ECONSTOR
Make Your Publications Visible.

A Service of
ZBW
Leibniz-Informationszentrum Wirtschaft
Leibniz Information Centre for Economics

Abbas, Muhammad Zaheer

Research Report

Canada's political choices restrain vaccine equity: The Bolivia-Biolyse case

Research Paper, No. 136

Provided in Cooperation with:
South Centre, Geneva

Suggested Citation: Abbas, Muhammad Zaheer (2021) : Canada's political choices restrain vaccine equity: The Bolivia-Biolyse case, Research Paper, No. 136, South Centre, Geneva

This Version is available at:
https://hdl.handle.net/10419/248637

Standard-Nutzungsbedingungen:

Die Dokumente auf EconStor dürfen zu eigenen wissenschaftlichen Zwecken und zum Privatgebrauch gespeichert und kopiert werden.

Sie dürfen die Dokumente nicht für öffentliche oder kommerzielle Zwecke vervielfältigen, öffentlich ausstellen, öffentlich zugänglich machen, vertreiben oder anderweitig nutzen.

Sofern die Verfasser die Dokumente unter Open-Content-Lizenzen (insbesondere CC-Lizenzen) zur Verfügung gestellt haben sollten, gelten abweichend von diesen Nutzungsbedingungen die in der dort genannten Lizenz gewährten Nutzungsrechte.

Terms of use:

Documents in EconStor may be saved and copied for your personal and scholarly purposes.

You are not to copy documents for public or commercial purposes, to exhibit the documents publicly, to make them publicly available on the internet, or to distribute or otherwise use the documents in public.

If the documents have been made available under an Open Content Licence (especially Creative Commons Licences), you may exercise further usage rights as specified in the indicated licence.

