Asian Journal of Science and Applied Technology
ISSN: 2249-0698 (P) Vol.9 No.1, 2020, pp.38-46

DOI: https://doi.org/10.51983/ajsat-2020.9.1.1046

Patenting Essentials: Pharmaceutical Boon or Bluff?

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(Received 5 April 2020; Revised 27 April 2020; Accepted 19 May 2020; Available online 26 May 2020)

***Abstract* - Lack of availability of medicines can be attributed to various reasons, but the most important and essential one is the high prices of these drugs. The exorbitant prices of drugs are due to the Intellectual Property protection granted to such drugs. It is a huge responsibility for the governments of various countries to keep the prices of medicines low so that the commoners are benefitted. This responsibility is much more on the government of an emerging country. Many times, it has been seen that governments come under immense pressure exerted by the developed & the industrialized countries and also the worldwide medicinal industry. The TRIPS agreement offers the standards required to be fulfilled for grant of a patent, including patents for medicines. There are many safety standards set out by TRIPS for the prevention of patent abuse. But it is of the utmost requirement that there is clarity as to how such standards can be used to prevent patents from creating a hurdle in access to medicines, especially the essential ones. This paper focuses on clarifying this aspect by studying various instruments, the Doha declaration which prioritized public health over IP, the lacunas in the Doha declaration which prevents it from solving all problems, the failure of the World Trade Organization to make sure that generic medicines are exported to the under-developed or the emerging countries, etc.**
***Keywords*: Medicines, Patent, Pharmaceutical Industry, developing country, industrialized, TRIPS, Intellectual Property, Doha Declaration, World Trade Organization.**

I. INTRODUCTION

More than 10 million people all around the world are killed by infectious diseases every year. The emerging and the underdeveloped countries have to face bigger problems because of lack of funds and infrastructure and also because they don't get access to the required medicines because of its hiked prices. These nations constitute a large share of the world and thereby contribute to more deaths. The most common causes of death throughout the world are HIV/AIDS, respiratory problems, cancer, tuberculosis, and malaria. Cancer alone is a cause of death for millions of people all over the world who are mostly unable to reach out to the medicines available, as they are costly. The reason for such a hike in the price of the medicines is the stringent protection provided to these medicines under IP law. The government faces huge pressure from the multi-national pharmaceutical companies when it tries to lessen the price of the medications to make it easily accessible.

The TRIPS arrangement, which was accepted by the adherents of the WTO, lays down the basic requirements of patent protection, under which, the protection granted to medicines are also provided. This agreement has been criticized because of its basic criteria for patent protection provided, as it makes the production of essential drugs a monopoly business, thereby keeping business above public health. Though certain safeguards to get away with the harmful effects of patent abuse has been laid down under TRIPS, they are not of much help as it does not provide any aid to get access to the medications.

In 2001, the Fourth WTO Ministerial Conference agreed upon a statement on TRIPS and community health which was recognized as the 'Doha Declaration'. In this 'Declaration', the Sovereign rights of the governments of the respective nation-states to guard community health were affirmed. This 'Declaration' was welcomed by all and was seen as a light of hope as it prioritized public health over IP protection. It was thought that the 'Declaration' would be able to resolve the age-long issue of availability of medications. However, it was seen that the 'Declaration' was not able to keep up to the expectations and was not able to resolve the varied kinds of issues that were present. The fallacies of the 'Declaration' came into the light, even more, when the World Trade Organization was unable to solve the issue regarding production and exportation of the generic medicines in countries where its production doesn't take place.

II. RESEARCH OBJECTIVE

The research paper aims to analyze the present global scenario regarding the accessibility of essential drugs all over the world. This paper gives a global picture as to how even today, there is a controversy regarding patent shield to drugs and the accessibility of essential and generic drugs to people. Although various steps have been taken to give importance to public health and welfare, the outcomes have not been productive enough and the underdeveloped and developing countries have mostly been in the receiving end. The issue discussed in this paper has immense importance because of its relevance in practical life. The paper elaborates on the measure taken to uphold public welfare and the reasons for which they have failed.

III. RESEARCH METHODOLOGY

The researchers have selected the present topic keeping in mind the relevance of the discussed issue in the present circumstances. The method used for research in this paper is a doctrinal method. An analysis regarding the measures taken to increase the accessibility of medications on a global level has been done using this method of research. Legal, as well as non-legal authorities, have been referred to for research. Case studies, statutes, judgments, research papers, judicial opinions, books of both National and International repute, authentic online sources, research papers, reports, National as well as International journals have been accessed. Opinions of experts, as well as research scholars, have been taken into consideration to collect the required material information.

