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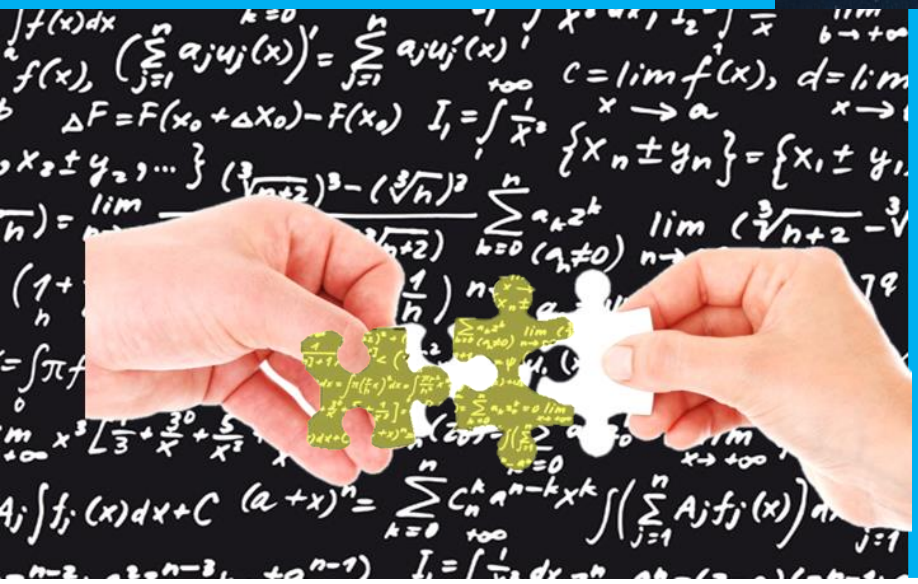
Towards more affordable medicine: A proposal to waive certain obligations from the Agreement on TRIPS



Biswajit Dhar

KM Gopakumar

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WORKING PAPER

Towards more affordable medicine:

A proposal to waive certain obligations from the Agreement on TRIPS

Biswajit Dhar [1]

KM Gopakumar[2]

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[1] Professor of Economics, Jawaharlal Nehru University, New Delhi, India and adviser to ARTNeT.
[2] Legal Advisor, Third World Network, Penang, Malaysia.

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Abstract

Access to medicines at prices patients can afford has been a recurrent concern for the global community ever since the Agreement on Trade Related Aspects of Intellectual Property (TRIPS) was adopted in 1995 as one of the agreements under the World Trade Organization (WTO). In 2001, WTO Members emphasised that the “TRIPS Agreement does not and should not prevent Members from taking measures to protect public health … and 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” (World Trade Organization 2001: paragraph 4). Subsequently, the adoption of the Doha Declaration provided clarity with regard to the flexibilities in the TRIPS Agreement and many developing countries used these flexibilities to facilitate access to medicines when in need (especially in the HIV/AIDS context). Such need might have again occurred with the COVID-19 pandemic. Using the recently submitted proposal by India and South Africa, discussed by the TRIPS Council in the WTO in October 2020, this working paper discusses some possible ways forward in dealing with some specific obligations under the Agreement on TRIPS with an objective of enhancing world’s chances for prevention, containment, and treatment of COVID-19.

Keywords: waiver, pharmaceuticals, TRIPS, India, South Africa, WTO, WIPO, medicine, vaccine, COVID-19

JEL codes: F14, I110, O33

Contents

1. Introduction

Access to medicines at prices patients can afford has been a recurrent concern for the global community ever since the Agreement on Trade Related Aspects of Intellectual Property (TRIPS) was adopted in 1995 as one of the agreements under the World Trade Organization (WTO). The TRIPS Agreement is a charter for strengthening intellectual property rights (IPRs) protection and enforcement, which provides holders of intellectual property (IP) with enhanced opportunities to extract rents from the users of proprietary products. The former had claimed that such rents were vital for incentivising their research and development efforts. However, over the years, evidence of excessive rent-seeking by IP holders has only grown.[1]

Possibly the most glaring of such examples was exceptionally high prices that several large pharmaceutical companies had charged in the 1990s after the onset of the HIV/AIDS, last of the major pandemics to have had worldwide ramifications. In South Africa, the cost of a year's treatment using the HIV anti-retroviral medicines marketed by these companies to the South African health service was US$ 10,000 at the time when its per capita GDP was US$ 3550 (The Guardian 1999).

