DAA. In 2015 the patent application of Gilead is invalidated in the European Union as the result of patent opposition filed by the Medicines du Monde.[284]

4.5.5. Compulsory License

The TRIPS agreement provides the provision of compulsory license or government use to control the abuses of patent monopolies. State government may issue compulsory license to make drug accessible to its patients. Developed countries and pharmaceutical industry always built pressure on the countries who tried to issue compulsory license. However, state authorities should take their decision, independently without any pressure, keeping in view benefit of public at large and state responsibility to provide health facilities to its citizens.

Malaysian government took a very bold step to issue compulsory license for Gilead's branded drug Sovaldi (Sofosbuvir). Government of Malaysia realized that to achieve the WHO goal and to eliminate hepatitis C till 2030 is not possible until the treatment is accessible and affordable. Government negotiate with Gilead to reduce prices but negotiation come with no result so government decided to go for compulsory license and on 20th September 2017 patent barrier was left out and compulsory license was issued to scale up treatment of hepatitis C patients.[285] Drug was charged at $ 11200 for 28 day treatment and after the issuance of government use compulsory license the treatment cost

[284] Medecins Sans Frontierers, "Not even close", https://www.msf.org/sites/msf.org/files/hepc_issuebrief_hep_c_2017.pdf , last accessed 27 January 2022.
[285] the MSF: Access Campaign, "Malaysia's compulsory license for Sofosbuvir is a positive step for public health and innovation", 11 February 2019, https://msfaccess.org/malaysias-compulsory-license-sofosbuvir-positive-step-public-health-and-innovation , last accessed 29th January 2022.

through generic Sofosbuvir was reduced at $ 30 per treatment.[286] In counter reply Gilead issue voluntary license to Malaysia, Thailand and Ukraine. [287]

4.6. Medicine Patent Pool

After the TRIPS agreement the pharmaceutical products start protecting under the patent system worldwide. Patent system results in the high prices of medicines and to make medicine affordable the idea of Medicine Patent Pool (MPP) emerged. MPP tried to respond efficiently towards the current IP environment and to reduce the access to medicine issue in developing countries.

The idea of medicines patent pool (MPP) was first time introduced in 2002 during an international conference on AIDS by James Love. This idea was based on the model of USA as it created a pool in 1917 for essential aircraft patents. Knowledge Economy International (KEI) and Medicine san Frontiers (the MSF) proposed UNITAID (medicine financing agency) to introduces a patent pool of medicines to control the abuses of patent system and to ensure the availability of AIDS medicines for people in need. UNITIAD was very reliable player to start this task as it had trustworthy financing and mass purchasing capacity.[288] Initially the UNITIAD target the ARVs for treating AIDS and then it expand its work to other medicines for treating other diseases such as HCV.

[286] World Health Organization, Progress report on access to hepatitis C treatment: Focus on overcoming barriers in low and middle income countries, March 2018, 12, https://apps.who.int/iris/bitstream/handle/10665/260445/the WHO-CDS-HIV-18.4-eng.pdf last accessed on 24th January 2021.

[287] Stewart Angus, "Malaysia in the middle: Tackling Hep C in an unfair world", The Medicine Maker, 9 September, 2021, https://themedicinemaker.com/discovery-development/malaysia-in-the-middle-tackling-hep-c-in-an-unfair-world#:~:text=The%20drug%20came%20with%20a,sofosbuvir%20(priced%20at%20%24300) , last accessed on 29 January 2022.

[288] Hoen., E.,The Medicines Patent Pool. The Politics of Medicines (encyclopaedia) , 2012, Available at: https://haiweb.org/encyclopaedia/medicines-patent-pool/ , last accessed on 24 September 2021.

Medicine patent pool (MPP) makes the process very easy and simple for generic drug makers. Before the MPP the generic manufacturers have to pass through a difficult procedure before making and selling a FDC[289] (fixed-dose combination). A FDC contains multiple combinations and a generic manufacturer if interested in voluntary license then he has to obtain license from all different patent holders separately. The MPP make the procedure easy and if all the patent holders have license with the MPP, generic manufacturer has to deal single entity. Ellen 't Hoen (2012) used the term "one-stop-shop" for MPP.

4.6.1. Efforts of Medicine Patent Pool for HCV medicines

A very important step had been taken by the MPP regarding the affordable access of hepatitis C medication. UNITAID in its meeting of Executive Board on 4th November 2015 approved the proposal of MPP to enhance access of affordable life saving DDAs (Direct Acting Antiviral) for hepatitis C patients. The MPP did a lot of efforts for the HIV medicines and now it is going to follow the same model for getting license for generic manufacturers of HCV medicines.[290] CEO of the World Hepatitis Alliance, Raqual Peek, said "The recent approval of new treatments with greater efficacy and low side effects represents an incredible opportunity to move closer to eradication, but only if these drugs are affordable and accessible"[291]

[289] Fixed-dose combination means where the treatment is based on different medicine and each medicine is patent by different pharmaceutical companies. An example of FDC is first line ARVs for HIV/AIDS which consist of tenofovir by Gilead, lamivudine by GlaxoSmithKline and either nevirapine by (Boethringer-lngelheim) or efavirenz by (Merck).
[290] Medicine Patent Pool, The Medicine Patent Pool Expands Mandate to Hepatitis C and Tuberculosis Treatment, News and Publication, 6th November 2015,https://medicinespatentpool.org/news-publications-post/the-medicines-patent-pool-expands-mandate-to-hepatitis-c-and-tuberculosis-treatment , last accessed on 23rd January 2022.
[291] ibid

In 2015, MPP was successfully get a voluntary license agreement with the Bristol Myers Squibb (BMS) for declatasvir and its combination, which is a DDA used to treat HCV patients. This agreement enabled the generic manufacturers that they could manufacture and sell the drug in 112 low- and middle-income countries which are the home of more than 65% of HCV patients worldwide.[292] In 2020 BMS also declared that it will withdraw or lapse its market authorization and meanwhile patent in these countries will not be enforced. This decision makes the availability of declatasvir in more than 20 countries which are not in the MPP licensing territory.[293] In 2017, the MPP successfully entered into an agreement for ravidasvir with pharmaceutical DAA which is effective for all six genotype.[294]

Another significant progress by the MPP is that in 2018 it successfully entered into a new agreement which introduced a royalty free licensing with originator company AbbVie for glecaprevir/ pibrentasvir to treat hepatitis C patients in 99 low- and middle-income countries. AbbVie realizes that the affordable access to HCV treatment is basic to eliminate hepatitis C globally. This agreement enables the generic manufacturer in low- and middle-income countries to assure affordable access to HCV treatment.[295]

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[292] Medicines Patent pool, Declatasvir, November 2015, https://medicinespatentpool.org/licence-post/daclatasvir-dac , last accessed on 17 January 2021.
[293] World Health Organization, Accelerating access to hepatitis C diagnostics and treatment, overcoming barrier in low and middle –income countries: Global progress report 2020, ix, file:///C:/Users/user/Downloads/9789240019003-eng.pdf , last accessed on 27 January 2022.
[294] Medicine patent pool, Ravidasvir, April 2017, https://medicinespatentpool.org/licence-post/ravidasvir , last accessed on 12 February 2022.
[295] AbbVie/ news center, AbbVie and Medicine Patent Pool Complete New Licensing Agreement, Nov12, 2018, https://news.abbvie.com/news/media-statements/abbvie-and-medicines-patent-pool-complete-new-licensing-agreement-to-ensure-sustainable-access-to-pan-genotypic-hepatitis-c-medicine-glecaprevirpibrentasvir.htm , last accessed on 15 February 2022.

4.7. Hepatitis C and Pakistan

More than 40% of hepatitis C patients live in China, Egypt, India and Pakistan. In Pakistan more than 10 million people are infected with HCV in 2020. Pakistan has the highest HCV burden worldwide.[296] With huge population and high exposure rate risk of more prevalence increased and according to an estimate 240,000 new infections added annually and enlarged the disease burden.[297] Pakistan has few diagnosis services and people in rural areas are suffered more with hepatitis C and due to late diagnosis annual reporting of liver cancer and liver cirrhosis increased threefold.[298] In 2019 survey was conducted by the WHO in 12 low and middle income countries to check the HCV burden and other efforts taken by the state authorities to control the disease. This survey provides very important information regarding strategies adopted by each country towards regulatory approval, price controlling means and patent status of HCV medicines.[299] Pakistan is also one of these countries whose efforts with regard to HCV treatment and elimination by 2030 are considered as appreciable. the WHO reports also suggests other countries with limited resources and high disease burden to take benefit from the experience of these countries.[300]

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[296] World Health Organization, Accelerating access to hepatitis C diagnostics and treatment, overcoming barrier in low and middle –income countries: Global progress report 2020, 12, file:///C:/Users/user/Downloads/9789240019003-eng.pdf , last accessed on 27 January 2021.
[297] Ministry of National Health Services, Regulation and Coordination(NHSRC) Pakistan, National Hepatitis Strategic Framework for Pakistan 2017-2021, http://www.emro.who.int/pak/programmes/prevention-a-control-of-hepatitis.html, 12, last accessed on 19 January 2022.
[298] World Health Organization, Accelerating access to hepatitis C diagnostics and treatment, overcoming barrier in low and middle –income countries: Global progress report 2020, 12, file:///C:/Users/user/Downloads/9789240019003-eng.pdf , 27 January 2021.
[299] World Health Organization, Accelerating access to hepatitis C diagnostics and treatment, overcoming barrier in low and middle –income countries: Global progress report 2020, 2, file:///C:/Users/user/Downloads/9789240019003-eng.pdf , last accessed on 27 January 2021.
[300] Ibid

Prices of DAAs to treat HCV are much affordable in low- and middle-income countries due to voluntary license or the absence of patent in these countries make it possible to increase competition through generic entry.[301] Affordability increased access to DAAs and increase access strengthen the goal of eliminating HCV. Number of patients who had started treatment of DAAs boost from 1 million in 2015 to 1.5 million in 2016 and half of the patients treated with DAAs in 2016 are from Pakistan and Egypt.[302]

Medicines of HCV are very affordable in Pakistan and this affordability led towards the starting of treatment by many people. Price reduction through generic competition is very important tool and it is used very effectively in Pakistan. In 2018 the prices of HCV medicines were jump down more than 75% and new prices fallen from 80 USD to 15 USD. Now, the cost of HCV medicines for 28-day treatment is 7 to 10 USD in Pakistan and in Egypt it is 16 USD for 28-day treatment.[303] Lowest prices of HCV treatment are enjoyed by Pakistan. But this price reduction is not available in many other countries. There are price variations by the pharmaceutical companies in some countries that limit access and in other countries patent barriers limit access to affordable medicines. High prices of HCV are a main hurdle in scale up the treatment.

[301] World Health Organization, Progress report on access to hepatitis C treatment: Focus on overcoming barriers in low and middle income countries, March 2018, vii, https://apps.who.int/iris/bitstream/handle/10665/260445/the WHO-CDS-HIV-18.4-eng.pdf , last accessed on 24th January 2022.
[302] Ibid
[303] World Health Organization, Accelerating access to hepatitis C diagnostics and treatment, overcoming barrier in low and middle –income countries: Global progress report 2020, viii, file:///C:/Users/user/Downloads/9789240019003-eng.pdf , last accessed on 27 January 2021.

4.8. Efforts of Pakistan towards achieving the WHO target of eliminating HCV by 2030

The Punjab is the most populated province of Pakistan. The increasing incidents of hepatitis forced the provincial government to initiate the prevention and control program for hepatitis in 2005. The federal government also recognized the serious of issue and very next year the federal government also launched the "Prime Minister Prevention and Control Program for Hepatitis" in 2006.[304] Pakistan had conducted a national survey in 2007 with objective to evaluate the existence of hepatitis B and hepatitis C cases in the country. This survey concluded that 2.5% of population was HBV positive and 5% of population was HCV positive. It was also estimated that these 5% patients will expose infection to further approximately 8 million people. Survey validated the efforts of the government to control HCV infection and it also highlight that the issue of hepatitis need to be addressed more seriously.[305] After the 18th constitutional amendment in 2010 the health became the provincial subject so the Prime Minister Prevention and Control Program for Hepatitis was handed over to the provinces. After this amendment the program was titled as "Chief Minister Hepatitis Prevention and Control Program" (HPCP)in 2011.[306]All provinces including Punjab, Sind, Baluchistan and KPK have

[304] Punjab Hepatitis Action Plan(PHAP), 2019-22, file:///D:/chapter%204/hep%20c/hepatitis%20C%20in%20pakist/punjab-hepatitis-action-plan-final-version.pdf , last accessed on 18 January, 2022.
[305] H. Qureshi et al., "Prevalence of hepatitis B and C viral infections in Pakistan: finding of a national survey appealing for effective prevention and control measures," *Eastern Mediterranean Health Journal* 16, (2010), 15-23, https://applications.emro.who.int/emhj/V16/supp/16_S_2010_015_023.pdf?ua=1 , last accessed on 3rd February 2022.
[306] Punjab Hepatitis Action Plan(PHAP), 2019-22, 25, file:///D:/chapter%204/hep%20c/hepatitis%20C%20in%20pakist/punjab-hepatitis-action-plan-final-version.pdf last accessed on 18 January, 2022.

continued their prevention and control programs for hepatitis. The objectives of all HPCP are almost same with little modification and these objectives include

- To prevent of infection through vaccination
- Screening and treatment of chronic infections
- To create awareness in general public regarding prevention and control of hepatitis
- To promulgate and implement effective health policies
- To strengthen health care system by improving capacity building and infrastructure

Punjab is being the most populated province of Pakistan has highest burden of hepatitis C then other provinces. Government took initiative to control and treat HCV infections and for this purpose it conducted a survey in Punjab from 2017 to 2018. The survey concluded that in spite of all efforts the HCV infection raised from 6.7 to 8.9 in 2008 to 2018 respectively.[307] Government realized that a stepped-up response is direly needed to control HCV and to achieving the goal of the WHO. For achieving these objectives, the government has introduced a National Hepatitis Strategic Framework (NHSF).[308]

4.8.1. National Hepatitis Strategic Framework (NHSF)

After the 18th amendment the health became the provincial subject however the federal government after considering the seriousness of issue decided to develop National Hepatitis Strategic Framework. Ministry of health assigned the duty to the Technical

[307] Punjab Hepatitis Action Plan(PHAP), 2019-22, 6, file:///D:/chapter%204/hep%20c/hepatitis%20C%20in%20pakist/punjab-hepatitis-action-plan-final-version.pdf last accessed on 18 January, 2022.
[308] Ibid.

