ACCESS TO MEDICINES AND HUMAN RIGHTS – A CRITICAL REVIEW OF INTERNATIONAL TRADE RELATED IP BARRIERS AND ITS OPERATION DURING COVID-19

Sushma George Mathew[1]& Parvathi Balachandran[2]

Department of Law, Mar Greogorios College of Law, Department of Law, Ramaiah College of Law

Abstract - The Covid-19 pandemic, an international health emergency has brought back into focus the debate on access to medicines. Unhindered access to medicines is an essential prerequisite for achieving public health indicators. Even though India's public spending of health is relatively low, access to cheap and effective medicines for a wide variety of needs is a hallmark of the Indian health system. India clinched the sobriquet 'pharmacy of the world', when pharmaceutical companies such as the Serum Institute of India, Biological E, Dr Reddy's etc manufactured and supplied lifesaving drugs at comparatively trifling prices. A conducive intellectual property environment which barred product patents for medicines till 2005 spurred the growth of this manufacturing industry. The implementation of TRIPS obligations post-2005 and the current global health crisis has opened a cavernous need for the manufacture and supply of therapeutic and diagnostic equipment in large volumes. As the world turns to India, Brazil and South Africa to meet it needs, the countries are mooting a waiver of TRIPS protection on medicines and medical equipment.

The first part of this paper is a study of the WTO/TRIPS regime's approach to public health and access to medicines. The paper will examine the impact of the TRIPS provisions on public health, particularly the possibilities of a 'waiver' of TRIPS obligations or else the exercise of 'flexibilities' provided for under the TRIPS regime. While the 'waiver' of TRIPS obligations is an inherent part of the WTO system as agreed to in the Marrakesh Agreement, the highlight on 'flexibilities' including compulsory licensing largely draws on the jurisprudence generated by Doha Declaration on TRIPS and Public Health. The second part of the paper will juxtapose the WTO's rules on access to medicines vis-à-vis the wider human rights jurisprudence on right to health, and the consequences of this interaction between the WTO norms and human rights norms.

[1] Assistant Professor, Mar Gregorios College of Law, Thiruvananthapuram
[2] Assistant Professor, Ramaiah College of Law, Bengaluru

Keywords – TRIPS, Doha Declaration, Public health, access to medicines, right to health

I. INTRODUCTION

The Covid-19 pandemic, an international health emergency that stares in the face of the world rages on. As emergency responses from social vaccines to advanced innovations in science are spurred on vehemently, the world of medical science places its best bet on vaccine formulations and treatment protocols,if life is to return to 'normal' at some foreseeable future.

In a span of one year and a little more, vaccines to prevent the intensity of the pandemic have made market entries, authorized by emergency use protocols of World Health Organization (WHO) as well as domestic regulators. In India too, 2021 heralded itself with much promise on the vaccine front. On January 2, 2021, the Drugs Controller General of India issued licenses authorizing restricted emergency use for Covishield (developed by Oxford-AstraZeneca consortium) and Covaxin (indigenously developed by BharatBiotech in collaboration with ICMR).[3]Front line health workers, police personnel, and municipality workers were given priority during the first phase of vaccination in February, 2021. By March, 2021, vaccines became available for those above 60 years of age as well as those above 45 years with co-morbidities. All along the initial months, concerns about vaccine hesitancy absorbed the attention of policy makers and governments. There was little discussion about vaccine availability and vaccine shortages. Therefore, it was no wonder that by March 10, 2021, India had also sent abroad 58 million vaccine doses to almost 65 countriesunder its so called 'Vaccine Maithri' scheme. [4]

By April, 2021, when the second wave of the pandemic had clearly hit Maharashtra, and Delhi, vaccine availability became a serious issue of concern. Reasons on what went wrong were aplenty – the Indian government did not give sufficient consideration to the idea of placing advance orders on vaccines (as other developed countrieshad done as early as June 2020), the government had been clearly lax in scaling up manufacturing capabilities, international and national patent regimes stood in the way of vaccine equityetc

[3] Press Statement by the Drugs Controller General of India (DCGI) on Restricted Emergency approval of COVID-19 virus vaccine, PRESS INFORMATION BUREAU - GOVERNMENT OF INDIA(May 11, 2021) https://www.icmr.gov.in/pdf/press_realease_files/HFW_DCGI_energency_use_authorisation_03012021_2.pdf

[4] Vaccine maitri: 5.8 crore Made-in-India Covid vaccine doses supplied to over 65 nations, INDIA TODAY**(**May 11, 2021) https://www.indiatoday.in/coronavirus-outbreak/video/vaccine-maitri-5-8-crore-made-in-india-covid-vaccine-doses-supplied-to-over-65-nations-1777871-2021-03-10

