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SOUTH CENTRE

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PROMOTING JORDAN'S USE OF COMPULSORY LICENSING DURING THE PANDEMIC

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ABSTRACT

This paper addresses the difficulties in utilizing Article 31 bis of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) on compulsory licensing for the export of pharmaceuticals during the pandemic through the case study of Jordan. This paper also recommends that Jordanian officials seek to capitalize on the pandemic whilst the Jordanian Defense Law and Orders are in effect to include Emergency Use Authorization (EUA) as a direct ground for applying compulsory licensing, introduce clauses similar to those introduced by countries who have signed FTAs with the US, as well as deactivate harmful clauses within its national laws that prevent the application and utilization of a compulsory license. Further, Jordanian officials should seek the opportunity, considering the change of stance of the Biden administration towards compulsory licensing, to re-negotiate favourable terms in the Jordanian – US Free Trade Agreement (JUSFTA). Moreover, Jordanian officials should also form a syndicate that calls for the overhauling of TRIPS at Article 31 bis when an EUA is invoked in any country.

Este documento aborda las dificultades para utilizar el artículo 31 bis del Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (Acuerdo sobre los ADPIC) sobre la concesión de licencias obligatorias para la exportación de productos farmacéuticos durante la pandemia a través del estudio de caso de Jordania. Este documento también recomienda que los funcionarios jordanos intenten sacar provecho de la pandemia mientras la Ley y las Órdenes de Defensa jordanas estén en vigor para incluir la Autorización de Uso de Emergencia (EUA) como motivo directo para aplicar licencias obligatorias, introducir cláusulas similares a las introducidas por los países que han firmado ALC con EE.UU., así como desactivar las cláusulas perjudiciales dentro de sus leyes nacionales que impiden la aplicación y utilización de una licencia obligatoria. Además, los funcionarios jordanos deberían buscar la oportunidad, teniendo en cuenta el cambio de postura de la administración Biden respecto a las licencias obligatorias, de renegociar términos favorables en el Acuerdo de Libre Comercio entre Jordania y EE.UU. (JUSFTA). Además, los funcionarios jordanos también deberían formar un sindicato que exija la revisión del ADPIC en su artículo 31 bis cuando se invoque un EUA en cualquier país.

Ce document aborde les difficultés liées à l'utilisation de l'article 31 bis de l'accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (accord sur les ADPIC) concernant les licences obligatoires pour l'exportation de produits pharmaceutiques pendant la pandémie, à travers l'étude de cas de la Jordanie. Ce document recommande également que les responsables jordaniens cherchent à tirer parti de la pandémie pendant que la loi et les ordonnances de défense jordaniennes sont en vigueur pour inclure l'autorisation d'utilisation d'urgence (EUA) comme motif direct d'application de la licence obligatoire, introduire des clauses similaires à celles introduites par les pays qui ont signé des accords de libre-échange avec les États-Unis, ainsi que désactiver les clauses préjudiciables dans ses lois nationales qui empêchent l'application et l'utilisation d'une licence obligatoire. En outre, les fonctionnaires jordaniens devraient saisir l'occasion, compte tenu du changement de position de l'administration Biden à l'égard des licences obligatoires, de renégocier des conditions favorables dans l'accord de libre-échange entre la Jordanie et les États-Unis (JUSFTA). En outre, les fonctionnaires jordaniens devraient également former un syndicat qui demande la révision de l'article 31 bis de l'accord sur les ADPIC lorsqu'un EUA est invoqué dans n'importe quel pays.

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1. INTRODUCTION

COVID-19 is an exceptional virus because of its high transmissibility and mortality rate. COVID-19 has affected around 500 million people worldwide and has claimed over 5 million lives.[1] These figures change on a daily, if not hourly basis. The fact that real-time information exists on COVID-19 shows the magnitude and effect that this virus is having on lives. Whilst the information on threatening viruses is not a new phenomenon, the insistence on vaccinations and monitoring of vaccination doses globally is certainly as novel as the virus itself.[2]

Research initially focused and explored existing drugs, especially Remdesivir, in an attempt to deal with the COVID-19 virus.[3] Consequently, some countries, such as Hungary and Russia, issued compulsory licenses to increase the production of Remdesivir.[4] Producing a vaccine in the circumstances, was not foreseeable.[5]

There were three contributory factors which lead to the fast development of the COVID-19 vaccine; a financial factor, a sociological factor and a regulatory factor. The financial aspect was achieved through public funding, governments through taxpayers' money and charitable trusts.[6] The sociological factor was achieved when thousands of volunteers contributed to the required third clinical trials phase,[7] thereby accelerating and providing the essential safety and efficacy data. Lastly, the regulatory factor was achieved through government involvement. The focus of this paper is on achieving change through the regulatory factor.

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[1] WHO Coronavirus (COVID-19) Dashboard. Available from https://covid19.who.int/ (accessed 29 March 2022).
[2] WHO estimates that around 8.7 billion doses of vaccinations have been administered. Ibid.
[3] Viviana Muñoz Tellez, "The COVID-19 Pandemic: R&D and Intellectual Property Management for Access to Diagnostics, Medicines and Vaccines" South Centre Policy, Brief No. 73 (2020), Available from https://www.southcentre.int/wp-content/uploads/2020/04/PB73_The-COVID-19-Pandemic-RD-and-Intellectual-Property-Management-for-Access-to-Diagnostics-Medicines-and-Vaccines_EN-3.pdf, p. 2.
[4] Hungary issued three compulsory licenses end of 2020. Hungarian Intellectual Property Office (2020). Available from https://www.sztnh.gov.hu/en (accessed on 29 March 2022); World Trade Organization (WTO), COVID-19 and trade – Hungary (2022). Available from https://www.wto.org/english/tratop_e/covid19_e/covid_details_by_country_e.htm?country=HUN (accessed on 29 March 2022); WTO, COVID-19 and trade – Russia (2022) .Available from https://www.wto.org/english/tratop_e/covid19_e/covid_details_by_country_e.htm?country=RUS (accessed on 29 March 2022).
[5] This is because, typically, a vaccine undergoes a lifecycle of pre-clinical, clinical trial process with three phases and a further regulatory phase before the manufacturing process begins to ensure the vaccine's safety and efficacy which normally takes around 10 to 15 years to develop. Stefan Harrer, Pratik Shah, Bhavna Antony, Jianying Hu "Artificial Intelligence for Clinical Trial Design", *Trends in Pharmacological Science*, vol. 40, Issue 8, (August 2019) pp 577-591; Centers for Disease Control and Prevention, Vaccine testing approval process. Available from https://www.cdc.gov/vaccines/basics/test-approve.html (accessed on 29 March 2022). Before the COVID-19 vaccines, the fastest vaccine to be rolled out to the public was the mumps vaccine which only took four years from the pre-clinical stage to licensing. Nsikan Akpan, "Why a coronavirus vaccine could take way longer than a year", *National Geographic*, 10 April 2020. Available from https://www.nationalgeographic.com/science/article/why-coronavirus-vaccine-could-take-way-longer-than-a-year#close (accessed on 29 March 2022).
[6] See Policy Cures Research. Public, philanthropic & industry funding for COVID-19 R&D (2022). Available from https://www.policycuresresearch.org/covid-19-r-d-tracker, (accessed on 29 March 2022); Michael Safi, "Oxford/AstraZeneca Covid vaccine research was 97% publicly funded", *The Guardian*, 15 April 2021; Richard G. Frank Leslie Dach Nicole Lurie, "It Was The Government That Produced COVID-19 Vaccine Success", *Health Affairs*, 14 May 2021.
[7] "Pfizer and BioNTech 'appreciate the continued participation of the approximately 44,000 trial volunteers and remain committed to the companies' pledge to always make their safety and well-being the companies' top priority". Pfizer, "Pfizer and BioNTech Celebrate Historic First Authorization in the U.S. of Vaccine to Prevent COVID-19", (11 December 2020). Available from https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-celebrate-historic-first-authorization (accessed on 29 March 2022) para 6.