Responding to the growing incidence of HIV/AIDS, the South African Government amended its Medicines and Related Substances Control Act, 1965, and included several provisions aimed at ensuring that medicines were available at affordable prices. Besides controlling prices of medicines, the amendments allowed issuing the compulsory licences for producing medicines in South Africa. These amendments were challenged by 40 major pharmaceutical companies (High Court of South Africa 1998). The pharmaceutical companies contended that the rights enjoyed by the patentees in the patent regime introduced after the implementation of the TRIPS Agreement would be severely truncated if the provisions of the South African law on affordable medicines were implemented by the government (Dhar 2001). Facing mounting public pressure, the pharmaceutical companies withdrew the case in 2001 (Swarns 2001)

[1] A report of the World Health Organization provided evidence of the high prices of medicines across therapeutic groups, and in particular, cancer medicines (World Health Organization 2018).

Subsequently, response against such excessive rent seeking came from other developing countries, led by India, South Africa, and Brazil, who proposed that additional flexibilities must be incorporated in the TRIPS Agreement enabling WTO member countries to address public health concerns. They proposed the TRIPS Agreement and Public Health, which was backed by 60 developing countries, including 41 belonging to the African Group, before it was adopted at the Doha Ministerial Conference in 2001 (World Trade Organization 2001).

This Declaration was important on several counts. First, it recognised 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". Secondly, while it recognised that intellectual property protection is important for the development of new medicines, it also recognised the concerns about the effects of the Agreement on prices of medicines. And, finally, WTO Members emphasised that the "TRIPS Agreement does not and should not prevent Members from taking measures to protect public health … and 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" (World Trade Organization 2001: paragraph 4).

In operational terms, the Declaration gave WTO members three sets of tools to address the problem of high prices of medicines arising from the exercise of IPRs. These are: (i) the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted; (ii) the right to determine what constitutes a national emergency or other circumstances of extreme urgency; and (iii) freedom to establish their own regimes for exhaustion of intellectual property rights without challenge, subject to the most favoured nation and national treatment provisions. Further, for the WTO Members with insufficient or no domestic manufacturing capacities in the pharmaceutical sector, who could face difficulties in making effective use of compulsory licensing provisions to produce the necessary medicines, the Declaration provided a window, in Para 6, through which these countries can import cheap medicines from any country. This window was finally provided through an agreed decision to implement Para 6, which was adopted in 2003 (World Trade Organization 2003) and the TRIPS Agreement was subsequently amended (World Trade Organization 2015) to allow "eligible" countries to import the

patented medicines and for potential exporters to export them.[2] However, the cumbersome procedural requirements make the mechanism non-attractive for users and till date there is only one instance of its use. However, the adoption of the Doha Declaration provided clarity with regard to the flexibilities in the TRIPS Agreement and many developing countries used these flexibilities to facilitate access to medicines especially in the HIV/AIDS context.

2. 2020 Waiver Proposal of India and South Africa at the WTO

The COVID-19 pandemic has once again brought a similar response from India and South Africa. The two countries have tabled a joint proposal, which was discussed by the TRIPS Council, seeking waiver from certain obligations under the TRIPS Agreement for the "prevention, containment, and treatment of COVID-19" (World Trade Organization 2020a). Kenya and Eswatini have also supported this Proposal.

Using the provisions of Article IX of the Marrakesh Agreement Establishing the WTO, the proposal makes a request to the General Council of the WTO, to waive the implementation, application, and enforcement of four forms of IPRs covered by the TRIPS Agreement for some years for the prevention, containment, and treatment of COVID-19. The scope of waiver includes the following: copyright and related rights, industrial designs, patents, and trade secrets. It should be noted here that the waiver of legal obligations under WTO agreement is not new. Since 1995, of the waivers that were granted, three were from TRIPS obligations (World Trade Organization 2016).[3]

The India-South Africa proposal has been tabled in the backdrop of the cautionary note issued by the WTO that the "COVID-19 pandemic represents an unprecedented disruption to the global economy and world trade, as production and consumption are scaled back across the globe". The two countries have argued that 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

[2] However, this window has not benefited the potential beneficiaries. It has been used only once when Rwanda decided to import the triple combination anti-retroviral drugs, Zidovudine, Lamivudine and Nevirapine from Apotex Inc. in Canada (WTO. 2007). The usefulness of this window was reduced considerably as the supplier could provide the medicines after 2 years (South Centre. 2010). See also, Rao. 2006.