Meanwhile, a few months old discussion on waiver of intellectual property ("IP") rights over Covid related medicines and equipment was once again resurrected in the context of vaccine shortages. On October 2, 2020, Indian and South Africa made a jointcommunication to the Council for Trade-Related Aspects of Intellectual Property Rights ('TRIPS Council')for waiver from certain provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19. The communication focused on the significance of cooperation amongst WTO members so as to facilitate increased and prompt access to medicines, vaccines, opportunities for manufacturing medical products for opening up avenues for medical research and development all of which are indispensible in this battle against the pandemic.[5] In November 2020, the matter was taken up for further discussion with supporting examples. South Africa pointed out that how Regeneron and Eli Lily had locked up manufacturing capacities in bilateral deals for monoclonal antibody therapeutics, [6]and therefore to that extent patents operated an obstruction on access to medicines. In addition, South Africa also put forward the example of how Pfizer's patent over the lifesaving pneumococcal vaccine, a WHO recommended inoculation to prevent childhood pneumonia prevented the widespread use of this vaccine in lower- and middle-income countries. Incidentally, in India Médecins sans Frontier (MSF) has filed an application in the Delhi High Court calling for the revocation of the patent granted to Pfizer for the drug, alleging that the vaccine formulation is only an incremental innovation on an existing formulation, pointing out that the European Patent Office has revoked its patent granted to Pfizer.[7]

The world community that leads the demand for waiver of IP not only includes governments of least and middle-income countries but also international agencies such MSF and the World Health Organization (WHO). MSF has brought forward a briefing paper on how waiver of IP can be beneficial. MSF's chief argument is that a case-by-case approach and use of flexibilities under the WTO will not be beneficial. This is primarily because the pharmaceutical industry is likely to flex licensing agreements to its

[5]Waiver from certain provisions of the trips agreement for the prevention, containment and treatment of Covid-19 - Communication from India and South Africa, WORLD TRADE ORGANIZATION (May 11, 2021) https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True

[6] South Africa and India push for COVID-19 patents ban, THE LANCET(May 12, 2021) https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext

[7] Pfizer Gets Pneumonia Vaccine Patent, Months After Inclusion in India's Universal Immunization Plan, THE WIRE (May 12, 2021) https://thewire.in/health/india-gives-pfizer-patent-for-pneumococcal-vaccine

benefit.[8]WHO's Chief Scientist has admitted to the fact that WHO would welcome a patent waiver during the period of the pandemic.[9]

This paper examines the debates surrounding waiver of intellectual property rights in the context of Covid-19 as a public health emergency. The pharmaceutical industry is traditionally monopolistic and assertive of its self-interest given the high R & D costs that it incurs; therefore, the industry is unlikely to give in to a demand for waiver. Irrespective of what the political outcome is from the demand for a waiver, access to medicines and vaccines is remains a relevant concern of academic and industry debate. The first part of this paper is a study of the WTO/TRIPS regime's approach to public health and access to medicines. The paper will examine the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS' or 'TRIPS Agreement') provisions on public health, particularly the implication of a 'waiver' of TRIPS obligations or else the exercise of 'flexibilities' provided for under the TRIPS regime. While the 'waiver' of TRIPS obligations is an inherent part of the WTO system as agreed to in the Marrakesh Agreement, the highlight on 'flexibilities' including compulsory licensing largely draws on the jurisprudence generated by Doha Declaration on TRIPS Agreement and Public Health ('Doha Declaration'). The second part of the paper will juxtapose the WTO's rules on access to medicines vis-à-vis the wider human rights jurisprudence on right to health, and the consequences of this interaction between the WTO norms and human rights norms.

II. TRIPS OBLIGATIONS AND ACCESS TO HEALTH CARE

TRIPS is a multilateral agreement on intellectual property brought into being on the understanding that a uniform and basic level of intellectual property protection is necessary to reduce distortions to international trade. TRIPS came into effect on January 1, 1995. The Agreement sets standards onprotections that extend towards all types of intellectual property including copyrights, trademarks, patents, geographical indicators, industrial designs, layout and designs of integrated circuits, and trade secrets. Even though the Agreement places paramount importance on protecting intellectual property, it

[8] India and South Africa proposal for WTO waiver from intellectual property protections for COVID-19-related medical technologies - Briefing Document, MÉDECINS SANS FRONTIER (May 11,2021)https://msfaccess.org/india-and-south-africa-proposal-wto-waiver-ip-protections-covid-19-related-medical-technologies

[9] WHO strongly supports TRIPS waiver, not time to worry about patents, profits: Chief Scientist Swaminathan, ANI (May 21, 2021)
https://www.aninews.in/news/world/europe/who-strongly-supports-trips-waiver-not-time-to-worry-about-patents-profits-chief-scientist-swaminathan20210511050042/

does in certain circumstance accommodate a waiver of its provisions or alternatively flexibility in the implementation of its provisions. A detailed discussion on waivers and flexibilities is provided in subsequent sections but before that an overview of TRIPS and its relation to public health and access to medicines is first provided.