Governments have proven, during this pandemic, that they are a "new player"[8] when it comes to access to pharmaceuticals. Governments have directed funding towards researching for the COVID-19 vaccine, amended their domestic legislation to improve access to compulsory licensing,[9] and empowered pharmaceutical companies by 1) allowing the production of the COVID-19 vaccine ahead of regulatory and official approval,[10] 2) succumbed to Emergency Use Authorization (EUA) requests by pharmaceutical companies,[11] 3) made assurances to pharmaceutical companies regarding liability[12] and subsequently set-up compensation funds and schemes.[13]

EUA was one way in which pharmaceutical companies asserted their bargaining power. Pharmaceutical companies such as Pfizer/BioNTech have provided vaccines to countries on the proviso that an EUA was granted. This meant that governments had to issue an EUA before any vaccines were dispatched.[14] Pharmaceutical companies, thus, utilized the regulatory process to navigate the difficulties associated with introducing a vaccine to the public.

This paper is divided into two sections the first of which explains the compulsory licensing issue, the difficulty in applying compulsory licensing and the restraints in applying this TRIPS

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[8] Germán Velásquez (2022) *COVID-19 Vaccines: Between Ethics, Health and Economics* in Vaccines, Medicines and COVID-19 How Can WHO Be Given a Stronger Voice? Springer South Centre, E-Book at p. 18.

[9] Médecins Sans Frontiers (MSF), "Compulsory licenses, the TRIPS waiver and access to COVID-19 medical technologies", MSF Briefing Document, May 2021. Available from https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSF_AC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf (accessed on 29 March 2022).

[10] K. V. Iserson, (2021). SARS-CoV-2 (COVID-19) Vaccine Development and Production: An Ethical Way Forward. *Cambridge Quarterly of Healthcare Ethics,* vol. *30* No.1, pp59-68; WHO's Joint Statement from the International Coalition of Medicines Regulatory Authorities and World Health Organization, "Statement for healthcare professionals: How COVID-19 vaccines are regulated for safety and effectiveness", 11 June 2021, Available from https://www.who.int/news/item/11-06-2021-statement-for-healthcare-professionals-how-covid-19-vaccines-are-regulated-for-safety-and-effectiveness (accessed on 29 March 2022).

[11] Gov.UK, "UK medicines regulator gives approval for first UK COVID-19 vaccine" 2 December 2020. Available from: https://www.gov.uk/government/news/uk-medicines-regulator-gives-approval-for-first-uk-covid-19-vaccine (accessed on 29 March 2022); Pfizer, "Pfizer and BioNTech Celebrate Historic First Authorization in the U.S. of Vaccine to Prevent COVID-19", 11 December 2020, Available from https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-celebrate-historic-first-authorization (accessed on 29 March 2022).

[12] There is no shifting in liability when it comes to Jordanian Public Order, in relation to safety and against grave acts. See Ahmad Muflah Khawalda, "Exemption Condition about Contractual Responsibility – A comparative study", 2011 Dar Al Thaqafa, p.136.; The US and EU's therefore implemented no-fault compensation schemes. The US's Public Readiness and Emergency Preparedness Act for Medical Countermeasures against COVID–19 excludes tort claims from products that help to control a public health crisis. Further, this Act has broader global application because the declaration by HHS secretary stated that the coverage of the declaration would be "without geographic limitation," immunity from suits in state and federal courts would be possible even if vaccinations were administered outside the United States. Federal Register / Vol. 85, No. 52 / Tuesday, March 17, 2020 / Notices. Available from https://www.govinfo.gov/content/pkg/FR-2020-03-17/pdf/2020-05484.pdf ; Dixon, Lloyd, Kenneth R. Feinberg, Nicholas M. Pace, and Paul Rheingold, "COVID-19 Vaccine Liability and Compensation in the United States", Santa Monica, CA: RAND Corporation, 2021. Available from https://www.rand.org/pubs/presentations/PTA1138-2.html (accessed on 29 March 2022); Similarly, EU Pharmaceutical companies have asked to be exempted for liability and for a compensation scheme to be put in place. Wouter Pors, Evelyn Tjon-En-Fa, Flora Peel, February 2021, "A vaccine for COVID-19: risks and liabilities from an international perspective", Bird & Bird, February 2021. Available from https://www.twobirds.com/en/news/articles/2020/netherlands/a-vaccine-for-covid-19-risks-and-liabilities-in-international-perspective; AstraZeneca asked for clauses to shift their responsibility for the COVID-19 medication Ludwig Burger, Pushkala Aripaka, "AstraZeneca to be exempt from coronavirus vaccine liability claims in most countries", *Reuters*, 30 July 2020.

[13] Dixon, Lloyd, Kenneth R. Feinberg, Nicholas M. Pace, and Paul Rheingold, "COVID-19 Vaccine Liability and Compensation in the United States", Santa Monica, CA: RAND Corporation, 2021. Available from https://www.rand.org/pubs/presentations/PTA1138-2.html (accessed on 29 March 2022).

[14] Pharmaceutical companies have asked countries to provide liability exclusions. Adam Parsons, "COVID-19: Pfizer boss says company aims to send out vaccine within hours of approval", *SKY NEWS*, 19 November 2020. Available from https://news.sky.com/story/covid-19-pfizer-boss-says-company-aims-to-send-out-vaccine-within-hours-of-approval-12136224.

flexibility during a pandemic. The second section makes recommendations to Jordan to deal with the compulsory licensing issue whilst taking into account technological, burdensome policy restraints.

2. BACKGROUND

Jordan is a developing, upper middle-income country,[15] with a population of 11 million[16] that has been affected severely by the COVID-19 pandemic. Jordan's first reported COVID-19 case was in March 2020[17] and the first shipment of vaccines was on 12 March 2021.[18] The current reported statistics of COVID-19 in Jordan are around 1.7 million confirmed cases and about 14,000 confirmed deaths.[19]

Jordan is a WTO member and thus is bound to enforce the TRIPS Agreement. Jordan should therefore be able to benefit from the TRIPS flexibilities to increase its access to pharmaceuticals especially in the context of the COVID-19 vaccines.

