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Trade Politics And Policies Regarding Access To Cancer Drugs

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ABSTRACT

Life is unpredictable. Lifestyle changes in our fast-paced world make human beings strive to achieve their livelihoods amidst stress. This has resulted in numerous types of diseases, among which is cancer. The causes of cancer are vast and exhaustive in their list. Despite ongoing research aimed at identifying these causes, determining the precise factors behind cancer remains a daunting task in many cases. Apart from the challenge of diagnosing the causes, the next significant hurdle is the affordability of the expensive drugs required to treat patients with cancer. This article sheds light on trade politics and policies surrounding access to cancer drugs. The paper is divided into three parts. First part deals with trade politics and policies of state on patent laws. Second deals with compulsory licensing policy on access to drugs. Third would discuss in detail about the non-affordability of cancer drugs. Finally, would come up with suggestions to sort out the issue to non-affordability of cancer drugs. The suggestion is that state should consider the interest of patients who are non-affordable to cancer drugs and therefore join hands with medical and trade community to overcome the hurdles that cause non-affordability.

KEYWORDS: Trade, Politics, Policy, Non-Affordability, Cancer.

INTRODUCTION

The proverb 'No pain, no gain' has transformed in today's world to 'No pain for one, no gain for another.' Corporations, especially pharmaceutical ones, thrive on profiting from the pain caused by novel diseases in others. Medicines are priced exorbitantly, leaving the poor patients

with scarce access to them, preventing them from alleviating their pain or curing their diseases. While making the world entirely disease-free may be impossible, enabling people to access and afford medicines for treatment, pain relief, or extending life expectancy is within our reach. This article aims to address the issues related to drug access, particularly focusing on cancer drugs. This paper is divided in to three parts. First part deals with trade politics and policies of state on patent laws. Second deals with compulsory licensing policy on access to drugs. Third would discuss in detail about the non-affordability of cancer drugs. Finally, would come up with suggestions to sort out the issue to non-affordability of cancer drugs. The suggestion is that state should consider the interest of patients who are non-affordable to cancer drugs and therefore join hands with medical and trade community to overcome the hurdles that cause non-affordability.

TRADE POLITICS AND STATE POLICIES REGARDING PATENT LAWS

The evolution of human beings has brought about significant changes. However, selfishness is inherent in our genes and has transformed over time to manifest itself differently. The only distinction in this evolution is that selfishness was previously expressed through warfare, whereas now it is channelled through trade. The realist theory of international politics posits that selfishness lies at the core of human nature. Nevertheless, this manifestation of selfishness does not yield benefits unless it is cloaked in the guise of promoting the welfare of others. Present-day trade is often presented as liberal, yet, in contrast, it often adopts a protectionist approach. Trade politics play a role in shaping a state's policies, and when a state leans toward liberalizing international trade rather than imposing trade restrictions, it can lead to contentious politics. In the endeavour to balance the interests of the public and traders, a state establishes certain standards that serve as governing policies.

Trade holds immense significance; without it, development is jeopardized. International trade, in particular, creates a bridge towards establishing a new world order, where people can reap maximum benefits. Trade fosters a society in which individuals become mutually dependent, reducing the likelihood of conflicts and fostering peace and cooperation. Furthermore, trade impacts various facets,

including the environment and human rights. As a result, it serves as the cornerstone for policies designed to influence trade for the benefit of all. The policy-making process strives to identify inputs that prioritize societal welfare and aims to incorporate societal preferences at its core. Alongside these preferences, it is crucial to understand trade's impact on different economic actors within society. Any trade policy must strike a balance between the interests of traders and the public. It cannot be a one-sided decision-making process; its benefits should be accessible to both traders and the public. Policy-making is influenced by those advocating for societal benefits and, conversely, by those with specific trade-related interests.

Tracing the history of trade reveals that it all began with the barter system—exchanging goods—before money was invented to simplify transactions. Money quickly emerged as a crucial element in survival. Despite its importance, money cannot replace a person's life, and trade policies strive to reflect this reality. The aftermath of World War I and II brought economic crises that challenged nations worldwide to formulate policies to overcome the economic impact. The necessity of an institution to address economic crises led to the establishment of the World Trade Organization (WTO). Prior to the WTO, the General Agreement on Tariffs and Trade (GATT) represented the only agreement binding states concerning trade matters. However, GATT lacked a regulatory framework and enforcement mechanisms. In 1995, the WTO was founded to regulate trade related to goods, services, and all aspects of intellectual property.

