April 2022 Volume-1 Issue-2

Contemporary Swadeshi

TRIPS AGREEMENT-DEMAND FOR TRIPS WAIVER FOR COVID-19

Ashwani Mahajan

Anil Sharma

Contemporary Swadeshi

TRIPs Agreement - Demand for waiver of certain provisions of the Agreement for the prevention, containment and treatment of COVID-19

Ashwani Mahajan
Professor of Economics,
PGDAV College
(University of Delhi)

Anil Sharma
Chartered Accountant

Publication
Swadeshi Jagaran Foundation
"Dharmakshetra", Babu Genu Marg,
Sector-8, R.K. Puram, New Delhi-110022
Tel.: 011-26184595
Website: www.swadeshionline.in
Email: swadeshipatrika@rediffmail.com, editor.swadeshionline@gmail.com

ABSTRACT

At the outset, bringing intellectual property rights control, in the garb of dealing with their trade related aspects through TRIPS Agreement, in the Marrakesh Agreement was a mistake committed on 15th April, 1994. Exceptions permitted in the TRIPS Agreement on the issue of public health were ineffective as they were structured with lots of conditions which were either difficult to comply with or were impractical. While the TRIPS Agreement was proposed to address 'trade related issues' around intellectual property rights but the rules introduced, took it far beyond the context and have adverse implications for the international human rights to health as enshrined in Article 25 of the Universal Declaration of Human Rights (1948).

After struggling for six years on the issue of public health and easy access of medicines and new research and development of new medicines, the developing countries, the least developed countries and the civil society achieved some success in the shape of a Work Programme related to implementation of TRIPS Agreement in a manner supportive of public health as part of Doha Declaration. Once again, the conditions for compulsory licencing were made so much rigid, cumbersome and litigation prone that it could very rarely be used.

Processes of refusal to grant patents, allowing generic drug manufacturers to use the patented invention to obtain market approval, compulsory licencing, importing under compulsory licencing and for anti-competitive practices, which are being publicized as exceptions on pharmaceutical patents, are so cumbersome, full of conflicts and legal issues that no developing country is willing to use those flexibilities.

Whatever small was achieved in Doha Declaration as TRIPS flexibilities has been made ineffective by developed

countries, especially USA by forcing developing countries as well as the least developed countries to incorporate more restrictive conditions known as TRIPS Plus and Data Exclusivity while offering them some other tariff concessions in trade through bilateral free trade agreements.

TRIPS Agreement was amended in December, 2005 by adding Article 31 bis and an Annexure with the objective of providing legal basis for a WTO member to grant compulsory licences exclusively for the production and export of affordable generic medicines to other members that cannot domestically produce or cannot be produced in the needed quantity of the desired medicines. This was the first amendment in the Agreement since 1995 and came into force on 23rd January, 2017. But the newly inserted article could be implemented only after passing necessary legislation or making amendments in the existing laws in each of the prospective importer as well as exporter country. Many governments have not amended their domestic patent laws for various reasons.

India, Africa Group and other supporting countries have proposed a TRIPS waiver for vaccine for treatment of COVID-19 which was initially opposed by the developed countries including USA, EU and Japan, who later on agreed to text based negotiations. Whereas US agreed to accept TRIPS waiver for Covid Vaccine, EU continued to oppose any TRIPS waiver for long. Now, whereas there is no concusses on the contours of TRIPS waiver, and 12th Ministerial Conference is scheduled between 12 and 15th June, 2022, a Chair's text has been submitted by the chairperson of TRIPS council of WTO. It is expected that a decision shall be taken on this in forthcoming MC in June, 2022.

The Paper suggests alternative strategies for India and other developing and least developed countries to adopt in case TRIPS waiver is not granted at WTO in MC 12 at Geneva in June, 2022.

TRIPs Agreement - Demand for TRIPs waiver for vaccine for treatment of COVID-19

For the last two years, humanity has been passing through a terrible pandemic, whose end is not in sight in the near future. Humanity is not only faced with the burden of disease, lack of vaccination in a major part of the world and expensive medicines and treatment after the disease is haunting all especially, the poor. In such a situation, universal availability of vaccines and cheap medicines and treatment in case of disease, has become a necessary condition to save humanity. It is worth noting that companies have patent and other intellectual property rights of medicines and equipments, necessary for the treatment of Covid-19. Moreover, companies also possess control over the formulations and raw materials of Corona vaccines.

Due to the alertness of the government, the efforts of scientists and the hard work of the corona warriors in India, India has been much better than many countries of the world in battling this pandemic. With nearly 191 crore doses of vaccination 87 crore people have been fully vaccinated, which is 63.4 percent of the country's population. It is believed that Indian population has got good immunity to fight Covid-19, it is hoped that India will also be able to save itself from the new Omicron variant. But the rest of the world is not so fortunate. There are many countries in the world where the process of vaccination has not yet started. Expensive medicines and treatment are no less than a death knell for the poor people of these countries.

What exemption from TRIPS means?

In October last year, a petition was made by India and South Africa in the World Trade Organization seeking exemption from Trade Related Intellectual Property Rights (TRIPS), so that vaccines and corona medicines in the world are made available to the entire humanity on affordable basis. Globally, TRIPS mandates countries to honour intellectual property rights. The exemption from TRIPS would mean that companies that have intellectual property rights on vaccines, medicines and medical equipment would be revoked for the period so decided, and many countries of the world, including India, would be able to produce these vaccines, medicines and devices on their own. This demand of India and South Africa got the support of more than 100 member countries of WTO. Although initially, the US was opposing it, later it changed its stand and supported exemption from TRIPS, though only for the vaccine. But the European Union continued to oppose the proposal. Although there has been some relaxation in their stance recently, but still they are proposing many conditions before giving their consent.

The Ministerial Conference of the World Trade Organization which was earlier proposed from 30th November to 3rd December in Geneva (Switzerland), where a decision was expected, was postponed due to the spread of the Corona pandemic. Due to the threat of more waves, there is concern in the whole world whether humanity will continue to suffer without vaccine and treatment, or a decision will be taken soon for this. It is believed that had the proposal of India and South Africa on TRIPS waiver was accepted in time, the speed of vaccination across the world would have been much faster. But it is a matter of regret that the countries like US and European Union, whose companies possess most of patents and other intellectual property rights (IPRs), had been blocking the prevention and cure from disease. It is worth noting that the US,

though has consented for TRIPS exemption from vaccine, but has not yet agreed to extend the same for medicines.