Advisory Group (TAG) to frame a policy for NHSF 2017-2021which must be in line with the WHO strategy to eliminate hepatitis by 2030. TAG with the coordination of different national and international bodies i.e. national and provincial Technical Working Groups (TWGs), experts from Centre for Disease Control and Prevention (CDC) USA and the WHO Eastern Mediterranean Regional Office's team, worked together and succeed to formulae the strategy.[309] Government launched the National Hepatitis Strategic Framework (NHSF) on 8th October 2017 and Federal Minister, Sara Afzal Tarar, signed the affirmation. NHSF is work through the different partners including federal and provincial health authorities, hepatitis programs of each province and different non-government organizations. NHSF ensures to implement provincial action plan for elimination of hepatitis.[310]

NHSF has a vision as "In Pakistan; viral hepatitis transmission is halted and every one living with viral hepatitis has access to safe, affordable and effective prevention, care and treatment." It set the goal to eliminate hepatitis by 2030 and target to achieve 30% reduction in new viral hepatitis incidents and 10% reduction in related deaths.[311]Pakistan showed excellent commitment and made great progress in treating HCV patients

[309] Ministry of National Health Services, Regulation and Coordination(NHSRC) Pakistan, National Hepatitis Strategic Framework for Pakistan 2017-2021, http://www.emro.who.int/pak/programmes/prevention-a-control-of-hepatitis.html, last accessed on 19 January 2022.
[310] Punjab Hepatitis Action Plan(PHAP), 2019-22, file:///D:/chapter%204/hep%20c/hepatitis%20C%20in%20pakist/punjab-hepatitis-action-plan-final-version.pdf last accessed on 18 January, 2022.
[311] Ministry of National Health Services, Regulation and Coordination(NHSRC) Pakistan, National Hepatitis Strategic Framework for Pakistan 2017-2021, http://www.emro.who.int/pak/programmes/prevention-a-control-of-hepatitis.html, last accessed on 19 January 2022.

annually. Number of patients increased from 65,000 to 160,000 from 2015 to 2016 respectively.[312]

4.9. Way to control the price of HCV treatment in Pakistan

Pakistan has the highest HCV burden and the most effected group belongs to 35 to 55 years of age and it is the most creative period of one's life. The 10 million people who are infected with HCV if failed to cure and diagnose at proper time then there is very strong apprehension that they might be affected with cirrhosis and hepatocellular carcinoma (HCC). In Pakistan HCC is third preventable malignancy. Huge number of patients of HCV is the constant threat of spreading new infections. The only way to control the disease is to start a prevention and control program on national level and to ensure the licensing and availability of affordable new DAA.[313] Pakistan has started its prevention and control programs on national and provincial level with the mutual co-operation of federal and provincial governments as stated above. It was also the vision of these prevention and control programs to make the DAA cheapest and affordable. In Pakistan to control the HCV extra ordinary efforts needed to fight against the lethal combination of poverty and disease burden as more than one third populations is living beyond the line of poverty.

Before the introduction of DAA, interferon injections were used to treat HCV patients and the treatment through interferon was very problematic as it had many side effects.

[312] Ministry of National Health Services, Regulation and Coordination(NHSRC) Pakistan, National Hepatitis Strategic Framework for Pakistan 2017-2021, http://www.emro.who.int/pak/programmes/prevention-a-control-of-hepatitis.html, 30, last accessed on 19 January 2022.

[313] Umer et al., "Role of generics in treatment of hepatitis C infections", Journal of Ayub Medical College, 4suppl, 28 (2016).890-894,https://www.researchgate.net/publication/354687406_ROLE_OF_GENERICS_IN_TREATMENT_OF_HEPATITIS_C_INFECTION , last accessed on 27 January, 2022.

After the introduction of DAA, the treatment of HCV became more easy and secure. In Pakistan, Gilead successfully registered its block buster drug Sovaldi in Pakistan. DRAP (Drug Regulatory Authority of Pakistan) fixed the price of Sovaldi as RS. 1,940 for single tablet and total cost for 28 days treatment was RS. 55,000. Ferozsons reduces their prices further to Rs. 36,000 per pack.[314] Ferozsons was a partner with Gilead after the launch of HCV. Initially Ferozsons started an innovative way of treatment on "named-patient basis" and then by enlarging access program in low middle income countries Ferozsons was the authorised partner of Gilead to manufacture and distribute the generic drugs of HCV in Pakistan.[315]

On 5th October the DRAP, after considering the seriousness of issue, took the initiative and grant registration to 14 pharmaceutical companies to manufacture the HCV medicines. Ferozsons was granted right to sell the HCV medicine at the rate of Rs. 55,000 per pack however this price was very high and unaffordable for many poor patient of Pakistan. It was estimated that the registration of more firms will increase competition and lower the price of treatment as the one of the company (Everest pharmaceutical) offer lesser price of HCV treatment as Rs. 11,000 per pack.[316] After the registration of pharmaceutical companies to manufacture the HCV generic drug Sofosbuvir. Ferozsons also reduced the price of its life saving drug Sovaldi at 36,000 per pack. Due to this

[314] Choudhary Asif, Sovaldi in Pakistan, 21November, 2014, https://www.natap.org/2014/HCV/120314_06.htm , last accessed on 1st February, 2022
[315] Ferozsons Labortories Limited, https://ferozsons-labs.com/partnership/ , last accessed on 21 January 2022.
[316] Choudhary Asif, 14 pharmaceutical companies allowed to manufacture hepatitis C oral drug, DAWN, 17 October,2015, https://www.dawn.com/news/1213648 , last accessed on 3 February, 2022.

blockbuster drug the sale of Ferozsons raised from Rs. 2.5 billion to Rs. 9 billion with growth of 222% annually.[317]

4.9.1. Patent status of different HCV medicines in Pakistan

Ensuring access to affordable of HCV treatment by the new DAA is not an easy task. The state authorities if determined to promote equitable access to HCV treatment than they have to consider certain aspect very carefully. First of all, it is very important to clearly know about the patent status of different the DAA in that jurisdiction. Before adopting any strategy to deal with affordability of medicines it is very important to have knowledge about the patent status in that country as it helps to determine the different options available accordingly.

The patent status of different DAA in Pakistan is as that the primary patent for Sofosbuvir is not filed and other patent though filed but not granted. The patent for Declatasvir compound is withdrawn and for Declatasvir crystalline form is not filed. The patent for Ledipasvir compound is withdrawn and patent on Ombitasvir compound is filed but not granted. Patent is granted for glecaprevir compound and for pibrentasvir compound is filed but not granted yet. Glecaprevir/pibrentasvir is recommended by the WHO for the treatment of chronic the HCV infection.[318]

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[317] Hasan Taimor, "Pakistan drug companies rarely bring innovative products to market. Ferozsons broke the mould", Pakistan Today, January 10,2021, https://www.pakistantoday.com.pk/2021/01/10/pakistani-drug-companies-rarely-bring-innovative-products-to-market-ferozsons-broke-the-mould/ , last assessed on 5 January, 2022.

[318] Meds Pal, The Medicine Patents and License Database, Medicine Patent Pool, https://www.medspal.org/?keywords=PAKISTAN&product%5B%5D=Dasabuvir%2FOmbitasvir%2FParitaprevir%2FRitonavir+200%2F8.33%2F50%2F33.33+mg&product%5B%5D=Imatinib+100+mg&product%5B%5D=Sofosbuvir+400+mg&product%5B%5D=Sofosbuvir%2FDaclatasvir+400%2F60+mg&product%5B%5D=Sofosbuvir%2Fledipasvir+400%2F90+mg&countries%5B%5D=Pakistan&disease_area%5B%5D=Hepatitis+C+(HCV)&page=1 , last accessed on 6th February, 2022.

4.9.2. Pakistan as the member of Medicine Patent Pool licenses and bilateral agreement

In 2015 the Medicine Patent Pool entered into an agreement for declatasvir with Bristol Myers Squibb. By this agreement generic manufacturers were allowed to sell the drug in 112 countries and Pakistan is also one of these countries.[319] In 2018 AbbVie entered into a royalty free agreement with Medicine Patent Pool for glecaprevir/pibrentasvir to treat chronic HCV infection. This agreement enabled the generic manufacturers to sell their generic drug in 96 low- and middle-income countries and Pakistan is also included in the list.[320] In order to facilitate the access to HCV treatment Gilead took a very appreciate able step and gave license to generic manufacturers for Sofosbuvir, Ledipasvir, velpatasvir and voxilaprevir and their combinations. As per this agreement licensee is allowed to manufacture and sell in 112 low- and middle-income countries, Pakistan is also included in the list.[321]

4.9.3. Role of Drug Regulatory Authority of Pakistan (DRAP)

The DRAP and the Minister of State (Health) Sara Afzal Tarar should be praised for their efforts for making equitable and affordable access to HCV medicines. Sara Afzal Tarar advised in her speech advised the local manufacturers to complete the registration process quickly in term of quality, safety and effectiveness of their product (generic Sofosbuvir). As a response 16 companies applied for the registration of their generic

[319] Medicine Patent Pool, Declatasvir, November 2015, https://medicinespatentpool.org/licence-post/daclatasvir-dac , last accessed on 7 February, 2022.
[320] Medicine Patent Pool, Glecaprevir/Pibrentasvir(G/P), November 2018, https://medicinespatentpool.org/licence-post/glecaprevir-pibrentasvir-g-p, last accessed on 7 February, 2022.
[321] Gilead announces generic licensing agreement to increase access to hepatitis C treatment in Developing Countries, Gilead: Press Releases, September 15, 2014, https://www.gilead.com/news-and-press/press-room/press-releases/2014/9/gilead-announces-generic-licensing-agreements-to-increase-access-to-hepatitis-c-treatments-in- , last accessed on 8 February 2022.

Sofosbuvir and the DRAP to ensure the quality of product and accuracy of data on the spot inspection of the companies were made and it revealed that some provide fake information.[322]

Keeping in view the sensitivity of disease and importance of matter the DRAP take initiative and registered 9 local generic companies to produce HCV drug. To ensure quick availability of medicine the DRAP complete the registration process in two weeks. According to the law (Drug Pricing Policy 2015) the price of the generic drug will be 30% less than the original branded drug and accordingly it should be 26,000. Keeping in view, the high burden of disease, poor financial conditions of people of Pakistan and international trend about the reduction in Sofosbuvir price the DRAP set the price of generic Sofosbuvir RS.5,868 for 28 tablets. For this purpose, DRAP modify the provision of Drug Pricing Policy 2015 with the endorsement of Prime Minister.[323]

DRAP also provided consent to local manufacturing company to manufacture raw material, the Active Pharmaceutical Ingredient (API), for Sofosbuvir. After this approval Pakistan has become 5th country that can produce raw material for drug and this initiative make price more affordable.[324]

[322] Ministry of Information and Broadcasting, Government of Pakistan, PR No.104 Registration of generic version of new molecule, A breakthrough treatment drug for Hepatitis-C Islamabad, http://pid.gov.pk/site/press_detail/2596 , last accessed on 18 February 2022.
[323] Ministry of Information and Broadcasting, Government of Pakistan, PR No.104 Registration of generic version of new molecule, A breakthrough treatment drug for Hepatitis-C Islamabad, http://pid.gov.pk/site/press_detail/2596 , last accessed on 18 February 2022.
[324] Ministry of Information and Broadcasting, Government of Pakistan, PR No.104 Registration of generic version of new molecule, A breakthrough treatment drug for Hepatitis-C Islamabad, http://pid.gov.pk/site/press_detail/2596 , last accessed on 18 February 2022.