In response to the pandemic, a royal decree, upon the recommendation of the Jordanian ministers, was issued to activate Jordan's Defense Orders which grant the Prime Minister the power to deactivate domestic laws to protect public's health,[20] including the constitutional right

[15] UN World Economic Situation Prospectus New York 2020. Available from https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/WESP2020_Annex.pdf (accessed on 29 March 2022); World Bank, Jordan's statistics. Available from https://data.worldbank.org/country/JO (accessed on 29 March 2022).

[16] Jordan's Department of Statistics. Available from http://dosweb.dos.gov.jo/ (accessed on 29 March 2022).

[17] The first reported COVID-19 case reported in Jordan was in March 2020. "Jordan confirms first case of coronavirus", *Jordan Times*, 3 March 2020.

[18] WHO Jordan News, "First shipment of European Union-funded COVID-19 vaccines from COVAX Facility arrives in Jordan", 13 March 2021. Available from http://www.emro.who.int/jor/jordan-news/first-shipment-of-european-union-funded-covid-19-vaccines-from-covax-facility-arrives-in-jordan.html (accessed on 29 March 2022).

[19] WHO Jordan, Available from https://www.who.int/countries/jor/ (accessed on 29 March 2022).

[20] Jordan invoked its Defense Law No. 13 of 1992 on 17th March 2020. See also Article 4 of the Defense Order No. 13 of 1992 which states:
The Prime Minister may exercise the following powers:

> A. Place restrictions on the freedom of persons to gather, move, and reside, and arrest and detain suspects or persons who are dangerous to national security and public order. B. Entrusting any person with carrying out any work or performing any service within his ability. C. Searching people, places, and vehicles without being bound by the provisions of any other law, and ordering the use of appropriate force in the event of a reluctance.
> D. Setting possession of movable and immovable property, postponing the payment of debt and the outstanding obligations. E. Preventing, restricting, or restricting the import, export, or transfer of materials from one place to another, specifying dealing with them and prohibiting their concealment, destruction, purchase or bartering them, and setting their prices.
> F. Seizure of any land, building, road, or source of water and energy, establish work on it related to defence, remove any trees or installations over it, and order it to be managed, exploited, or regulated using it.
> G. Evacuation or isolation of some areas and imposing curfews.
> H. Determine the dates of opening and closing public stores, in whole or in part.
> I. Organizing and determining the means of transport and transportation between the different regions, closing any road, path, or stream of water, or changing its direction and preventing traffic on it or regulating it.
> Y. Monitor messages, newspapers, publications, pamphlets, drawings, and all means of expression, propaganda, and advertising before they are published, seized, confiscated, suspended, and closed places of their preparation.
> K. Preventing taking pictures or making designs or maps for any specific place or thing that might benefit the enemy, preventing keeping near these places and things with any photographic devices or materials for making pictures, designs and maps, and preventing staying or delaying in such places without a legitimate excuse.
> L. Cancellation of licenses of firearms, ammunition, explosives, or explosive materials that are used in the manufacture of explosives, preventing their manufacture, sale, purchase, transfer, or disposal of them, and ordering their delivery and seizures, and closing their stores and storing them.
> M. Preventing the manufacture, sale, purchase, or possession of telecommunications equipment and ordering their delivery and seizure.

to place restrictions on freedoms such as to impose lockdowns[21] and limit instances in which employers can dismiss employees.[22]

[21] See Jordanian Defense Orders No. 1 & No. 2.
[22] See Jordanian Defense Order No. 6 and its Sub-Orders.

3. THE COMPULSORY LICENSING ISSUE

There are essentially two hurdles to go through before a compulsory license is issued in Jordan: meeting the grounds for applying a compulsory license; and subsequently the requirements imposed by the procedures to apply for compulsory licenses.

3.1 Applying for Compulsory Licenses in Jordan

Article 31 (b) of TRIPS allows countries to reproduce medicines for the domestic market without the patent holder's authorization subject to stipulations which include:

> (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. **This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public noncommercial use**. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable**.** In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly. [Emphasis added].

The Doha Declaration on the TRIPS Agreement and public health (Doha Declaration) has helpfully reaffirmed that countries have the "freedom to determine the grounds upon which a license is granted".[23] The Doha Declaration, therefore, clarified that countries, such as Jordan, could determine the grounds for granting a compulsory license and that these are not exclusive to emergency situations.[24] This means that Jordanian law could choose to apply compulsory licensing in a variety of situations.

However, Jordan signed a Free Trade Agreement with the United States (JUSFTA) which adds restrictions on Jordan's utilization of compulsory licensing. JUSFTA restricts compulsory licensing to use for "public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency",[25] and on the proviso that "use is limited to use by government entities or legal entities acting under the authority of a government".[26]

Regarding the first limb, the circumstances of COVID-19 are unprecedented. Jordan has managed to contain the virus through a series of commendable countermeasures, such as activating Defense Orders and Sub-Orders, as mentioned above, yet it is inconceivable to describe COVID-19 with words other than a national emergency, if not a global crisis,[27] thereby constituting a national emergency and satisfying the first limb.

Regarding the second limb, which limits the use to "government entities or legal entities", governmental entities in Jordan include: the prime ministry, ministries and governmental

[23] Doha Declaration on the TRIPS Agreement and public health (WT/L/540) (Doha Declaration) at para 5(b).
[24] Doha Declaration at para 5(c).
[25] JUSFTA Article 4 Sub-clause 20(b).
[26] Ibid.
[27] However, this is despite the view that "emergency" does not necessarily equate to pandemics. Kapczynski "Going Local in the Era of TRIPS Implementation" in R. Dreyfuss and C. Rodriguez-Garavito, *Balancing Wealth and Health: The Battle over Intellectual Property and Access to Medicines in Latin America* (OUP 2014), p. 266.

agencies where the Ministry of Health forms a governmental entity.[28] This stipulation means that if a compulsory license is granted then vaccines shall be administered solely by the Ministry of Health, as authorized by the Jordanian Government.

For a country to consider compulsory licensing, its legal system needs to have laws in place to allow the government to issue a compulsory license.[29] This has been done by Jordan's national law.[30]

Jordan, therefore, could technically use compulsory licensing to produce or import COVID-19 vaccines during the pandemic. However, it has not done so,[31] and there is no evidence to suggest that Jordanian officials have ever considered compulsory licensing before now or as a result of the pandemic.[32]

The immediacy of using a compulsory licensing during a pandemic in Jordan is hampered by Article 39.3 of TRIPS. Article 39.3 of TRIPS requires members to protect undisclosed information.[33] Further, footnote 11 of Article 22 in JUSFTA states that "Jordan shall at a minimum protect such information against unfair commercial use **for the same period of time the other country is protecting such information against unfair commercial use**".