Before the WTO, Intellectual Property Rights were safeguarded through various conventions, such as the Paris Convention, Berne Convention, Madrid Protocol, and Lisbon Agreement, depending on the type of intellectual property. The Paris Convention mainly dealt with the protection of inventions and patent-related matters. However, the Agreement on Trade-Related Aspects of Intellectual Property (TRIPs) aimed to establish harmony and uniformity in intellectual property rights protection among TRIPs members, requiring them to either incorporate TRIPs provisions into their laws or enact new legislation in line with TRIPs principles. This approach of incorporating TRIPs provisions or enacting new legislation is known as a sui

generis system. Among the various kinds of intellectual property rights, patents are one type.[1]

A patent, as a form of intellectual property right, is granted to individuals who devise new innovations. This includes the invention of products or processes that exhibit an inventive step not obvious to someone skilled in the relevant field and capable of industrial application. Patenting an invention provides the holder with a limited period of exclusivity over that invention. The concept of patenting evolved from the concept of monopoly. The historical roots of patenting can be traced back to Emperor Zeno of the Byzantine Empire, who granted one year of monopoly rights to chefs for their signature dishes. This concept later extended to other newly produced goods. Granting monopolistic rights actually encouraged innovation and the development of new technologies. However, the negative impact of these monopolies on the public prompted their curtailment. As a result, limited-time monopolies were introduced, with the aim of striking a balance between encouraging innovation and avoiding the detrimental effects of prolonged monopolies.[2]

By the 12th century, Queen of Britain issued letters of patent to individuals who introduced new technologies and demonstrated interest in establishing industries in Britain. These letters contained a clause requiring the technology inventor to teach the innovation to the nation's people in exchange for monopolistic rights. Over time, the scope of monopolistic rights expanded to include entertainment. This expansion eventually led to restrictions on the issuance of letters of patent, as evidenced by the Darcy v. Allen case. In 1623, the Statute of Monopolies was enacted, aimed at curbing restrictive trade practices. Despite various changes, the British patent law of 1852 marked a significant milestone. Given that many countries were British colonies, these patent laws served as a model for newly independent nations to formulate their own legislation.[3]

On the international stage, the Paris Convention for the Protection of Industrial Property of 1883 emerged, introducing principles such as the most favoured nation clause and national treatment. This convention also marked the introduction of the priority date concept in patent application filing and outlined conditions for issuing compulsory licenses due to non-working or insufficient working of patents. The TRIPs agreement aimed to achieve

uniformity in the application of intellectual property law. Due to inequality in economic status members of world nations were given time to incorporate the provisions of TRIPs and the time to change was known as transition period. Besides allotting transition period to incorporate the provisions of TRIPs it was not that easy to do in developing and least developed nations.[4]

The provisions of TRIPs were largely shaped by Dunkel's draft, a proposal originating from developed, developing, and least-developed nations. However, critics argue that the provisions and recommendations in Dunkel's proposal favoured developed nations, as the technicalities of the draft were not well understood by developing and least-developed nations.Dunkel's draft was considered as the draft that was made to treat unequal equally. Specifically, stringent product patenting provisions related to life-saving drugs have posed challenges for accessing life-saving medications in developing and least-developed countries. Nonetheless, TRIPs did incorporate certain exemptions to mitigate the impacts of product patenting, including provisions for importing drugs to nations incapable of producing the required medications. This was tried to be achieved through the policy of compulsory licensing.[5]

COMPULSORY LICENSING POLICY ON ACCESS TO DRUGS

The concept of compulsory licensing was introduced within the framework of the Paris Convention. According to the Paris Convention, contracting members can legislate laws related to compulsory licensing in order to prevent patent abuses. However, the use of compulsory licensing is subject to specific conditions. To qualify for compulsory licensing benefits, the party seeking such a license must demonstrate the failure or insufficiency in working the patented invention. In addition to the issuance of compulsory licensing, patent forfeiture can sometimes be employed as a means to mitigate the negative impacts of patenting. Nevertheless, the forfeiture of a patent requires proving that issuing a compulsory license alone is inadequate to prevent patent abuse.