4.9.4. **Getz Pharma V Federation of Pakistan**[325]

Case was brought before the Sind High Court and a notification was challenged on the ground that Drug Pricing Mechanism (DPM) which is created under the DRAP Act 2012 (7 (c)(viii)) requires that the price of generic substitute should be 30% less than the original brand. Petitioner applied for the registration of the generic drug with a trade mark of Sofiget (Sofosbuvir 400mg). The price was fixed by the authorities at Rs. 5,868 which is not less than the 30% of the original brand but it is 15.4% of original brand price. Council for petitioner also contended that the Ferozsons was allowed to sell the HCV drug at the rate of Rs. 1,14,000 for three months treatment. The petitioner prayed that he may be permitted to sell Sofiget at the rate of Rs. 26,600 for 28 tablets as it is 70% of originator brand. Representative of Federation explain the court that from the period when the price of the originator was fixed till to-date the prices of Sofosbuvir fell down globally. The objective of fixing this low cost was to that the HCV treatment would be affordable for the poor people of Pakistan.[326]

When the council for the petitioner insisted again on this point that the price of generic be within 70% of original brand the court made a remark "that why not set the generic's price of Rs. 5,868/- as the baseline and let the respondent follow the formula of 30% increase in the originator's price i.e. Rs. 7,628.4 being 30% more than the price of the generic,". The representative from the Ministry of Health explained the court that the price one set cannot be decreased before four years or the entry of three generic.[327]

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[325] 2017 PLD 157 Kar. HC, https://caselaw.shc.gov.pk/caselaw/view-file/MTA3NTc4Y2Ztcy1kYzgz , last accessed on 7 February, 2022.
[326] Ibid.
[327] Ibid.

Court explained that though the Constitution of Pakistan did not provide the explicit provision for right to health however the right to life under article 9 and right to dignity of man under article 14 in court opinion give birth to "right to health". Court also gave reference to the International Convenient on Economic Social and Cultural Rights (ICESCR) which put obligation on state to provide health facilities and protect right to health. Court reaffirmed that state not allowed to favor expensive medicines just to facilitate few people. Court ordered to ensure access to affordable treatment as fundamental right. The price fixed for generic Sofosbuvir as Rs. 5,868 was declared as legal and petition was dismissed.[328]

4.10. Hepatitis C in India

Hepatitis prevalence rate in India is 0.5% to 1.5% and approximately 10 million people are affected with HCV. Limited data is available regarding HCV prevalence in India. Only few studies were conducted in few states of India so it could not provide exit data regarding nationwide prevalence.[329] According to an estimate in India every year more people are died from hepatitis then HIV/AIDS and tribal areas are more effected with the disease.[330]

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[328] Ibid.
[329] Gupta Varun et al., "Newer direct-acting antivirals for hepatitis C virus infection: perspective for India", *Indian Journal of Medical Research* v.146,1 (2017): 23-33, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5719604/pdf/IJMR-146-23.pdf , last accessed on 13 February 2022.
[330] Pondey Kundan and Singh Jyotsna, "Hepatitis C: India has failed to tackle the deadly disease", Down to Earth, 27 July, 2016, https://www.downtoearth.org.in/coverage/health/hepatitis-c-is-india-faltering-to-deal-with-the-disease--55078 , last accessed on 15 February, 2022.

4.11. Nation Viral Hepatitis Control Program in India

Taking into account the seriousness of issue National Viral Hepatitis Control Program was launched by the government of India from 2018-2019 with RS 600 crore budget. The idea behind to start this program was to treat and prevent people from viral hepatitis. Under this program free diagnosis, screening and treatment services are provided for all patients. Government negotiated price reduction with local manufacturer of HCV drug that are authorized under the Gilead license and try to convince them to reduce price for national program. Treatment cost negotiated with Punjab government was RS.7000 and Haryana succeed to negotiate less. However overall cost of HCV treatment is reduced all over the country and it is round about the RS.5000 per treatment.[331] Treatment through DAA is cost effective with short duration and it also enhances life expectancy approximately 8 years.[332]

4.12. Cost for the treatment of HCV in India

Treatment of HCV by DAA is very effective and safe but price of new DAA is very high in many countries and treatment is not affordable for many people. But in India the treatment of HCV is very affordable. Sofosbuvir, declatasvir and Ledipasvir are made by several local generic manufacturers in India and price is low. This low cost is even failed to scale up treatment rate and the reason is lack of budget for HCV and non-seriousness

[331] Ghosh Abantika, "Free treatment for HCV in new scheme to be launched this year", The Indian Express, 16 February 2022, https://indianexpress.com/article/india/free-treatment-for-hepatitis-c-in-new-scheme-to-be-launched-this-year-5016945/ , last accessed on 16 February 2022.
[332] Anand Abhinav and Shalimar, " Hepatitis C virus in India: Challenges and Success", *Clinical Liver Disease* vol 18, 3(2021) 150-154, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8518332/pdf/CLD-18-150.pdf , last accessed on 13 February 2022.

of government.[333] Studies conducted in India reveal that the use of generic DAA is not only cost effective but also save life time medical cost of treating late-stage disease. HCV when not timely treated may lead towards liver cancer or cirrhosis that resulted in high treatment cost.[334]

4.13. India as the member of Medicine Patent Pool and bilateral agreement

On 15 September, 2014 a big breakthrough occurred in HCV treatment by Gilead Science. The companies entered into a license agreement with seven Indian generic companies and allow them to manufacture generic Sofosbuvir to distribute in 91 low- and middle-income countries, the list of the countries is also provided by the Gilead. License agreement enables the Indian generic manufacturer to enjoy complete technology transfer regarding manufacturing process to scale up production rapidly.[335] Licensing agreement by Gilead is a significant step which helps the low- and middle-income countries to have affordable access to HCV treatment. This agreement is a step to achieve the humanitarian objectives of company.

Medicine patent successfully entered into an agreement with for DAA declatasvir with Bristol Myers Squibb in November 2015. Under this agreement generic

[333] Aggarwal Rakesh et al., Cost effectiveness of hepatitis C treatment using generic direct acting anti-viral, available in India. PLoS ONE 12(5) e0176503, https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0176503&type=printable , last accessed on 13 February 2022.
[334] Ibid.
[335] Press Releases: "Gilead announces generic licensing agreement to increase access to hepatitis C treatment in developing countries", Gilead: creating possible, 15 September 2014, https://www.gilead.com/news-and-press/press-room/press-releases/2014/9/gilead-announces-generic-licensing-agreements-to-increase-access-to-hepatitis-c-treatments-in-developing-countries , last access on 13 February 2022.

manufacturers are allowed to sale the drug in 112 countries and India is also included in these countries. These countries are the home of 65.4 % of the HCV burden globally.[336]

4.14. Patent status of different HCV medicines in India

Patent is granted in India for Sofosbuvir active metabolite (2005) and for Sofosbuvir process, intermediates & product by process (2011). Patent is rejected for Sofosbuvir active metabolite (2011) and for declatasvir synthesis process (2010) is also rejected. Some other patents other patent are also filed but not granted and patent oppositions are also filed against them like Sofosbuvir compound and declatasvir compound.[337]

In January 2015 the Indian patent office reject the patent application of Gilead for Sofosbuvir under section 3(d) of patent Act but after 18 months in May 2016 the patent office grants the same patent. This topic was hot among the social activists and criticised that the Indian patent office reversed the decision under pressure of USA. During this period,the USA president Barrack Obama also visit the India. It was reported that the officials who take the step to reject patent "faced a backlash"[338]

India is considered as the pharmacy of developing world. Low- and middle-income countries depend on India to fulfill their 76% need for antiretroviral drugs. Before 2005 pharmaceutical patent were not protected under the patent law of India and country

[336] Medicines Patent pool, Declatasvir, November 2015, https://medicinespatentpool.org/licence-post/daclatasvir-dac , last accessed on 28TH February 2022.
[337] Meds Pal, The Medicine Patents and License Database, Medicine Patent Pool, https://www.medspal.org/?product%5B%5D=Glecaprevir%2FPibrentasvir+100%2F40+mg&product%5B%5D=Glecaprevir%2FPibrentasvir+50%2F20+mg%2Fpellets&product%5B%5D=Ravidasvir&product%5B%5D=Sofosbuvir%2FDaclatasvir+400%2F60+mg&product%5B%5D=Sofosbuvir%2Fledipasvir+400%2F90+mg&countries%5B%5D=India&page=1 , last accessed on 14 February 2022.
[338] Padma T.V, "All you need to know: September's crucial verdict on the Sofosbuvir patent saga", Science the Wire, 3rd September, 2016, https://science.thewire.in/health/patent-sofosbuvir-hepatitis-gilead/ , last accessed on 16 February 2022.

promote generic competition. India amended its patent law to fulfill the WTO requirement and allow patent for pharmaceutical, but it included all safeguard to protect public health. Constant pressure is put on India by the multinational pharmaceutical companies to waive its public health safeguards.[339]

4.15. Conclusion

Pharmaceutical patents start protected after the implementation of the TRIPS agreement. The TRIPS provide protection to pharmaceutical patent but also provide safeguards to protect public health. During HIV/AIDS pandemic the issue of pharmaceutical patent and high prices criticized a lot and the world witnessed that the pharma greed killed millions of HIV/AIDS patients in low- and middle-income countries. World has learned a lot from the HIV/AIDS experience about how to control the misuses of patent monopolies and which strategies should be adopted by the state to control the uncontrolled prices of patented medicines. The WHO and other international institutions also started work to gather to control the misuses of patent by the pharmaceutical companies.

In Pakistan, the prices of the HCV treatment are very affordable and according to the WHO report prices in Pakistan are cheapest in the world. There are multiple reasons for this low price first is that the Pakistan is the member of Gilead license territory for DAA. Secondly DRAP registered 14 more generic companies for HCV medicine and it intensified the competition. Though Ferozsons claim that it has authorization of Gilead so DRAP should not register other generic companies to manufacturers but due to “no

[339] Ibid.

patent" DRAP allowed generic companies to manufacture and sell the drug. The price which is set by the authorities was challenged by the one of the generic companies (Getz Pharma) in the Sind High Court that price should be 30% less the originator brand but the price which was determined for the Gets pharma was very low. Sind High Court dismissed the appeal and maintains decision in favor of HCV patients. So, the registration of more generic firms, absence of patent and decision of Sind High court leads towards the low price of the HCV treatment in Pakistan.

India also successfully reduced the price of HCV treatment though the Indian patent office granted some of the key patent on HCV drug. The reason for the low price is the voluntary license that is given to the 11 Indian base generic companies by the Gilead to produce and sell the generic Sofosbuvir to the 101 low- and middle-income countries including India. These 11 local generic companies lead towards the competition and as a result reduced the price of the HCV treatment.

CHAPTER 5

AVAILABILITY AND AFFORDABILITY OF CANCER MEDICINES IN PAKISTAN AND INDIA

In recent years, there is a prominent increase in cancer cases worldwide and so is the case in Pakistan and India. Cancer treatment is very expensive and at time unaffordable even for developed states. In this chapter we will examine the situation of cancer treatment its cost and patent status and its effects on the affordability and availability of treatment in both jurisdictions i.e. Pakistan and India.

5.1. Cancer

Worldwide cancer has become second leading cause of death. In 2020, 10 million people died from cancer and it means one in six death accords from cancer.[340]. In 2020 highest number of deaths caused by the lung cancer, 1.80 million people died of it and 685,000 people died of breast cancer. In 2020 there were 2.6 million new cases of breast cancer and 2.21 million cases of lung cancer were diagnosis.[341] Deaths from cancer can be reduced if early diagnosed and treated properly. Cancer has many kinds and some kind of cancer like breast cancer and cervical cancer have high cure rate if diagnose early and treated by best practices. Treatment available for cancer have variation in different income countries, 90% of high-income countries have complete treatment options for

[340] Cancer, World Health Organization, February 2022, https://www.who.int/news-room/fact-sheets/detail/cancer , last accessed in 22 May 2022.
[341] Cancer, World Health Organization, 3rd February 2022 , https://www.who.int/news-room/fact-sheets/detail/cancer#:~:text=Key%20facts,and%20rectum%20and%20prostate%20cancers , last accessed on 1 March 2022.

cancer patient while only 15% of low middle income countries have inclusive treatment options.[342]

Cancer is the large cluster of multiple diseases that can infect any organ of the body. Cancer is the abnormal growth of cells, beyond their normal boundaries and it widen to other organ of body. In recent years cancer burden increased globally, it extremely effects the financial, physical and emotional life of the individuals, families, societies and health care systems. A large number of cancer patients, in low- and middle-income countries, have lack of access to cancer treatment as their health systems are not able to manage the disease burden.[343]

5.2. Causes of Cancer

Cancer is the formation of normal cells which turns into tumor. Cancer has different stages of its development it starts from precancerous lesion and turns into a malignant tumor. There are many factors which become the reason for the abnormal working of cells. It includes genetic factors and some external factors such as physical carcinogen, chemical factors for Cancer carcinogens and biological carcinogens.[344]

5.3. Risk factors for Cancer

Use of cigarette, consumption of alcohol, less physical activities, unhealthy diet, and polluted air are the common risk factors for cancer. Chronic infections are also

[342] Cancer, World Health Organization, 3rd February 2022 , https://www.who.int/news-room/fact-sheets/detail/cancer#:~:text=Key%20facts,and%20rectum%20and%20prostate%20cancers , last accessed on 1 March 2022.
[343] Cancer, World Health Organization, https://www.who.int/health-topics/cancer#tab=tab_1 , last accessed on 2 March 2022.
[344] Cancer, World Health Organization, February 2022, https://www.who.int/news-room/fact-sheets/detail/cancer , last accessed in 22 May 2022.

increase the risk factors for cancer. It is mostly common in low- and middle-income countries. According to a report of the WHO in 2018, 13% of cancer were the result of chronic infection including hepatitis B, hepatitis C, human papilloma virus HPV and Epstein virus. If risk factors are avoided properly then 30% to 50% cases of cancer can be reduced.[345]