Further, a pharmaceutical product must be approved before it can be imported, marketed and administered to the Jordanian population.[34]

3.2 The Mechanism of Compulsory Licensing

The mechanism of applying compulsory licensing in Jordan proves difficult. This is because of technological restraints, burdensome conditions as well as policy considerations.

(a) Technological restraints

[28]Official Site of the Jordanian E-government. Available from https://form.jordan.gov.jo/wps/portal/Home/GovernmentEntities/Ministries/!ut/p/z1/hc9NC4JAEAbg39LBqzPZKtptKRM_ipIg20to2CqpK-uWfz-pTIE2t3d4XpgBBgmwJr2XPFWIaNJqyEdmnShx9yZ61N8ZMUEabRauF8XBjhhweAL8MRSB_euzMUKn1huYztL3FiGucWWYA3BCJyTmDJG8wcgNATBeiez1D22ymc2ByfySy1zqNzmsC6Xabq6hhn3f61wIXuX6Wei3q4bfSoXoFCSfFto6wXJbH-yOTh7rqZq4/?uri=nm:oid:Z6_A4ET50GAIQ2R40ALNCEGLRJA16 (accessed on 29 March 2022).

[29] Hilary Wong, "The case for compulsory licensing during COVID-19" *Journal of Global Health*, vol. 10, No 1 (June 2020) .

[30] Jordan's Patent Law No.32 of 1999 at Article 22 D states that "The Minister may grant a license to use a patent to third parties without obtaining the patentee's consent in any of the following cases exclusively: D If the exporting will be done to countries which suffer from pandemics or epidemic illnesses in compliance with the Kingdom's obligations under the World Trade Organization agreements and the decisions issued pursuant thereto". However, Jordan's national law constricts the use of parallel importation Jordan's Patent Law No. 32 (1999) which states at Article 21 (A)(1) that the patent owner has a right in "Preventing others, if the owner of the patent does not obtain the approval of making the product in question, using it, using it, offering it for sale, selling, or importing it, if the subject of the patent is a product."

[31] Jordan have not invoked or attempted to invoke any measures affecting trade in intellectual property. WTO, COVID-19, and Trade – Jordan. Available from https://www.wto.org/english/tratop_e/covid19_e/covid_details_by_country_e.htm?country=JOR (accessed on 29 March 2022); See WTO's Policy Tracker. Available from COVID-19 IP Policy Tracker (wipo.int).

[32] Ibid.

[33] Article 39.3 of TRIPS states that:

> Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products **which utilize new chemical entities,** the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

[34] Nicholas Vincent, "TRIP-ing Up: The Failure of TRIPS Article 31bis", Gonzaga Journal of International Law 2020, Available from SSRN: https://ssrn.com/abstract=3778945.

The manufacturing of pharmaceuticals requires a series of industrial policies. Improving manufacturing capabilities[35] as well as extending global public policies to encourage distribution and access in the vaccine industry are factors that need to be taken into consideration.[36]

Jordan, as a developing country, does not possess the manufacturing capacity to produce the large volumes required for the COVID-19 vaccine[37] and therefore, Jordan will require aid for the domestic manufacturing process as well as the process of importation from another jurisdiction.[38]

(b) Burdensome conditions

Compulsory licensing for countries without manufacturing capacity in pharmaceuticals is governed by Article 31 *bis* of TRIPS. The Doha Declaration had addressed the limitations in applying compulsory licensing under Article 31(f) of TRIPS through Paragraph 6 to assist countries with limited manufacturing capabilities in that field.[39] However, the Paragraph 6 solution remained unworkable.[40]

Article 31*bis* essentially "allows pharmaceutical products made under compulsory licenses to be exported to countries lacking production capacity"[41] and incorporates an appendix which deals, inter alia, with assessing lack of manufacturing capability in the importing country.[42]

There have been no reported cases of using compulsory licensing through incorporating Article 31 *bis.*[43] The only reported instance of a compulsory license incorporating Article 31 *bis* remains Apotex Inc., a generic Canadian pharmaceutical company, which exported HIV/AIDS medication to Rwanda. Apotex Inc. vowed not to use the Paragraph 6 solution again because of its complexity.[44] Indeed, the constraints of applying Article 31 *bis* persisted and include "complex procedural requirements" which starts with negotiation process for a

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[35] L. Barqawi, "Sudan's access to medicine: to TRIPS or not to TRIPS", European Intellectual Property Review 41 (8) 2019, 499.
[36] Felix Lobo, *Restructuring the Global Vaccine Industry*, Research Paper No. 134 (Geneva, South Centre, September 2021). Available from RP134_Restructuring-the-Global-Vaccine-Industry_EN-1.pdf (southcentre.int).
[37] Abu Allan, Almothanna & Abu Kasim, Nor & Mustapha, Mazlina & Mohammed Shah, Sabarina. "An overview of Jordanian manufacturing sector in light of current regional political situation" (2018) ResearchGate. Available from https://www.researchgate.net/publication/327014151_AN_OVERVIEW_OF_JORDANIAN_MANUFACTURING_SECTOR_IN_LIGHT_OF_CURRENT_REGIONAL_POLITICAL_SITUATION ; See also J. Subhan , "Scrutinized: The TRIPS Agreement and Public Health" (2006)Vol. 9 Issue (2) McGill Journal of Medicine.
[38] The Doha Declaration Paragraph 6 Implementation Decision states that: "We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement."
[39] The Doha Declaration Paragraph 6 Implementation Decision states that: "We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement."
[40] WTO, "WTO IP rules amended to ease poor countries' access to affordable medicines" (*WTO News*, 23 January 2017).
[41] WTO, "Members OK amendment to make health flexibility permanent", (*WTO News,* 6 December 2005).
[42] Ibid.
[43] Nirmalya Syam, Viviana Munoz, Carlos M. Correa, and Vitor Ido, "The Doha Ministerial Declaration on TRIPS and Public Health on its Twentieth Anniversary" Policy Brief No. 107, November 2021. Available from PB107_The-Doha-Ministerial-Declaration-on-TRIPS-and-Public-Health-on-its-Twentieth-Anniversary_EN.pdf (southcentre.int)
[44] Ibid., South Centre "The Doha declaration on TRIPS and public health: Ten years later – The state of implementation" Policy Brief No. 7, November 2011. Available from https://www.southcentre.int/wpcontent/uploads/2013/06/PB7_-Doha-Declaration-on-TRIPS-and-Health_-EN.pdf; Germán Velásquez (2022) "COVID-19 Vaccines: Between Ethics, Health and Economics", in *Vaccines, Medicines and COVID-19 How Can WHO Be Given a Stronger Voice?*, Springer South Centre, E-Book; A. Weber. and L. Mills, "A One-Time-Only Combination: Emergency Medicine Exports Under Canada's Access to Medicines Regime", (2010) 12 (1) Health and Human Rights in Practice 109.

voluntary license, it is accompanied by notifications of importer/exporter status to the WTO and could be jeopardized by the patent holder.[45]

The process of providing the medication as prescribed above took 27 months by Apotex Inc. which negates the role of a compulsory license in rapidly dealing with a national need. The Government of Bolivia had sought a compulsory license by notifying the WTO in February 2021[46] and yet no compulsory license has been issued to date.