The TRIPS Agreement make a mention of public health or health in the following provisions, Article 8 (Principles), Article 27 (Patentable subject matter), and Article 31bis (Other use without authorization of the right holder). In addition to the above, Article 7 (Objectives) of the TRIPS Agreement is inferred to have direct relation with discussions on TRIPS and public health.

It is the fundamental commitment of the TRIPS agreement that promoting technological innovation, the transfer and dissemination of technology while ensuring the benefit of producers and users of such knowledge, shall also promote socio-economic welfare. It emphasizes the need to strike a balance between competing interests.[10]

Article 8 of the Agreement acknowledges that it is the undeniable right of Member States to take requisite measures necessary for public health and in the interest of the general public while simultaneously protecting intellectual property rights. It also stresses the need for such measures to confirm to the provisions of the TRIPS Agreement. Article 8 therefore authorizes Member States to design laws and regulations with due regard to public health concerns.

From a public policy perspective and from the viewpoint of Member States of WTO representing the South, Article 7 & 8highlights their concerns within TRIPS. These provisions impress upon the reader of the TRIPS Agreement that itis not a pure IP legal framework but one that recognizes***social and economic welfare*** of populations impacted by IP regimes and their application in trade. In other words, Article 7& 8 emphasizes that IP regimes should serve the larger public good rather than be an end in itself.[11]

An examination of the drafting history of Article 7 & 8 discloses that they were brought into being at the instance of developing countries that had to concede to a master draft advanced by developed countries to all types of intellectual property that they owned and had an interest in protecting. [12] Commentators in particular pointed out that it was achievement for the developing countries to have placed these articles as part of body of the treaty and not it's Preamble. Scholars have also pointed out that Article 7

[10]TRIPS, Article 7.
[11]Thamarr Romero, Articles 7 and 8 as the basis for interpretation of the TRIPS Agreement, SOUTH CENTRE (May 14, 2021) https://www.southcentre.int/wp-content/uploads/2020/06/PB-79.pdf
[12] Peter K. Yu, The Objectives and Principles of the TRIPS Agreement, 46 HOUS. L. REV. 979, 1003 (2009).

& 8 strengthen the operative provisions of TRIPS, and has to be read in the light of General Comment 17 to the ICESCR, which states that "intellectual property is a social product... [with] a social function" and that "the private interests of authors should not be unduly favoured and the public interest in enjoying broad access to their productions should be given due consideration."[13]

Even though there are no expansive interpretation guidelines for Article 7 & 8, the recent decision of the WTO Dispute Settlement Panel in the case of Australia – *Tobacco Plain Packaging* as well as the Doha Declaration has advanced the general understanding of these two provisions. Incidentally, paragraph 4 of the Doha Declaration on TRIPS Agreement and Public Health states that TRIPS "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" (paragraph 4, Doha Declaration).[14]

III. WAIVER OF TRIPS OBLIGATIONS

The Marrakesh Agreement Establishing the WTO ('WTO Agreement'), its scope, structure and functioning lays down in Article IX that it shall continue the process of decision making by consensus followed by the GATT regime. Only where a matter cannot be agreed upon by consensus will the matter be put to vote. TRIPS being a Multilateral Treaty under the WTO regime, it is the WTO Ministerial Conference and the General Council which has exclusive right to adopt interpretations to TRIPS on the recommendation of the TRIPS Council. Apart from the WTO Ministerial Conference's right to adopt interpretations to TRIPS, Article IX sub clause 3 then provides for separate route of waiver of TRIPS or similar WTO multilateral treaties.

A process of waiver begins with a request for waiver submitted to the TRIPS Council by a WTO Member State. The TRIPS Council shall within a period of 90 days consider the matter and submit a report on the merits of the waiver to WTO Ministerial Conference. Where a consensus eludes the Ministerial Conference on the subject matter of the waiver, it is be decided by a majority of three-fourth.Decisions of the Ministerial Conference granting a waiver shall state the exceptional circumstances justifying the decision. Waivers are granted for a period of one year with yearly renewal by the Ministerial Conference until the termination of the circumstances giving rising to the waiver.