5.4. Treatment for cancer

Proper and early diagnosis is the first and the foremost important step in cancer treatment. Cervical cancer, breast cancer, colorectal cancer and oral cancer have high cure rate if diagnosed early and treated with best practices. Treatment for cancer consisted of surgery, radiation therapy and a systematic therapy. Systematic therapy may include chemotherapy, targeted biological treatment or hormonal therapy. Selection of proper treatment according to the cancer type and individual capacity of patient and in time completion of treatment can give the best therapy results. First of all, it is also very important to set a target for cancer treatment. The primary goal might be to cure cancer or to prolong the life of patient (improving the patient's quality of life). Availability of comprehensive cancer treatment is varied in different jurisdictions as high income countries have 90% of treatment options but low-income countries have only 15%.[346]

5.5. Global Burden of Cancer

Cancer has become a serious concern for all economies and the burden of cancer is increasing every year. In 2008, there were 12.6 million cases of cancer, these numbers

[345] Ibid
[346] Ibid

increased in 2018 as 18.1 million and it is predicted that in 2040 there will be 29.4 million cases of cancer worldwide.[347] Every state observes increase in cancer cases from the last 20 years and in 2018, 9.6 million and in 2020, 10 million people died of cancer. It is also reported that 1 in 6 deaths occurs due cancer.[348] Children are also becoming the victim of cancer. Every year almost 400,000 children are diagnosed with cancer. There is no specific known cause for cancer in children. According to the latest studies, there are only few types of cancer which are caused due to daily life or environmental factors. Only 10% of children diagnosis with cancer have genetic factor. However, further research is required to identify the reasons behind the cancer in children.[349]

Cancer is the leading cause of death for children and adolescence. Children in developing countries are also at high risk of cancer. Cure rate of cancer for children is varying in different jurisdictions as in high income countries cure rate is over 80% while in low middle income countries it is less than 30%. Reasons for this poor cure rate are multiple including delay diagnosis or mis-diagnosis, lack of accessing accurate care and discontinuation of treatment. Cure rate would be increased up to 80% if proper services for cancer treatment are provided it includes affordable generic drugs and the list of the Essential Medicines provided by the WHO for children. After the completion of treatment proper monitoring is required periodically to check the long-term effects of cancer treatment and reappearance of disease.[350] It can be predicted that less productivity

[347] the WHO Report on Cancer: Setting Priorities, investing wisely and providing care for all, Geneva: World Health Organization; 2020. License: CCBY-NC-SA 3.0 IGO, 29,file:///D:/chapter%205/who%20and%20cancer/who%20report%20on%20cancer%202020.pdf , last accessed on 14 March 2022.
[348] Ibid, p 17.
[349] the WHO, Childhood Cancer, 13 December, 2021, https://www.who.int/news-room/fact-sheets/detail/cancer-in-children , last accessed on 27 May 2022.
[350] Ibid.

and premature deaths would cost more loss to developing countries especially cancer hit the one who is the sole earner of his whole family consisting of 6 to 7 members.

World Health Assembly in its resolution acknowledge that in developing country huge number of cancer patient effect the development of state especially when the most productive group of society (young people) unable to perform their role. The WHO recognized that there are high number of morbidity and mortality rate due to cancer and this is an alarming situation for developing countries and there is need to provide adequate funding to start cancer prevention and control program with quality treatment access.[351]

Cervical cancer is fourth most common cancer among women. One woman died in every two minutes from cervical cancer. In 2018, worldwide the number on women diagnosis with cervical cancer was 570,000 and 311,000 died from it.[352] 85% of cervical cancer cases are take place in developing countries. It is curable if diagnosis early but delay diagnosis causes lot of causalities in low middle income countries.[353]

In recent years, a lot of efforts and innovations are made for the improved treatment of cancer however the uptake of these technologies and medicines is limited to the high-income countries. There are a lot of inequalities among the nation regarding the

[351] Resolution and decisions, Cancer prevention and control, WHA58.22, https://apps.who.int/iris/bitstream/handle/10665/20372/WHA58_22-en.pdf?sequence=1&isAllowed=y , last accessed on 30th May 2022.
[352] the WHO, Cervical cancer, https://www.who.int/health-topics/cervical-cancer#tab=tab_1 , last accessed 31 May 2022.
[353] Milena Alec and Dierre Vassilakos, Cervical cancer in developing countries, https://www.gfmer.ch/ccdc/cervical-cancer.htm , last assessed 31 May 2022.

availability of cancer treatment. The WHO report on cancer highlights that early detection and proper treatment facilities can save the life of 7 million people till 2030.[354]

Cancer has a very strong socio and economic effects. It affects the patient, his friends, family and the whole society. Cancer treatment is very expensive and unaffordable for many people all around the world but the situation is worst for developing countries. This is the reason that cancer is considered as the second name of death for poor people. The treatment of cancer is available but prohibitively expensive and this situation distress patients and their families financially and psychologically. Cancer burden seriously affects the economy of a country as absence from work result in less productivity and premature death also create a gap in form of loss of workforce contribution. According to a study conducted in China, India, Brazil, South Africa and Russia in 2012 and revealed that these states faced a loss of 46.3 billion dollar due to premature deaths.[355]

5.6. The WHO and Cancer

The WHO realized very well about how much cancer is affecting the world and that low- and middle-income countries have high burden of cancer with limited financial resources. World Health Assembly passed a resolution in 2017 for the prevention and control of cancer. The WHO puts its political commitments into action and takes other

[354] the WHO Report on Cancer: Setting Priorities, investing wisely and providing care for all, Geneva: World Health Organization; 2020. License: CCBY-NC-SA 3.0 IGO, 23,file:///D:/chapter%205/who%20and%20cancer/who%20report%20on%20cancer%202020.pdf , last accessed on 13 May 2022.
[355] the WHO Report on Cancer: Setting Priorities, investing wisely and providing care for all, Geneva: World Health Organization; 2020. License: CCBY-NC-SA 3.0 IGO, 23,file:///D:/chapter%205/who%20and%20cancer/who%20report%20on%20cancer%202020.pdf , last accessed on 16 May 2022.

initiatives to control cancer.[356] The WHO in its resolution emphasized that death from cancer can be mitigate if proper measures are adopted at national and international level. It highlights that there is dire need effective, safe and affordable treatment, adequate technology, diagnosis and screening of cancer. It concluded that all these efforts are possible with national commitments and international cooperation. This resolution appreciates the pharmaceutical sector for their investment in research and innovation to treat cancer patient and also show great concern for unaffordable high cost of treatment. It reiterates the member states to use the TRIPS flexibilities to increase safe and affordable access to cancer treatment.[357]

The WHO launched two global initiatives to control cancer mortalities first is the "Global initiatives for childhood cancer" and second is the "Elimination of the cervical cancer as public health problem". In 2018 the WHO take another important step to save the life of million children who suffered from cancer each year. It started the Global Initiative for Childhood Cancer. The objective of this program was to provide assistance and support to the member states and enable them to start high quality cancer program for children. The WHO set a target to achieve more than 60% survival rate for childhood cancer till 2008. This target is actually double then the current cure rate. St. Jude Children's Research Hospital and the WHO are working very actively for childhood cancer. As in 2021 they, with mutual efforts, launched "Global Platform for Access to

[356] Ibid.
[357] Seventieth World Health Assembly, Cancer prevention and control in the context of an integrated approach, WHA 70.12(2017), https://apps.who.int/iris/bitstream/handle/10665/275676/A70_R12-en.pdf?sequence=1&isAllowed=y , last accessed on 30th May, 2022.

Childhood Cancer Medicines". This platform provides quality cancer medicines for children without any interruption with all standards of care.[358]

The WHO took another initiative for cancer as Elimination of cervical cancer as public health problem. The global strategy was outlined to eliminate cervical cancer and set a goal for all countries to achieve not more than 4 cases per 100,000 women for cervical cancer. This goal is supported by three pillars first is to prevent, second is to screen and third is to treat the pre-cancerian lesions by early diagnosis.[359]

In 2019 the WHO, for the first time, prequalified a bio-similar of trastuzumab which is used to treat breast cancer and provide the patients of breast cancer an opportunity to have effective and affordable treatment. General Director of the WHO, in 2020 the WHO provides a global strategy to eliminate cervical cancer.

5.7. Cancer in Pakistan

Cancer is the main cause of death all around the world and so is the case in Pakistan. However, limited data is available for cancer morbidity and mortality on national level and available data provide statistics about different region like Lahore or Karachi. After 18th Amendment health became the provincial subject so there is lack of research and co-ordination among provinces regarding cancer statistics. There is dire to mobilize the national efforts to collect data about cancer morbidity and mortality and possible risk factors to control the prevalence of cancer.

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[358] the WHO, Childhood Cancer, 13 December, 2021, https://www.who.int/news-room/fact-sheets/detail/cancer-in-children , last accessed on 27 May2022

[359] Seventy third World Health Assembly, WHA 73.2, Global Strategy to accelerate the elimination of cervical cancer as public health problem, 2020, https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R2-en.pdf , last accessed on 31 May 2022

For our research we get data about cancer in Pakistan from Globocan.[360] Pakistan ranked number 5th with 251.3 million populations (2024). In Pakistan numbers of new cancer cases diagnosed in 2020 were 178,388 including 88,015 men and 90,373 women. The numbers of deaths in 2020 due to cancer were 117,149 and numbers of prevalent cases in 2020 were 329,547.[361] Lip and oral cancer is more common in men with 12.9% (11,395 patients) and breast cancer is more common in women with 28.7% (25,928 patients).[362] There is apprehension that actual incidence of cancer in Pakistan might be more than this as there is no proper system for registration of cancer cases and coordination among the provinces on data sharing is also missing. Due to the limited cancer treatment options and expensive diagnosis process it is quite possible that many cancer patients remained without diagnosis particularly in rural and undeveloped areas of Pakistan.

Breast cancer is the most common in Pakistani women as in 2020 almost 26,000 women are diagnosed with breast cancer and 13,500 died of it. In Asia, Pakistan has the highest burden of breast cancer. According to the health experts lack of awareness and limited treatment options are the main reason for this high mortality rate. Early screening and proper treatment is very important to save the patient life but in Pakistan both of these opportunities are not easily available. Women in Pakistan are very reluctant to share this disease as they considered breast as a "secret organ". Lack of female oncologist makes the situation worst; breast check up by the male oncologist made the women more

[360]Globocan is an international online data base that provides cancer statistics and mortality rates of 185 countries. It works under International Agency for Research on Cancer with collaboration of the WHO.

[361] International Agency for Research on Cancer, Pakistan: Globocan 2020, https://gco.iarc.fr/today/data/factsheets/populations/586-pakistan-fact-sheets.pdf , last accessed on 7th June 2022.

[362] Ibid

reluctant for treatment and this situation leads towards late diagnosis. Religious and cultural barriers also added towards no treatment. Married women fear of that their husband might go for second marriage and unmarried women fear of due to this disease no man will marry her. This is the reason that 89% of cases of breast are diagnosed at a late stage and difficult to cure and treat.[363] There is need to create awareness in women that if breast cancer diagnosed early then it might be cured without surgery. There is need to train more female oncologist and awareness campaign should be organized to encourage women for proper screening and convey to them that early diagnosis will result in successful treatment.

Cervical cancer is very common in women, after the breast cancer, especially who are under the age of 50 years. Cervical cancer is curable if diagnosed early but mortality rate is very high in Pakistan as over 70% of patient diagnosed at late stage. Exact data about the cervical cancer is not available in Pakistan as it is an ignored disease. 98% of deaths by cervical cancer occur in developing countries and reason is no vaccination and late diagnosis. In Punjab a cross-sectional study was conducted the result revealed that 72% cases of cervical cancer belong to lower income group of Punjab. Risk factor for cancer includes unprotected sex, sex in early age, early reproductive cycle, poor economic conditions, HPV infection etc. Young women are at great risk of cervical cancer with advance stage of disease in Pakistan.[364]

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[363] S Khan, "Pakistan: How patriarchy is raising the risk of deadly breast cancer," Made for Minds, https://www.dw.com/en/pakistan-how-patriarchy-is-raising-the-risk-of-deadly-breast-cancer/a-59755880 , last accessed on 7 June 2022.

[364] Syeda Asma Batool, Sumera Sajjad and Husna Malik, "Cervical cancer in Pakistan", *Journal of the Pakistan Medical Association,* Vol67,7(2017): 1074-1077, https://jpma.org.pk/article-details/8281 , last accessed on 9th June 2022.

The WHO revealed that cervical cancer prevalence is increasing in Pakistan as in 2002 there were 9 cases of cervical cancer in 100,000 but it was increased in 2008 from 9 to 19. Though these cases are less than the developed countries but mortality rate is much high due to the late diagnosis. In Pakistan almost 20 cases of cervical cancer reported daily and Pakistan is among the top ten countries which has highest mortality due to cervical cancer.[365]

5.8. Treatment facilities for cancer patients in Pakistan

In Pakistan, the treatment facilities for cancer patient are quite inadequate. The Shoukat Khanam Memorial Hospital is only one private sector hospital which has all the facilities to treat cancer. Due to the limited capacity,the Shoukat Khanam never treat the patient with advance stage. They used their means for those whom have more chances to cure. The PAEC (Pakistan Atomic Energy Commission) has eighteen hospitals to treat cancer in different districts of Pakistan but these hospitals have limited capacity and cannot provide treatment to all cancer patients.