(c) Policy considerations

Further, Jordanian officials have not introduced any measures to deal with compulsory licensing, possibly due to conflicting messages from developed nations.

Nevertheless, as mentioned above paragraph 6 of the Doha Declaration has only been invoked once, and there has been an argument that the difficulty in using paragraph 6 was "not for technical reasons, the main problem is political… as an "incredible political pressure" is put on countries considering using it."[47]

The introduction of Article 31 *bis* has not improved the political situation for developing countries as evidenced by the statements made by the United Nations (UN), and The World Trade Organization (WTO) calling on governments to assist with vaccine distribution.[48] Furthermore, the WTO recognized the political constraints in accessing vaccines and has asserted that " [a]ll blockages to expanding supply must be removed, and we call on WTO members to accelerate negotiations towards a pragmatic solution around intellectual property".[49]

Furthermore, developing countries were not assisted by the conflicting messages on utilizing compulsory licensing as a TRIPS flexibility. Developed countries initially dissuaded the use of compulsory license, for example, the European Union (EU) IP enforcement report 2020 has criticized many developing countries such as India and Ecuador for allowing the use of compulsory licenses if patent holders do not fulfil the obligations of supporting the production locally. Similarly, the United States Trade Representative (USTR) 2020 Special 301 report has condemned countries that have improved their laws to utilize compulsory license or used compulsory licensing.

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[45]Ibid., p. 9; Carlos Correa, "Will the Amendment to the TRIPS Enhance Access to Medicines". Policy Brief No. 57, South Centre, January 2019. Available from https://www.southcentre.int/wpcontent/uploads/2019/01/PB57_Will-the-Amendment-to-theTRIPS-Agreement-Enhance-Access-to-Medicines_EN-1.pdf;
Muhammad Zaheer Abbas, *Canada's Political Choices Restrain Vaccine Equity: The Bolivia-Biolyse Case*, Research Paper No. 136 (Geneva, South Centre, September 2021). Available from https://www.southcentre.int/tag/biolyse-pharma/.

[46] WTO document IP/N/8/BOL/1.

[47] Catherine Saez, "Main Recommendations Of UN High-Level Panel On Access To Medicines Presented at WTO's Intellectual Property Watch" *Intellectual Property Watch* ,7 March 2017 at para 14; United Nations Secretary General's High Level Panel Access to Medicines, *Report of the United Nations Secretary General's High Level Panel on Access to Medicines- promoting innovation and access to health technologies* (September 2016).

[48] Antonio Guterres's lecture at the 18th Nelson Mandela Annual Lecture virtually on Nelson Mandela International Day (18 July). The theme of the lecture is "Tackling the Inequality Pandemic: A New Social Contract for a New Era." Available from https://www.un.org/en/coronavirus/tackling-inequality-new-social-contract-new-era (accessed on 29 March 2022); WTO's Seventh Meeting of the Multilateral Leaders Task Force, December 17, 2021: "From Vaccines to Vaccinations" Joint Statement. Available from https://www.wto.org/english/news_e/news21_e/covid_22dec21_e.htm.

[49] Kristalina Georgieva, Tedros Adhanom Ghebreyesus, David Malpass and Ngozi Okonjo-Iweala, "A new commitment for vaccine equity and defeating the pandemic", WTO joint statement. Available from [WTO | A new commitment for vaccine equity and defeating the pandemic] accessed on 29 March 2022.

However, the messages shifted during the pandemic, and developed countries advocated for compulsory licensing when the TRIPS waiver was being negotiated.[50] Moreover, the TRIPS waiver, which was a solution that was proposed to deal with COVID-19 based on the voluntary compliance of pharmaceutical companies,[51] was supported by the Biden Administration,[52] which surprised many due to Trump's Administrations' former refusal to grant the waiver.[53] The stance by the Biden Administration was opposed by many developed nations which claimed that a TRIPS waiver is not necessary in light of the TRIPS flexibilities.[54]

The conflicting response towards granting compulsory licensing is confusing to developing countries and it remains to be seen whether developed nations' positions will shift once more when COVID-19 stops being a public emergency.[55]

[50] See the USTR 2021 Report; See also WTO document IP/C/W/672.
[51] Yousuf A Vawda and Bonginkosi Shozi, *Utilising Public Health Flexibilities in the Era of COVID-19: An Analysis of Intellectual Property Regulation in the OAPI and MENA Regions*, Research Paper No. 141 (Geneva, South Centre, November 2021).
[52] "Biden commits to waiving vaccine patents, driving wedge with pharmaceutical companies", *Washington Post*, 5 May 2021. Available from https://www.washingtonpost.com/health/2021/05/05/biden-waives-vaccine-patents/.
[53] Andrea Shalal and Jeff Mason, David Lawder, "U.S. reverses stance, backs giving poorer countries access to COVID vaccine patents", *Reuters*, May 5, 2021. Available from https://www.reuters.com/business/healthcare-pharmaceuticals/biden-says-plans-back-wto-waiver-vaccines-2021-05-05/.
[54] Communication From the European Union to the Council for TRIPS, *Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property*, Brussels 4 June 2021. Available from https://trade.ec.europa.eu/doclib/docs/2021/june/tradoc_159606.pdf ; "COVID: Germany rejects US-backed proposal to waive vaccine patents", *BBC,* 6 May 2021. Available from https://www.bbc.com/news/world-europe-57013096.
[55] See Thomas Mulier, Andy Hoffman, and John Lauerman, "WHO Exploring When and How to Declare End of Covid Emergency" (*Bloomberg,* 11 March 2022).

4. RECOMMENDATIONS FOR JORDAN

Taking the above into consideration, the following recommendations are made to address the Jordanian Government's disregard and reluctance in applying compulsory licensing during the pandemic.

4.1 Defense Orders and EUA

As mentioned above, the Jordanian Government has enacted the Defense Law during the pandemic which allows the Prime Minister to exert a wide range of powers in order to contain the COVID-19 pandemic. This paper recommends utilizing EUA[56] as a direct ground to apply compulsory licensing in Jordan when the Defense Law has been invoked.