[3] For an updated list of waivers, see WTO 2019.

of medical products essential to combat COVID-19". Given the large increase in demand for 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, it becomes imperative that supply-side shocks eliminated. At the same time, critical shortages in these medical products have also put at grave risk patients suffering from other communicable and non-communicable diseases.

The relevance of the Waiver Proposal stems from three concerns. The first is that exercise of intellectual property rights have impeded or are threatening to impede availability of medical products at affordable prices (Hillman 2020). Second, IP protection on various technologies can have a chilling effect on the innovation process involving COVD-19 medical products as potential innovators may to be inhibited in their efforts to develop new products.[4] The third concern is that although WTO Members have carried out amendments to the TRIPS Agreement to enable access to medicines during public health emergencies, especially in countries which do not have domestic manufacturing capacities, the procedural complexities have not allowed smooth implementation of this mechanism, as stated earlier. In view of the tardy implementation of this mechanism, the United Nations Secretary-General's High Level Panel on Access to Medicines had recommended that "WTO Members should revise paragraph 6 decision in order to find a solution that enables a swift and expedient export of pharmaceutical products produced under compulsory license. WTO Members should, as necessary, adopt a waiver and permanent revision of the TRIPS Agreement to enable this reform" (United Nations Secretary-General's High-Level Panel on Access to Medicines 2016: 27).

The Waiver Proposal if adopted provides the policy space to take measures to ensure availability of COVID-19 medical products. Further, it provides legal clarity and shields Member States against political pressures to take measures to address the problems of access and affordability of COVID-19 related medical products.

[4] An interesting initiative was taken in April 2020 by a group of scientists and intellectual property lawyers who had encouraged the companies to make their "intellectual property available free of charge for use in ending the COVID-19 pandemic and minimizing the impact of the disease". They group argued, "It is a practical and moral imperative that every tool we have at our disposal be applied to develop and deploy technologies on a massive scale without impediment". See Open Pledge 2020.

There are, therefore, important pointers for the WTO members to take decisive steps which can ensure that their obligations under the TRIPS Agreement do not prevent them taking measures for meeting urgent needs of humanity. In other words, it is imperative to go beyond the existing flexibilities for addressing public health concerns arising from the exercise of patent rights over medicines, and to cover, as the Waiver Proposal does, all medical products, including diagnostics, therapeutics, vaccines, and medical equipment required exclusively for preventing the spread and to cure coronavirus. Thus, the Waiver Proposal does not seek waiver of Members' obligations with regard to IPRs on all other medical products.

In order to effectively respond to the COVID-19 pandemic, a wide range of medical products have become absolutely essential. Many of these products, including their parts and components, are often proprietary items; they are protected through various forms of IPRs, mainly, copyrights, trademarks, industrial designs, and patents. 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. Each of these forms of IPRs pose challenges to the mass production of these products. For instance, copyrights on software source codes of diagnostic platforms can adversely affect their large-scale production, thus increasing the cost of diagnostics for the patients. A similar limitation can arise if industrial designs are used to protect medical products or their components. In this paper, we will elaborate on the importance of seeking waivers from the obligations to implement two forms of IPRs, namely trade secrets and patents.

A. Importance of waivers from obligations to implement trade secrets

One important form of trade secret concerning pharmaceuticals is covered under Article 39.3 of the TRIPS Agreement. These laws came into prominence after global pharmaceutical companies insisted on using them to prevent drug regulatory authorities (DRA) to rely on their clinical trials' data, to grant marketing approval for generic products. The United States and the European Union have been seeking between 5 and 10 years of protection for such data (Dhar and Gopakumar 2006). The TRIPS Agreement does not require member countries to do so; it only mandates that regulatory agencies must protect clinical trials' data against "unfair commercial use". It

may be noted that DRAs are allowed to the disclosure of data only after taking measures against unfair commercial use. Waiver from the application of trade secrets would allow regulatory agencies to use some of this data in public interest and to facilitate prompt entry of multiple producers medical product of vaccine monoclonal antibodies (mab) in the market.