In government hospital the treatment facilities for cancer patient are inadequate. Cancer medicines are not available on regular basis and radiation machines are also available in few numbers. Most of the radiation machines are out of order or non operative due to this situation the burden is increased on the working machines. Five to eight month is a normal time period which is given to the cancer patient for his turn and during this waiting period many of the cancer patients died. Radiation though not cured

[365] Rahat Kamal, "Pap smear: the life saving test", THE EXPRESS TRIBUNAL, November 17, 2014. https://tribune.com.pk/story/790620/pap-smear-the-life-saving-test , last accessed on 10th June 2022.

but control the pain which is unbearable in advance stage of disease.[366] Government hospitals in Pakistan have miserable conditions for providing cancer medicines. Medicines are provided but not on regular basis as due to shortage of funds or for any other reasons no one knows when the supply of medicines stopped and for how much time.

As we see on 19 September, 2019 cancer patients protested in front of Punjab Assembly because the Jinnah and Mayo hospital administration refused to give cancer medicines from the last two months and the treatment of the patient were stopped. Hospital administration said that the government of Punjab has withdrawn its program due to the lack of funds. Cancer patients revealed during the protest that some of them will die due to the non-availability of medicines and will not join the next protest. Cancer medicines are not affordable for poor patient and also not easily available in the market. This non availability and non-affordability make the situation worst for patients.[367]

On 18 February, 2020 a protest was made by the Prof. Dr. Masood-ur-Rauf with a large number of people in front of MS office against the shortage of life saving medicines in Nashter Hospital Multan. They warned that if the problem was not addressed in few days, they will go for strike. They also highlighted that many cancer patient died in last six months due to the shortage of medicines.[368]

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[366] Shahzada Irfan Ahmad, "For less than required: Special Report", TNS, 15 October, 2017, https://www.thenews.com.pk/tns/detail/564185-far-less-required , last accessed on 8th June 2022.
[367] The Newspaper 's staff Reporter, " Cancer patients in Lahore protest denial of free drug", DAWN. September 19, 2019, https://www.dawn.com/news/1506003 , last accessed on 8th June 2022.
[368] By our Correspondant, " Shortage of life saving drugs at Nishtar Hospital: Doctors stage demo, take out relly in Multan", International THE NEWS. February 18, 2020,

On 11 March, 2021 cancer patients were assembled at Kalma Chowkand stop the Metro Bus service as a protest and they demanded to keep continue the delivery of cancer medicines as it was stopped by the government. This protest was also against the increased cost of Gleevec a cancer medicine which is equally important like oxygen for patients. Cost of Gleevec was 0.4 million for one month treatment which was unaffordable for many people in Pakistan.[369]

Another protest by the cancer patient was organized on 12 May, 2022 against the laziness of Punjab government for failure to supply cancer medicines in four hospitals of Punjab. More than 5,500 patients were registered and getting medicines from these five hospitals. Patient reported that continuous use of these medicines is very important to save their lives and their doctor also advised to use these medicines regularly but due to stoppage of medicine by the government the cancer patient have to abandon their treatment.[370]

Treatment for cancer is very costly and almost unaffordable in Pakistan. In government sector facilities are not available properly as stated above and in private sector though the facilities are available but the cost of cancer treatment is so high that majority of people cannot pay it. The average cost of radiation for 15 days treatment is about RS. 300,000 to RS. 500,000. Medicine of cancer is also very high cost. Cancer medicines are not manufacture in Pakistan and most of the drugs are imported. Local

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https://www.thenews.com.pk/print/615775-shortage-of-life-saving-drugs-at-nishtar-hospital-doctors-stage-demo-take-out-rally-in-multan , last accessed on 8th June 2022.

[369] M A Zubairy, "Cancer patient against non-provision of free medicines", BUSINESS RECORDER. March 11, 2021, https://www.brecorder.com/news/40072401/cancer-patients-protest-against-non-provision-of-free-medicines , last accessed on 8th June 2022.

[370] Asif Chaudhry, " Lahore's cancer patients protest disruption of medicine supply", DAWN. May 12, 2022, https://www.dawn.com/news/1689162 , last accessed on 8th June 2022.

manufacturing can make the situation better and prices affordable. Herceptin a cancer drug (injection) which is imported in Pakistan cost 130,000 but the same medicine is available in India INR 5000.[371]

The Drug Regulatory Authority of Pakistan determines the prices of medicines in Pakistan. The DRAP works under the authority of federal government and Drug Act 1976 did not provide any transparent calculation formula for price fixation. The WHO conducted a survey to evaluate the prices of branded and generic drugs and revealed that prices in Pakistan are high for 3.30 to 2.26 time then the international price practices. Affordability is the matter of great concern for patients in Pakistan as 45.5% of population living beyond the line of poverty. Treatment of cancer in Pakistan is very difficult and adversely affect by many factors. There is a lack of data about the actual number of cancer patients, inadequate provisions about the health facilities which result in the pitiable availability of cancer drugs. New and advance treatment of cancer is unaffordable due to the limited resources and doctors avoid to prescribe such new patented medicines.[372]

Only 2% of the cancer drugs are locally produced and rest of the cancer drugs are imported from India, USA, UK and China. More than 50 % of cancer drugs are imported from India to treat different types of cancer. These cancer medicines especially of Indian origin are not entered in Pakistan by legal way but these are smuggled medicines. These smuggled medicines are often include fake, low quality and suspicious generics which

[371] Shahzada Irfan Ahmad, "For less than required: Special Report", TNS, 15 October, 2017, https://www.thenews.com.pk/tns/detail/564185-far-less-required , last accessed on 8th June 2022.
[372] M. Rehan Sarwat et.al., "Availability of anticancer medicines in public and private sector, and their affordability by low, middle and high income class patients in Pakistan", BMC Cancer, vol18,14(2018). https://bmccancer.biomedcentral.com/track/pdf/10.1186/s12885-017-3980-3.pdf , last accessed on 20 June 2022

badly affect the health of the cancer patient. After the treatment of months and spending thousands of rupees, patient came to know that the smuggled medicines they were using are ineffective or of low quality.[373]

Indian medicines are of good quality and cheap than the medicines imported from UK, USA and China but when these medicines entered by illegal means then it becomes difficult to maintain a particular temperature failure, to which made the medicine ineffective and ultimately it badly affects the health of cancer patient. Cancer medicines are used regularly and if supply is suspended then it may result in the death of the patient whose life is depending on regular supply.[374] It is the duty of the government of Pakistan and the DRAP to look into the matter and make the importation of generic drugs through legal means and also take some special initiatives for local manufacturing of the cancer medicines.

5.9. Pakistan's Pharmaceutical Sector

Pakistan is ranked at six in world for having a large number of populations but share of Pakistan in global pharmaceutical market is 0.31% only. Currently there are total 329 pharmaceutical companies in which 350 are national companies and 29 are multinational companies. Pakistan has faced a lot of challenges in its health sector due to its poor economic condition and huge population. At the time of independence there were no pharmaceutical industry in Pakistan and local needs were fulfilled by the imports of

[373] M. Waqas Bhatti, " Cancer patient suffer as spurious medicines of Indian origin being smuggled into Pakistan", INTERNATIONAL THE NEWS. DECEMBER 21, 2019, https://www.thenews.com.pk/print/586215-cancer-patients-suffer-as-spurious-medicines-of-indian-origin-being-smuggled-into-pakistan , last accessed on 23rd June 2022.
[374] M. Waqas Bhatti, " Cancer patient suffer as spurious medicines of Indian origin being smuggled into Pakistan", INTERNATIONAL THE NEWS. DECEMBER 21, 2019, https://www.thenews.com.pk/print/586215-cancer-patients-suffer-as-spurious-medicines-of-indian-origin-being-smuggled-into-pakistan , last accessed on 23rd June 2022.

the medicines. Government of Pakistan realized the need for pharmaceutical industry and two units were created; one was "Khuram Chemicals Limited" and the other was "Antibiotics Private Limited". Pharmaceutical industries were flourished during this period and get a prominent position in Asia.[375]

Pharma sector of Pakistan entered into another phase; the government introduces the Drug Act 1972 (Generic names). It was first time in the world that a generic medicine was promoted. The objective of this Act was to encourage the generic drugs and for this purpose it was prohibited to use brand name on the product and doctors was advised not to use the brand name of product on the prescription. This legislation encouraged the local manufacturers to compete with multinational pharmaceutical companies and it was expected that this competition led towards the lower prices of medicines. But in 1975, the license of 38 companies was cancelled due to the substandard product, the cancelation adversely affects all the companies hence the export market also affected.[376]

In 1991 a new period was started and under the policy of free play the local companies were allowed to fix price like multinational companies and led the national companies to flourish. However local companies provided medicines on lower prices and also succeeded in winning the government tender to supply medicines in government

[375] M. Asif and M. Usman Awan, "Pakistan Pharmaceutical Industry in WTO regime- issues and prospects" Institute of Quality and Technology Management, University of the Punjab Lahore, Pakistan, http://pu.edu.pk/images/publication/PPI_in_WTO_%20regime-Issues_and_Prospects.pdf , last accessed on 14 June 2022.

[376] Zaheer-ud-din Babar et al., " The Pharmaceutical Industry, Intellectual Property Rights and Access to medicines in Pakistan", *ResearchGate*, https://www.researchgate.net/publication/304819584_The_PharmacthEUtical_Industry_Intellectual_Property_Rights_and_Access_to_Medicines_in_Pakistan , last accessed on 14 June 2022.

hospitals. MNCs adopt marketing strategy and influence the doctors to prescribe their branded medicines in return of different incentives.[377]

New patent regime of Pakistan is formed keeping in view the international standards and it is blamed that the regional needs and benefit of local pharmaceutical industry is totally ignored. Multinational companies keep full eye on patent law of Pakistan and take full advantage of flexible patent provisions and won many court cases against the local pharmaceutical companies. Local pharmaceutical industry put the burden on PPO (Pakistan Patent Office). Local industry blamed that PPO is not able to deal with the challenges which were imposed by the TRIPS agreement.[378]

GlaxoSmithKline challenged the manufacturing of Lamivudine, a hepatitis B medicines, by a regional company Biocare. The ADJ (Additional District Judge) passed an exparte interim order and stopped the Biocare from manufacturing and selling disputed Lamivudine. Later on Biocare provide two arguments in its favour, the first was that the process of making Lamivudine by Biocare is different from the GlaxoSmithKline and also provided the details of its process. The second argument was that the basic patent o Lamivudine was expired on 7th February, 2006 and the subsequent patent was the patent of addition which also expires with the basic patent. ADJ dismissed the application for interim injunction but the High Court issued an interim and stopped the Biocare from manufacturing and selling the disputed product. Biocare filed an appeal to

[377] M. Asif and M. Usman Awan, "Pakistan Pharmaceutical Industry in WTO regime- issues and prospects" Institute of Quality and Technology Management, University of the Punjab Lahore, Pakistan, http://pu.edu.pk/images/publication/PPI_in_WTO_%20regime-Issues_and_Prospects.pdf , last accessed on 14 June 2022.

[378] Zaheer-ud-din Babar et al., " The Pharmaceutical Industry, Intellectual Property Rights and Access to medicines in Pakistan", *ResearchGate*, https://www.researchgate.net/publication/304819584_The_Pharmacthe EUtical_Industry_Intellectual_Property_Rights_and_Access_to_Medicines_in_Pakistan last accessed on 14 June 2022.

Supreme Court but Supreme Court ordered that the order of the high court is just and proper.[379]

In Merk verses Hilton Pharma the single judge of High Court Sind decided the matter in favor of patent holder. The precise facts of the case are as that during the patent period the defendant successfully obtained market approval for the sale of patented product. The defendant raised the following arguments that it is a premature suit because the disputed product had not been launched and defendant also claimed that the process of making disputed product is different from the plaintiff. High Court rejected these defenses and held that under section 30(1)(3) it is not necessary that actual infringement occurred and suit is maintainable if there is probability that infringement will occur. It is the TRIPS plus obligation in the patent law of Pakistan. It was also decided that the burden of proving the fact that the disputed product made of different process would be on defendant otherwise it will be presumed that the plaintiff's patented process is used.[380]

Additional District Court of Islamabad in a case named as Lily verses Werrick (a local company) decides, without full trial, that infringement of patent is occurred. The court decided that by putting disputed product in the market the defendant violate the decree of the court and proceeding were started for the execution and enforcement of decree by the plaintiff.[381]

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[379] Shire Biochem Inc. Versus English Pharmcuetical Industry, Lahore High Court Lahore, CLD 1038,2006, https://pakistanlaw.pk/case_judgements/46862/shire-biochem-inc-versus-english-pharmacthe EUtical-industries#comments , last accessed on 17 June 2022.
[380]Hasan Irfan Khan, " Recent Trends in Ptent Enforcement", United Trademark and Patent Services, 2008, http://www.buildingipvalue.com/08_AP/223-225UnitedTrademark.pdf , last accessed 17 June, 2022.
[381] ibid

It is the duty of the patent office to keep all the flexibilities of the TRIPS in mind while making its laws and policies. Article 7 of the TRIPS affirms that the objectives of IPRs are to benefit both the parties i.e. users of technology and the producers of technology. The IPRs should be used for the mutual benefit of producers and users of technology and it must be use in a way to promote technology transfer, dissemination of knowledge and social and economic welfare.