---

[13] ECOSOC, Comm. on Econ., Soc. & Cultural Rights, General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from Any Scientific, Literary or Artistic Production of Which He Is the Author (Article 15, Paragraph 1(c), of the Covenant), 1 35, U.N. Doc. E/C.12/GC/17 (Jan. 12, 2006) [hereinafter General Comment No. 17].

[14]Declaration on the TRIPS Agreement and Public Health, WORLD TRADE ORGANIZATION (May 15, 2021) https://www.who.int/medicines/areas/policy/tripshealth.pdf?ua=1

The most notable waiver to TRIPS followed directly from the Doha Declaration. The Doha Round of trade negotiations was launched in 2001 to lower trade barriers between states. Intellectually property-based trade barriers were a pressing issue that concerned this set of negotiations. Consequently, in November 2001 the Doha Declaration of the TRIPS Agreement and Public Health was adopted (details of which are discussed below). The Doha Declaration being soft law awaited implementation. In August 2002 the text of a waiver proposal based on the Doha Declaration was put forward but it failed. In August 2003, the waiver decision was adopted by the TRIPS Council.[15] The waiver stipulated that medicines manufactured subsequent to a compulsory licensing arrangement need not be provided predominantly for the local markets but may be made available in other markets too. There was also a waiver of the requirement that adequate compensation should be paid to a right holder when a compulsory license is issued. The waiver in practice implied that "Article 31(f) of the TRIPS Agreement is waived for the exporting country member on the condition that an eligible importing member notifies the TRIPS Council that it has insufficient or no manufacturing capacity in the pharmaceutical sector for the product in question".[16] Eventually this waiver went on to become an amendment to the TRIPS Agreement. Article 31bis was added to the TRIPS Agreement through the Protocol of 6 December 2005 that entered into force on 23 January 2017 and finalizes the procedure for export of medicines to developing and least developed countries where such medicines are manufactured further to a compulsory licensing arrangement.

The current proposal for waiver of patents on Covid equipment and medicine was submitted in October 2020. The TRIPS Council of May 2021 considered the issue and is likely to submit its report to the WTO ministerial Conference in November, 2021. As there has been a disregard of the 90-day period by the TRIPS Council since the request for waiver by India and South Africa,experts believe that this proposal will not see any immediate outcome as envisaged in the text of the WTO Agreement and TRIPS. [17] Public health activists in India argue that a waiver would be welcome and use the example ofRemedesivir as a

[15] WT/L/540 and Corr.1 , Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WORLD TRADE ORGANISATION (May 15,2021) https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

[16] Isabel Feichtner, *The Waiver Power of the WTO: Opening the WTO for Political Debate on the Reconciliation of Competing Interests*, 20(3) EUROPEAN JOURNAL OF INTERNATIONAL LAW, 615, 628 (2009), https://doi.org/10.1093/ejil/chp039

[17] David Lawder, WTO vaccine waiver could take months to negotiate, faces opposition -experts, REUTERS (May 16, 2021) https://www.reuters.com/world/china/vaccine-ip-waiver-could-take-months-wto-negotiate-experts-2021-05-06/& Andrew Green, TRIPS waiver tripped up in WTO by 'third way', Devex (May 16, 2021) https://www.devex.com/news/trips-waiver-tripped-up-in-wto-by-third-way-99329

prime example– a waiver of patent onRemedesiver by its patent holder Gilead Sciences would ensure that not only does the price of this drug fall in India but also make the drug available for export.[18]

IV. FLEXIBILITIES UNDER TRIPS

At the Fourth Ministerial Conference at Doha (2001), the WTO had conferred upon Members States the mandate to negotiate aspects of TRIPS that posed difficulties at the implementation level. Consequently, the Doha Declaration was "designed to respond to concerns about the possible implications of the TRIPS Agreement for access to medicines."[19] The Declaration affirms that governments' have the right to access the flexibilities provided for under the TRIPS Agreement and "clarifies some of the forms of flexibility available, in particular compulsory licensing and parallel importing."[20]

Paragraph 4 of the Doha Declaration emphasizes that each provision of TRIPS Agreement is to be understood and interpreted in tune with its objectives and principles. It clarifies that every member is vested the freedom to grant compulsory licenses and also decide the circumstances in which these may be granted. Significantly it also recognizes members' right to assess when there occurs a national/extreme emergency/public health crises including epidemics.

Paragraph 4 (a) affirms that in line with general principles of international law, the WTO and its is associated agreements will be interpreted having due regard to the rule on the purposive interpretation of treaties. This rule is found both in customary international law as well as in Article 31(1)Vienna Convention on the Law of Treaties.