TRIPS waiver needed more now

Though, India has been successful in more or less controlling the pandemic, with ongoing spread of the infection in the interest of the humanity, the importance of TRIPS waiver has increased much more. It is true that if this decision is taken soon, we can still save many lives. Although some people in India, are also arguing that today, India is capable of vaccinating its entire population and it will soon achieve the objective of universal immunisation. Moreover, when many companies are already giving voluntary licenses of their patented medicines to Indian companies, there is hardly any importance of TRIPS waiver for India. They also argue that India has manufactured a good and effective vaccine itself, sufficient for India and even for exports, it can also take advantage of IPR and sell the same to the world. In this regard we must not forget that India and South Africa's demand for TRIPS waiver was not only for their own countries but for the whole of the humanity. Even if the argument, that some foreign companies in India have given voluntary licenses of medicines necessary for the treatment of corona to Indian companies is accepted the fact remains that but their price is still very high. Therefore, if these drugs are exempted from the provisions of TRIPS, then these drugs will be much more affordable and help the poor people in their treatment in India and the rest of the world. Not only this, according to the terms of the voluntary license, Indian companies can generally make and sell these medicines in India itself.

In such a situation, it is believed that even after getting voluntary licenses, these medicines will not be available to more than half of the world's population, which will be a very unfortunate situation for the humanity. In fact, the delay in the

TRIPS waiver goes against the spirit of the TRIPS Agreement of the World Trade Organization and the 'Doha Declaration on TRIPS and Public Health'. Therefore, a voluntary license is no substitute for a compulsory license, resulting from TRIPS waiver in WTO.

INTRODUCTION TO TRIPS AGREEMENT

Trade Related aspects of Intellectual Property Rights (TRIPS) Agreement is Annex 1C to the Marrakesh Agreement establishing World Trade Organisation (WTO) on 15th April, 1994. The Agreement was made effective w.e.f. 1st January, 1995. Article 7 of the TRIPS Agreement defines the objectives of the Agreement. As per that Article, the protection and enforcement of intellectual property rights (IPRs) 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.

The Agreement covers copyright and related rights, trademarks, geographical indications, industrial designs, patents and layout designs of integrated circuits. The Agreement, which has 70 Articles, inter alia, providing for standards concerning the availability, scope and use of IPRs, their enforcement and dispute prevention and settlement.

After signing the TRIPS Agreement, the member countries were required to amend their domestic laws and regulations concerning IPRs to incorporate requirements of TRIPS Agreement. On the issue of public health, the TRIPS Agreement permitted few exceptions which were also required to be incorporated in the domestic laws and regulations.[1] These exceptions include (among other things), Do we need to include exception in detail, adopt measures necessity to protect public

health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development.

Doha Development agenda and public health

In the light of the global economic slowdown and to maintain the process of reform and liberalization of trade policies, the 4th Ministerial Conference at Doha on 14th November, 2001 adopted a Work Programme in its Declaration which incorporated an expanded negotiating agenda necessary to address the challenges facing the multilateral trading system.

Para 6 of the Work Programme related to implementation and interpretation of TRIPS Agreement in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines.[2] In this connection, a separate Declaration was also adopted. It was also agreed that negotiations under the Work Programme shall be concluded not later than 1st January, 2005.

The Separate Declaration on the TRIPS Agreement, recognizing the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics, acknowledged the need for wider national and international action to address these problems.[3] The relevant portion of the Declaration is reproduced herein below:

"4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which

provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
d. 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, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. 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."

The General Council, in its meeting held on 30th August, 2003decided that the obligations of anexporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of apharmaceutical

product(s) and its export to an eligible importing Member(s) in accordance with the certain terms.

However, this Decision was with a condition that it would get terminated for each member on the date on which an amendment to the TRIPS Agreement replacing its provision stakes effect.[4]

TRIPS plus and data exclusivity

Despite the Doha Declaration many developing countries have been coming under pressure to enact or implement, through Free Trade Agreements (FTAs) with developed countries, even tougher or more restrictive conditions in their patent laws than are required by the TRIPS Agreement these are known as TRIPS-Plus provisions. TRIPS-Plus obligations include:

(1) extension of patent terms to compensate for delays in the examination of a patent application or in obtaining market approval for a drug (for example extending the term of a patent longer than the twenty-year minimum, or introducing provisions that limit the use of compulsory licences or that restrict generic competition),

(2) patent linkage requirements that prevent the marketing approval of generic versions of a medicine when patents relating to it exist (required in USFTAs);

(3) requirements to grant patents for second indications of known pharmaceuticals (this refers to exclusive rights, granted over the pharmaceutical test data submitted by companies to drug regulatory authorities);

(4) periods of exclusivity for test data (It means that information concerning a drug's safety and efficacy is kept confidential for a period of, say, five or ten years) and

(5) enhanced enforcement provisions for instance, in relation to border measures (allowing customs authorities to seize goods on suspicion of infringement of a patent in cases of importation, exportation or transit).

Another provision like TRIPS Plus is data exclusivity. It is a backdoor way of preventing competition, so that even when a medicine is not protected by a patent, a pharmaceutical company will receive a minimum period of market monopoly when artificially high prices can be charged. For example, If a generic manufacturer wants to register a drug in that country, it is not allowed simply to show that their product is therapeutically equivalent to the originator product. Instead, it must either sit out for the exclusivity period, or take the route of repeating lengthy clinical trials to demonstrate the safety and efficacy of the drug trials that have already been undertaken. This happens even when the originator product is not patented. TRIPS Plus and Data Exclusivity have a disastrous impact on access to medicine.

TRIPS agreement and access to medicines

In September, 2006, WTO issued a Fact Sheet narrating the Obligations and Exceptions on pharmaceutical patents under TRIPS Agreement where references of various articles on Eligibility for Patenting, Research Exception, Compulsory Licensing, importing under compulsory licensing and Anti-competitive practice were given.[5]

Amendment to TRIPS agreement

An amendment was needed to the TRIPS Agreement to provide the legal basis for WTO members to grant special compulsory licences exclusively for the production and export of affordable generic medicines to other members that cannot domestically produce the needed medicines insufficient quantities for their patients. The General Council of WTO in its meeting at Geneva on6th December, 2005, amended the TRIPS Agreement and submitted to the members for acceptance. The Protocol was open for acceptance by members until 1st December, 2007 or such later date as decided by the Ministerial conference.[6]

The amendment inserted a new 'Article 31bis' into the TRIPS Agreement as well as an Annex and an Appendix to the Annex.[7]

The newly inserted clause is reproduced herein below:

Article 31bis

The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.

Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable apharmaceutical product

produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.

Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994."

Some relevant parts of the Annex to the TRIPS Agreement are reproduced herein below:

"1. For the purposes of Article 31bis and this Annex:

(a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health(WT/MIN(01)/DEC/2). It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included;

(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system set out in Article 31bis and this Annex ("system") as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system as importing Members and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

3. In order to ensure that the products imported under the system are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation."

The Amendment to TRIPS Agreement through the Protocol of 6th December, 2005 came into force on 23th January, 2017 when two third number of WTO members notified the ratification of the Protocol amending the TRIPS Agreement.