The justification for data protection provided by the major pharmaceutical companies, and which the governments in the industrialised world seem to have accepted in its entirety, as elaborated below, is the high cost of clinical trials. According to a Tufts University study conducted in 2003, which was supported by the pharmaceutical industry, clinical trials accounted for more than 58 per cent of costs incurred for developing a new drug (Dhar and Gopakumar 2006; 5077). The study estimated that the average number of patients enrolled for clinical trials while seeking marketing approvals of a new drug were in excess of 5,300. This number was significant, for the number of patients' enrolment formed the basis of clinical trials' costs, which the Tufts University study claimed was US$ 802 million. The same group of researchers updated their study in 2016 in which they more than tripled their estimate of drug development costs to $2.6 billion. As in the 2003 paper, the $2.6 billion figure was based largely on data on clinical trial costs (Love 2018).

The reality of clinical trials has, however, become known after the Food and Drug Administration (FDA), the regulatory agency of the United States, began providing data on clinical trials from 2015. FDA has reported that in 2019, four main therapeutic areas in which approvals were granted were, haematology, oncology, neurology and psychiatry and sleep disorders (FDA 2020; 9). A total of 18,853 patients were enrolled for approval of 28 drugs. This implies that average patients enrolled for each drug trial was just over 673.

Notwithstanding the growing evidence that they are inflating the costs of developing new drugs by making exaggerated claims regarding production of clinical trials data, pharmaceutical companies have found support from several industrialised countries. Clinical trials and other test data are provided statutory protection ranging from five years in the United States and eight years in Canada, during which the covered product would enjoy market exclusivity. In both jurisdictions, the period of exclusivity grant is that the product must be a new chemical entity that has never been approved by the

regulators; variation of a previously approved entity such as a salt, ester, enantiomer, solvate or polymorph do not qualify for protection (Armouti and Nsour 2016: 291). In the European Union member states, a 10-year data protection and market exclusivity are provided for high-tech products, including biotechnology and those that "represent a significant innovation or therapeutic advance" (Armouti and Nsour 2016: 291).

The process of producing COVID-19 vaccines have brought forth several instances where companies have not allowed critical information about the safety and efficacy of their products to be put in public domain. An editorial in a recent edition of Nature magazine has revealed that "a worryingly high number of people around the world" have said that they would not get inoculated. This would keep them exposed to COVID-19 and would delay the end of the pandemic. The factors driving people to rejecting the vaccines include "concerns about approvals being rushed, suspicion of the pharmaceutical industry and a pandemic of vaccine misinformation are combining to erode the public's trust in the process by which vaccines are approved for use" (Nature 2020). The concerns in the minds of the public at large can be put to rest, provided national authorities do not allow safety and efficacy data for COVID-19 related medical products to be treated as trade secrets.[5]

B. Patents and access to COVID-19 related medical products

Several countries are facing limitations in accessing technologies for producing medicines for COVID-19 even for a proprietary medicine like Remdesivir, which merely ameliorates the suffering of the patients and is not a cure for the viral infection. The originator company, Gilead Sciences, has issued voluntary licences to some companies in developing countries, including a few Indian companies. However, the developing countries continue to face high prices and supply shortages in the absence of generic production. The voluntary licences have two limitations: one, the prices at which the product is currently available in India are relatively high, and two, the medicine cannot be exported to other countries.

Globally, two contrasting sets of initiatives have been taken, both of which are in response to the exclusive monopolies that are conferred by patent rights. The first is

[5] Although four companies, Moderna, Pfizer, Janssen, AstraZeneca have made their vaccine trial protocols public (the last named has released the protocols only for the trials in the United States), several questions are still being raised about the veracity of the data. For details, see Doshi 2020.

the COVID-19 Technology Access Pool, an initiative by the World Health Organization (WHO) in response to a request by the President of Costa Rica, Carlos Alvarado Quesada to the Director-General of the WHO, to “undertake an effort to pool rights to technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic” (World Health Organization 2020). Importantly, this is a voluntary mechanism wherein holders of the rights to knowledge, data and technologies are expected to agree to the pooling of these resources. In contrast, the second set of initiatives are strengthening the provisions to grant compulsory licenses that have been written into the laws of several countries, including those from the industrialised world.