Paragraph 4(b) & (c) emphasis upon the right of members to exercise the flexibility of compulsory licensing and paragraph 4(d) refers to a second flexibility know as parallel importation. In this paper, the feasibility of compulsory licensing as flexibility during the time of Covid-19 pandemic is examined.

V. COMPULSORY LICENSING UNDER TRIPS

It was in 1623 that the UK statute of monopolies introduced Compulsory Licensing. Thereafter it gradually evolved and in 1883 it was introduced as an integral part of patent legislation in UK. It was

[18]Biswajith Dhar & K.M. Gopakumar, Safeguarding the World's Response to COVID-19 from the Intellectual Property Police, The Wire (May 9, 2021) https://thewire.in/business/safeguarding-the-worlds-response-to-covid-19-from-the-intellectual-property-police

[19] The Doha Declaration Explained, WORLD TRADE ORGANIZATION (May 22, 2021) https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm

[20]*Id.*

primarily targeted at patents wherein public demand was unmet or where interested people were prohibited from utilizing an invention. This trend deeply influenced most of the subsequent patent legislations across countries including the International Convention for the Protection of Industrial Property, also known as the Paris Convention. Thus the question of patent waiver arouse only if Compulsory Licensing failed to address the issues encountered. Thus Compulsory Licensing emerged as an efficient tool to resolve the consequences of exclusive patent rights.

A "compulsory license"[21] is an authorization given by a national authority to a person, without or against the consent of the title-holder, for the exploitation of a subject matter protected by a patent or other intellectual property rights.p.3

Article 31 of TRIPS Agreement authorizes WTO Member countries to provide for compulsory licenses in respect of certain patents.[22]In times of national emergency or extreme emergency or in cases of public non-commercial use member countries are directed to first negotiate or seek approval from the patentee of the vaccine or drug for the manufacture of the same to meet the demand through a voluntary license. In case of failure of such attempts TRIPS in Article 31 (b) allows members to issue Compulsory license to domestic manufacturers to produce these without the patent holder's permission.[23] Despite this, a cumbersome issue with respect to Compulsory Licensing is Article 31 (g), which makes provision of the termination of a compulsory license as soon as the circumstances which led to its grant, cease to exist. This would mean uncertainty for the licensees right, thus discouraging the use of the mechanism of compulsory licensing, thus defeating its purpose.[24]

Since the adoption of TRIPS, Article 31(f) TRIPS posed a significant obstruction in access to medicines. Article 31(f) TRIPS mandatorily requires that a proposed user of compulsory license shall use the compulsory license to predominantly supply the domestic market. Member States of the WTO from the South found the provision a significant obstruction in the achievement of public health objectives, as these States relied upon cheap import of medicines to tackle health crisis. Many countries faced with ongoing epidemics such as HIV/AIDS, tuberculosis, malaria etc, which had an absence of pharmaceutical manufacturing capacities, pushed for relaxations to Article 31(f) which eventually led to the enactment of Article 31bis.

---

[21] Carlos M. Correa, INTELLECTUAL PROPERTY RIGHTSAND THE USE OF COMPULSORY LICENSES: OPTIONS FOR DEVELOPING COUNTRIES 3 (Centre of Advanced Studies, University of Buenos Aires, Working Paper No.5, October 1999).
[22]*Id*. at 8
[23]*Id*. at 9
[24]*Supra* note 21.

Article 31bis lays down a procedure for accessing medicines through import from manufacturing countries in the event of national emergency or other circumstances of extreme urgency.

Article 31bis was created with the needs of the developing and least developed countries in mind as certain countries in the Annex to the TRIPS Agreement ("Annex", elaborating upon Article 31bis), such as Australia, Switzerland, United States, Norway have all agreed not to benefit from the special procedure provided for in Article 31bis.

Article 31bis states that an eligible importing member may make a notification to the TRIPS Council about the name and quantity of the product in need, establish that the importing country has 'insufficient manufacturing capacity' (a defined term in the TRIPS Agreement) in the pharmaceutical sector for the production of the medicine and confirm that if the drug is patented in its territory, it will grant a compulsory license in accordance with Articles 31 and 31*bis* of the TRIPS Agreement.

