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An Integrated Approach to TRIPS Flexibilities in the Post-pandemic Era

One of the consequences of incorporating the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), dealing with a non-trade issue - intellectual property rights (IPRs) - in 1995 into the international trade regime regulated by the World Trade Organisation (WTO), was that it remains a contested agreement.[1] So contested, that it is so far the only WTO Agreement that has had to be amended. Its implementation has been controversial, with flexibilities available, in the patent regime in particular, being called into question. These controversies, though they never ceased, have resurfaced with vigour during the COVID-19 pandemic twenty five years later.

Exceptions to TRIPS Disciplines

One of the key controversies relates to exceptions to patent protection. Unlike border measures, which the GATT was traditionally used to discipline, IPRs have territorial application. When the TRIPS agreement was being negotiated, even the developed countries did not have identical treatment of various aspects of IPRs in their national laws. That gave rise to the need to provide ample scope for flexibilities in implementation. Developing countries had their own wish list of such flexibilities such as the objective of transfer and dissemination of technology and the principle of public interest and prevention of abuse of IPRs. This gave rise to many exceptions to IP standards.

The least controversial have been the exceptions built into Article 30 of the agreement, because they neither conflict with the normal exploitation of a patent nor prejudice the legitimate rights of the patent owner. Parallel import, in particular international exhaustion, rendered non-justiciable under its Article 6, is controversial but the treaty terms are clear enough to allow national level discretion, and the Doha Declaration on

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Public Health agreed as part of the Doha Ministerial Conference of the WTO in 2001 clarified that each member was free to establish its own regime for exhaustion.[2] Compulsory licensing inscribed in Article 31, permitted under the agreement with a long list of strings attached, has been the most problematic. Therefore, while Articles 30 and 6 have had a comparatively inhindered use by WTO members, developed countries have raised objections repeatedly to the use of compulsory licences, both within the WTO dispute settlement mechanism and in their bilateral relations with the users of the provisions. None of them reached a stage where scope of its use was finally adjudicated in the WTO, thus leaving sufficient wriggle room to the use of such licences, particularly because Article 31 does not specify the grounds for such use.

Patenting of pharmaceutical products, because of the higher importance of human health compared to business or the economy, has been the most controversial. The controversy erupted with the HIV-AIDS crises in South Africa. The HIV-AIDS pandemic had become a full blown global health problem by the time the potential benefactors of the TRIPS agreement started looking for rewards for their innovation-led economic operators. The result was a human rights crisis of major proportions, triggered by global pharmaceuticals companies starting a legal battle in South Africa.

The South African Trigger

By late 1990s, one in five South Africans was HIV-AIDS infected, as were 45 per cent of its military personnel.[3] Since, with USD 2600 per capita income, none could afford a USD 1000 a month dose of antiretroviral treatment then available, the Government introduced Section 15C in the South African Medicines and Related Substances Control Act (MRSCA) in 1997 enabling parallel imports of HIV-AIDS drugs from cheaper sources, primarily the generic manufacturers in India.[4]

Bristol Myers and other multinational pharmaceutical companies challenged Section 15C on the ground that it invoked parallel imports and compulsory licences, albeit both permissible under the TRIPS agreement. The US government also put pressure, by including South Africa in the Priority Watch List under their Special 301 law and by withdrawal of the GSP benefits. AIDS activists struck back, led by Ralph Nader, Representative Jesse Jackson and the Congressional Black Caucus, resulting in the government demurring in its plans to take South Africa to the WTO dispute settlement mechanism and promising not to pressurise it on parallel imports. In the Seattle Ministerial Conference of the WTO in 1999, the then US President Bill Clinton promised to adjust the US trade policy to enable poor countries like South Africa to gain access to essential medicines. The Bush administration that succeeded reaffirmed that it would not come in the way of developing countries seeking to utilise flexibilities available within the TRIPS agreement to resolve their public health crises.[5]

The muscular approach of the pharmaceutical industry then gave way to a defensive position by WTO Member governments and pressure built up to seek a formal clarification regarding

1 Carolyn Deere, in *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reforms in Developing Countries* Oxford University Press, 2009, page 304