Under Article 31 of the TRIPS agreement, Governments or third parties are allowed to utilize patented inventions without the authorization of the rights holder. This usage can be extended to cater to the domestic market's needs. In the 2001 Doha Declaration, Paragraph 6 was introduced,

which broadened the scope of issuing compulsory licensing. While Article 31 (f) limited unauthorized usage only for domestic purposes, Paragraph 6 expanded this to include waiving patent rights for pharmaceutical products imported or exported to markets in other developing and least developed countries that are in dire need of medicine, lack manufacturing capacity, or are unable to produce the required quantity. This expansion was intended to be incorporated as Article 31 Bis in the TRIPS agreement. However, the ratification to add the same was not that easy.[6]

Now, the immediate question pertains to the implementation of Article 31 Bis. While Article 31 Bis discusses importing and exporting to fulfil the demands of developing and least developed nations, certain aspects remain unaddressed. Particularly, it fails to clarify the procedure for obtaining additional drugs required once the quantity of the drug is specified. Consequently, the process of compulsory licensing becomes complex. Thus, in cases where the need for additional drugs arises beyond the initial requirement, the article does not indicate whether a new request must be made or if the initial request for compulsory licensing suffices to fulfil the raised demand.[7]

Subsequently, the responsibility falls upon domestic policy makers to incorporate these provisions into their national legislations, particularly in the context of least developed and developing nations. Despite the heightened necessity for implementing compulsory licensing, its application remains inadequate. Notably, the conditions for issuing compulsory licenses do not explicitly encompass orphan diseases or life-threatening conditions. The issuance of compulsory licenses for cancer drugs following the TRIPS agreement has been minimal. Only countries such as India and Thailand have issued compulsory licensing, citing exorbitant drug prices and their lack of affordability by its citizens. It is therefore imperative to explore the various implications that contribute to rendering cancer drugs unaffordable.

NON-AFFORDABILITY TO CANCER DRUGS

Disease does not discriminate between poor and rich. Both suffer equally the pain of disease and loss is equal. However, the treatment and access to medication to prevent and treat cancer is not available equally to people present in

least developed countries, developing nations and developed nations. The cost of treatment is exorbitantly high making it non-affordable by the patients of low-income group countries. A 2020 report of World Health Organisation shows that the population affected by non-affordability to cancer drugs belong to Asian and African continent. Can people die of pain merely they don't have purchasing power to afford for the medicine that could help them prevent, control or cure from the diseases they have? Cancer the deadliest disease affects the people of any age. Mere money should not pose a threat to human survival. Hence Governments should take initiative to procure drugs for their citizen in low cost and find other sources to encourage generic drug industry to come up with alternative medicines to cure cancer.

In U.S.A the big pharmaceutical giant tries to thrive profit from medications to cancer. As these pharmaceutical companies have a big say in the politics of U.S.A thereby laws are framed to uplift the benefits of pharmaceutical company. Being a developed nation U.S.A has a valid say in international trade and can stop trade sanctions to those countries that would seek benefits against the interest of these pharmaceutical companies. As India and Thailand issued compulsory licensing, U.S.A brought them under watch list as per section 301 of USTR Act 1974 and tries to impose trade restriction and barrier terming them as an unsafe zone to conduct trade. India issued compulsory license to treat kidney cancer for the drug Sorafenib and Thailand granted compulsory licences to erlotinib, letrozole and docetaxel to treat lung, early stages of breast cancer and breast cancer respectively.Bringing India and Thailand in watch list by USA made many countries not to taking any chance to issue compulsory licence as U.S.A would impose barriers on trade sanctions. Apart from challenging the issue of compulsory licensing the evergreening of patent and provisions of data and market exclusivity was a challenge for the developing and least developed nations to access life-saving drugs especially of Cancer.[8]Data exclusivity brings barriers to address the inequities concerning cancer. In developing nation and least developed nation the most important issue is with respect to increase in death rate and increase in new patients affected by different kinds of Cancer.[9]There has been a high raise in patient from the report submitted by World Health Organisation in 2012 and subsequently in 2018. The

number of Children getting well from Cancer in developed countries are 80% more than that of Children affected and getting recovered from Cancer in developing and least developed countries. Only reason behind the death and unable to prevent cancer is only due to high pricing of drugs which would cure or prevent the cancer cells. The pricing of drug is considered to be high as the income of people in developing country and least developed country is very meagre to the price fixed.