IV. HYPOTHESIS

This research paper has tried to draw a fresh perspective on how pharmaceutical patents have affected production, export, and access to medicine. In this regard, the researchers have hypothesized that the global outlook may reveal certain lacunae in the two primary International agreements governing the whole aspect of medicines and access to it by nation-states, namely the TRIPS Agreement and the declaration at Doha. The lacunae might result in nation-states having a wide arena to abuse their power to override patents and this paper tries to prove the correctness of the hypothesis, for the sake of pointing out a scope of improvement. The two agreements are the basis of the discord between IPR and accessibility of essential drugs. The arguments are necessarily valid depending on several positive and negative grounds and it may be appropriate to assume that the discussion is going to be fairly detailed.

V. TRIPS AND ACCESS PROBLEM

Millions of people die every year due to the lack of medications. On top of that, investment in R&D of pharmaceutical industries, in emerging countries, has come to a standstill. With the advent and implementation of TRIPS and the protection provided to inventions under patent laws, the cost of the medications has exceeded the affordable limits. According to figures, more than twenty-five per cent of the global population lacks access to drugs and medicines. The conditions of the underprivileged nations of Africa and Asia are even worse. The reasons are lack of proper climatic conditions and non-availability of essential drugs.

There are numerous factors which can cause difficulties in the arena of accessibility of essential drugs. The causes of unavailability may be problems related to logistical supply and storage, quality of drugs, wrong drug selection, uneconomical prescription, unfitting use, and exorbitant prices. However, despite such adverse scenarios, the production of essential drugs in the emerging and underprivileged nations is stagnant. The reason behind this is that the respective nations are not being able to recoup the cost of R&D, which is required for the production of these medicines.

Certain NGOs, after studying the entire situation, had concluded that with the implementation of TRIPS, two outcomes are possible. Firstly, there can be an increase in the production of drugs because of the protection provided. However, accessibility will become even more difficult, especially for poor countries as there can be a steep increase in the prices of the drugs. Secondly, the implementation of the standards by the WTO can lead to a decline in the manufacturing of medications by the local manufacturer. This may ultimately lead to a drop in the production of generic and innovative quality medicines. Along with these problems, it is also seen that the emerging nations have been facing constant pressure from the developed countries to implement ‘TRIPS-plus’. The term ‘TRIPS-plus’ is a non-technical term with no definition provided anywhere.

However, this term means to provide patent protection beyond the 20 years limit as has been laid down under TRIPS. Implementing ‘TRIPS-plus’ would further tighten patent protection given to drugs and thereby increase the scope and possibility of monopolising the business. The WIPO (World Intellectual Property Organization) and the developed nations have often assisted the emerging and the under-developed countries to observe the provisions laid down in TRIPS. However, this assistance has been offered without taking into consideration the health and welfare of the people. The trend has always been towards providing stringent patent protection to medications for the betterment and increase in business of the industrialized countries and multinational companies (MNC’S).

VI. EVOLUTION OF DEBATE BETWEEN IPR AND ACCESS TO DRUGS

A. South African Trade Clash

“The South African Pharmaceutical Manufacturers Association and 39 medicinal manufacturers out of which mostly were multinational, filed a suit against the government of South Africa on February 1998, challenging the Medicines and Related Substances Control (Amendment) Act of 1997 and stated that it violated the TRIPS agreement and the Constitution of South Africa.” The modification had presented a legal outline, intending to grow the affordability of medications. The most important provisions added were regarding the general replacement of off-patent medications, see-through pricing for medications, and parallel ingress of patented drugs.

Initially, the medicinal companies got support from the governments back at home. To force the Local Government, revoke the alterations made, the government of US suspended trade assistance and threatened to put restrictions in trade. The US was joined by the European Union which increased the level of compression. Embarrassing the then Presidential Candidate Al Gore, the AIDS activists effectively promoted the provisions of the modified legislation. The demonstrators at election campaigns confronted the candidate and accused him of the assassination of children in Africa. Slowly and steadily, with increasing public agitation, the US stopped providing its support and by May 2000, the pharmaceutical corporations could no longer be dependent on the respective home governments. The Medicinal businesses were asked to pull out of the case by everyone. It was tough for the corporations to maintain its stand that the modifications dishonored South Africa's commitments to the world because it was based upon a legal draft of the WIPO Committee of Experts. All these points forced the corporations to drop the case in April 2001. The case brought out two important points before the world. First, that the flexibilities under TRIPS and their use were required to be clarified so that the emerging countries could utilize the same without any legal or political threat. Second, the industrialized countries cannot exert trade pressure to defend the interests of their multinational companies without consequences at home.