2 See Doha Ministerial Declaration WT/MIN(01)/DEC/W/2 of 14 November 2001

3 Sabin Russell in 'New Crusade to Lower AIDS Drug Costs', *The San Francisco Chronicle*, 24 May 1999

4 Prof. William W Fisher III and Dr Cyrill P Rigamonti in 'The South Africa AIDS Controversy: A Case in patent Law And Policy, *Law of Business and Patents*, Harvard Law School, 10 February 2005. It is noteworthy that India had time until 2005 to provide product patents to drugs, and had a vibrant generic industry already,

5 *Ibid.*

unhindered availability of TRIPS flexibilities. Smaller developing countries having no medicine manufacturing capabilities wanted changes in Article 31(f)[6] of the TRIPS agreement, which provided that compulsory license shall be predominantly used for the domestic market.

The use of compulsory license was now no longer viewed with concern under the TRIPS regime. More importantly, the big pharmaceutical firms were reconciled to make exceptions for serious health crises. Academic experts had started suggesting as early as in 1998 that relevant interest groups in both developed and developing countries should treat TRIPS as a set of default rules to be bargained around within a cooperative framework.[7]

Bargaining around TRIPS

Such bargaining around began with the efforts to stem the AIDS crisis in Africa, with five intergovernmental organisations (UNFPA, UNICEF, WHO, UNAIDS and the World Bank) collaborating with five pharmaceutical firms (Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Merck, F. Hoffman-La-Roche and Abbot Laboratories) to form the Accelerating Access Initiative (AAI) in May 2000 to provide AIDS medicines to developing countries at 10-20 per cent of the price charged in developed countries. In the same year, the Global Alliance for Vaccines and Immunization (GAVI) another multi-agency organisation began an initiative to supply vaccines for diseases primarily afflicting people in poor countries. It was followed by the Global Fund to fight HIV-AIDS, Tuberculosis and Malaria established by the UN Secretary General Kofi Annan in January 2002 and Clinton Foundation Fund in November 2003, apart from various NGOs acting individually or collectively.

In parallel, negotiations to take forward the work mandated by the Doha Public Health Declaration continued, which involved, under paragraph 6 of the Declaration, finding a solution to the restriction in Article 31 (f) of the TRIPS agreement. The negotiations were contentious, controversial and tortuous. Developed countries and their pharmaceutical firms were wary of further erosion of patent rules, but public pressure required action in favour of public health concerns. Finally, a waiver mechanism to circumvent Article 31 (f) was agreed to in August 2003, resulting in an amendment of the TRIPS agreement in December 2005. However, it took until 2017 for the requisite two-third WTO Members to ratify it. The solution was so unimplementable that only one case of supply of an anti-retroviral from Canada to Rwanda has been reported under the mechanism. Public health initiatives again started bargaining around the TRIPS disciplines.

UNITAID in 2006 was the first such initiative post TRIPS amendment. It provides access to medicines to poor countries but also invests in innovation of drugs and diagnostics. In 2010, it founded a Medicine Patent Pool, the first initiative for non-exclusive voluntary licensing and patent pooling. After the Ebola outbreak, India was instrumental along with Norway and the Gates Foundation to launch the Coalition for Epidemic Preparedness Innovations

[6] It is important to note here that pursuant to Article 31(k), when compulsory licenses are used by the governments to remedy anti-competitive practices, there is no requirement that those licenses be granted predominantly for supply of the domestic market. See page 474, Resource Book on TRIPS and Development, Cambridge University Press, 2005.

[7] J.H.Reichman and David Lange in 'Bargaining around the TRIPS Agreement: The case for Ongoing Public Private Initiatives to Facilitate Worldwide Intellectual Property Transactions', Duke Journal of *Comparative International Law,* Volume 9, No.1

(CEPI) in 2017 for developing vaccines. Thus, a gentle nudge towards public funded research and sharing of patent protected medicines for public health objectives began.

The contest between TRIPS and public health has resurfaced with the COVID-19 pandemic, and South Africa again has a role. Having receded into a second consecutive recession before Covid19 struck, South Africa was perilously close to an economic disaster when almost half of the employed lost their jobs permanently.[8] In its contribution[9] on 17th July 2020 to the TRIPS Council of the WTO, South Africa has argued that not only patents, but other IPRs are equally in the need of reconsideration. It points out that until a prophylaxis is on the market, preventive measures in the form of personal protective equipment like masks, face shields and sanitizers, which are in short supply, are needed. It refers to IPRs embedded in Artificial Intelligence related to detection and tracing tools for the virus, 3D printed ventilator valves, and trade secrets on cell lines and genomics as issues going beyond patents. The debate on the proposal in the WTO is yet to conclude.