A Paper written by Vitor Palmela Fidalgo in June, 2017 pointed out that Article 31 bis of TRIPS is not self-executing, meaning it will not become effective immediately without the implementation of the necessary ancillary legislation in each country. The author suggested that political will on the part of some African governments is needed to accept the amendment to TRIPS and implement it in national legislation as soon as possible.[8]

A paper published in Journal of International Business Policy in July, 2020by Eduardo Urias and Shyama V. Ramani concluded that "Compulsory licensing is often invoked as a panacea for the constraints imposed by TRIPS to ensure access to needed patented medicines during times of health crises. In our systematic review, we verified a mean pricereduction between 66.2 and 73.9% for the 24compulsory licensing events for which price data are available. Therefore, it would seem that compulsory licensing is indeed an effective mechanism for price

reduction with increased availability."

The Paper pointed out that "It makes sense for a government to issue a compulsory license to procure a branded drug for a health crisis only if there are alternative existing generic producers or potential generic producers of the same. The latter could be national companies or a set of actors (e.g., a consortium with universities, public laboratories, investors, public agencies, and firms) in the national innovation system, which can re-engineer and manufacture the required drug in sufficient quantities. In such cases, if no alternative sources to a patent drug are available, a compulsory license will serve no purpose. Thus, in the long run, the best option for developing countries seems to be to build bargaining strength through investment in improving scientific, technological, and innovation capabilities in pharmaceuticals."[9]

Intellectual Property Council at WTO debated issue of access to medicine on 8-9 November, 2016 when Brazil, India, China and South Africa had requested putting on the agenda the recent report of the High-Level Panel on Access to Medicines, convened by the United Nations Secretary-General Ban Ki-moon last year. The co-sponsorsintroduced the report, highlighting the recommendations calling for WTO members to respect the Doha Declaration on TRIPS and Public Health and to make full use of the flexibilities allowed under the TRIPS Agreement for access to medicines. [10]

During the debate, the United States said that although it is strongly committed to identifying practical ways to increase access to safe, effective, affordable and life-saving medicines around the world and to support policies that drive the development of new medicines, it was disappointed by the narrow perspective of the report, which raised fundamental questions regarding the legitimacy of the conclusions. It noted that intellectual property rights and trade are essential to medical innovation, which is fundamental to promoting global health.

The European Union said that it did not share the panel's assumption that there was policy incoherence. A “holistic approach” was needed and has been put in place by the EU to integrate a variety of tools, such as intellectual property and financing, and to balance the need to finance research while ensuring that affordable medications reach those in need. The EU also noted that a number of the report's recommendations were not in line with EU policy.

Switzerland, Japan and Norway signaled similar concerns about the “narrow scope” of the report. Switzerland noted that the report had not been mandated or endorsed by members of the United Nations and duplicated work on intellectual property and public health already taking place.

On the other hand, Egypt, Indonesia, Bangladesh and Bolivia welcomed the report.

WTO in 2018 published a document under the title “MAINS TEAMING TRADE TO ATTAIN THE SUSTAINABLE DEVELOPMENT GOALS”.It acknowledged that Sustainable Development Goals (SDGs) put significant emphasis on the role trade plays in promoting sustainable development and recognised the contribution that the WTO can make to the 2030 Agenda especially in areas such as poverty reduction, health, education and the environment. One of the main objectives of SDG 3: 'Good Health and Well Being' is to ensure access to affordable medicines for all.[11]

Target 3.B of SDG 3 calls for countries to “support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in

particular, provide access to medicines for all".

The Document claimed that as part of this balance, the TRIPS Agreement includes a number of flexibilities that can help to design the intellectual property (IP) regime in a manner that is supportive of access to affordable essential medicines and vaccines, some of which were also clarified through the Doha Declaration on the TRIPS Agreement and Public Health. Among the flexibilities in the TRIPS Agreement is an extended transition period until 2033during which LDCs are not required to provide for the protection of patents and undisclosed information, such as clinical trial data. Also, WTO members are free to put in place an IP regime that allows them to "parallel import"originator medicines without the permission of the intellectual property holder from third countries where these are sold at lower prices. They also have the option to apply certain exceptions and limitations for example, to patent rights, such as compulsory licences.

It further claimed that the amendment to the TRIPS Agreement entered into force on 23 January 2017 after a campaign to encourage governments to follow through on the commitments they had made. It applies to all members who have accepted it. The amendment has been implemented in the domestic legislation of about 85% of the world's exporters of pharmaceutical products. Consequently, developing and least-developed countries in this group now benefit from a sound and secure additional legal pathway to access affordable medicines according to WTO rules.

An article by Siobhan Elizabeth Stade Murillo, published in Indiana International and Competition Law Review in October, 2017,claimed that "The TRIPS Agreement directly conflicts with the right to health because it includes such strict patent laws, and the requirement that binds each country to the GATT agreement. These strict patent protections drive up the price of

HIV/AIDS drugs. This has forced a black market for drugs to emerge, particularly in Central America. The bottom line is that intellectual property rights cut off access to HIV/AIDS drugs for people that need them. Despite the role that patents have played in maintaining higher drug costs for public health programs across countries, this controversy has not led to a revision of TRIPS. Instead, the Doha Declaration was issued in November 2001 and higher drug costs have remained. While the TRIPS Public Health Amendment is commendable, it has been hit with immense criticism. Critics argue that not only is the amendment controversial, but it often goes unimplemented and thus fails its established purpose.

The WTO is one agent that can grant compulsory licenses for the production and export of generic medicines to developing countries with insufficient manufacturing capacity in the pharmaceutical area. This is referred to as the 'paragraph six solution' and was implemented in 2003. Despite this 'paragraph six solution' is used very infrequently.

The issue of pharmaceutical drug affordability is a huge public and political concern. The increasing price of drugs is constantly denying people access to sometimes lifesaving medicines and it is simply not fair to deprive anyone of their constitutional rights to both health and healthcare. It seems that an additional amendment to TRIPS is in order. If this is not a viable option, then countries need to start making the compulsory licensing models more workable, implement strategies with minimal obligations on potential licensees, and importing countries to ensure better access to medicines under TRIPS flexibilities. Medicines are not simply commercial commodities. For some, they are basic human needs. Given the potential loss of life that may occur under TRIPS, something must be changed to ensure basic human rights. Countries have a duty to prevent such unreasonably high costs for access to

essential medicines. At a minimum, TRIPS patent protections should be lessened to the extent necessary to ensure the basic fundamental right to health."[12]

TRIPS agreement and India

Professor Atsuko Kamiike In an Article titled 'The TRIPS Agreement and Pharmaceutical Industry In India' published by SAGE in Journal Of Inter-disciplinary Economics in December, 2019, depicted in detail the history of Indian Pharma industry.