B. The AIDS Programme in Brazil

The Brazilian AIDS programme, whereby Brazil has been offering wide-ranging AIDS care since the mid-1990s including antiretroviral treatment, saw a reduction in AIDS-related mortality by 50% between 1996-1999. In a span of just 2 years, 472 million USD was saved by Brazil. This success could be credited to the fact that Brazil could produce medicines locally. Moreover, by utilizing the threat of production under an enforced licensing system, Brazil has also been successful to accumulate patented drugs at lower prices. "Compulsory licensing is permitted in Brazil, under Article 68 of the Brazilian Patent Law." This feature allows a patent to be used without the consent of the holder. In 2001, an action was taken against Brazil concerning Article 68, by the US at the WTO dispute settlement body. The provision lays down a requirement of working locally, which means that the Brazilian patent holders need to produce their commodities within Brazil itself. If a company does not comply with the same, the patent will be subjected to enforced licensing after 3 years. A corporation can escape this only by showing that it is not monetarily viable to produce the goods in Brazil or that the requirement is an unjustified one. If the corporation is allowed to work its patent by importation instead of producing in Brazil, parallel import by others will be permitted.

The US reasoned that this particular provision of the Brazilian Patent Laws, is discriminatory and that it curtails the rights of patent holders. They claimed that this provision is in contravention to "Article 27.1 and 28.1 of TRIPS". Brazil, in reply to the charges, argued that the provision aligns with the agreement as well as "Article 5.4 of the Convention of Paris, which allows for compulsory licensing in such scenarios". This action of the US came under the scanner and pressure of the NGO community all over the world. Brazil in many instances had said that it will aid the emerging countries by providing them with the technical knowledge to increase their respective capacities to manufacture medicines, especially the ARV drugs. The NGO communities feared that the action taken by the US would hamper this initiative undertaken by Brazil. Subsequently, the US withdrew the action.

C. The Non-Governmental Organizations

The NGOs, around the world, have played a crucial part in clarifying the provisions of TRIPS which can help in increasing accessibility of essential medications. A very important provision in this regard is the one which deals with Compulsory Licensing, enabling a government to provide a license to a third person or a governmental institution without the accord of the patent-holder for using the invention in question. "However, according to Article 31 of the agreement, the actual holder retains the IP rights and is paid suitable compensation as per the realities and conditions of a given case." In March 1999, the first International meeting took place, on the use of "Compulsory Licensing" to surge accessibility of AIDS medications. "It took place at the *Palais des Nations* in Geneva and was organised by the Consumer Project on Technology, Health Action International and MSF." Later on, this same set, planned a conference on accessibility issue in the Globalization Era, in Amsterdam. The conference engrossed on launching a working group on TRIPS and accessibility of medications in the WTO, keeping in mind the effect of business policies on the under-developed & the established countries and a public well-being outline for the understanding of the crucial attributes of WTO agreements. It was the duty of the group to solve questions in relations to – utilization of compulsory licensing to facilitate growth in accessibility of medications, machinery to permit the manufacture of medications for export markets (nations which have a deficient manufacturing capacity or no production capacity at all), patent blockades to research, and excessively obstructive & anti-competitive explanations of TRIPS rules on maintaining the safety of the health registration information. Besides, the group was also supposed to scrutinize burden-sharing tactics for R&D that allows nations to study a broader range of policy tools to endorse R&D and to ponder upon the real-world problems in underprivileged nations of managing IP systems. The National governments were urged by the Amsterdam Statement to grow a novel and pioneering machinery to ensure capital for R&D. The Statement has worked as a role model for NGOs and other enthusiasts.

D. The WTO Ministerial (1999)

The subject of civic health and accessibility of medications did receive consideration in the WTO Ministerial in Seattle in 1999, due to multiple reasons, but was not a part of the official agenda. First, a suggestion to grant compulsory licenses for drugs on the list of essential drugs of the WHO. was made by a Common Working Paper section on TRIPS. This offer could have restricted the use of Compulsory Licensing rather than ensuring, that it became a valuable tool to fight access barricades caused by patent abuse. Seattle was chosen as a place to announce an alteration in the US policy on IPR and access to medicines by the then US President Clinton. Due to the policies of the US government in South Africa, it had come under aggressive pressure from the AIDS activists. The task of developing and establishing a procedure to analyze the health-related issues that arise due to the application of the trade-related IP laws and policy of US was given to the "United States Trade Representative and the Department of Health and Human Services" under the new policy. The US president, specifically referring to the South African state of affairs on the HIV AIDS crisis, said that the US will henceforth implement its health-care and trade policies in such a way so as to ensure that individuals in the underprivileged nations are not deprived of the vital medications urgently required. In May 2000, the President dispensed an executive command related to the accessibility of HIV/AIDS medications and medical machinery, in support of the use of Compulsory Licensing. "Even though this policy reform played its part in breaking the taboo on the utilization of compulsory licensing in the medical field, concentration towards TRIPS and accessibility of essential drugs at the WTO was abstracted by the fall of the conference."