EUA, in effect, has expedited the process in which vaccines reach the public. The regulation placed for EUAs was instantaneous. On 2 December 2020, Pfizer became the first pharmaceutical company to seek approval for the COVID-19 vaccine under the EUA in the United Kingdom and subsequently in the United States.[57]

Furthermore, the EUA has facilitated the full approval and licensing of the COVID-19 vaccines as evidenced by the FDA full vaccine approval of the Pfizer BioNTech vaccine for the public over the age of 16, and[58] Moderna's vaccine.[59] This means that Pfizer and Moderna will continue to sell and advertise their vaccines even after the pandemic ends. The EUA has effectively accelerated the licensing process of COVID-19 vaccines and introduced a route through which pharmaceutical companies can capitalize on during this pandemic to perform global clinical trials on the public.[60]

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[56] WTO has explained that Emergency Use Listing is a "a procedure for assessing **unlicensed vaccines**, therapeutics and in vitro diagnostics during public health emergencies with the ultimate goal of expediting the availability of these products to people who need them" [Emphasis added]. Whereas the U.S. Food Drug Administration (FDA) defined EUA as the "mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic".US Food and Drug Administration, "Emergency Use Authorization for Vaccines Explained" (2022). Available from https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained (accessed on 29 March 2022) at para 1.

[57] Gov.UK, "UK medicines regulator gives approval for first UK COVID-19 vaccine" 2 December 2020. Available from: https://www.gov.uk/government/news/uk-medicines-regulator-gives-approval-for-first-uk-covid-19-vaccine (accessed on 29 March 2022); Pfizer, "Pfizer and BioNTech Celebrate Historic First Authorization in the U.S. of Vaccine to Prevent COVID-19", 11 December 2020, Available from https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-celebrate-historic-first-authorization (accessed on 29 March 2022).

[58] U.S. Food & Drug Administration, "FDA Approves First COVID-19 Vaccine" (23 August 2021). Available from https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.

[59] U.S. Food & Drug Administration, "Coronavirus (COVID-19) Update: FDA Takes Key Action by Approving Second COVID-19 Vaccine", (31 January 2022). Available from Coronavirus (COVID-19) Update: FDA Takes Key Action by Approving Second COVID-19 Vaccine | FDA.

[60]See Sandra Crouse Quinn, Amelia M. Jamison, Vicki Freimuth, "Communicating Effectively About Emergency Use Authorization and Vaccines in the COVID-19 Pandemic", *American Journal of Public Health* vol. 111, no. 3 (March 1, 2021) on understanding of EUA standards compared with FDA approval standards and how and why EUA standards changed during 2020; C. Hermes, "COVID-19 vaccines shouldn't get emergency-use authorization" MIT Technology Review, 13 November 2020. Available from https://www.technologyreview.com/2020/11/13/1012098/covid-19-vaccines-fda-emergency-use-authorization-opinion/.

Jordan granted its first EUA on the 14 December 2020.[61] EUA in Jordan, similar to the UK, is a conditional time-based EUA for a year.[62] Jordan's Food and Drug Administration (JFDA) issued the EUA within its "Instructions for the Emergency Use of Medicines for the year 2021" in the Law Gazette on 17 October 2021. The EUA authorized "the emergency use of an unapproved medicinal product or an unapproved use of an approved medicinal product for certain emergency circumstances".[63]

Pharmaceutical companies providing the vaccines, under an EUA, should, in essence, expect, that the issuance of a compulsory licensing is a possibility.

In accordance with the powers granted to the Prime Minister when the Defense Law is invoked, the Jordanian Prime Minister could deactivate Article 21.A.1 and Article 21.A.2 of Jordan's Patent Law, which require the patent owner's approval to utilize a patent.[64] These articles should be deactivated when the Defense Law applies in Jordan and when an EUA[65] has been invoked in any country in the world. This means that when the US and EU granted their EUAs, Jordan should have had a direct ground to start applying for a compulsory license.

An EUA should substitute the negotiation process for a voluntary license and the notification process required under the WTO to apply for a compulsory license. This is because an EUA is a procedural step that is taken between a government and pharmaceutical company, as outlined above, when a national emergency is declared. This would eliminate burdensome elements required to apply for Article 31 *bis*.

Further, there should be a dedicated sub-clause at Article 22 of Jordan's Patent Law[66] which addresses the situation when an EUA has been granted. The additional sub-clause at Article

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[61] Video interview with the general manager at JFDA Nizar Muheidat on 15 December 2020. Available from https://www.youtube.com/watch?v=_VCH6MD9-MU (accessed on 29 March 2022).

[62] Article 6 of the Instructions for the Emergency Use of Medicines for the year 2021.

[63] Article 2 of the Instructions for the Emergency Use of Medicines for the year 2021. Furthermore, the EUA was granted because the following criteria was met:

1. There was a serious or life-threatening disease or condition;
2. Evidence of effectiveness of the medical product was presented in accordance with JFDA's guidance;
3. A Risk Benefit Analysis was carried out where the potential benefit of the product outweighs its risks.
4. No alternatives were present to the medicinal product. Guidance issued by the JFDA in the Instructions for the Emergency Use of Medicines for the year 2021. Available from http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/Draft%20documents/%D9%85%D8%B3%D9%88%D8%AF%D8%A9%20%D8%AA%D8%B9%D9%84%D9%8A%D9%85%D8%A7%D8%AA%20%D8%A7%D9%84%D8%A7%D8%B3%D8%AA%D8%AE%D8%AF%D8%A7%D9%85%20%D8%A7%D9%84%D8%B7%D8%A7%D8%B1%D8%A6%20%D9%84%D9%84%D8%A7%D8%AF%D9%88%D9%8A%D8%A9%20%D9%84%D8%B3%D9%86%D8%A9%202020.pdf.

[64] Jordan's Patent Law No.32 of 1999 states:

A - The patent owner acquires the following rights: -

1- Preventing others, if the owner of the patent does not obtain the approval of making the product in question, using it, using it, offering it for sale, selling, or importing it, if the subject of the patent is a product

2- Preventing others, if the owner of the patent has not obtained the approval of the method of manufacture, or of using the product made directly in this way, or offering it for sale, sale, or import, if the subject of the patent is the method of making

[65] EUA in Jordan has been approved to 4 vaccines. These are Pfizer/BioNTech, Sputnik, Oxford/AstraZeneca and Sinopharm (Beijing). Covid 19 Vaccine Tracker in Jordan. Available from https://covid19.trackvaccines.org/country/jordan/ (accessed on 29 March 2022) ; See also "عبيدات: الشركات المصنعة للقاح أخلت مسؤوليتها من آثاره الجانبية" , *Addustoor* ,March 4, 2021, Amman. Available from https://www.addustour.com/articles/1203041?utm_campaign=nabdapp.com&utm_medium=referral&utm_source=nabdapp.com&ocid=Nabd_App.

[66] Article 22 of Jordan's Patent Law No.32 of 1999 states the following grounds for granting a compulsory license: The Minister may grant a license to exploit the invention only to the owner of the patent and without his consent in any of the following cases exclusively:

A- If the use of the relevant government agencies or others who are authorized by these authorities to use the patent is a necessity for national security or emergency situations or for non-commercial public benefit purposes, provided that the owner of the patent is notified when this becomes possible.