"The Indian pharmaceutical industry has achieved production self-sufficiency and has been one of the largest drug exporters in the world since the late-1980s. It has also shown promising global competitiveness. The Indian pharmaceutical industry continues to expand across the world. This success has been attributed to the industry's ability to conduct research and development (R&D) and to develop generic drugs acquired and improved under the weak patent protection regime enabled by the Patent Act, 1970 from the 1970s to the1990s. The Patent Act, which recognized process patents but not product patents, paved the way for advances in indigenous Indian R&D. Moreover, the DPCO, introduced in 1970 with the aim of supplying drugs to the poor at affordable prices, gave the Indian pharmaceutical industry the incentive to export rather than sell to the domestic market because drugs could be sold at higher prices in overseas markets. Good manufacturing practice (GMP), a system for ensuring that products are consistently produced and controlled according to quality standards, increased the reliability of Indian drugs in the global market. The Indian pharmaceutical industry gradually accumulated R&D capabilities and had achieved trade surpluses with nations all over the world by the late 1990s.

Under the TRIPS Agreement, the pharmaceutical industry became globalized. The pharmaceutical Global Value Chain (GVC) has been re-structured and has now expanded to emerging countries like India. Indian pharmaceutical firms have

been participating in the pharmaceutical GVC through strategic alliances with multinational pharmaceutical companies in the post-TRIPS period. GVC participation is conducive to technology transfers and technological upgrading. Indian pharmaceutical firms are upgrading while operating in the GVC by adopting state-of-the-art technologies.

The TRIPS Agreement has not only increased R&D expenditures in the Indian pharmaceutical industry but also changed its R&Dorientation. Indian pharmaceutical companies are increasing their investment in R&D for product innovation. The new R&D focus is on novel drug delivery systems (NDDS), new drug development research (NDDR), and R&D for bio-pharmaceuticals. some Indian companies have adopted a strategy of developing new molecules and licensing them out to large global pharmaceutical companies in the early stage of clinical development. Collaborative research with global pharmaceutical companies is increasing. India was the first country to start R&D for bio similars. Bio similars have been available in India since the early 2000s, well before their arrival in Europe in 2006 and the recent introduction of a regulatory pathway in the United States. Indian companies are aiming to receive marketing approval of bio similars in regulated markets.

The contract research and manufacturing services (CRAMS) business, a kind of outsourcing business, has been growing rapidly in India. CRAMS deals with manufacturing and research activities. Many Indian companies have entered CRAMS, and the number of specialized CRAMS companies has increased. In the post-TRIPSperiod, India has become a preferred outsourcing destination for global pharmaceutical companies and is becoming a global manufacturing and R&D hub. The TRIPS Agreement has made the Indian pharmaceutical industry more R&D oriented and -intensive, pushing it up to the higher end of the GVC. Moving up the value chain implies a

continuous process of change, innovation, and productivity growth. Regarding functional upgrading, India used to be engaged mainly in contract manufacturing. Now, Indian firms are also undertaking contract research. India's position in the GVC has changed from that of contractor to that of partner.[13]"

Srividhya Raghvan, in the very beginning of her Research Paper No. 20-32, Legal Studies Research Paper Series, published in October, 2020, wrote the following line:

"Alas! WTO's imagination is limited to creating private wealth at the cost of public health."

While quoting her earlier Paper written with Brian Manning and published in 2010, she said "There is a need for a balance between innovation and access. The role of the WTO as the gatekeeper for minimizing and eliminating trade barriers remains important in taking a strategic leadership position for health-related matters. If global productivity is affected due to lack of access to available medication, global trade suffers. Despite this reality, the WTO has remained normative and divorced from the real impact of local realities on larger health issues. Its stature as a global organization notwithstanding, the WTO has shown a remarkable tendency to succumb to rhetoric and pressures from corporate interest and powerful countries, which are susceptible to pandering by powerful trade lobbies. Consequently, the WTO has been irrelevant in ensuring access to medication as a means to strengthen productivity and global trade.

Indeed, the WTO's failure to balance innovation with access has caused, contributed to, and affected access to medications. The actions of the WTO have actively contributed to morphing access to lifesaving medications into a luxury by creating an elite global class of people with access to health care and medication. While the WTO's emphasis on patents on lifesaving medications played a role in innovation, it largely facilitated corporations from disengaging with issues that raise public policy, public health, and right to life concerns both by commissions and

omissions that denied access to lifesaving medications.

The WTO has been criticized for its inability to curtail countries with higher bargaining parity, such as the US, from taking actions that result in TRIPS-plus trade privileges being detrimental to countries with lower bargaining parity. For example, in February 2020, the US-India Memorandum of Understanding on Intellectual Property Rights for the exchange of knowledge and training of officials working in offices undertaking IP management in India presented serious concerns. The US Patent and Trademark Office training Indian patent office personnel on the Indian statute which incorporates more TRIPS flexibilities than the US is an appalling proposition." She concluded her Paper with the following paragraph:

"While innovation is an important mandate, the IP regime's imbalances have not accounted for local realities, largely contributing to a crisis in global access to medication. While the TRIPS Agreement's deficiencies and its disengagement with realities are important aspects, the WTO's inaction and its singular focus on trade dissociated with local realities have mired the organization since inception. Meanwhile, the rhetoric of innovation has not helped innovation nor helped establish the patent regime as a vehicle for innovation. In fact, the patent regime has transformed into a barrier to innovation and access to medicine, profoundly impacting the WTO negatively to a point of rendering it irrelevant."[14]

TRIPS waiver for vaccine for treatment of COVID-19

Council for Trade-Related Aspects of Intellectual Property Rights on 2nd October, 2020 circulated a communication from India and Africa relating to waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of Covid-19. The communication highlighted that on

11 March 2020, the World Health Organization (WHO) declared the coronavirus disease 2019 (COVID-19) to be a global pandemic, after having announced a related Public Health Emergency of International Concern (PHEIC) on 30 January 2020. The Communication urged that in present context of global emergency, it is important for WTO Members to work together to ensure that intellectual property rights such as patents, industrial designs, copyright and protection of undisclosed information do not create barriers to the timely access to affordable medical products including vaccines and medicines or to scaling-up of research, development, manufacturing and supply of medical products essential to combat COVID-19. [15]

India and Africa urged that an effective response to COVID-19 pandemic requires rapid access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need. As new diagnostics, therapeutics and vaccines for COVID-19 are developed, there are significant concerns, how these will be made available promptly, in sufficient quantities and at affordable price to meet global demand. Critical shortages in medical products have also put at grave risk patients suffering from other communicable and non-communicable diseases.

In these exceptional circumstances, they request that the Council for TRIPS recommend, as early as possible, to the General Council a waiver from the implementation, application and enforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement in relation to prevention, containment or treatment of COVID-19. It was also requested that the waiver should continue until widespread vaccination is in place globally, and the majority of the world's population has developed immunity

hence we propose an initial duration of [x] years from the date of the adoption of the waiver. The Council for TRIPS has had extensive discussions on the proposal and received comments on the proposed draft decision text.