E. The WHO

The 1996 World Health Assembly was the first time when the civic health community elevated worries regarding the effect of globalization and global trade arrangements on access to medications. The WHO's medicine policy was set out by a "resolution on the Revised Drug Strategy (RDS)". In 1998, the resolution provided the WHO with the directive to issue the initial guideline along with recommendations to the adherent countries for adopting the provision of TRIPS while restricting the ill-effects of advanced levels of fortification under patents. The US and some European countries were unsuccessful in preventing the WHO from publishing the guide. During this time, the WHO's interference in trade matters was exceedingly debatable. The battle between public health and trade interest could be seen as a risk to the economic segment of the world. For example, in reply to the draft of the resolution of the WHO on the "RDS" and referring to the substantial worry amid the pharmaceutical industry, "the European Directorate-General for Trade of the European Commission stated in 1998 that health should not be prioritized over Intellectual Property. However, successive resolutions of the World Health Assembly have accomplished in strengthening WHO's mandate in the area of trade. The World Health Assembly settled on two resolutions in 2001 which spoke about the debate over TRIPS." It addressed:

1. The requirement of strong policies to ensure accessibility of general medicines.
2. The requirement to assess the effect of TRIPS on the accessibility of medicines, the domestic capacity to manufacture and evolution of new medicines.

F. European Union

The EU adopted a program that accelerated action on HIV/AIDS, malaria, and tuberculosis in 2001. It recognized the probable problems of TRIPS and the requirement to recalibrate its priorities. In addition to this, resolutions of many parliaments in Europe shifted to back the pro-public health approach of TRIPS. DG trade altered its strategy, acknowledging the worries of the emerging states, as a part and parcel of this approach. It stopped objecting to the use of compulsory licensing and became a supporter of a universal tiered-price evaluating scheme for medicines. These vagaries were opposite to what prevailed in Europe.

G. Stands of the other organizations

"The United Nations Programme on HIV and AIDS, the World Bank, Regional Organizations such as the Organization of African Unity and the Group of 77 are the other organizations that shared their stands on the issue of accessibility of drugs. The UN Sub-Commission for the Protection and Promotion of Human Rights pointed out the negative consequences of implementing TRIPS in the form in which it was. It stressed on the need for IPR to aid social welfare needs referring to pharmaceutical patents." The UNDP's human growth report pleaded for reframing the rulebooks of globalization so that they also work for the people and not just for the profits. WTO could no longer prevent itself from hearing the growing concern on TRIPS and its effects on the accessibility of medications.

VII. HISTORY OF THE DOHA DECLARATION

A. Proposal by Africa

The statement of the African parties on the need to tackle the lack of accessibility of essential medicines, to the TRIPS Council, led to the beginning of the planning for the Doha Declaration. Just 2 months post this, the TRIPS Council conducted its first session on the accessibility problem. In this meeting, the African troupe suggested dispensing distinctive declarations on the accessibility of essential drugs. Zimbabwe, the head of the African troupe stated referring to the horrendous AIDS catastrophe in Africa and increasing public worries that"*We propose that Members issue a special declaration on the TRIPS Agreement and access to medicines at the Ministerial Conference in Qatar, affirming that nothing in the TRIPS Agreement should*

prevent Members from taking measures to protect public health."

Two months later, in September 2001, another discussion was held by the TRIPS Council on the accessibility factor. A draft script for an official declaration on TRIPS and Public Health was presented by the African group and 19 other nations. To warrant that the TRIPS arrangement did not challenge the legal right of the WTO adherents to provide structure to their health measures, the draft addressed political principles. The provisions linked to enforced licensing, parallel imports, data fortification, and manufacture for export purposes were also clarified by the text. The draft also put forward a suggestion for reviewing the effect of TRIPS on the matter of public health and Research & Development for treating particular diseases affecting the people in the emerging and the underprivileged countries and avoiding them. US, Japan, Switzerland, Canada, and Australia distributed a different draft in the meeting and emphasized the importance of providing IP protection to R&D. It was designed for restricting the flexible nature of TRIPS during an emergency and disastrous situation. The draft circulated by EU, suggested an answer to the question of manufacture for export purposes to realize an enforced license in a state with inadequate or no manufacturing capacity by permitting production under the agreement.

B. The Doha Negotiations

Various discussions over the TRIPS agreement took place in Doha for a period of over three days. The discussions also included issues regarding public health dominance and other trade-related aspects. The main issue was whether to choose the first option or the second option of the Harbingston draft. The first option was opted by several member countries because of the reason that it took into consideration the general health of the people and was not only focused on the health crisis. Another reason for selecting the option was that the second option implied that it would neither change nor alter and not even create new rights under the declaration.