22 will state that an EUA should form a direct ground to grant compulsory licenses notwithstanding any bilateral Agreements or FTAs which limit their use, thereby overcoming administrative hurdles during extreme and national emergencies and facilitating procedural steps towards granting a compulsory license during a pandemic.

4.2 Amending Jordan's National Legislation

Jordanian policymakers should repeal harmful clauses within their national laws such as Article 8 of the Unfair Competition and Trade Secrets Law No. 15 of 2000 which states that:

> If a competent official authority requires providing data on secret tests or any data reached as a result of reasonable efforts to approve the marketing of drugs or agricultural chemical products, that use new chemicals, then this body must adhere to the following:
>
> a. **Protect this data from unfair commercial use by preventing anyone else who did not obtain the approval of its provider from relying on it to market such medicines and its products only after five years have passed since the date the provider of that data obtained approval to market his products**. [Emphasis added].

This Article means that a generic manufacturer, even if a compulsory license is warranted, will also have to wait five years from the marketing approval application date. This negates the urgency of a compulsory license. In line with what has been discussed above, the Prime Minister should deactivate this Article when the Defense Orders are invoked.

Furthermore, Jordanian policymakers could also attempt to update and amend their national laws, as per Australia, Chile and Colombia. These are countries that have also signed FTAs with the US which limit the use of compulsory licensing.

Australia has updated and amended their national laws in order to facilitate the issuance of a compulsory license during the pandemic; Australia has granted powers to its crown to allow the Australian government to step in when "action is necessary to deal with an emergency, or other public interest issues and access patented inventions and designs".[67]

Similarly, the Chilean Government has considered that a compulsory license was granted during less critical circumstances for Hepatitis C which gives grounds for granting a compulsory license during the pandemic.[68]

B- 1- If the owner of the patent did not exploit it or if his exploitation of it was not sufficient before the expiration of three years from the date of granting the patent or four years from the date of filing the registration application, that is, the two periods expire recently, but the Minister may decide to grant the owner of the patent an additional period if He found that reasons beyond the control of the owner of the patent had prevented this.

2- For the purposes of item (1) of this paragraph and without prejudice to the provisions of the relevant international agreements, importing the products subject of the patent to the Kingdom is considered an act of exploitation of the patent.

C- If it is decided, judicially or administratively, that the patent owner exercises his rights in a manner that prevents others from legitimate competition.

[67] Schedules 2 and 3 of Australia's Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Act 2020; MSF, Compulsory licenses, the TRIPS waiver, and access to COVID-19 medical technologies MSF Briefing Document (May 2021). Available from https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSF_AC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf (accessed on 29 March 2022).

[68] Knowledge Ecology International, English translation of Chile "Resolution for the granting of non-voluntary licenses referred to in article 51º Nº 2 of industrial property law Nº 19.030 to facilitate access and availability of medicines and technologies for the prevention, treatment and cure of coronavirus COVID-19." Available from

Finally, Colombia has issued Decree 476 of 2020 on which facilitates the issuance of a compulsory license and:

> declares a public health interest in drugs, medical devices, vaccines and other health technologies that are used for the diagnosis, prevention and treatment of COVID-19 and provides the framework of the State of Emergency, under which the SIC is fully capable of contributing with the information that will allow to determine if the products or procedures that are of interest and have patent protection in Colombia, as well as with technological searches in other patent documents, that may be useful at the time of manufacturing the products required in this emergency. [69]

The stance implemented by the index countries, in introducing clauses noting the urgency of the pandemic, should be replicated. The provisions quoted by the Australian and Colombian laws are more relevant to Jordan and could be implemented within Jordan's national laws.

4.3 Re-negotiating JUSFTA

Whilst no tangible benefits have been reaped from the U.S. support for the TRIPS waiver, the support by Biden's Administration is promising. It shows that the U.S. recognizes that this is a global pandemic that requires an immediate action. It is also a promising start towards re-negotiating favourable terms in free trade agreements ,such as JUSFTA, to increase access to medicines.

It is not impossible to amend the terms of JUSFTA.[70] JUSFTA states that a joint committee could be formed, and an amendment is possible.[71] Jordanian officials should seize the stance currently employed by the Biden administration towards the waiver in gauging more favourable terms regarding increased access to health for its public.

More specifically, Jordan should re-negotiate Article 4 Sub-clause 20 (b) of JUSFTA to remove the restriction on using compulsory licensing in situations of extreme urgency and limiting the use to governmental entities.

Furthermore, Jordanian officials should negotiate and seek assistance from the U.S. to initiate the use of compulsory licensing through Article 31 bis/ Paragraph 6.[72] The USTR's recent 301 Report of 2021 has been favourable towards utilizing compulsory licensing and has not condemned any countries in its recent report for introducing measures or enacting compulsory license which is an apparent departure from the USTR stance in its previous 301 Reports.[73]

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https://www.keionline.org/chilean-covid-resolution; WTO Policy Tracker. Available from COVID-19 IP Policy Tracker (wipo.int).

[69] WTO Policy Tracker. Available from COVID-19 IP Policy Tracker (wipo.int); William New, "Leaked Letter Shows Pressure on Colombia Not To Issue Compulsory Licence for Glivec", Health Policy Watch, 6 February 2018. Available from https://healthpolicy-watch.news/leaked-letter-shows-pressure-colombia-not-issue-compulsory-licence-glivec/.

[70] L. Barqawi, "TRIPS-Plus and US FTAs: Recommendations to Jordan, Bahrain and Sudan to Increase Accessibility to Medicines" Doctoral thesis, University of Central Lancashire 2020, p. 197.

[71] JUSFTA Article 15 Sub-clause 2(d).

[72] Jordan relies on its political ties and assistance from the U.S. US Department of State, "U.S. Relations with Jordan"(U.S. Department of State, 2 August 2018). Available from U.S. Relations With Jordan - United States Department of State accessed on 29 March 2022.

[73] For example, USTR 301 Report of 2020 at p. 15 states: "actions by trading partners to unfairly issue, threaten to issue, or encourage others to issue compulsory licenses raise serious concerns" and states that the "The United States will continue to monitor developments and to engage, as appropriate, with trading partners, including Chile, Colombia, Egypt, El Salvador, India, Indonesia, Malaysia, Russia, Turkey, and Ukraine". This is a similar stance the USTR's reports in 2019, 2018 and 2017.

4.4 Amending Article 31 bis

Amending domestic policy in Jordan is not enough. Article 31 *bis* remains unworkable. The amendment to Article 31, which led to the enactment of Article 31 *bis*, was to address the unworkable mechanism of paragraph 6 of the Doha Declaration.[74] This is even though paragraph 6 of the Doha Declaration was also an attempt to deal with the impracticality of Article 31 (f) of TRIPS as discussed earlier.