In Working Paper No. 20/2020 published by Asia-Pacific Research and Training Network on Trade, Professor Biswajit Dhar and Shri KM Gopa Kumar discussed some possible ways forward in dealing with some specific obligations under the TRIPS Agreement with an objective of enhancing world's chances for prevention, containment and treatment of COVID-19. The Paper pointed out that the flexibilities incorporated in the domestic legislations are predominantly to address the concerns on access to medicines in the context of patent protection and are not equipped to address the implications of other forms of IP on availability and accessibility such as copyrights on source codes of diagnostic platforms, clinical trials' data and industrial designs for medical products and components. Each of these forms of IPRs pose challenges to the mass production of these products and therefore, waivers from obligations being demanded has to cover these trade secrets also.[16]

The Paper analysed that the TRIPS agreement only mandates that regulatory agencies must protect clinical trials' data against unfair commercial use. It suggested that national authorities should not treat safety and efficacy data for COVID-19 related medical products as trade secrets in public interest. It should strengthen the provisions to grant compulsory licenses, encourage and attract enough from the holders of proprietary knowledge, data and technology into Covid-19 Technology Access Pool (C-TAP). The Paper further suggested that the major task for India and South Africa was to ensure strong backing for the Waiver Proposal from within the WTO and outside as in a member driven multilateral system, effective coalitions are vital for norm setting.

By means of a communication dated 21 May 2021, the delegations of the African Group, Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, the LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, Venezuela and Zimbabwe, taking into account the discussions and feedback received, submitted a revised draft decision text for the consideration of the Council for TRIPS.The revised text addresses the concern of continuous mutations and the emergence of new variants of SARS-COV-2 by focusing the text on "health products and technologies" as the prevention, treatment or containment of COVID-19 involves a range of products and technologies and intellectual property issues may arise with respect to the products and technologies, their materials or components, as well as their methods and means of manufacture. Another change was that it was proposed the waiver to remain in force for at least 3 years from the date of this decision subject to review and if such circumstances cease to exist, the General Council shall determine the date of termination of the waiver.[17]

On 4 June, 2021, the European Union submitted to the Council for TRIPS a communication on "Urgent trade policy responses to the COVID-19 crisis: intellectual property" (document IP/C/W/680).The relevant part of the draft text is reproduced herein below:

"We agree that —

a. A pandemic is 'a national emergency or other circumstances of extreme urgency' within the meaning of Article 31(b) of the TRIPS Agreement. For the purposes of issuing a compulsory licence pursuant to Articles 31 and 31bis of the TRIPS Agreement, a Member may waive the requirement of making efforts to obtain authorization from the right holder, provided for in Article 31(b).
b. In the circumstances of a pandemic and to support manufacturers ready to produce vaccines or medicines

addressing the pandemic at affordable prices for low- and middle-income countries, a Member may provide, for the purposes of determining the remuneration to be paid to the right holder pursuant to Article 31(h) and paragraph 2 of Article 31bis of the TRIPS Agreement, that the remuneration reflects the price charged by the manufacturer of the vaccine or medicine produced under the compulsory licence.

c. In the circumstances of a pandemic, for the purposes of Article 31bis and paragraph 2.c) of the Annex to the TRIPS Agreement, the exporting Member may provide in one single notification a list of all countries to which vaccines and medicines are to be supplied by the exporting Member directly or through indirect means, including international joint initiatives that aim to ensure equitable access to the vaccines or medicines1 covered by the compulsory licence. It shall be presumed that such joint initiatives supply those vaccines and medicines to eligible importing Members within the meaning of paragraph 1.b) of the Annex to the TRIPS Agreement."[18]

Following the decision to postpone the 12thMinisterial Conference (MC12) amid new corona virus variant concerns, delegations committed to continue engaging in various configurations in the coming weeks to try and harvest any outcome that may still be possible. At a formal meeting of the Council for TRIPS held on 29th November, 2021, WTO members support maintaining momentum of discussions on common IP COVID-19 response. Members also agreed to keep open in the agenda of the TRIPS Council the two proposals on the table subject to discussion the proposal by India and South Africa (IP/C/W/669/Rev.1 and the proposal by the European Union (IP/C/W/681).[19]

Tom Lee and Christopher Holt in their paper published in 'Insight' on 10th May, 2021, have expressed their opinion that the proposal by India and South Africa to waive TRIPS is based

on the mis-perception that IP protection serves as barriers to COVID-19 vaccine production. In fact, the difficulty of scaling up production is the key challenge and waiving TRIPS will do nothing to increase vaccine production. They have also pointed out that vaccine developed by Pfizer and Moderna were not currently approved by the Indian Government for use in India due to regulatory obstacles related to local clinical trials. India is pointing to IP protections as obstacle to obtaining vaccine they have not even approved for use in their country.[20]

Kluwer Patent Bloghas a different take on the whole issue. It wrote that "But was this proposal necessary in the first place? Interestingly, on 15 October 2020, the WTO published an "Informative Note" under the title The TRIPS Agreement and COVID-19, the reading of which casts doubts on whether any time and energy devoted to another useless modification of the TRIPS Agreement, such as the introduction of Article 31 bis (waivers for export purposes), would be worth it. Why was so much time, effort and so many newspaper headlines consumed in that amendment of the TRIPS Agreement to introduce export waivers, if nobody uses them?

Reading the "Informative Note" (the "Note") prepared by the WTO's Secretariat, which has gone relatively unnoticed and is actually good reading, illustrates that the TRIPS Agreement already contains the necessary legal armamentarium to address the need posed by Covid-19."[21]

In an Article published in Free Trade Bulletin of CATO Institute in December, 2020, James Bacchus expressed his views that solution to TRIPS Waiver by WTO lies outside the WTO.

"Unless WTO members reach a consensus, the multilateral trading system may be further complicated by a delay like that in resolving the two-decades-old dispute between developed and developing countries over the compulsory licensing and generic distribution of HIV/AIDS drugs. A new and contentious "North-South" political struggle definitely would not be in the interest of

the developed countries, the developing countries, the pharmaceutical companies, or the WTO. Certainly it would not be in the interest of the victims and potential victims of COVID-19.

This waiver controversy comes nearly two decades after the end of the long battle in the multilateral trading system over access to HIV/AIDS drugs. At the height of the HIV/ AIDS crisis at the turn of the century, numerous countries, including especially those from sub-Saharan Africa, could not afford the high-priced HIV/AIDS drugs patented by pharmaceutical companies in developed countries. Having spent billions of dollars on developing the drugs, the patent holders resisted lowering their prices. The credibility of the companies, the countries that supported them, and the WTO itself were all damaged by an extended controversy over whether patent rights should take precedence over providing affordable medicines for people afflicted by a lethal disease.