C. What does COVID-19 Technology Access Pool seek to achieve?

The COVID-19 Technology Access Pool (C-TAP) is aimed at providing the wherewithal to develop of products needed to fight COVID-19 and to scale-up manufacturing of COVID-19 related medical products and to remove all barriers so as to facilitate global availability of these products. This initiative is intended to provide the framework for sharing information, knowledge, data, and other resources that could expedite the development of such products and to ensure avoidable duplication of efforts in this regard. Underlying C-TAP is “objective of promoting open science in order to accelerate product development and to facilitate access to the resulting health technologies by pooling IP, data, regulatory dossiers, and manufacturing processes and other kinds of 'know-how’” (World Health Organization 2020: 4). As has been visualised, the benefits from this initiative would be sharing of proprietary knowledge and information of all kinds which would promote innovation and manufacturing of the targeted products globally. Non-exclusive and public-health driven licensing together with arrangements for technology transfer are being seen as the added benefits. For example, free licenses and pledges offered by the Open COVID Pledge and other initiatives and the waiving of patent rights by some companies on products that may prove effective against COVID-19 could be among the favourable outcomes of C-TAP.

The most significant challenge that C-TAP would face, which has been acknowledged by the proponents of the initiative, is to develop an operating model that is attractive enough for the holders of proprietary knowledge, data, and technology to forego their

commercial interests. Hence, voluntary pool mechanisms have little chance to be attractive for the technology holders.

D. Strengthening provisions relating to compulsory licences

Several countries have adopted measures for facilitating grant of compulsory licences. This instrument allows grant of a licence for producing a proprietary product in the country of grant in case the patent holder refuses to allow production of the product in that country.

Canada's Patent Act was amended (Bill C-13) to empower the Commissioner of Patents, on the application of the Minister of Health, to “authorize the Government of Canada and any person specified in the application to make, construct, use and sell a patented invention to the extent necessary to respond to a public health emergency that is a matter of national concern” (World Intellectual Property Organization 2020). These amendments also ensured that a patent-holder receives adequate remuneration for the use of the patent, placing limitations on the duration of the authorization, and ensuring that the patent-owner has recourse to the courts if any person authorized acts outside the scope of the authorization (World Trade Organization 2020: 9).

France enacted Emergency Law No 2020-290 of 23 March 2020 to meet the challenges posed by the COVID-19 epidemic and introduced a new article into the country’s public health code. Article L3131-15 of the Public Health Code gives extraordinary powers to the French Prime Minister, enabling him to impose compulsory licences where necessary, bypassing the general provisions in the Intellectual Property Code. These provisions may also affect other IP rights, such as designs, for instance to ensure the availability of PPE (World Intellectual Property Organization 2020).

Germany enacted the legislation, “Protection of the Population in the Event of an Epidemic Situation of National Significance” in March 2020 which stipulates that a patent shall have no effect in a case where the Federal Government orders that the invention is to be used in the interest of public welfare. A patent shall also not extend to a use of the invention which is ordered in the interest of the security of the Federal Republic of Germany by the competent highest federal authority (World Intellectual Property Organization 2020).

A commission of the Ecuadorian National Assembly passed a 20th March resolution asking the country's health minister to issue compulsory licences on products whose availability is important to the public health response to COVID-19. The Education, Culture, Science and Technology Commission also asked the minister to make use of Article 501 of the Código Ingenios, which authorises third parties to access and use a patentee's data, including clinical test data (Houldsworth 2020).

Israel's Minister of Health issued a permit allowing the government to import generic versions of lopinavir/ritonavir from India for exploring the possibility of treating COVID-19 patients (World Trade Organization 2020c: 9).

These legislative initiatives show the implicit acknowledgement of potential barriers posed by patent rights in ensuring availability of COVID-19 medical products at affordable price.

3. Waiver Proposal: The next steps

COVID-19 has triggered huge demand for medical products,[6] which is unlikely to decline soon, if the current predictions about the pandemic are any indicator. But in many countries, supplies have often not been able to keep pace with the growing demand. There is, therefore, a case for these medical products to be treated as global public goods and for creating an enabling environment for their production by both private and state-owned enterprises. However, in most developing countries, adequate public funding and access to appropriate technologies have both been seriously inadequate for facilitating production and ensuring availability of these medical products to meet the burgeoning demand. Moreover, IPRs have yet again emerged as an impediment to access to technology and know-how. Adoption of the Waiver Proposal could provide the legal clarity to address these barriers in an effective way.