The Annex also imposes obligations on exporting countries such as caps on production (including a specification that the entire production should be exported), special labelling requirements and disclosure the TRIPS Council on the quantities of medicines being exported to meet the national emergency or situation of extreme urgency. The above-described procedure is subject to annual review for compliance by the TRIPS Council. Till date, the Article 31bis regime has only been used by Canada to export antiretroviral drugs to Rwanda.[25] Moreover, both Médecins sans Frontier which supported Rwanda in this endeavor as well the generic manufacturer of the drug in Canada have come out heavily against the process which in practice bureaucratic and neither expeditious or nor easily workable.[26]

India has domestic laws on compulsory licensing found in Sections 82-94 of the Indian Patents Act, 1970. These provisions benefit both the domestic market as we the needs of countries that seek to import drugs from India for reasons of cost effectiveness. In the context of the current pandemic, a significant intervention that the government will have to make is to grant compulsory licenses under Section 92 of the Patent Act (Special provision for Compulsory Licenses on notification by the Central Government). Here, the government notifies a list of patents that should be subject to compulsory licensing and allows

---

[25] TRIPS Annual Review of the Special Compulsory Licensing System – Report to the General Council, WORLD TRADE ORGANIZATION, 12 (May 30, 2021), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/86.pdf&Open=True

[26] *Id.*; Also see, Kristina M. Lybecker& Elisabeth Fowler, *Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules*, JOURNAL OF LAW AND MEDICINE 222-239 (2009), file:///C:/Users/LENOVO/Downloads/Lybecker%20and%20Fowler%20-%20JLME%20-%20July%202009.pdf

individuals to commercialize the same subject to an application being made to the Controller of Patents. Section 92 removes a few of the typical conditions applicable to compulsory licenses, including a hearing of the patentee, in the interest of expediency. However, remuneration as fixed by the Patents Controller will become due to the patentee. The India Patent Act, 1970 does not end with the alternative of compulsory but also goes on to provide for 'take over' of a patent either by authorizing its use for government purposes - under Section 100 of the Patent Act (Power of the Central Government to Use Inventions for the Purpose of Government) – or permitting for the acquisition of the patent from the patent holder under Section 102 of the Patent Act, upon a payment of reasonable remuneration.

The Supreme Court of India in a *suo motto* petition, *In re: distribution of essential supplies and services during pandemic* is seized of the grave situation in India where there is severe shortage in access to medicines and vaccines.[27] The court's order dated April 30, 2021 has outlined the above legal framework that can be accessed by the government for addressing the shortage in medicines and vaccines and has urged the government to seriously consider the option of compulsory licensing given that countries such as Canada and Germany have already resorted to IP relaxations to facilitate access to medicines.

VI. TECHNOLOGY TRANSFER AND ITS RELEVANCE IN ACCESS TO MEDICINES

Technology transfer seems to be key to making vaccines available on a global level.[28] While compulsory is one way to ensure that medicines and vaccines and available to a wider population, commentators have often pointed that without transfer of technology much of the efforts at compulsory licensing will also be infructuous.[29]Legally, the WTO Members are under an obligation to support technology transfer to least developed countries. Article 66 of the TRIPS Agreement enjoins upon developed member countries to promote and encourage technology transfer to least developed countries by incentivizing their own enterprises and institutions. However, it very often so happens that this obligation is shouldered largely by middle income states such as Brazil and India.[30]

[27]https://main.sci.gov.in/supremecourt/2021/11001/11001_2021_35_301_27825_Judgement_30-Apr-2021.pdf; Also see, AmitenduPalit, Fight Covid with Compulsory Licensing https://www.financialexpress.com/opinion/fight-covid-with-compulsory-licensing/2248068/

[28] Priya Joi, The US adds it support to patent waivers for COVID-19 vaccines, GAVI – THE VACCINE ALLIANCE (May 9, 2021) https://www.gavi.org/vaccineswork/us-adds-it-support-patent-waivers-covid-19-vaccines

[29]Prabhash Ranjan, *Walk the Talk on TRIPS Waiver*, The Hindu, May 18, 2021, at 7.

[30] Dianne Nicol &OlasupoOwoeye, Using TRIPS flexibilities to facilitate access to medicines, BULLETIN OF THE WORLD HEALTH ORGANIZATION (May 16, 2021)
https://www.who.int/bulletin/volumes/91/7/12-115865/en/

Technology transfer in pharmaceutical industry implies transferring technology for any of three core stages of production – packaging, formulation and Active Pharmaceutical Ingredient (API).[31] Technology transfer in its wider sense implies "a series of processes for sharing ideas, knowledge, technology and skills with another individual or institution (e.g. a company, a university or a governmental body) and of acquisition by the other of such ideas, knowledge, technologies and skills" (as defined by the World Intellectual Property Organization).[32]Transfer of technology implies many restrictions on the transferee – "limits on further transfer of technology or know-how to third parties, the maintenance of trade secrets, preservation of patent monopolies for a certain period, price floors/ceilings, royalty payments and other terms may all be included in transfer agreements."[33]Data exclusivity relaxations might become necessary to make technology transfer arrangements complete but this is not always the case. [34]