The COVID Pandemic

The COVID-19 pandemic has struck much more egregiously than HIV-AIDS. Although IPRs, particularly patents, are still relevant, public debate is no longer on whether and how to straddle the IPR hump, but how to invest enough in the research and development of a treatment of the disease and a vaccine to prevent its continuing onslaught. Even pharmaceutical majors are fighting shy of openly claiming patent protection and are instead seeking public funding for research and committed buyers of the eventual successful treatment or vaccine. In response, the EU led Corona Global Response launched in May 2020 invested about USD 8 billion, while the US has invested USD 2.6 billion through its Biomedical Advanced Research and Development Authority.[10] Gilead's repurposed Remdesivir promises early recovery from the disease, and the United States government not only part-funded the research; it agreed to purchase most of its production. Gilead also licensed a cluster of manufacturers abroad, including a few in India, to supply to markets less rewarding than the US at lower prices.

The global collaboration for a vaccine requires a coherent global response. However, many international institutions have been in disarray in recent times. The United States has walked out of the WHO and rendered the dispute settlement system of the WTO dysfunctional; its squabbles with China delayed by three months a UN Security Council resolution on Covid 19. It is disparate efforts rather than a coherent global response that is driving the fight against the pandemic. The richer countries, therefore, are cornering the biggest piece of the eventual vaccine cake.

No doubt at the multilateral level, COVAX Advance Market Commitment (AMC) of GAVI has engaged 172 countries for a mechanism to supply the vaccine to at least 20 per cent of the population of poor countries. It has received commitments for USD 1.4 billion for research and development in 9 CEPI supported candidate vaccines

[8] 'Covid-19 has throttled South Africa's Economy' in The Economist, 18 July 2020

[9] Document IP/C/W/666 available on www.wto.org

[10] Matina Stevis-Gridneff and Lara Jakes, 'World Leaders Join to Pledge $ 8 Billion as US Goes It Alone' in New *York Times*, 4 May 2020, since increased to Euro 15.9 billion. See https://global-response.europa.eu/index_en

so far, though it needs a billion more to guarantee vaccination in poor countries.[11] The US, Russia and China are the big countries that have not opted in yet. GAVI has also initiated a COVAX Exchange Facility that will enable countries joining the facility to trade vaccines allocated to them in the event that the particular vaccine does not suit their needs. The Exchange is trying to leverage market forces to ensure that this facility does not fail.[12] Covid Moonshot is another such initiative, an open crowd sourced private sector led project with no intellectual property constraints that has pioneered in drug design field recently, and has many Indian scientists and pharmaceutical firms as its partners.[13]

Vaccine Nationalism

However, efforts at the national level are earning the epithet 'vaccine nationalism'. United States has entered into multi-billion dollar agreements with six pharmaceutical companies for an assured supply of a combined 800 million COVID-19 vaccine doses. It has inked deals with Pfizer (2 bn), GlaxoSmithKline (2.1 bn), Moderna (1.5 bn) and AstraZeneca (1 bn).[14] The United Kingdom has entered into similar multi-company agreements for 340 million doses.[15] Japan is on track to have 521 million doses of COVID-19 vaccine by mid-2021 by signing agreements with companies like Pfizer, AstraZeneca and Shionogi, a local Japanese company, though its population is a mere 126 million, to provide succour to the sportsmen that will converge there for the delayed Olympics.[16] Many developed countries have enacted laws or regulations to protect their public health needs during the COVID-19 pandemic by using compulsory licences or other means.[17]

In a way, it is a free for all at present, and affordability remains a big issue for poor countries. For example, Moderna's mRNA vaccine could sell at USD 70[18] a dose, making it virtually out of their reach. In this situation, it is an availability potential for developed countries and affordability potential for developing countries that guides all global efforts to invent, manufacture, secure and distribute a vaccine or a treatment for COVID-19.