Implementation of strict IPRs will decrease the option for domestic firms to flourish and take benefit from existing patent system. Though Pakistani legal system provides TRIPS flexibilities but practical use of these flexibilities for the benefit of local industry is not seen. To-date no compulsory license is issued. Patent office is granting patent frequently irrespective of this thing that the patent holder manufacture drug locally or imported it. Local industry also claimed that if proper, effective and comprehensive examination of patent application is not made it will lead towards the ever-greening of patent and a lot of new patents, hence patent term will exceed from twenty years.[382]

It is claimed that due to the current legal system and strict IPRs protection most of the cases are won by the multinational companies. Local industry claims that patent law should not be misused by the multinational pharmaceutical companies. On the other hand, Pakistan revised its intellectual property regime to make it the TRIPS compliance and to fulfill international standards. Pakistan intellectual property laws have made all statutory changes and now it is up to right holder to claim his right by the court of law.

[382] Zaheer-ud-din Babar et al., " The Pharmaceutical Industry, Intellectual Property Rights and Access to medicines in Pakistan", *ResearchGate*, https://www.researchgate.net/publication/304819584_The_PharmacthEUtical_Industry_Intellectual_Property_Rights_and_Access_to_Medicines_in_Pakistan last accessed on 14 June, 2022

But after all these efforts and after annoying the local industry the Pakistan IP laws are still criticized that these laws provide week protection to IPRs as Pakistan was on the watch list of the US Trade Representative in 2011.[383] Pakistan should learn from its experiences and by keeping itself the TRIPS agreement complained should promote local industry and needs of its people.

5.10. Local production of cancer medicines in Pakistan

Pakistan's Pharmaceutical Industry produce only 2% of the cancer medicines used in Pakistan, more than 50% of medicines used in Pakistan to treat cancer are of Indian origin and rest of the medicines are purchased from China, the Europe and United States. We share a long border from India and the relationship of both countries are not good due to which legal channel for importation are often closed so medicines reached to the patient by the illegal importation. This illegal importation increased the risk of ineffective and fake generic medicines. Due to this illegal importation, it becomes difficult to maintain the required temperature and this leads towards the no or less efficiency of the medicines.[384]

In Pakistan, oncologists prescribe conventional anticancer medicines and avoid prescribing new and patented anticancer medicines because these medicines are not affordable for majority of people in Pakistan. The most prescribed medicines to treat

[383] Ibid.
[384] M. Waqas Bhatti, " Cancer patient suffer as spurious medicines of Indian origin being smuggled into Pakistan", INTERNATIONAL THE NEWS. DECEMBER 21, 2019. https://www.thenews.com.pk/print/586215-cancer-patients-suffer-as-spurious-medicines-of-indian-origin-being-smuggled-into-pakistan

cancer in Pakistan are etoposide, cyclophosphamide and cisplatin. These medicines are affordable and generic of this medicine is also easily available in the market.[385]

Cyclophosphamide discovered in 1950 and it became a useful chemotherapy for patient of cancer. It was approved by FDA in 1959 as eight anti-cancer agents (cytotoxic). It includes in the essential medicine list of the WHO.[386] Cisplatin is used for chemotherapy and known to cure testicular cancer. It also used to treat other cancer as lung, cervical, bladder, and ovarian cancer. Cisplatin was discovered in 1965 by Barnett Rosenberg, PhD. It was an accidental because at that time it was believed that Platinum has nothing to do with biological activity. It was observed that platinum compound can block the cell division. It took two more years to identify the actual compound that control the cell division and named that compound as cisplatin. Testing was started on mice to observe whether cisplatin effect on tumor to block its cell division. They found positive result and in 1972 the trials were conducted on human to treat cancer tumor and got successful results. In 1978 it got FDA approval to treat cancer patient. Research is still ongoing and thousand analogies of cisplatin are developed with efforts to mitigate its toxic side effects.[387]

In 1966 Etoposide was first synthesized and it got approval from FDA to treat cancer in 1983. It is used as chemotherapy medication and help to treat different types of cancer. It is used in tablet and injection form. It is included in the "Essential Medicines" List of

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[385] M. Rehan Sarwat et.al., "Availability of anticancer medicines in public and private sector, and their affordability by low, middle and high income class patients in Pakistan", BMC Cancer, vol18,14(2018). https://bmccancer.biomedcentral.com/track/pdf/10.1186/s12885-017-3980-3.pdf last accessed on 20 June, 2022

[386] Cyclophosphamide, Wikipedia, https://en.wikipedia.org/wiki/Cyclophosphamide

[387] "The "Accidental" Cure-Platinum-Based treatment for cancer: The Discovery of Cisplatin", National Cancer Institute, 30th May, 2014. https://www.cancer.gov/research/progress/discovery/cisplatin last accessed on 20 June 2022

the WTO.[388] It shows that the patients in Pakistan are relying on the old treatment and they are not getting benefits from the new and advance technologies as these technologies are unaffordable for them. Pakistan just providing protection to foreign patent monopolies and our poor cancer patients are nor treated with new patented medicines due to high prices. It means our patent system work for the benefit of produces and not for the users as they are relying on the off-patented cancer medicines.

5.11. Patent status of different cancer medicines in Pakistan

In Pakistan it is very difficult to know the patent status of any medicines. IPO of Pakistan is unable to design a user-friendly website. It did not provide a database where patent information is provided. It provides a difficult procedure if anyone want to know the patent status of a medicine than the interested person has to fulfill a form along with the prescribe fee and then wait for the reply from the IPO. This is the reason that this highly important area is not worked by the researchers. There is no research available on the patent status of cancer medicines in Pakistan. For this research we got information from MedsPal a database developed by the Medicine Patent Pool and PAT-INFORMED hosted by the WIPO.

Sorafenib brand name Nexavar is an anti-cancer drug which is used to treat liver and kidney cancer. Bayer filed patent for Sorafenib on 06 March 2008 which was granted with patent number 142370.[389] The price of patented Nexavar (Sorafenib) in Pakistan is RS. 120,000 for a pack of 6o tablet of 200mg. It is prescribed by the oncologist as 2

[388] Alessandra Montecuco et. al., "Molecular Mechanism of Etoposide", EXCLI Journal, vol 14(2015) 95-108. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4652635/ last accessed on 21 June 22.
[389] Pharmaceutical composition comprising an omega-carboxyaryl substitutes diphenyl urea for the treatment of cancer, PAT-INFORMED: Patent Information initiative for medicines, https://www.wipo.int/patinformed/ last accessed on 23 June 2022.

tablets 2 times in a day it means a patient have to take 4 tablets (800mg) a day. One-month treatment cost of patented Nexavar is approximately is RS. 240,000. Nexavar might be used with combination of other chemo drugs according to the type of cancer and advance stag of disease and in this situation per month treatment cost might be double[390]

Nilotinib brand name Tasigna is an anticancer drug. Novartis filed patent for Nilotinib Benzamide free base and salt on 17 September, 2006 which was granted on 25 April, 2016. Novartis also filed another patent on compound formula and process to prepare these compounds used to treat the cancer. Patent on compound formula was also filed 3rd September, 2003 and granted on 24 November 2015 with patent number 147073.[391] Price of Nilotinib (Tasigna) for a pack of 120 capsules (150mg) is RS. 342,000. Oncologist prescribed 2 capsules twice a day (4 capsule in a day). Per month treatment cost of Nilotinib (Tasigna) without any combination of other chemo drug is RS. 342,000.[392]

Imatinib brand name Glivec used to treat patients. It helps to stop the growth of cancer cells or slow their growth. Novartis filed a patent for Imatinib tablet and was granted subsequently. The expected expiry of Imatinib patent is 22 April 2023.[393] The price of 400mg tablet of Glivec is 135,000 for 30 tablet of 400 mg. Glivec is recommended by oncologist twice a day so treatment cost of a month is approximately

[390] Nexavar Tablet 200 mg, Medical Store, 17 May, 2021, https://medicalstore.com.pk/product/nexavar-tablet-200-mg-6x10s/ last accessed on 23 June 2022.
[391] Nilotinib, PAT-INFORMED: Patent Information initiative for medicines, https://www.wipo.int/patinformed/ last accessed on 23rd June 2022.
[392] Tasigna capsule 150mg, Medical Store, 7 May 2021, https://medicalstore.com.pk/product/tasigna-capsule-150-mg-120s/ last accessed on 23rd June, 2022.
[393] Meds Pal, Medicine Patent Pool, https://www.medspal.org/?countries%5B%5D=Pakistan&disease_area%5B%5D=Cancer&product%5B%5D=Imatinib+400+mg&page=1 last accessed on 23rd June 2022.

270,000 without combination of any other chemo drug.[394] Above mentioned is just the cost of the one month treatment excluding the cost of consultancy, diagnosis, surgery and radiotherapy.

The drug Osimertinib, marketed as Tagrisso, is patented by AstraZeneca in Pakistan. It is a targeted therapy for non-small cell lung cancer with specific genetic mutations.[395] Oncologist prescribed one capsule of 80 mg twice a day and approximate cost of one month treatment is approximately is 490,000 without combination.[396]

Palbociclib brand name Ibrance is patent of Pfizer. Patent is granted in Pakistan for Palbociclib.[397] Usually Oncologist prescribed one capsule of 125 mg twice a day and approximate cost of one month treatment with Palbociclib is RS. 400,000/.[398]

One third population of Pakistan is living beyond the line of poverty. Monthly earning in Pakistan is at USD 150 which is approximately 30,000 Pakistani rupees.[399] It means a cancer patient who is earning 30,000 a month have to pay his whole year earning to purchase his one-month medicines. Due to the high cost of the cancer medicines many patients never started treatment and leave their selves on the mercy of fortune. Many

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[394] Glevic tablet 400mg, Medical Store, 21 October,2021, https://medicalstore.com.pk/product/glivec-tablet-400-mg-30-tablets-imatinib-mesylate/ last accessed on 23 June 2022.

[395] Medical Store, Tagrisso 80mg Tablets (Osimertinib) https://www.medspal.org/?Y291bnRyeT1JbmRpYSZjb3VudHJ5PVBha2lzdGFuJnByb2R1Y3Q9T3NpbWVydGluaWIlMjA4MCUyMG1nJiVFRiVCRiVCRCVFRiVCRiVCRCUxRQ last accessed on 15 June, 20022.

[396] https://medicalstore.com.pk/product/tagrisso-80mg-tablets-osimertinib/?srsltid=AfmBOopKKb3LEdYN2styI3knT6HtVKmjWggO84YjZnmXzUkwUh3OQf5u

[397] Meds Pal, Medicine Patent Pool https://www.medspal.org/?Y291bnRyeT1QYWtpc3RhbiZwcm9kdWN0PVBhbGJvY2ljbGliJTIwMTI1JTIwbWcmJUVGJUJGJUJEJUVGJUJGJUJEJTFF

[398] Medical Sore, Ibrance (Palbociclib) 125mg Capsules https://medicalstore.com.pk/product/ibrance-palbociclib-125mg capsules/?srsltid=AfmBOoo17f3lR4rXHBIxdeC73ecUSg_S31KOaTEjP2lccRIDBYHWTF-V

[399] Pakistan Monthly Income, CEIC, https://www.ceicdata.com/en/indicator/pakistan/monthly-earnings last accessed on 23rd June 2022.

people who started treatment have to abandon their treatment due to the unaffordable cost of treatment.

5.12. Cancer in India

Cancer is the leading cause of death all around the world and India ranks at number third in the world for having highest number of cancer cases. According to the Indian National Cancer Registry Program every year almost 13 lack new patient entered in cancer registry. ICMR (Indian Council of Medical Research) issued its report and estimate that in next five year there would be 12% increase in cancer cases in India and number would be as 26.7 million in 2021 and in 2025 it would be 29.8%.[400] In India seven types of cancer are prevailing more including lung cancer (10.6) more common in men, breast cancer ((10.5%) more common in women, esophagus cancer (5.8%), head and neck cancer 95.7%), stomach cancer (5.2%), liver cancer (4.6%) and cervical cancer(4.3%).[401]

5.13. Treatment of cancer in India

In India more than 53% cancer patient are getting free cancer treatment and almost up to 27% of cancer patient are getting cancer treatment at subsidized price. Government of India is also constructing new cancer hospitals. In Assam State annually 50,000 new cases of cancer reported and 70% are late diagnosis hence caused high mortality rate. Representative of government said that the construction of new cancer

[400] Vaitheeswaran Kulothungan et.al, "Burden of cancer in India-estimates of cancer crude incidence,YLLS,YLD and DALYS for 2021 and 2025 based on National Cancer Registry Program, BMS Cancer, vol 22: 527(2022) https://bmccancer.biomedcentral.com/articles/10.1186/s12885-022-09578-1 last accessed on 24th June 2022

[401] Ibid

hospitals and latest facilities in Assam will help to decrease 30% late diagnosis in next three years.[402]

Some of the private hospitals in India are providing state of the art health facilities and working as a hope for millions of cancer patient all around the world. Apollo Proton welcome cancer patient from 147 countries for cancer treatment and help the cancer patient to fight with cancer. Many people from Bangladesh, Kenya, Brazil, Bangalore, Zimbabwe and from other countries get successful cancer treatment from Apollo Proton.[403]

5.14. India's pharmaceutical sector

Indian pharmaceutical industry ranks at 3rd position worldwide in terms of its production capacity and rank on number 14th for it value. Value of Indian pharmaceutical industry is $ 41.7 billion and it is expected that in 2024 it will reach $ 65 billion. Pharmaceutical share in the export of the country is 5.15%. Pharmaceutical industry of India includes 3000 registered companies and 10,500 different manufacturing units. Generic industry of India is the largest in the world. Generic drugs of Indian origin are imported in more than 200 countries. More than 50% of globally used different kinds of vaccines are supplied by India. 40% demand of US's generic drugs are fulfilled by India. India supplies 25% medicines used in UK.[404] Indian pharmaceutical industry was

[402] "7 new cancer hospitals to offer affordable care in NE region", THE TIMES OF INDIA, 29 April, 2022, https://timesofindia.indiatimes.com/city/guwahati/7-new-cancer-facilities-to-offer-affordable-care-in-ne-region/articleshow/91163875.cms last accessed on 24th June 2022.
[403] Apollo Proton Cancer Centre, https://proton.apollohospitals.com/?utm_source=google&utm_medium=search&utm_campaign=gulf-brand-campaign&gclid=CjwKCAjwwdWVBhA4EiwAjcYJEB3ULSVY last accessed on 24th June 2022.
[404] Indian Pharmaceutical Industry, IBEF, March 2022, https://www.ibef.org/industry/pharmacthe Eutical-India# , last accessed on 24th June 2022.

considered as the pharmacy of the developing world but now it successfully becomes the demand for developed world too.