The clinical trial data is protected under Data exclusivity. The term of data exclusivity runs parallel to the period of patent. The term of data exclusivity becomes a barrier for generic drug industry as clinical data cannot be showed to get approval as this would be considered as infringement. Therefore, the FDA of USA would receive the applications of generic manufacturers of drug and would not approve the same until the patent has expired and the term of protecting the clinical data has expired. Therefore, apart from term of patent, data and market exclusivities tend to become an additional layer of protection that would deprive generic industry to produce drug and sell the medicines at lower cost for people living in developing and least developed nations. Next challenge for generic industry is to clear the safety test of USFDA. Hence it is not an easy task to produce medicine by generic industry and get clearance from FDA.

Though all diseases are painful they can be classified as First to be contagious and brings immediate death like trips d-19, second is contagious, non-curable and deadly however the death is not immediate like in HIV/AIDS and finally Disease that is not contagious and life threatening and death is not immediate like that of cancer. In these types the first kind of diseases are to be treated immediately as it would cause extreme national emergency and urgency which could be a reason to invoke compulsory licensing immediately as sought under TRIPS provision. Second kind of disease is also need to be addressed immediately as the spread of the disease is to be controlled to save the man-kind from extinction. However, there is no provisions and policy with the states to address the sufferings caused by third kind of disease and of rare diseases. As both the third kinds of disease and rare disease does not cause death immediately and will not come under the category of emergency or urgency situation. Rare diseases are those where none of

the researcher would like to venture as the cost of inventing a medicine for rare diseases could not profit them.[10] Hence it is a concern of international arena that treatment for cancer should be bound under TRIPs agreement just as it is addressed to that of HIV/AIDs and medicines should be made available to patients who are not in a position to afford for the same. Just because cancer patients of developing and least developed nations are not able to afford for the medicines they cannot be let to die. Hence TRIPs should include Cancer in the row of HIV/AIDS and compulsory licensing should be issued for the Cancer patients by fixing an affordable price. Just because cancer is not contagious the Cancer patients could not be led to suffer because the pain is deadly and every human being have a right to life include right live a healthy life and the same has been emphasised in Universal Declaration of Human Right. The basic concept of Intellectual Property is incentivising the creator. Hence economic opportunity is created to innovating pharmaceutical industry but not at the cost of public suffering.[11]

The policies of state should be framed in such a way to prevent the cause of Cancer. World Health Organisation in its annual report of 2020 says that the major cause for cancer especially lung cancer is smoking and laws should be made to control the same. Many Countries like UK and Australia has asked the tobacco sellers to use a plain packaging in order to make it less attractive and thereby prevent people from buying tobacco that would cause cancer. Several countries opposed their plain packaging laws and it was considered to be an act against the trademark law to identify one's goods and services. However, WTO panel supported the action of Australia and said the plain packaging law would be baby step towards curbing the usage tobacco and prevent lung cancer. Australian approach towards curbing tobacco was said to be the best approach to prevent the usage of tobacco that contributed for the deadly disease of cancer especially lung cancer. Hence as said always prevention is better than cure. States should make policy to curb the usage of tobacco. Besides all state should consider Cancer as a life-threatening disease and try to issue compulsory licensing on a war footing when prices are not affordable by the general public.

CONCLUSION

Health is wealth but in today's world wealth decides that who is eligible to better health. Today's big business is pharma industry and medication are a luxury for many people. People die of pain when there is medicine and they are not in a position to afford for the same. The condition of any cancer patient who cannot afford for medicine is the same as said above. Hence state has to make policies to intervene to reduce the financial cost to treat and prevent cancer. State should be able to make best policy to prevent and treat cancer and at the same time try to make an efficient implementation plan. Although data and market exclusivity pose as an impediment to access in midst of TRIPs Flexibility the state should employ multiple approaches to curb usage of tobacco and prevent cancer. This cannot be done by state alone but it should join hands with trade and medical fraternity to address the issue pertaining to prevention and curing Cancer. The agenda behind both medical and trade community with respect to this regard should not be profit motive or business oriented to achieve the desired results. Hence State should try to frame its policy to balance Trade and access to medicine in order to curb the non-affordability issues pertaining to cancer drugs.

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