Compulsory licensing of medicines is not popular with private drug manufacturers because it is a derogation from the customary workings of market-based capitalism. However, as these actions by WTO members in 2001, 2003, and 2017 illustrate, compulsory licensing is not a derogation from the balance struck by the members of the WTO between protecting IP rights and ensuring access to essential medicines. Rather, it is a crucial part of that balance. The balance struck in the WTO treaty includes the option of compulsory licensing during health emergencies.

As Stephen Ezell and Nigel Cory of the Information Technology and Innovation Foundation wrote, "A fundamental fault line in the debate over intellectual property pertains to the need to achieve a reasoned balance between access and exclusive rights." This fault line is much on display in the WTO rules on IP rights. These rules recognize that "intellectual property rights are private rights" and that rules and disciplines

are necessary for "the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights." Yet, where social and economic welfare is at stake, WTO members have sought to strike a balance in these rules between upholding IP rights and fulfilling immediate domestic needs.

In no event should IP rights become legal obstacles to ensuring early access to affordable medicines for everyone in the world during a pandemic that has already killed more than a million people worldwide and threatens to kill millions more. But also, in no event should WTO members act in ways that would eliminate the incentives that are essential to inspire the innovations that make new medicines possible. The solution is not another impassioned and prolonged multilateral impasse inside the WTO. The solution is multilateral action in international institutions and international endeavours outside the WTO."[22]

In the Second addition of their joint Publication "Promoting Access to Medical Technologies and Innovation" published in 2020, WTO, WIPO and WHO have inserted a special text under the title "An Integrated health, trade and IP approach to respond to the COVID-19 pandemic" as the text of the second addition was already completed before the COVID-19 outbreak.[23]

In spite of acknowledging that the COVID-19 pandemic is an extraordinary global public health crisis and it has created a pressing need for intensified global cooperation and equitable access to new technologies is of paramount importance, the publication has not clarified their respective stand on TRIPS waiver.

On the other hand, opposition submitted by some civil society organisations such as CAMD- India and TWN, Argentina-Fundacion GEP against patents on technologies that could be potentially used in a new COVID-19 medicine and demanding patent revocation, has been termed as traditional measures used by commercial competitors.

Way Forward

The next Ministerial Conference (12th MC) is fixed to be held on 13-15 June, 2022. India and Africa Group should persuade developed countries in bilateral discussions to support and allow TRIPS waiver for vaccine for treatment of COVID-19. They should ensure that a decision on this issue is taken in the 12th MC. If unanimous decision is not forthcoming, they should work for majority decision in this regard.

There is need to change the TRIPS Agreement again and the most important amendment would be deletion of para (f) of Article 31 of the Agreement and India with the support of other developing and least developed countries must act in this direction, if the TRIPS waiver for vaccine for COVID-19 pandemic is not granted soon. The fact that earlier amendment in the TRIPS Agreement came after persuasion of 10 years, should not discourage developing countries to make efforts in this direction.

COVID-19 is not going to be the last pandemic and therefore, to be future ready, India and other developing nations should work for suitable changes in the TRIPS Agreement for taking public health out of TRIPS Agreement as public health is an international human rights.

After the announcement of the USTR on 5th May to support the text-based negotiations on the waiver proposal many countries came forward to support the negotiation. However, the announcement of the EU is not clear in its support to the text-based negotiation. Further, the EU attempted to limit it to the scope of the TRIPS Waiver to only to the vaccine patents.

Swadeshi Jagran Manch wrote to European Union, expressing it displeasure on the Eu's stance. (BOX 1)

In response to SJM's letter, EU Secretariate in New Delhi said that ready to engage with WTO members to agree on a strong multilateral trade response to the pandemic. (BOX 2)

BOX-1

Swadeshi Jagran Manch

"Dharamakshetra, Sector-8, R.K. Puram, New Delhi
Ph. 011-26184595, Web: www.swadeshionline.in

20th May 2021

To

Mr. Ugo Astuto,
Hon'ble Ambassador
Delegation of the European Union to India and Bhutan
5/5, Shantiniketan, New Delhi - 110 021, INDIA

SUB: TRIPS Waiver Proposal

Dear **Ambassdor Astuto**,

The Swadeshi Jagran Manch (SJM) is writing to draw your attention to the EU's reluctance to support a text-based negotiation of TRIPS Waiver proposal to suspend certain intellectual property (IP) for the COVID19 medical products.

As you are aware that in view of the COVID-19, a worst pandemic faced by the humanity, India along with South Africa has proposed in October 2020 in WTO and urged WTO to grant a waiver for limited years (which will be negotiated by the TRIPS Council), from the implementation, application and enforcement of specific provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19.

As you know the international human rights obligation also includes an obligation to desist from taking measures that result in the infringement of human rights in other countries. Attempts to block the text-based negotiations is an indirect support to COVID 19 medical products goes against the concept of solidarity and even violate the right to health

guaranteed under Article 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR).

We would like to state that the best option before us is to scale up the production of various COVID19 medical products by removing the legal barrier against the freedom of operation. The approach of charity i.e. donating vaccines and other medical products is not a sustainable strategy. Further such an approach has also failed so far to effectively address the problem. This kind of approach is likely to lead to continuation of monopoly by a few companies over Covid19 medical products; and it will only accentuate the miseries of the people, as the same is likely to cause shortages and unaffordable treatment, which India and world has gone through in recent months.

It is also important to note that patent is not the only barrier, access to trade secret is critical to scale up the production of vaccines, diagnostics etc. Therefore, EU proposed COVID19 Vaccine Patent Pool is diversionary tactic rather than addressing the real issue. On this unprecedented international health Criss, it is important to keep peoples' health above the profit.

Against this background, we request you to unconditionally support the TRIPS Waiver Proposal and constructively engage in the text-based negotiation to conclude the negotiation at the earliest without compromising the purposes and objectives behind the proposal.

Looking forward to your reply

With regards,

Dr Ashwani Mahajan
National Co Convenor
CC-Embassies of all EU Member States

BOX-2

From: "BHASKAR Renita (EEAS-NEW DELHI)"
Renita.BHASKAR@eeas.europa.eu
Sent:Thu, 17 Jun 2021 12:18:58 +0530
To: "ashwanimahajan@rediffmail.com"
ashwanimahajan@rediffmail.com

Subject: RE: Submission on TRIPS Waiver Proposal

Dear **Dr Mahajan**,

Thank you for the below email. The EU Ambassador has requested me to reply on his behalf.

At the outset I would like to confirm that universal and fair access to COVID-19 vaccines and treatments is a top priority for the European Commission. Consequently, ramping up production, and sharing vaccines wider, faster, and at affordable cost is the single most effective way to fight the pandemic in all regions of the world at this critical moment.