Indian industry maintains an important and unique position in global pharmaceutical world. Industry is well equipped with the engineers and scientists who are ambitious to reach new heights. India 42 billion dollar's industry rely on China for Active Pharmaceutical Ingredients (API). It is cheap to import API from China because local production makes their cost high. After the military action between India and China, the India now seriously thinking and making serious efforts to be independent in making the API domestically. Now, with the support of government in 2000 India started the local manufacturing of 35 the API. It is estimated that local production of API will reduce the dependency on China more than 35%. Production incentives scheme was introduced and the government give incentives of 2 billion dollars to the local and foreign companies for starting the manufacturing of 53 API for which India heavily depend on China.[405]

5.15. Local production of cancer medicines in India

In India there are many companies who are manufacturing anticancer medicines for domestic use and for export purposes. When we talk about the manufacturer for cancer medicines in India we find many names. Beta Drug Ltd manufacture cancer medicines for local Indian market and to export in other countries including Nepal, Nigeria, Kenya, Myanmar, Ivory Coast, Srilanka etc. Medion Biotech another pharmaceutical company established in 2012. The company has its oncology franchises all around India. The

[405] Ravi Buddhavarapu, "India wants to be the 'pharmacy of the world'. But first, it must wean itself from China", Biotech and pharma: CNBC, May 2022, https://www.cnbc.com/2022/05/27/india-needs-to-fill-china-gaps-to-become-the-pharmacy-of-the-world.html , last accessed on 24th June 2022.

company is certified ISO9001:2015 and also manufactured oncology medicines for export purposes. There are many other names for manufacturing standard oncology medicines AstraZeneca, S.G. Biopharma, Zuvius Life Science, Jaj oncology etc.[406] Indian pharmaceutical industry is able to fulfil the local needs of its people. It just not is fulfilling the need of its cancer patient but ready to export and already exporting off-patented cancer medicines all around the world. There are many reasons behind this success including

- Indian pharmaceutical industry is very vibrant and progressive and equipped with dedicated and hardworking engineers/scientist.
- Indian government always support their industry. Government prioritises its industry and public's right to health over the international lobby.
- Patent law of India is designed so well with all the flexibilities of The TRIPS agreement and enable the industry to use patent system for the benefit of the poor patient.

5.16. Patent status of different medicines in India

Bayer, a German pharmaceutical company, successfully got patent for Sorafenib brand name Nexavar an anticancer drug used to treat liver and kidney cancer on 3rd March 2008. Bayer was charging very exorbitant price for its cancer medicines Nexavar. The price was set by the Bayer as RS. 2.8 lakh for one-month treatment. Due to the high cost of anticancer drug, it became unaffordable for many cancer patients in India. Nalco a

[406] Anti-Cancer Medicine Manufacturer in India, Pharma Third Party, https://www.pharmathirdpartymanufacturer.com/anti-cancer-medicine-manufacturers-in-india , last accessed on 24th June 2022.

local pharmaceuticalcompany in India moved an application on 29 July, 2011 for the compulsory license and offer to sell the generic Sorafenib at RS. 8,880 per patient for a month treatment. Nalco claim that it offers a low price keeping in view the poor patient of cancer in India. Indian patent office grant its first compulsory license under section 84 as reasonable requirement of public has not been fulfilled by the Bayer.[407] This decision by the Indian Patent Office is appreciated by the public health supporters. They think that that they should is decision will set a way for pharmaceutical companies to come forward and apply for compulsory license for other unaffordable drugs. This decision also gave a very strong massage to multinational companies that they should control exorbitant prices of their patented products in India otherwise they have to face the compulsory license.

Novartis filed patent for its anticancer medicines Nilotinib brand name Tasigna. Patent was filed in 2003and granted in 2009 and expected expiry date is in 2023.[408] Price of a pack of 28 capsules 150 mg Nilotinib (Tasigna) by Novartis in India is 11,500. Oncologist recommend 2 capsules twice a day. Treatment cost of Tasigna is approximately RS. 50,000 for one month treatment.[409] Patent for nilotinib is going to be expired next year so it is expected that the treatment cost would be more affordable.

Novartis filed patent for its branded product Glivec (Imatinib mesylate) in India which is used to treat blood cancer more common in eastern countries. In 2006, Indian patent office reject the patent of Novartis for Glivec under section 3(d). Patent office claimed that it is the modified version of already existing Imatinib and will not come

[407] Ankur Paliwal, " Indian company gets license to manufacture and sell patented cancer drug", Down To Earth, 12 March,2012, https://www.downtoearth.org.in/news/indian-company-gets-licence-to-manufacture-and-sell-patented-cancer-drug-37393 , last accessed on 23rd June 2022.
[408] Nilotinib, PAT-INFORMED: Patent Information initiative for medicines, https://www.wipo.int/patinformed/ , last accessed on 23rd June 2022
[409] Nilotinib, indiamart, https://dir.indiamart.com/impcat/nilotinib.html , last accessed on 23rd June, 2022.

under the definition of invention. Novartis filed its case in Supreme Court and in April 2013 the Supreme Court also decided the same that bioavailability of drug though improved but it did not enhance efficacy so it is not patentable.[410] A pack of 30 Imatinib (Glivec) tablet 400mg by Novartis is available in India at RS. 6,900. Oncologist prescribed one tablet of 400mg Imatinib twice a day and approximate cost of Glivec by Novartis for one-month treatment is RS. 13,000.[411] Due to no patent many other companies also making and selling generic Glivec at more less and affordable price.

The drug Osimertinib, whose patent is held by AstraZeneca. It is a targeted therapy for non-small cell lung cancer with specific genetic mutations. Patent for Osimertinib is granted in India and patent opposition is also filed.[412] Oncologist prescribed one capsule of 50 mg twice a day and approximate cost of one month treatment is approximately is 120,000 without combination.[413]

Palbociclib brand name Ibrance is patent of Pfizer. Patent is granted in Pakistan for Palbociclib.[414] Usually Oncologist prescribed one capsule of 125 mg twice a day and approximate cost of one month treatment with Palbociclib is RS. 10,000 [415]

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[410] Ravinder Gabble and Jillian Clare Kohler, " To patent or not to patent? The case of Novartis' cancer drug Glivec in India", Globalization and health, vol 10:3(2014) https://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-10-3#citeas last accessed on 23rd June, 2022

[411] Imatinib Glivec 400mg, indiamart, https://dir.indiamart.com/impcat/glivec-tablets.html last accessed on 23rd June, 2022

[412] Meds Pal, Medicine Patent Pool, https://www.medspal.org/?Y291bnRyeT1JbmRpYSZjb3VudHJ5PVBha2lzdGFuJnByb2R1Y3Q9T3NpbWVydGluaWIlMjA4MCUyMG1nJiVFRiVCRiVCRCVFRiVCRiVCRCUxRQ

[413] Mr.medin, Tagrisso 80mg Tablet, https://www.mrmed.in/medicines/tagrisso-80mg-tablet?srsltid=AfmBOopIUX7cX8HkuU_brAwGTNP0PVO5P4RurrDYBZ19RSUQ1bICJDve las accessed on 23 July,2022

[414] Meds Pal, Medicine Patent Pool, https://www.medspal.org/?Y291bnRyeT1JbmRpYSZwcm9kdWN0PVBhbGJvY2ljbGliJTIwMTI1JTIwbWcmJUVGJUJGJUJEJUVGJUJGJUJEJTFF

[415] Everyone.org, https://everyone.org/ibrance-palbociclib

5.17. Price differences of anticancer medicines in India and Pakistan

Here is the name of some anticancer medicines with their price and patent status in India and Pakistan. It will help us to see in a glimpse that too much price difference is exist among the two countries who shared a long border and have much similarity in their socio-economic conditions.

Name of Cancer medicine	Price of medicine in Pakistan for one month treatment/ Patent status	Price of medicine in India for one month treatment/ Patent status
Glivec (Imatinib)	270,000/Granted	13,000/Patent rejected
Tasigna (Nilotinib)	342,000/Granted	50,000/Granted
Nexavae (Sorafinib)	240,000/Granted	8,800/ Compulsory License is granted
Opsumit (Mecitentan)	166,725/ NA	1,750/ Granted
Herceptin (Transtuzumab)	130,000/ NA	5000 to 10,000/ Patent Rejected
Osimertinib (Tagrisso)	490,000/Granted	RS.120,000/ Granted/opposition is also filed
Palbociclib (Ibrance)	400,000/Granted	10,000/ Granted

This list is not exhausted but just to keep the focus of our study on the patent law of Pakistan we just give the name of few cancer medicines. There are many other medicines which are sold in Pakistan on very high price than in India. Temoside a cancer drug sold in Pakistan at the price of 31,000 and the same medicine by the same pharmaceuticalcompany in India is available at RS 2400. Young Pharmacist Association asked the authorities to investigate the issue. Another cancer medicine Votrient

(Pazopanib) is selling in Pakistan at RS. 49,376 and same medicines is available in India at RS. 8,700.[416] Indian pharmaceutical alliance also realized this fact that the prices of medicines are high in Pakistan. Representatives of Indian Pharmaceutical Alliance says that patient in Pakistan are paying more than 2 to 15 times than India because Multinationals dominate their local market.[417]

5.18. Reasons for the high prices of anticancer medicines in Pakistan

It is the responsibility of state to ensure the availability of medicines in public hospital if due to the lack of resources, it is not possible for state to provide all medicines in public hospitals than affordable access is very important. It is not possible for a single department to provide affordable medicines but multiple actors are involved to ensure affordability. There are many reasons for the high prices of cancer medicines in Pakistan.

5.18.1. Lack of local production

In Pakistan there is lack of local production and multinationals dominate especially for cancer medicines. Pakistan is importing cancer medicines from different countries including china, India, UK, USA. The cancer medicines that we are importing from India are more affordable than other countries and this is the reason that 50% cancer medicines are used in Pakistan are of Indian origin. No research is conducted in Pakistan in which prices have been compared between India and Pakistan, how for this research all medicines we checked are 10 to 15 times more expensive than in India.

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[416] News reporting :Lahore News, https://www.youtube.com/watch?v=uUujihAnezo last accessed on 26th June,2022.
[417] Pakistan Rx prices "up to 15 times higher than in India", the pharma letter, 22 August,2004, https://www.thepharmaletter.com/article/pakistan-rx-prices-up-to-15-times-higher-than-in-india , last accessed on 26th June 2022.

5.18.2. No Government support

Health sector in Pakistan is control by the government of each province. Health coverage in government hospital is inadequate and most of the time patients have to bear their health expenditure out of their pockets. Government should take serious efforts to control the prices of cancer medicines and also subsidize the price. Government should play its role in capacity building, improving access to cancer medicines and also start some initiatives to promote local production of cancer medicines by the local pharmaceutical companies.

5.18.3. Ineffective law and policies

Government should make effective laws and policies keeping in view international standards, practice of other states and need of local people. Local needs and local industry is totally ignored while making laws and policies. All stakeholders should set together and then formed effective policies. Patent law of Pakistan is poorly designed. It protects just the right of producers of technology and innovation and it totally ignored the rights of the users of technology. There is a dire need to create a room for local industry and designed patent law in such a way that it can become the source of dissemination of knowledge and transfer of technology.

5.18.4. Excessive patent protection

Excessive patent protection as provided in the Patent Ordinance 2000 without incorporating proper the TRIPS flexibilities lead towards lots of new patent and ever greening of already existing patents. Criteria for patentability is not strict hence many patents granted. Patent office granted patent to multinational pharmaceutical companies irrespective of this that these companies manufactured this medicine locally or just

import the medicines. Multinational companies are dominating our local markets and in return we are not benefitted as we can if make our legislation properly. It should be clearly mentioned in the Patent law of Pakistan that the local production of patented medicines be started so that the technology transfers in actual words and after the expiry of the patent term local production of patented medicine be started. Local production of patented medicines will lead toward the technology transfer to the local industry.

5.18.5. Failure of DRAP

In Pakistan, the Drug Regulatory Authority of Pakistan (DRAP) is responsible to control the prices of medicines. The DRAP is working under the authority of federal government. No particular method is provided under the Drug Act 1976 to determine the prices of medicines. The DRAP is responsible for the prices differences between India and Pakistan. There is need to create a balance and transparent system of Pakistan Drug Regulatory authority. List of registered medicines must be available publically and all the decision of regulatory authority must be disclosed publically.