The major task for India and South Africa is to ensure strong backing for the Waiver Proposal from within the WTO and outside. The most important first step towards this end is to garner the support of like-minded countries, as was done in case of the TRIPS and Public Health proposal. It seems some ground has already been made; in the TRIPS Council Meeting held on 16 October, 13 Member states, including India's South Asian neighbours, Bangladesh, Nepal, Pakistan, and Sri Lanka, fully supported the

[6] There has been already many papers on this topic, among others Mikic, Puutio and Gallagher (2020).

proposal, while 14 others, including China and Nigeria, gave qualified support. The WHO and UNAIDS also fully supported the proposal.

In a member-driver multilateral system, effective coalitions are vital for norm setting. Developing countries understand this very well since they have benefited by adopting this strategy. It is also a fact that such coalitions have relied on effective leadership, which India and South African have provided in the past. At this critical juncture for humanity, the two countries must ensure that their important joint initiative realises the desired objectives.

List of references

Armouti, Wael and Mohammad F. A. Nsour, 2016, Test Data Protection: Different Approaches and Implementation in Pharmaceuticals. 20 Marq. *Intellectual Property L. Rev. 267*. Available at: http://scholarship.law.marquette.edu/iplr/vol20/iss2/5.

Dhar, Biswajit, 2001, Patents and Licensing. *Economic Times*. 6 July.

Dhar, Biswajit and KM Gopakumar, 2006, Data Exclusivity in Pharmaceuticals: Little Basis, False Claims. *Economic and Political Weekly*. 6 December 6.

Doshi, Peter, 2020, Covid-19 vaccine trial protocols released: A rare opportunity for public scrutiny of these key trials. BMJ. 21 October. Available at: https://www.bmj.com/content/371/bmj.m4058.

FDA, 2020, 2019 Drug Trials Snapshots: Summary Report. January. Available at: www.fda.gov/media/135337/download.

High Court of South Africa, 1998, Pharmaceutical company lawsuit (forty-two applicants) against the Government of South Africa (ten respondents). Case number: 4183/98. Available at: http://www.cptech.org/ip/health/sa/pharmasuit.html.

Hillman, Jennifer, 2020, Drugs and Vaccines Are Coming—But to Whom? How to Make Sure Patents Don't Stand in the Way of Global Health. *Foreign Affairs*. 18 May. Available at: https://www.foreignaffairs.com/articles/world/2020-05-19/drugs-and-vaccines-are-coming-whom.

Houldsworth, Adam, 2020, The key covid-19 compulsory licensing developments so far. IAM. 7 April. Available at: https://www.iam-media.com/coronavirus/the-key-covid-19-compulsory-licensing-developments-so-far.

Love, James, 2019, The growing gap between what the public had been told R&D costs are, and the actual costs. *Knowledge Ecology International*. Available at: https://www.keionline.org/30869.

Mikic, Mia, Puutio, T. Alexander and James G. Gallagher, 2020, "Healthcare products trade and external shocks: The US-China trade war and COVID-19 pandemic", *ARTNeT Working Paper Series* No. 190, May 2020, Bangkok, ESCAP. Available at https://artnet.unescap.org/publications/working-papers/healthcare-products-trade-and-external-shocks-us-china-trade-war-and

Nature, 2020, COVID vaccine confidence requires radical transparency: Editorial. 29 September 2020. Available at: https://www.nature.com/articles/d41586-020-02738-y

Open COVID Pledge, 2020, Make the pledge to share your intellectual property in the fight against COVID-19. Available at: https://opencovidpledge.org/.

Rao, Niranjan, 2006, Para 6 of WTO Doha Declaration: Non-Solution of TRIPS Problem. *Economic and Political Weekly*. Vol. 41, No. 4. 28 January.

South Centre, 2011, The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation. Policy Brief. No. 7. 1 November. Available at:

https://www.southcentre.int/wp-content/uploads/2013/06/PB7_-Doha-Declaration-on-TRIPS-and-Health_-EN.pdf.

Swarns, Rachel L, 2001, Drug Makers Drop South Africa Suit over AIDS Medicine. *The New York Times*. April 20. Available at: https://www.nytimes.com/2001/04/20/world/drug-makers-drop-south-africa-suit-over-aids-medicine.html.