However, there is no single solution to achieving this goal and a multilateral response is urgently needed. This must be a global priority. The EU, at the forefront of this effort, and on 4 June 2021 made a proposal on how the rules-based global trading system can contribute to this goal by:

1. Facilitating trade and limiting export restrictions to keep supply chains open;
2. Expanding production, including through pledges by vaccine producers and developers, and;
3. Clarifying and facilitating the use of the TRIPS agreement flexibilities relating to compulsory licenses.

The EU is ready to engage with WTO members to agree on a strong multilateral trade response to the pandemic. In this spirit, we have constructively engaged in the text-based

discussion by putting forward our comprehensive proposal for the discussion in both the General Council and the TRIPS Council of the WTO.

I trust that clarifies the EU position on this critical matter.

Kind regards,

Renita Bhaskar
Minister Counsellor Head of Trade and Economic Affairs
Logo
Delegation of the European Union to India
Shanti Niketan 5/5, New Delhi 110 021, INDIA
Tel: (91-11) 6678 1919 Mobile: (91) 9311045416
Fax: (91-11) 6678 1955
Email: renita.bhaskar@eeas.europa.eu
website: http://eeas.europa.eu/delegations/india
like us on: www.facebook.com/EUinIndia

Expressing concerns about the procedures adopted by WTO secretariate and the attempts to limit the scope of TRIPS waiver, Swadeshi Jagran Manch, wrote to Commerce and Industry Minister Shri Piyush Goyal, on 18 February 2022. (BOX-3)

A new apartheid is emerging

Today a newer type of apartheid is emerging in the world and that is between vaccinated and unvaccinated. Recently, in the ministerial conference, which was to be held in Geneva, Switzerland, it was also stipulated that only those who have been fully vaccinated with a vaccine certified by World Health Organisation, would be able to participate, and others will have to satisfy organisers by getting the RTPCR test done, every 72 hours. Significantly, there are many countries in the world where vaccination has not yet started or is in a very nascent stage. That is, such countries whose representatives are not vaccinated, will

BOX3

Swadeshi Jagran Manch

Dharamakshetra, Sector-8, R.K. Puram, New Delhi
Ph. 011-26184595, Web: www.swadeshionline.in

18-02-2022

To

Shri Piyush Goyal
Hon'ble Minister of Commerce and Industry
Government of India, New Delhi

Shri **Piyush Goyal ji**

This has reference to a petition made by India and South Africa in the World Trade Organization, under your able leadership in October last year, seeking exemption from Trade Related Intellectual Property Rights (TRIPS), so that vaccines and corona medicines in the world are available to the entire humanity on affordable basis. Globally, TRIPS mandates countries to honour intellectual property rights. The exemption from TRIPS would mean that companies that have intellectual property rights on vaccines, medicines and medical equipment would be revoked for the period so decided, and many countries of the world, including India, would be able to produce these vaccines, medicines and devices on their own. This demand of India and South Africa got the support of more than 100-member countries of WTO.

As you are aware that the WTO Secretariat is engaging with EU, US, South Africa, and India to find a solution to TRIPS Waiver. However, it is unprecedented that the Secretariat is having textual discussions at the Ministerial level, without the involvement of technical advisors. In any case, we understand, that India is standing up to the pressure of the EU, US and the WTO Secretariat. We call on you to continue the same, to ensure that any outcome of the discussions should result in an effective and useful outcome for access and should expand the flexibilities provided by the TRIPS Agreement. In this regard we wish to

bring the following points for your consideration:

- Scope of the TRIPS Waiver decision should not only include vaccines but also therapeutics and diagnostics
- The Waiver outcome should go beyond the compulsory license (CL) mechanism (Article 31 and 31bis of the TRIPS Agreement which are about patents) and should include trade secret protection under Article 39.3, which is very essential for the generic production of vaccines and COVID19 monoclonal antibodies.
- It should cover both patented productions and products with pending patent applications.

Regarding the process of negotiations, we wish to highlight that –

- The WTO Secretariat, US and EU may stress on secrecy and confidentiality. However, we should also stress the importance for each country to ensure that it is properly advised and supported. Hence secrecy should not impact the national decision-making process of a country, and government may seek advice of experts including those of the Centre of WTO Studies, key civil society organisations, and the academia.
- The WTO Secretariat is notorious for its support of US and EU positions and consequently misleading and inaccurate legal analyses and technical input. Further, given that world over, people are waiting for a good outcome, it is absolutely crucial to ensure that the outcome is sound and credible before it is agreed to. India should ensure that the South African Minister shares the same view. India should not agree to any text until it has been fully vetted and endorsed by India's technical experts.
- It is also important for both India and South Africa to inform other key co-sponsors (member countries) on the state of play and take them, in confidence before agreeing to anything. That will enhance the confidence in India and support future alliances in the WTO. Additionally, where

there is disagreement from the EU and US, the support of other developing countries will be invaluable.

Any solution to the TRIPS Waiver should make a substantial improvement on the existing flexibilities including with respect to trade secret, to provide material benefit to developing countries supporting the proposal of India and South Africa. India needs the support of other developing countries to maintain our bargaining power at the WTO. Therefore, we need to consider the sensitivities of other developing countries before accepting any solution on the TRIPS waiver

There are disturbing news coming from a section of media that a small group of WTO members deliberating on the TRIPS Waiver, are discussing suggestions to limit the geographical scope of the implementation of the waiver - plans that seek to exclude India and China. It is understood that the US and the EU have, in their own ways favoured a limited application of such a waiver. Some suggestions include restricting the waiver only to African countries, or to exclude India and China among other possibilities. Its obvious that India will not accept any such proposal, however, we have to defeat these proposals.

No doubt, efforts of our scientists, industry, corona warriors and the government, we have been able to address the challenge of the worst pandemic, which continues to haunt a sizable section of humanity. We need to understand that India's fight for TRIPS waiver is not for our people only, but its for the global humanity, especially the developing and least developed countries. We need to fulfil our responsibility towards humanity to get rid of this pandemic and TRIPS Waiver assumes significant importance for the same.

We at Swadeshi Jagran Manch humbly request you to take note of the developments in this regard, and take the proposal forward in the interest of India and humanity globally.

Warm regards

Dr Ashwani Mahajan
National Co Convenor

not be able to be represented in international forums will be restricted for such meets.

In such a situation, the need of the hour is that all the rich countries including USA and Europe, who are endangering humanity by opposing the demand for TRIPS waiver, be boycotted at every global platform. Press, media, intellectuals and people representatives, should create such an environment that these countries give their consent for TRIPS waiver. This is the only way to save the humanity.