The evidence that some aspects of the IP system are constraining rather than enabling innovation and creativity has already prompted many social scientists, research companies, and artists to explore new business models, incentive systems, and public-private collaborations.[19] As the knowledge economy grows, government agencies, scientists, public interest groups, and industries from developing and developed countries will share priorities and concerns with respect to IP policy that defy North-South divide.[20] It is in this context that the South African proposal to the TRIPS Council needs support of India as a step for securing global public health. Bill Gates has said that India is capable of producing the COVID-19 vaccine for the entire world.[21] Pune based Serum Institute of India alone supplies 1.2 billion vaccine doses to the world annually and has additional capacity to produce 400-500 million doses, with more planned additional investments lined up.

It is pertinent to note that even developed countries participating

[11] See https://www.who.int/news-room/detail/24-08-2020-172-countries-and-multiple-candidate-vaccines-engaged-in-covid-19-vaccine-global-access-facility, accessed on 31 August 2020

[12] See https://genevahealthfiles.wordpress.com/2020/08/27/the-covax-exchange-gavis-plans-to-let-countries-trade-in-vaccines/

[13] See https://postera.ai/covid for background of Covid Moonshot Project and

[14] Stephen Buranyi, in 'Vaccine nationalism stands in the way of an end to the Covid19 crisis' in *The Guardian*, 14 August 2020

[15] Amitabh Sinha, in 'Explained: What Does Vaccine Nationalism Mean?' in The Indian Express, 29 August 2020

[16] Rocky Swift, in 'Japan, eyeing Olympics, lines up half billion doses of Covid19 vaccine' reported by Reuters, 28 August 2020

[17] For a detailed account of such steps, see South Centre Brief at https://www.southcentre.int/wp-content/uploads/2020/06/PB-80.pdf

[18] Stephen Buranyi, in 'Vaccine nationalism stands in the way of an end to the Covid19 crisis' in The Guardian, 14 August 2020

[19] Dean Baker, Arjun Jayadev and Joseph Stiglitz, in 'Innovation, Intellectual Property and Innovation: A Better Set of Approaches for the 21st Century', providing many examples of IP constraining development, available at https://www8.gsb.columbia.edu/faculty/jstiglitz/sites/jstiglitz/files/IP%20for%2021st%20Century%20-%20EN.pdf

[20] Carolyn Deere, in 'The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reforms in Developing Countries' Oxford University Press, 2009, page 323

in the last TRIPS Council meeting of the WTO on 30 July 2020 indicated that voluntary pooling of rights and other voluntary licensing arrangements have provided for safe and effective diagnostics medicines and vaccines for the COVID-19 response and scaling up the production of medicines and vaccines. Should such voluntary mechanisms fail, they admitted the TRIPS agreement had sufficient avenues not only with regard to patents but also with regard to IP rights.[22]

Such avenues, like the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in the manner conducive to social and economic welfare and to the balance of rights and obligations on the one hand, and formulation of domestic laws and regulations which are deemed necessary to protect public health and nutrition on the other, and to promote public interest in sectors of vital importance to their socio-economic and technological development, are available. However, due to the aggressive stance of many developed countries in enforcing key IPRs as per the TRIPS agreement, these avenues were not pursued with vigour by developing countries. Moreover, many developing countries succumbed to TRIPS plus disciplines in bilateral and multilateral agreements that further constrained their ability to protect national interest. However, with the WTO weakened due to the US intransigence on revitalising its Appellate Body and the general weakening of global governance, these avenues may be more frequently opted for by developing countries in dire need of the COVID-19 vaccine.

In the current pandemic, many right holders have voluntarily pledged or given access to intellectual property by facilitating access to key scientific journals or open source designs for personal protective equipment or design specifications for ventilators. This needs to expand, like in the case of Covid Moonshot mentioned earlier, to vaccines and treatments, so that public health can prevail over patent monopoly. Otherwise, a new dialogue may start on the basis of the South African proposal, and eventually result in a negotiated settlement as happened in August 2003, but through more contentious, controversial and tortuous modalities. It is another matter that this may have to await a revival of multilateralism, that is the crying need of global governance on our planet.

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[21] Quoted by Vijay Kasi and Anirudh Batra of Kearney in an article 'Race for the Covid Vaccine: Are Indian Vaccine Makers Ready to Supply to the World?' in The Economic Times, 29 August 2020

[22] WTO's report on the meeting at https://www.wto.org/english/news_e/news20_e/trip_30jul20_e.htm, accessed on 31 August 2020

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