The Guardian, 1999, How drug giants let millions die of Aids, 19 December 1999. Available at: https://www.theguardian.com/uk/1999/dec/19/theobserver.uknews6.

United Nations Secretary-General's High-Level Panel on Access to Medicines, 2016, Promoting Innovation and Access to Health Technologies. September. Available at: https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf.

World Health Organization, 2018, Technical report: pricing of cancer medicines and its impacts: a comprehensive technical report for the World Health Assembly Resolution 70.12: operative paragraph 2.9 on pricing approaches and their impacts on availability and affordability of medicines for the prevention and treatment of cancer.

World Health Organization. Geneva. Available at: https://apps.who.int/iris/handle/10665/277190.

World Health Organization, 2020, Operationalising the COVID-19 Technology Access Pool (C-TAP): A Concept Paper. Available at: https://www.who.int/docs/default-source/essential-medicines/intellectual-property/who-covid-19-tech-access-tool-c-tap.pdf?sfvrsn=1695cf9_2.

World Intellectual Property Organization, 2020, COVID-19 Policy Tracker. Available at: https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/access.

World Trade Organization, 2001, Declaration on the TRIPS Agreement and Public Health: Adopted on 14 November 2001. WT/MIN(01)/DEC/2. 20 November. Available at:https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/Min01/DEC2.pdf&Open=True

World Trade Organization, 2003, Implementation of Paragraph 6 of the Doha Declaration on TRIPS Agreement Public Health: Decision of 30 August 2003. WT/L/540. 2 September. Available at: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/L/540.pdf&Open=True.

World Trade Organization, 2007. Notification under Paragraph 2(A) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Rwanda. IP/N/9/RWA/1. 19 July. Available at: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/N/9RWA1.pdf&Open=True.

World Trade Organization, 2015, Protocol Amending the TRIPS Agreement: Expected benefits of the Paragraph 6 System of Special Licences for export of medicines. WT/GC/W/696. 23 February. Available at: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/GC/W696.pdf&Open=True.

World Trade Organization, 2016, Waivers – 1995-2015: Note by the Secretariat. WT/GC/W/718. 27 June. Available at: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/GC/W718.pdf&Open=True.

World Trade Organization 2019, Waivers – 2019: Note by the Secretariat. WT/GC/W/795. 18 December. Available at: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/GC/W795.pdf&Open=True.

World Trade Organization, 2020a, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from India and South Africa. IP/C/W/669. 2 October Available at: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True.

World Trade Organization, 2020b, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from India and South Africa – Addendum. IP/C/W/669/Add.1. 21 October. Available at: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669A1.pdf&Open=True.

World Trade Organization, 2020c, The TRIPS Agreement and COVID-19: Information Note. 15 October. Available at: https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf.

orum on Financing for Development, Unfairtobacco, Global Policy Forum, MISEREOR.

B20 Task Force, 2017. *Open, Dynamic and Inclusive Labor Markets: Harnessing the Potential of Technological Change and Creating a Global Level Playing Field,* Berlin (DE): B20 Germany.

Bacchetta, M. & Jansen, M., 2003. *Adjusting to trade liberalization: The role of policy, institutions and WTO Discipline,* Geneva (CH): WTO.

Bacchetta, M., Milet, E. & Monteiro, J.-A., 2019. *Making Globalization more Inclusive: Lessons from Experience with Adjustment Policies.* Geneva (CH): World Trade Organization.

Beattie, A., 2009. *False Economy: A Surprising Economic History of the World.* London (UK): Penguin Books.

Bloom, N., Handley, K., Kurman, A. & Luck, P., 2019. *The Impact of Chinese Trade on U.S. Employment: The Good, The Bad, and The Debatable,* Cambridge (MA): NBER.

Cedefop, 2009. *Using tax incentives to promote education and training,* Luxembourg (LU): European Center for the Development of Vocational Training.

Cutler, W. & Bell, J., 2018. *Adjusting to Trade: Asia-Pacific Approaches to Assisting Displaced Workers,* New York (NY) and Washington (DC): Asia Society Policy Institute.

EDFI, 2016. *Bridging the skills gaps in developing countries: A practical guide for private-sector companies,* Brussels (BE): European Development Finance Institutions.