Apprehensions of Swadeshi Jagran Manch about attitude of developed countries were proved right, with the circulation of chair's text (Text prepared by the chairperson of TRIPS council), said to be prepared after informal discussion, conceding that there was no concusses on the issue. (BOX-4)

BOX 4
CHAIR'S TEXT

Globally, TRIPS mandates countries to honour intellectual property rights. The exemption from TRIPS would mean that companies that have intellectual property rights on vaccines, medicines and medical equipment would be revoked for the period so decided, and many countries of the world, including India, would be able to produce these vaccines, medicines and devices on their own. This demand of India and South Africa got the support of more than 100-member countries of WTO. WTO Secretariat has been engaging with EU, US, South Africa, and India to find a solution to TRIPS Waiver. However, it is unprecedented that the Secretariat is having textual discussions at the Ministerial level, without the involvement of technical advisors. In any case, India has been standing up to the pressure of the EU, US and the WTO Secretariat.

We need to ensure that any outcome of the discussions should result in an effective and useful outcome for access and

should expand the flexibilities provided by the TRIPS Agreement. In this regard we wish to bring the following points for your consideration:

▪ Scope of the TRIPS Waiver decision should not only include vaccines but also therapeutics and diagnostics

▪ The Waiver outcome should go beyond the compulsory license (CL) mechanism (Article 31 and 31bis of the TRIPS Agreement which are about patents) and should include trade secret protection under Article 39.3, which is very essential for the generic production of vaccines and COVID19 monoclonal antibodies.

▪ It should cover both patented productions and products with pending patent applications.

Regarding the process of negotiations, we wish to highlight that –

▪ The WTO Secretariat, US and EU may stress on secrecy and confidentiality. However, we should also stress the importance for each country to ensure that it is properly advised and supported. Hence secrecy should not impact the national decision-making process of a country, and government may seek advice of experts including those of the Centre of WTO Studies, key civil society organisations, and the academia.

▪ The WTO Secretariat is notorious for its support of US and EU positions and consequently misleading and inaccurate legal analyses and technical input. Further, given that world over, people are waiting for a good outcome, it is absolutely crucial to ensure that the outcome is sound and credible before it is agreed to. India should ensure that the South African Minister shares the same view. India should not agree to any text until it has been fully vetted and endorsed by India's technical experts.

▪ It is also important for both India and South Africa to inform other key co-sponsors (member countries) on the state of play and take them, in confidence before agreeing to anything. That will enhance the confidence in India and support future

alliances in the WTO. Additionally, where there is disagreement from the EU and US, the support of other developing countries will be invaluable.

Any solution to the TRIPS Waiver should make a substantial improvement on the existing flexibilities including with respect to trade secret, to provide material benefit to developing countries supporting the proposal of India and South Africa. India needs the support of other developing countries to maintain our bargaining power at the WTO. Therefore, we need to consider the sensitivities of other developing countries before accepting any solution on the TRIPS waiver.

There are disturbing news coming from a section of media that a small group of WTO members deliberating on the TRIPS Waiver, are discussing suggestions to limit the geographical scope of the implementation of the waiver - plans that seek to exclude India and China. It is understood that the US and the EU have, in their own ways favoured a limited application of such a waiver. Some suggestions include restricting the waiver only to African countries, or to exclude India and China among other possibilities. Its obvious that India will not accept any such proposal, however, we have to defeat these proposals. No doubt, efforts of our scientists, industry, corona warriors and the government, we have been able to address the challenge of the worst pandemic, which continues to haunt a sizable section of humanity. We need to understand that India's fight for TRIPS waiver is not for our people only, but its for the global humanity, especially the developing and least developed countries. We need to fulfil our responsibility towards humanity to get rid of this pandemic and TRIPS Waiver assumes significant importance for the same.

Government of India needs to take note of the developments in this regard, and take the proposal forward in the interest of India and humanity globally.

References:

1. Https://www.wto. Org/English/res_e/booksp_e/wtoagreementpreface_e.pdf (accessed on 10.4.2022).
2. WTO, WT/MIN(01)/DEC/1 20 November, 2001.
3. WTO, WT/MIN(01)/DEC/2 20 November,2001.
4. WTO,GC, WT/L/540 and Corr.1, 1 September, 2003.
5. Https://www.wto. Org/factsheet_pharma00-O4_e.htm.
6. WTO, GC, WT/L/641 , 6 December 2005.
7. Ibid.
8. "Article 31bis of TRIPS: How can African countries benefit from this amendment?", a Paper by VitorPalmelaFidalgo in June ,2017.
9. "Access to Medicines after TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence" published in Journal of International Business Policy in July, 2020 by Eduardo Urias and Shyama V. Ramani. (www.jipb.net accessed on 10.4.2022).
10. WTO: 2016 NEWS ITEMS, 8 and 9 November, 2016.
11. "MAINSTEAMING TRADE TO ATTAIN THE SUSTAINABLE DEVELOPMENT GOALS" published by WTO in 2018. ISBN978-92-870-4272-9.
12. "Fair or Fraud: Has the protocol amending TRIPS flourished or failed?" an article published by Siobhan Elizabeth Stade Murillo, published in Indiana International and Competition Law Review in October, 2017.
13. 'The TRIPS Agreement and Pharmaceutical Industry In India' published by SAGE in Journal Of Inter-disciplinary Economics in December, 2019, authored by Atsuko Kamiike, Professor at Research Institute for Economics and Business Administration, Kobe University, Japan (journals.sagepub.com/home/jie accessed on 18.2.2022).
14. Research Paper No. 20-32, Legal Studies Research Paper Series, titled "World Trade Organisation: A Barrier to Global Public Health?" published in October, 2020 by SrividhyaRaghvan, Professor of Law at Texas A&M University.
15. WTO. IP/C/W/669, 2 October 2020.
16. Working Paper No. 20/2020 titled 'Towards more Affordable medicine: A proposal to waive certain obligations from the Agreement on TRIPS', published by Asia-Pacific Research and Training Network on Trade by Professor BiswajitDhar and Shri KM Gopakumar.
17. WTO.IP/C/W/669/Rev.1, 25 May 2021.
18. WTO.IP/C/W/681, 18 June 2021.
19. WTO. TRIPS. 29 November 2021.
20. "INTELLECTUAL PROPERTY, COVID-19 VACCINES AND THE PROPOSED TRIPS WAIVER", published in 'Insight' on 10th May, 2021 by Tom Lee and Christopher Holt.
21. "Was the recent skirmish on the TRIPS Agreement and COVID-19 really worth it"? - Kluwer Patent Blog (http://patentblog.kluweriplaw.com/2020/10/26).
22. "An unnecessary proposal A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines", an Article by James Bacchus published in Free Trade Bulletin of CATO Institute in December, 2020.
23. Second addition of the Joint Publication "Promoting Access to Medical Technologies and Innovation" published in 2020, by WTO, WIPO and WHO under the title "An Integrated health, trade and IP approach to respond to the COVID-19 pandemic".

Rs. : 50/-

Swadeshi Jagaran Foundation

"Dharmakshetra", Babu Genu Marg,
Sector-8, R.K. Puram, New Delhi-110022
Tel.: 011-26184595, **Website:** www.swadeshionline.in