Therefore, the declaration would have no impact and significance at all. However, countries like the US, Korea, Switzerland, Australia, and Canada preferred the second option. Finally, after three long days of discussion, a compromise was entered into whereby it was agreed upon that TRIPS shall in no circumstances take away the rights of the adherents of the WTO to guard civic health and to provide accessibility of medications to all.

From the language of the text, it could be deciphered that unmitigated rights have been provided to the member countries to shield public health. The text clearly stated that if IPR stood as a barrier in the way of providing public health then it should be overridden.

The Declaration in paragraph 5 states that how certain provisions of TRIPS can be used to overcome the barriers which come along with IPR protection and how to come out of the accessibility problem. It states that the provision of compulsory licensing can be used at any point of time on any ground. There is no necessity that it can be issued only in cases of urgency or emergency. Although certain members had proposed to limit the grounds of compulsory licensing only in cases of emergencies like pandemics and in cases like HIV/AIDS, it was rejected. Moreover, what constitutes a national emergency could be decided by the member nations itself.

The LDC (Least Developing Countries) was also given an exemption under this declaration, whereby they were given an extension till 2016 instead of 2006; a ten-year-long extension for the implementation of the procedures of the product patent regime. However, this policy was not pre-determined in the negotiations. The US had tried to put forward its own opinion of formulating policy in the Pre-Doha period, whereby it stated to provide a transition period up to 2016 for the implementation of patents on pharmaceutical products and a moratorium for dispute settlement to the Sub Saharan African areas. However, the sub-Saharan African region did not fall in the category of the least developing countries and this policy of Europe was considered to break the unity of the emerging nations and was termed as the "divide and conquer" policy and rejected at Doha. Only a limited extension in cases of section 5 i.e. patents and section 7 i.e. undisclosed information of TRIPS was provided. This extension was not to apply to the rest of the provisions of the Agreement which deal with pharmaceuticals. The provisions and language of the declaration were ambiguous regarding the fact that whether the provisions of 'mailbox' application and 'exclusive marketing rights', as provided in Article 70 of TRIPS, are to be provided by the LDC or not. However, the proposal regarding the extension of deadlines was accepted for the LDC's as it will help those countries to think and formulate their policies over a certain period with the benefit of being able to produce and import generic medicines. However, it was held that the ten-year extension will only be beneficial for the LDC, i.e., only 30 countries out of 140 member countries of the World Trade Organization.

The problem, which continued unsettled, was that how the states, which did not have manufacturing capacity, can use the provisions of compulsory licensing, similar to that of nations having the ability to manufacture, since "Article 31(f) of TRIPS states that compulsory licensing is mainly to be provided for supply in the domestic market". Though the issue was unresolved, an acknowledgement about the same had been made in Paragraph 6 of the declaration and expeditious steps were instructed to be taken by the Council of TRIPS and a report was to be provided to the General Council by the year 2002.

VIII. PHARMA INDUSTRY ON THE WTO DECLARATION

The WTO Declaration was deemed unnecessary by most of the pharmaceutical giants around the world. They argued that patents weren't an issue and that it would have an extreme effect on the industry if patent protection was weakened as the entire industry was dependent on their research and development capabilities. Amidst the warm welcome that the "Declaration of TRIPS and Public Health received from the International Federation of Pharmaceutical Manufacturers (IFPMA), concern was expressed by several individuals. For instance, several medicinal companies in the US requested that the United States Trade Representation (USTR) re-open negotiations even post-agreement on the text of the Declaration." IFPMA has consistently warned against the risks involved in compulsory licensing, and they multiplied their efforts in the past few years since NGOs started proposing that patent barriers be overcome through systems of compulsory licensing. IFPMA maintains its stance till date and has gone on record to declare that enforced licensing system is a risk to good community health as it refutes patients around the globe, the imminent remunerations of R&D proficiencies of the research-based industry, from which novel treatments come.

The countries were free to decide the grounds for compulsory licensing, which was a clear reason as to why the generic drug industry greeted the Declaration with enthusiasm. There, however, was a slight concern about the fact that there could be unilateral pressure for which countries would be influenced to not utilize the provisions of the Declaration in an optimum manner. It was thus suggested that the WTO adherents labeled as 'advanced' should ensure that they adhered to practicing the Declaration and not applying the aforesaid unilateral pressure.

As predicted, the making of inexpensive drugs became reliant on compulsory licensing post-2005. However, the issue is that manufacturing under a compulsory license is restricted to chiefly supplying the local market. There is a need to permit the export of drugs from the country where they have been patented to the one that issues a compulsory license, and that is the exact problem. The Declaration also skipped on giving a clear interpretation of the issue regarding the protection of data as laid down in Article 39.3 of TRIPS, which thoroughly disappointed the generic drug industry. The restrictive interpretation may lead to postponements in introducing common medications and the unintended extension of EMR beyond a decided patent protection term. The barriers would rise in the arena of registration of general medications produced under a compulsory license.