WHO and other agencies have for sometime been studying the need for the local production of medicines and vaccines through transfer of technology to developing countries. As far as medicines are concerned, the WHO's approach has been to identify the Essential Drugs List and prioritize the local production of such drugs through technology transfer arrangements.[35]As far as vaccines go, local production is not always cost effective. However, international agencies have in the past advised on local production from the perspective of national health security.[36]

Upon tracing the history of local production of pharmaceutical products, it becomes clear that in the 1970s, developing countries had a limited capacity for production drugs. This very often created public health crisis in low income and middle-income countries urging United Nations Industrial Development Organization (UNIDO), United Nations Conference on Trade and Development (UNCTAD), United Nations Development Programme (UNDP) and WHO to collaborate on the matter. Circa this period the international community attempted the negotiation of an International Code of Conduct for Technology Transfer but this eventually had to be abandoned due to the deep differences between the North and the South.[37] Today the developing world and its manufacturing capacities in India, China, Brazil and South Africa have high capacities for local production of medicines.

---

[31]SUERIE MOON, WORLD HEALTH ORGANIZATION, PHARMACEUTICAL PRODUCTION AND RELATED TECHNOLOGY TRANSFER, 39 http://www.who.int/phi/en/
[32]*Id.*at 20.
[33]MOON, *supra* note 31, at 43.
[34]MOON, *supra* note 31, at 45;
[35]MOON, *supra* note 31, at 15.
[36]WENFENG GONG ET AL., INCREASING ACCESS TO VACCINES THROUGH TECHNOLOGY TRANSFER AND LOCAL PRODUCTION, WORLD HEALTH ORGANIZATION 1 (May 21, 2021)
[37]MOON, *supra* note 31, at 16.

As far as vaccines go, there is a similar story of vaccine production. In the 1970s vaccine productions had slumped and international organizations had to intervene in subsequent decades to secure appropriate quantities of vaccines. Local production of vaccines unlike medicines can be difficult for the singular reason that vaccines are complex biological products as opposed to medicines which involve a chemical synthesis which can be easy to establish.[38] Also, local production of vaccines is often hinged upon appropriate transfer of know-how and R&D development in the transferee state and patents are not seen as primary culprits preventing the local production of vaccines.[39]

Notwithstanding the complications in transfer of technology to developing countries on vaccine production, it has been established that local production of vaccines undoubtedly makes access to vaccine much easier. As of 2011, statistics prove that 64% of all EPI vaccines procured by the United Nations come from developing countries.[40] The three most common vaccines that illustrate this fact is the local production of Hib vaccine, Hepatitis B vaccine, and the Meningitis A vaccine.

To conclude, scholars have opined that the wealthy countries are not inclined to promote local production of pharmaceuticals[41]unless of course the medicine has no commercial future or manufacturing capacities are inadequate in the developed world. As far as vaccines, it is the case that often-developing countries with large income and population size are likely secure technology transfer agreements with large multinational vaccine producers but smaller, lower-income countries may be not secure technology transfers unless it is with public support.[42]

VII. RECONCILING HUMAN RIGHTS REGIMES ON ACCESS TO MEDICINES WITH THE WTO REGIME

The right to health as well as the right to access essential medicines is a well-recognized human right in the international human rights system as well as in various domestic jurisdictions. Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) sets out that "State Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." General Comment 14 (2000), ICESCR, explaining the scope and content of Article 12 states that States have the obligation to respect, protect and fulfill the right to health in its manifold forms including safe access to drugs. The 'Core Obligation' of States as identified by

[38]GONG, *supra* note 36, at 6.
[39]GONG, *supra* note 36, at 5.
[40]GONG, *supra* note 36, at 6.
[41]MOON, *supra* note 31, at 41; Also see, Abbott FM., *The Doha Declaration on the TRIPS Agreement and public health: Lighting a dark corner at the WTO*, 5 JOURNAL OF INTERNATIONAL ECONOMIC LAW 469–505 (2002), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1493725
[42]MOON, *supra* note 31, at 47.

the General Comment includes the obligation "to provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs." General Comment 14 also make a brief reference to the fact that Article 12 recognizes the "[t]he right to treatment includes the creation of a system of urgent medical care in cases of accidents, epidemics and similar health hazards, and the provision of disaster relief and humanitarian assistance in emergency situations." Government obligations, assistance and intervention so as to effectively address pandemics are thus clearly a part of the international human rights jurisprudence on the right to health.