5.19. Conclusion

This chapter provides the detailed description about the cancer medicines, its cost and the patent status of different anticancer medicines in Pakistan and India. A comparative study has been conducted between the two jurisdictions (Pakistan and India) and it is examined that India incorporated and used the TRIPS flexibilities very efficiently hence enable to control the prices of cancer treatment in India. India successfully incorporates section 3(d), stop the way for ever greening of patent and ease the way for generic producers hence ensure affordable access. India used its compulsory license provisions and open way for generic entry of anticancer medicines in India. By issuing the compulsory license India gave a very strong stroke to the multinational pharmaceutical companies with a massage that the public health is the primary aim of India. Cancer treatment cost is very high in Pakistan, it granted patent on cancer medicines frequently and it results in the high cost of patented treatment. Proper use of the TRIPS flexibilities is not seen in Pakistan and this non usage make the situation more vulnerable for cancer patient in Pakistan. Multinational companies selling their patented cancer medicines in Pakistan on very high prices in Pakistan as compared to India as these multinational companies know that patent law of Pakistan has no teeth to defend the right of its people. Pakistan should learn from the Indian patent law and should include the flexibilities in the Patent Ordinance 2000 and to make it useful for local people instead of just protecting foreign patents.

CONCLUSION AND RECOMMENDATIONS

Precise conclusion of present research with recommendation will be provided here. After the detailed discussion earlier, it is concluded that the right to health is a recognized right on national and international level. Right to health includes to provide appropriate health facilities and availability and affordability of medicines is the basic component of health facilities. If a country fails to ensure availability and affordability of medicines, it means that state fails to provide health facilities to its citizens and duty of state towards right to health is not fulfilled. Millions of people died in low and middle income countries due to lack of medicines. These diseases are curable but people in poor countries have no access to medicines or if medicines are available but not affordable for them. All international human rights documents and treaties recognized the right to health and also realized the link between right to health and economic resources. Affordability of medicines is very significant component to the health facilities.

There is direct link between patent protection and affordability concerns. Patent monopolies lead towards the high prices of medicines due to the lack of competition. After The TRIPS agreement, all the WTO members are bound to provide the patent protection to medicines. The TRIPS agreement was not introduced and implemented over night. After a lot of discussion and negotiation between developed and developing countries the TRIPS was implemented. The TRIPS agreement after considering the demand of developing countries provides a range of flexibilities. The objective behind these flexibilities is to mitigate the effects of patent on public health and local industry.

Intellectual property rights protection was a social contract in which a balance was created between the producers of technology and the users of technology. With the passage of time, it was realized that the balance was lifted over and the economic interest of the inventor prevail over the right of general public. Usage of the TRIPS flexibilities can maintain a balance between the rights of users and producers. The CIPIH's report also highlights that developing countries are not incorporate the flexibilities in their national legislation and if some countries incorporate one or more flexibilities in their national legislation but gape still exist between the incorporation of flexibilities and use of these flexibilities. Access to affordable medicine may become easier if the accurate incorporation of flexibilities and right usage are made together. There might be many reasons for this non usage like lack of political will or lack of technical expertise. It is also a fact that the IPR and patent are the arcane subjects and there are only few experts in developing countries.

Pakistan incorporates the TRIPS flexibilities in the Pakistan Patent Ordinance 2000, but fails to take the full advantage of these flexibilities as we can see in the Indian patent law. Law maker left a lot of room for misinterpretation and misunderstanding of poorly incorporated flexibilities. Terms are defined so broadly, the patentability criteria is not strict, compulsory licensing provisions are inadequately designed, provide only few grounds to issue compulsory license. If Pakistan have strict patentability criteria than we could reject the patent on Imatinib, an anticancer medicines. India refused to grant patent on Imatinib u/s 3(d) and prefer public health over economic interest. The price of patented Imatinib in Pakistan for one-month treatment is Rs. 270,000; price of Imatinib by the same multination company in India is Rs. 13,000 for one-month treatment. This is

how the India stop the way of ever greening and ensure affordable access to an anticancer medicine.

Treatment facilities in Pakistan for cancer patients are pathetic. Government hospitals fail to provide continuous treatment for cancer patients. It was examined that every year supply of cancer medicines are suspended by the government hospitals for multiple reasons as the 98% of cancer medicines are imported. Pakistan has very limited manufacturing capacity of cancer medicines, only 2% of cancer medicines are manufacture in Pakistan and rest of the medicines are imported from other countries including India. We cannot take benefit from compulsory licensing provisions for cancer medicines because of limited manufacturing capacity. Doha Declaration realize this fact and this issue is resolved in august 30 Decision that the country have no manufacturing capacity can issue compulsory license for import purpose and the other country with manufacturing capacity can issue compulsory license for export purpose. Pakistan should also legislate provision of Decision of 2003 in its patent law to make compulsory licensing provision workable for cancer medication. Pakistan cannot go for the compulsory license of cancer medicines without legislation. It might be the reason for high prices of cancer medicines as multinational companies have keen eye on the law of each state and they know the week position of Pakistan's patent law. India issues its first compulsory license for nexavar (Sorafinib) an anticancer medicine and price of Sorafinib reduced from 220,000 to 8,800 for one-month treatment. We can also take benefit from the compulsory license issued in India if we had provision in Pakistan Patent Ordinance 2000 to issue compulsory license for import/export purpose.

There is immense need to utilize the TRIPS flexibilities to control excessive grant of foreign patent in pharmaceutical industry. It will help to control price as we saw in chapter four that no patent is granted in Pakistan for the HCV medications and the prices are very affordable. Due to no patent in Pakistan, the prices of the HCV medication cheapest worldwide. Serious efforts by all the organ of society were remarkable during the HCV medication same commitment and seriousness needed by all the sectors of society to control the exorbitant prices of cancer treatment. More grounds of granting compulsory license will help and encourage local industry and ensure affordable access. Such other amendments are also very necessary to make which can help to transfer the technology and become source of dissemination of knowledge in true sense.

In the end, it will be concluded that to ensure right to health and to ensure affordability of medicines is not possible for health sector alone and the collaboration among the other sectors of society is very imperative. The Alma Ata Declaration on public health also realized this fact that all the sector of society should come forward to protect public health. Declaration understands that in present scenario and due to advancement in science and technology, international cooperation is required to maintain right to health globally. The Alma Ata Declaration put an obligation particularly on developed nation to cooperate with countries having limited resources in the health sector. It is a reality that developing counties cannot ensure affordability of medicines without the help of developed nation. Efforts of state by utilizing all its resources and support by international community can help to improve the health sector in Pakistan. Help by international community can be bifurcate into two categories. First is the direct help and second is the indirect help. Direct help is to provide training to the doctors or

donate some cancer medicine but indirect help means a lot. Indirect help means that whenever the government tries to use flexibilities no international pressure is build and government should allow to use the TRIPS flexibilities to mitigate the suffering of poor cancer patient. It also includes that the state authorities when try to amend their poorly worded flexibilities with enforceable and effective provision than they should not keep under watch list but should be encourage and assisted.

In order to conclude, it must be added that we should not confined our self to incorporate effective grounds to grant compulsory license but we should use this provision when needed as India did. It was also observed that the grant of compulsory license in India change the strategy of multinational companies in India and now these companies frequently issue voluntary license to domestic firms. We should also give a message to multinational companies to cooperate with domestic firms so that the technology transfers in true sense. It is possible just with the amendment in the Patent Ordinance 2000 and to start local manufacturing of anticancer medicines.

SUGGESTIONS AND RECOMMENDATIONS

Patent law of Pakistan has some of the TRIPS flexibilities but it fails to incorporate these flexibilities effectively and forcefully. Just the wording of the TRIPS agreement is reproduced without making further elaboration. The TRIPS agreement while providing flexibilities intentionally left some point so that the member states may fill gap according to their needs but Pakistan fail to fill that space accordingly. There is an immense need to amend patent law of Pakistan to make it more the TRIPS compliance and useful for local needs. This research suggests some general and some specific recommendations for legislature to amend patent law and for court to interpret patent from public health

perspective as Doha Declaration on the TRIPS and Public Health reaffirms in paragraph 4 that The TRIPS agreement should be interpreted from public health perspective. This research also has some recommendations for government regarding local pharmaceutical industry. In order to ensure right to health and to ensure affordability of medicines is not possible for health sector alone, but it is possible with the collaboration of all other sectors of society. Followings are recommendation of this research:

1) The very first recommendation of this research is to incorporate the TRIPS flexibilities into the Patent Ordinance2000 under the light of Doha Declaration on the TRIPS and Public Health with effective grounds for using these flexibilities. It is very important, not only for the affordability of the cancer medicines but also it will help to improve overall health infrastructure. These are some specific recommendations which are made as under:
    i) The first recommendation is that Patent Ordinance 2000 must adopt strict patentability criteria to avoid ever greening of patent as our patentability criteria lenient than India. This is the reason that we grant patent but India rejects patent as it did not fulfil the criteria of invention (Glivec, Imatinib). Our pharmaceutical industry did not allocate any budget for research and development because R & D required the budget of millions which it cannot afford. When local industry did not have research and development activities than lenient provisions to grant patent will help the multinational companies to occupy the local markets.
    ii) The second specific recommendation is that we should strengthen our parallel importation provisions. The Pakistan pharmaceutical industry is not equipped

with latest knowledge and technology, no manufacturing capacity for cancer medicines revealed this fact. Multinational companies realised this fact; this is the one of the reasons that these multinational companies sold same medicines in India on very lower price than Pakistan. As we can see in case of Tasigna, Herceptin and Opsumit, there is a lot of difference in prices of these cancer medicines. In this situation we can take help from parallel importation. Effective parallel importation provisions enable to import medicines from the country where it is on cheap rate.

iii) One third population of Pakistan is living beyond the line of poverty and cancer treatment is very expensive and unaffordable for majority of people living in Pakistan. 60% to 70% of health expenditures are bear by the people and health facilities by the government is very low as compare to the international standards. Country like Pakistan where health expenditure made out of pocket, state must make its laws and policies more vigilantly. Compulsory license provisions must include high prices of medicines as a ground of granting compulsory license. These provisions will give a strong message to the multinational pharmaceutical companies that government may issue compulsory license if prices of medicines are out of control.

iv) The objective of patent protection was twofold. A balance was created that the invention will be protected and in return society will get the technology and knowledge. But this phenomena of transferring technology and knowledge is missing as almost all cancer medicines are imported in Pakistan and just packed here and ready for sale. If the patented product is imported in Pakistan

by the patent holder and no local production is started than how the technology will be transferred. Keeping the patent information in the patent office will not transfer the technology unless the local production plants are started. Patent law of Pakistan must compel the multinational pharmaceutical to manufacture their product in Pakistan if they want to continue the enjoyment of patent right, as India did.

v) The pharmaceutical industry of Pakistan has very limited manufacturing capacity for cancer medicines. It means Pakistan cannot take benefit from compulsory license provision for medicines it did not have manufacturing capacity. Doha Declaration realised this issue in 2001 and a committee to provide solution. The solution was given in Decision of 2003, in which export was allowed for countries with no manufacturing capacity. But Pakistan after 19 years of this relaxation did not incorporate these provisions into Pakistani patent law. This shows the seriousness and concern of authorities on right to health. Amendment should be made to allow compulsory license for import/export purpose. After incorporating all these provisions, we will be able to negotiate on better footing with multinational pharmaceutical sector for reduction in price.

2) The courts in Pakistan, until the amendment is made, must decide all matters related to patent and public health in a moderate way. Balance between the economic interest and public health should be maintained by the courts. Courts must ensure that the non-state actors must not interfere with the duty of state to provide health facilities to its citizens. Doha Declaration also asserts that whenever conflict arises between right

to health and patent, right to health will prevail. Courts in Pakistan should also follow this principal for public health.

3) Local production of medicines is very important for technology transfer and for affordable access of medicines. the WHO and The European Union with combine efforts start a program “Improving Access to Medicines in Developing Countries” for technology transfer and local production of medicines in developing countries. Pakistan ranked at sixth but its contribution in global pharmaceutical market is 0.13% only. Only 2% of cancer medicines are manufactured in Pakistan and we depend on other countries to fulfil our local needs. There is dire need to improve our local manufacturing capacity. Pakistan should learn from its neighbouring countries India and China who occupy the global pharmaceutical industry.
4) International scenario changing quickly. Supply of cancer medicines suspended many times due to the cold relationship with India or for some other reason as recently during Russian attack on Ukraine also affect the supply of API which result in the lack of production and supply of many medicines and all this leads towards the high prices. Pakistan starts its government owned pharmaceutical industry and also provides support to the local industry to encourage them. India depends on China for API and 80% API are imported from China. After the war on border with China, India starts production of the API locally and also gave incentive of 2 billion to local and multinational companies to start the production of API locally. Following the foot step of India, we should also start the manufacturing of cancer medicines and emphasized the multinational companies to start production units in Pakistan and

develop an export market of medicines in Pakistan. In whole process our local industry will learn and progress.

5) It was very difficult to get the information about the patent status of different anticancer medicines in Pakistan. No information was available on the website of intellectual property office of Pakistan. When the contact is made to the officials they told a lengthy procedure, consisting of fill a form and pay prescribed fee, for getting information about the patent status of different medicines. This research recommends the patent office to design a user/researcher friendly website so that whenever information required can be obtained without any inconvenience. It will increase the trend to make more researches and more suggestions on the topic of patent and public health.

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