IX. POST-DOHA SCENARIO

The grim reality of today is that despite the WTO endeavoring to adopt legislations so that life-saving drugs may be accessible to the poorest of the poor, TRIPS and the Doha Declaration are failing miserably. It is perhaps an appropriate critique that the Declaration failed to address the educational and radical blockades that emerging countries have faced and continue to face. Its primary focus was to somehow penalize medicinal giants who give to the world life-saving drugs and deprive them of their patent rights. The Declaration is a toothless tiger because of its superficial language and issue that needs to be addressed, perhaps through another well-drafted declaration.

A. Barriers in Developing Nation to Drugs & Patent Holder's Desecrated Rights

Patent holders suffer a great loss if emerging countries make use of compulsory licensing. Such countries can bypass patent rights if their negotiations with corporations fail, and this whole situation discourages them from further research. However, it is diseases like malaria and HIV/AIDS that need research, and these diseases mostly affect the emerging countries. Lack of incentives for profit may push-back the research tendencies due to the huge investment that research requires. It is quite a real problem, as the number of drugs that the FDA receives for approval is already declining because the idea of 'innovation' through research is becoming obscure.

Poverty, corruption, and lack of healthcare infrastructure are even more significant a barrier for accessibility of life-saving drugs rather than patent rights or high prices. On average, emerging nations devote hardly one-tenth of their budgets on healthcare, including medicinal products and that results in higher out-of-pocket spending by people for medications they need. This leaves them with fewer funds for other necessities like food, clothing, and housing. Household poverty may thus be considered a direct reason for illness. Aggravating the problem is the fact that the correct medications do not reach the individuals they were intended for, because even if people may be able to afford it, healthcare providers are absent. Lack of infrastructure to provide for laboratories that would be capable of monitoring the necessary blood tests or for doctors who can properly administer medicines affects the administration of compound drugs such as anti-retroviral which may treat HIV and AIDS.

Corruption, as stated earlier, may affect the production in the following ways:

1. It is quite common for government officials to accept 'kickbacks' for the purchase of medicines. These officials then hoard such drugs or sometimes select a different medicine from what is needed.
2. The distribution system has various steps and there is a tendency for the medications to be stolen at any one of them.

3. Officials often demand extra 'fees' to expedite the process of approval for products and facilities, getting it through the hands of the Customs department or even for fixing prices.
4. Medical professionals follow a prescribing process. Violations of market code and practices may adversely affect the same.
5. Suppliers may be subjected to a demand for additional favours as a condition for being allowed to supply medicines prescribed.
6. Fake, harmful medicines may be allowed to circulate in the market for the sake of cheap availability.

Any number of provisions aimed at lowering prices or working the way around patent holders' rights is not going to work in an emergency if better government policies are not framed nationally.

B. Inadequate Phrasing in the Doha Declaration

There are numerous paragraphs in the Doha Declaration that reek of possibility of abuse, thereby also rendering provisions of TRIPS as void. They have the potential to wholly destabilize the compulsory licensing system. The utilization of compulsory licensing by the adherents of the WTO was not explained satisfactorily in the Doha Declaration as was apparent from the broad language of the said document. An example would perhaps be the term 'public health problem' as has been mentioned under the very first paragraph of the Declaration, which speaks of WTO acknowledging the severity of civic health problems like HIV/AIDS, malaria, tuberculosis diseases which are widespread in emerging and least developed countries. We must realise, however, that such a definition leaves open a floodgate for what a nation may label as a public health problem. The criticism seems valid that one who holds a patent may be forced to be subject to a compulsory license for a disease as absurd as erectile dysfunction arbitrarily declared a 'health-emergency'. This extreme example best explains the lack of direction in the overall phrasing and how a country could misuse this lacuna.

Paragraph 6 is the next most ambiguous part of the Declaration. It contains the provision for a State to be able to import drugs through a parallel Paragraph 6 system if it does not have production capabilities in the medicinal sector or faces hitches in effectively using the compulsory licensing system as has been provided under the TRIPS Agreement. There is an absence of preciseness in the Declaration which could explain that a nation must be confronted with a genuine health problem and it lacks resources to acquire the medications from the patent holders to combat the same. The glaring error here is the ability of a country to falsely declare a health-emergency in their area, not attempt to manufacture a drug of their own and simply use the Paragraph 6 system to acquire the desired drugs at the cheapest possible rates and store them.