Jordanian officials should form a syndicate with other Arab nations and developing countries in order to propose recommendations on how to deal with amendments on Article 31 *bis*. This is in line with the efforts that resulted in the TRIPS waiver that was proposed by India and South Africa as an immediate solution and response to the pandemic and strengthened by the members joining its calls for a waiver.[75]

The way Jordanian officials should deal with Article 31 *bis* of TRIPS is by treating it as an unfavourable clause in a legal contract.[76] There are a few ways to deal with an unfavourable clause, either by waiving it, amending/re-defining it to a more favourable clause,[77] or introducing a superseding clause.

(a) Negotiating an amendment of Article 31 *bis*

The amendment in Article 31 *bis,* the TRIPS annex and appendix to annex, identified who would be eligible to apply for a compulsory license,[78] the terms for utilizing the flexibility[79] as well as monitoring the usage of the flexibility.[80] However, many developed countries have opted out from the provisions of Article 31 *bis* as importers.[81]

Additionally, the fact that the amendment, which was approved by the WTO in 2005,[82] has not been fully ratified by all countries, even though it is now in full effect,[83] shows that the amendment has not been straightforward and that ratifying TRIPS is not a straightforward act because of various reasons including the very structure of the WTO Agreements[84] and the immense pressures against introducing flexibilities.[85]

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[74] R. Kuhn and R. Beall, "The time for pharmaceutical compulsory licensing has expired" (2012) vol. 18, No. 8 Nat Med 1168; R. Beall and R. Kuhn, "Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis" (2012) vol. 9 No.1 PLoS Med.

[75]WTO communication, *Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19*, Council for Trade-Related Aspects of Intellectual Property Rights, 25 May 2021, IP/C/W/669/Rev.1.

[76] This would be in line with Article 28 of the Vienna Convention on the Law of the Treaties (Vienna Convention), on the applicability of treaties, which states that "Unless a different intention appears from the treaty or is otherwise established, its provisions do not bind a party in relation to any act or fact which took place or any situation which ceased to exist before the date of the entry into force of the treaty with respect to that party" as well as Articles 31 and 32 of the Vienna Convention on interpretation and supplementary means of interpretation.

[77] Part IV of the Vienna Convention on amendment and modification of treaties applies; namely Article 40.

[78] See "Appendix to the annex to the TRIPS agreement" which identifies an assessment of the manufacturing capacities in the pharmaceutical sector.

[79] Annex to the TRIPS Agreement at para. 2.

[80] Annex to the TRIPS Agreement at para. 7.

[81] This includes "Australia, Canada, the European Communities with, for the purposes of Article 31*bis* and this Annex, its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States." Footnote 3 of the Annex to TRIPS Agreement.

[82] WTO, Amendment of the TRIPS Agreement (2022). Available from WTO | intellectual property (TRIPS) and public health: Members accepting amendment (accessed on 29 March 2022).

[83] Ratification has been extended for eight times until 31 December 2023. WTO, Amendment of the TRIPS agreement – eighth extension of the period for the acceptance by members of the protocol amending the TRIPS agreement, document WT/L/1122 ,23 November 2021. Available from directdoc.aspx (wto.org) .

[84] WTO, Understanding the WTO: the agreements overview: a navigational guide, Available from WTO | Understanding the WTO - Overview: a navigational guide (accessed on 29 March 2022).

[85] Global Commission on HIV/AIDS and the Law 2012, 81 Available from https://hivlawcommission.org/report/ (accessed on 29 March 2022).

Nevertheless, amending TRIPS is not impossible.[86] Article 31 should mention that when an EUA is invoked, even for a limited period, then this will constitute an automated right to utilize compulsory licensing notwithstanding any negotiated texts within FTAs. Moreover, Article 31 *bis* could also be re-defined to include steps which generic companies could take along with realistic deadlines that will be expedited during crucial times such as a pandemic.

A superseding clause such as a pandemic clause specific for COVID-19 and their variants could also be incorporated into TRIPS[87].

(b) Repealing/Suspending Article 31

Repealing or suspending the obligations under Article 31 of TRIPS can be achieved through Part V of the Vienna Convention on invalidity, termination and suspension of the operation of treaties applies, namely Article 54 which states: "The termination of a treaty or the withdrawal of a party may take place: (a) in conformity with the provisions of the treaty; or (b) at any time by consent of all the parties after consultation with the other contracting States". This means that repealing will be on a mutual understanding between the member states.

Further ground to repeal or suspend Article 31 could be achieved through invoking the TRIPS security exception at Article 73, which could suspend the obligations under the TRIPS Agreement in the case of an international emergency.[88] It is of course arguable that COVID-19 is an international emergency.

Repealing Article 31 will in effect result in repealing Article 31 *bis.*

[86] As evidence by Article 40 (2) of the Vienna Convention which states "Any proposal to amend a multilateral treaty as between all the parties must be notified to all the contracting States, each one of which shall have the right to take part in: (a) the decision as to the action to be taken in regard to such proposal; (b) the negotiation and conclusion of any agreement for the amendment of the treaty".

[87] This would also fall under Article 40 of the Vienna Convention in terms of amending TRIPS.

[88] Carlos M. Correa, "Expanding the production of COVID-19 vaccines to reach developing countries Lift the barriers to fight the pandemic in the Global South", South Centre Policy Brief No.92, April (2021); South Centre, "COVID-19 Pandemic: Access to Prevention and Treatment is a Matter of National and International Security". Available from https://www.southcentre.int/covid-19-openletter/..ßf; Frederick Abbott, *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic*, Research Paper, No. 116 (Geneva, South Centre, August 2020). Available from https://www.southcentre.int/wpcontent/uploads/2020/08/RP-116-reduced_1.pdf.

5. CONCLUSION

In conclusion, Jordan is not able to utilize compulsory licensing during the pandemic because of various pre-existing factors such as JUSFTA, the burdensome application of Article 31 bis, technological restraints as well as political considerations. To that effect, there is no evidence that Jordan has attempted to obtain a compulsory license during the pandemic.

The utilization of the EUA by governments shows the proactive role that governments have undertaken in dealing with COVID-19, this is despite the limitation of liability criticism.

Whilst EUAs are not a new prospect they could pave the way for Jordanian officials to implement favourable laws and repeal harmful clauses laws during the pandemic, especially whilst the Defense Orders are activated. Additionally, Jordan should capitalize on the stance of the Biden Administration to renegotiate more favourable terms within its JUSFTA to utilize compulsory licenses and increase its public's access to health as well as seek support from the US on ways to implement compulsory licensing.

Furthermore, Jordan could form a syndicate to call for an Article 31 *bis* overhaul. The fact that a TRIPS amendment has taken place, despite the opt out by many developed nations of identifying as importers, is also a positive step and indicative that amending TRIPS is a possibility.

The efforts which led to the success of the Doha Declaration need to be repeated. It is evident that this is not going to be the last pandemic. Another round to keep up with the developments and restrictions introduced by COVID-19 needs to be discussed. Provisions need to be put in place to deal with future outbreaks.

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