Evenett, S. J., 2019. Protectionism, state discrimination, andinternational business since the onset of the Global Financial Crisis. *Journal of International Business Policy,* p. 9–36.

Kerr, W. R. & Moloney, E., 2018. *Vodafone: Managing Advanced Technologies and Artificial Intelligence,* Cambridge (MA): Harvard Business School.

King, A., 2015. *The Future Of Crash Testing Is Digital, And This Is How It Works.* [Online]
Available at: https://jalopnik.com/the-future-of-crash-testing-is-digital-and-this-is-how-1747788970

King, A., 2019. *Auto Makers Are Improving Operations With Help From Industrial IoT.* [Online]
Available at: https://www.forbes.com/sites/vinaynathan/2019/03/29/the-iiot-is-driving-results-for-the-automotive-industry/#78833ae034ad

Mercer, 2019. *The Four Key Factors Companies Consider When Relocating.* [Online]
Available at: https://www.mercer.com/our-thinking/the-four-key-factors-companies-consider-when-relocating.html

OECD, 2007. *Promoting Pro-Poor Growth: Policy Guidance for Donors, DAC Guidelines and Reference Series,* Paris: OECD Publishing.

OECD, 2013. *Enhancing Skills through Public-Private Partnerships in Kazakhstan's Information Technology Sector,* Paris (FR): OECD Publishing.

Otuki, N., 2015. *Employers get tax break to hire fresh graduates.* [Online]
Available at: https://www.businessdailyafrica.com/news/Employers-get-tax-break-to-hire-fresh-graduates/539546-2748726-ehok03/index.html

Oxfam, 2018. *Reward Work not Wealth,* Oxford (UK): Oxfam.

Rabinovitch, S., 2011. China labour costs soar as wages rise 22%. *Financial Times*, 26 October.

Rappa, J., 2012. *Incentives for Hiring or Retaining Recent College Graduates,* Hartford (CT): Office of Legislative Research (Connecticut).

Robinson, G., Zhou, M. & Maulia, E., 2019. *How the death of fast fashion is transforming Asia's garment industry.* [Online]
Available at: https://asia.nikkei.com/Spotlight/Cover-Story/How-the-death-of-fast-fashion-is-transforming-Asia-s-garment-industry

Studwell, J., 2013. *How Asia Works.* New York (NY): Grove Press.

Suri, T. & Dorval, L., 2019. *Constraints to entrepreneurship: Findings from pilot studies in kenya and Uganda,* London (UK): International Growth Center.

The Economist, 2016. Technology Quarterly: The Future of Agriculture. *The Economist*, 9 July.

Tilley, J., 2017. *Automation, robotics, and the Factory of the Future,* Ny (NY): McKinsey&Company.

WEF, 2018. *The Future of Jobs Report,* Geneva (CH): World Economic Forum .

William, K. R. & Emer, M., 2018. *Vodafone: Managing Advanced Technologies and Artificial Intelligence,* Cambridge (MA): Harvard Business School.

World Bank, 2019. *Business Reforms in Starting a Business.* [Online]
Available at: https://www.doingbusiness.org/en/reforms/overview/topic/starting-a-business

World Bank, 2020. *Business Reforms in Getting Credit.* [Online]
Available at: https://www.doingbusiness.org/en/reforms/overview/topic/getting-credit

World Intellectual Property Organization (WIPO), 2020. *China Becomes Top Filer of International Patents in 2019 Amid Robust Growth for WIPO's IP Services, Treaties and Finances.* [Online]
Available at: https://www.wipo.int/pressroom/en/articles/2020/article_0005.html

World Trade Organization and United Nations Conference on Trade and Development, 2013. Chapter 6: Analysing the distributional effects of trade policies. In: *A Practical Guide to Trade Policy Analysis.* Geneva (CH): WTO & UNCTAD.

Zahonogo, P., 2016. Trade and economic growth in developing countries: Evidence from sub-Saharan Africa. *Journal of African Trade,* pp. 41-56.

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ARTNeTontrade

@ARTNeTontrade

ARTNeT Group

artnetontrade@un.org

ARTNeT Secretariat, United Nations ESCAP

Rajadamnern Nok Avenue

Bangkok 10200, Thailand

Tel: +66(0) 22881410

Fax: +66(0) 22881027