The exercise of the right to health since its recognition in 1966 seldom came into contact with the intellectual property rights regime. The two areas of law and their conflict came to the attention of the international community with the consideration of TRIPS in the 1990s and also the need to evolve a *sui generis* system for the protection of traditional knowledge.[43] At that point in time scholars concluded that the intellectual property regime lacked a serious human rights approach in its implementation.[44] The 2000/7 resolution of the Sub-Commission on the Promotion and Protection of Human Rights brought out the conflict between intellectual property rights and human rights when the statement stated that intellectual property rights were a serious barrier to the achievement of economic, social and cultural rights.[45] Subsequent human rights approaches to intellectual property rights issues sought to affirm the normative supremacy of the human rights system over the intellectual property rights system. In an atmosphere of conflict between human rights and intellectual property rights, scholars have opined that increasing the development of soft law instruments on intellectual property rights and its relation to human rights as well as the articulation of maximum intellectual property rights standards i.e., the limits of IP regimes (as opposed to minimum intellectual property rights standards which is the TRIPS approach) is desirable.[46]

Apart from Article 12, ICESCR there is a provision in the same covenant which has implications on the relation between human rights and intellectual property rights. Article 15 (Participation in Scientific and Cultural Activities), ICESCR, and its sub clause Article 15 (1) (b) sets out that "State Parties to the Covenant recognize the right of everyone…to enjoy the benefits of scientific progress and its

[43]Laurence R. Helfer, *Human Rights and Intellectual Property: Conflict or Coexistence?*, 5 MINN. INTELL. PROP.REV. 47, 52(2003), https://scholarship.law.umn.edu/cgi/viewcontent.cgi?article=1399&context=mjlst#:~:text=INTRODUCTION%3A%20CONFLICT%20OR%20COEXISTENCE%3F,virtual%20isolation%20from%20each%20other

[44]*Id.* at 52.

[45]HELFER, *supra* note 43, at 56.

[46]HELFER, *supra* note 43, at 52.

application." The Committee on Economic, Social and Cultural Rights in General Comment 17 (2006), explores the scope of the Article 15 (1) (b) to remark that:

> Ultimately, intellectual property is a social product and has a social function. States parties thus have a *duty to prevent unreasonably high costs for access to essential medicines,* [emphasis added] plant seeds or other means of food production, or for schoolbooks and learning materials, from undermining the rights of large segments of the population to health, food and education.

Going by the Vienna Declaration and Programme of Action on Human Rights (1993) and its principle of universality, indivisibility, interdependence and interrelatedness of all human rights, the right to health and right to participate and enjoy the benefits of scientific progress are concomitant rights that need to be released together. The international human rights regime clearly emphasizes that privileging intellectual property rights regimes over access to medicines affects erodes the dignity of humans who are to beneficiaries of both systems.

Even though the conversation on intellectual property rights, access to medicines and human rights is far from over, in hindsight the period between 2000 and 2006 was a period of creative dialogue between the international human rights regime and the WTO regime resulting in the achievements at Doha.[47]

VIII. CONCLUSION

Exactly two decades since the Doha Declaration, the spirit of the Declaration remains unrealized and there is very little progress in advancing access to medicines at the ground-level, whether it is through local manufacturing of drugs or international trade in medicines to solve public health crises. The TRIPS Agreement amendment and its Protocol to Article 31bis (for facilitating trade in medicines during national emergencies or situations of extreme urgency) await further ratification by 33 Member states of the WTO. The WTO procedure for provision of cheap medicines for emergency situations has not seen use except on one occasion. Clearly, the WTO-TRIPS mechanism that emphasizes upon compulsory licensing is seen with suspicion and it has become difficulty to allay fears of trade disputes in the event of an exercise of this mechanism.

In the context of the current pandemic, at the domestic level, compulsory licensing certainly looks like the way ahead to cope with immediate shortage in medicines and vaccines. However, if the international

[47] See, Christopher Butler, Human Rights and the World Trade Organization: The Right to Essential Medicines and the TRIPS Agreement 5 J. INT'L L. & POL'Y 5:1, 5:21 (2007).

community also recognizes that local is global in this pandemic, they will have to take concrete steps towards aWTO waiver on intellectual property rights (in whatever form that pharmaceutical companies will agree to)so that medicine shortages can be adverted at local, national and international levels and government attention may move to more pressing concerns such as vaccine equity. Finally, the experience of the pandemic calls on governments,international organizations and corporations to return torenewed consultations on access to medicines based on a robust human rights framework.