X. EXPORT AND PRODUCTION OF MEDICINES

Contrary to the positive spirit of Doha, there was a failure on the part of the WTO post the conference to deliver on the promise that before the end of 2002, a solution would be found to allow the manufacture of medications for export to nations that do not have adequate manufacturing capability. The key players had different opening actions in the TRIPS Council. The EU submitted two feasible options. The first one was a modification to Article 31(f) of TRIPS, whereby an exception would be created to the condition that Compulsory Licensing is only for the local market. The second choice was that of permitting manufacture for export as a conditional exception under Article 30. A dispute settlement moratorium, in which the member countries would agree not to lodge a complaint in WTO against nations that help others in need by exporting drugs, was suggested by the US. It was also insisted by them that any solution would apply to HIV/AIDS, tuberculosis, and malaria. Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Malaysia, Sri Lanka, Thailand along with the African group proposed an amendment to Article 31 deleting the part that restricts compulsory licensing, principally for the local market, or to construct an imposing clarification recognising the right of member nations to permit manufacturing for export without the approval of the patent holder addressing public health requirements in another nation.

A solution based on Article 30 of TRIPS was favoured by the World Health Organisation. On 17th September 2002, in a statement to the TRIPS council, the "WHO set out the characteristics of a resolution to the Doha declaration *"paragraph 6 problem"*, desirable from a public health perspective as follows.

"A stable international legal framework; transparency and predictability of the applicable rules in the exporting and importing countries; simple and speedy legal procedures in the exporting and importing countries; equality of opportunities for countries in need of medicines, even for products not patented in the importing country; facilitation of a multiplicity of potential suppliers of the required medicines, both from developed and developing countries; and broad coverage in terms of health problems and the range of medicines."

It was concluded by the WHO:
"Thus, the basic public health principle is clear: the people of a country which does not have the capacity for domestic production of a needed product should be no less protected by compulsory licensing provisions (or indeed other TRIPS safeguards), nor should they face any greater procedural hurdles, compared to people who happen to live in countries capable of producing the product. Among the solutions being proposed, the limited exception under

article 30 is the most consistent with this public health principle. This solution will give WTO Members expeditious authorization, as requested by the Doha Declaration, to permit third parties to make, sell and export patented medicines and other health technologies to address public health needs."

A group of NGOs proposed that members may give an exemption to the complete exclusive rights provided by an appropriate patent to allow all actions related to manufacturing for export to another state of a patented product or product obtained by a patented process under Article 30 of TRIPS. This group pointed out that the Article 30 approach is economically viable, workable, and administratively simple.

The European Parliament on October 23, 2002, implemented the 196th alteration to the EU Directive relating to pharmaceutical products for human consumption. The modification provided that production will be allowed if the manufacture of the pharmaceutical product is done with an intent to export to another country which has allotted a compulsory license for that commodity, or where a patent is not in existence and if a request on this regard has been made to the appropriate public health authorities of that country. This approach is consistent with that of the WHO in the TRIPS Council.

Unfortunately, the negotiations took an opposite turn. A deep division was seen between the emerging countries, that wanted a feasible solution, and the Globalised world which tried to restrict the scope of any resolution. Most delegates were ready to welcome a compromise which was far from ideal to meet the 2002 target.

It became known as the "Motta Text". The Motta text seemed to be disagreeing with the Doha Declaration which provided for implementing the TRIPS agreement in such a manner so that access to medications for all is encouraged. The countries were prepared to accept the text even though it was far from ideal. The delegates were called upon by the NGOs to discard the text. In the end, the proposal was vetoed by the US. The lobby of medicinal companies had been aggressive, especially in the US, to limit the scope of diseases and eligible countries.

The US took into account the broad definitions of the scope of the disease, vetoed the proposal, and declared a unilateral pause on disagreements. The European Commission followed up on a past suggestion of US and recorded diseases for which the resolution could apply and announced an advice-giving role for the World Health Organisation in case a participant nation wished for the same. The developing countries rejected this suggestion and objections were raised against it all over the globe. Individual Medical Professionals, consumer groups, NGOs, medical organisations, and human rights groups were not in favour of thinning the ambit of the Doha Declaration. The discussions in the WTO developed quite inexplicable with trade dialogues trying to fix public health priorities. In January 2003, a proposal was made by the chair of the TRIPS Council to approve a statement that there is an understanding that the resolution "*under paragraph 6 of that Declaration as being essentially designed to address national emergencies or other circumstances of extreme urgency*", to make the Motta Text pleasant for US.

This suggestion was also discarded by emerging countries. Medicines Sans Frontiers reacted aggressively to this and urged its members to discard the proposal. Compulsory Licensing was never meant to be used only during emergency circumstances and it is undesirable to restrict the use of this feature for nations without manufacturing capacity, while the objective of the negotiations on paragraph 6 was to remove the barricades to use compulsory licensing.

A. The Present Scenario

Today, India stands tall as the largest supplier of generic drugs on a global scale, close to 70%. In terms of Over the Counter (OTC) medicines, the said rate is around 21% and the rest 9% is patented drugs. That makes 100% of India's pharmaceutical supply to the world, which includes drug intermediates, drug formulations, bulk drugs, herbal products, and surgical equipment. In terms of volume, the Indian market is currently the third-largest in the world, and in terms of value, it stands at an impressive rank of 13.

There is the availability of a skilled workforce in India and the country itself is a large base for raw materials, which gives the industry a definite competitive advantage to establish itself as global research, manufacturing, and development hub.

1. Market Size

50% of the total worldwide demand for vaccines, 40% of the demand for basic medicine in the US, and 25% of all medicinal demand of the U.K. are met by India as the provider.

The best example in this regard would perhaps be the global demand for antiretroviral drugs to battle AIDS, a supply that is fulfilled by Indian pharmaceutical firms for up to 80%. "The value of export from India stood at US$ 19.13 billion in 2018-19 and reached US$ 13.69 billion in 2019-20 (till January 2020) and is expected to reach US$ 20 billion by the end of the year. USA (US$ 119.18 million), Russia (US$ 10.33 million), UK (US$ 9.83 million), South Africa (US$ 3.63 million), and Nigeria (US$ 1.71 million) turned out to be the biggest importers of Indian pharmaceutical products in 2018 to 2019."

2. Investments and Recent Developments

An approval has come from the Union Cabinet to amend the present Foreign Direct Investment (FDI) policy applicable to the medicinal sector. Under the automatic route, this would allow FDI up to 100%. Subject to certain conditions, its use would be in the engineering of health equipment. Between 2000 and 2019, data released by the Department of Industrial Policy and Promotion (DIPP) showed that a cumulative worth of US $15.98 billion of FDI was attracted by the pharmaceutical and drugs sector.

XII. CONCLUSION

While the WTO has taken steps in an effort to attain some sort of equilibrium between the need for life-saving medicines to be delivered to emerging countries and the patent holders' rights to gain profit from the sale, the result of these steps is deficient. In other words, the WTO's actions to help uphold patent rights and balance it with emergency health situations have been a massive failure. The very fact that an individual emerging country has the liberty to decide as to what constitutes an 'emergency' frustrates the entire purpose of the balance sought for. Such countries could easily work around a holder's rights by using compulsory licensing and parallel importation. That would effectively stun the research on presently incurable diseases as there will remain no prospective profits from the same. In the meantime, it has also been established that several emerging countries still lack essential drugs to help cure actual national health emergencies, which further exposes the blunt-toothed nature of TRIPS and the Doha Declaration. Millions of people will continue to die unless this problem is solved.

The researchers believe that the WTO needs a subsidiary international organ which may act as a supervisor for emerging countries' accessibility of drugs and other medicinal products. Individualism by a nation in the scenario of negotiation with a patent holder bears no fruit as neither will the country end up receiving the drugs nor will the holder's rights be upheld, as is quite apparent. 'Health crisis' thus has to have a standard international definition which can be applied to see if a country has one, and essential life-saving drugs have to be given to such a country which may be suffering. Both these tasks may be assigned to such an international body. This will require an arrangement among all countries to sacrifice patent holders' rights in certain restricted situations so that human lives can be saved. Non-ambiguous terms of guidance need to be provided by the WTO for this subsidiary organ. It should be a better draft with fewer lacunae. Terms like "adequate remuneration," "public health problem," "national emergency," and "reasonable commercial terms" need to be assigned appropriate definitions. The core of any international agreement is the definitions and until those are clarified, no association or nation will be able to suitably implement these agreements in the intended spirit of the WTO.

Indeed, the two major hurdles that the WTO cannot do anything about, are a developing country's infrastructure and the level of corruption that prevails therein. This international body could entirely be responsible to oversee the distribution of drugs as stated above, and take measures to cut-down corruption by the government which would be an absolute setback to corrupt officials by and large. Expert health professionals could be engaged in determining the quantity while the distribution of drugs is carried out as and when necessary.

On the Indian forefront, it is so projected that the Indian expenditure on medicine shall rise by approximately 11% over the coming 5 years. Having said that, it may be appropriate to conclude that India shall become one of the countries that would be right at the top as far as such spending is concerned. On another note, better growth in domestic sales would be greatly dependent on the ability of a medicinal company to produce medicines for the evolving diseases plaguing the modern world, like cardiovascular issues, diabetes, issues related to mental health, cancer, etc., which are seeing a steep rise in terms of the number of patients. The Indian government has taken numerous steps to scale back costs and expenses in healthcare. Prompt introduction of general medications into the market has persisted to be their primary focus and is anticipated to ensure profits for the Indian medicinal corporations.

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