WWW.ECONSTOR.EU

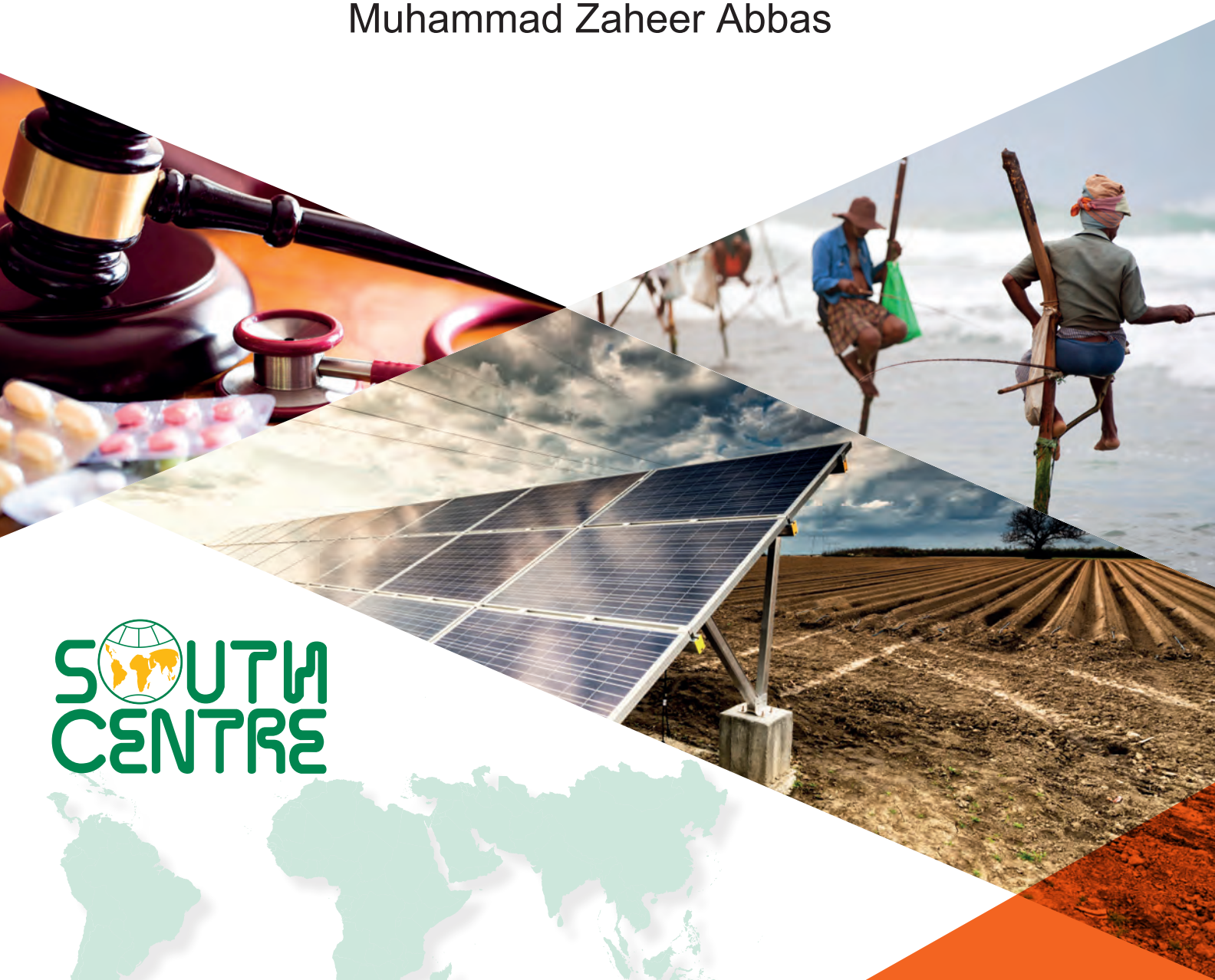
Mitglied der Leibniz-Gemeinschaft

136 Research Paper

September 2021

Canada's Political Choices Restrain Vaccine Equity: The Bolivia-Biolyse Case

Muhammad Zaheer Abbas



SOUTH CENTRE

RESEARCH PAPER

136

CANADA'S POLITICAL CHOICES RESTRAIN VACCINE EQUITY: THE BOLIVIA-BIOLYSE CASE

Muhammad Zaheer Abbas, PhD*

SOUTH CENTRE

SEPTEMBER 2021

* Dr. Muhammad Zaheer Abbas, Chief Investigator with the Australian Centre for Health Law Research (ACHLR), is a Postdoctoral Research Fellow at the Faculty of Business and Law, Queensland University of Technology (QUT), Brisbane, Australia. In this role, the author is working with Professor Matthew Rimmer on his Australian Research Council Discovery Project 'Inventing the Future: Intellectual Property and 3D Printing' (Project ID: DP170100758). This paper benefitted from Professor Matthew Rimmer's actionable and valuable feedback on an earlier draft. The author would also like to acknowledge with great appreciation his wife Dr. Shamreeza Riaz for her unconditional support and valued cooperation. The views presented in this article and any mistakes are, however, the sole responsibility of the author. E-mail: muhammadzaheer.abbas@connect.qut.edu.au

SOUTH CENTRE

In August 1995 the South Centre was established as a permanent inter-governmental organization. It is composed of and accountable to developing country Member States. It conducts policy-oriented research on key policy development issues, and supports developing countries to effectively participate in international negotiating processes that are relevant to the achievement of the Sustainable Development Goals (SDGs). The Centre also provides technical assistance and capacity building in areas covered by its work program. On the understanding that achieving the SDGs, particularly poverty eradication, requires national policies and an international regime that supports and does not undermine development efforts, the Centre promotes the unity of the South while recognizing the diversity of national interests and priorities.

NOTE

Readers are encouraged to quote or reproduce the contents of this Research Paper for their own use, but are requested to grant due acknowledgement to the South Centre and to send a copy of the publication in which such quote or reproduction appears to the South Centre.

The views contained in this paper are attributable to the author/s and do not represent the institutional views of the South Centre or its Member States. Any mistake or omission in this study is the sole responsibility of the author/s.

Any comments on this paper or the content of this paper will be highly appreciated. Please contact:

South Centre
International Environment House 2
Chemin de Balexert 7-9
POB 228, 1211 Geneva 19
Switzerland
Tel. (41) 022 791 80 50
south@southcentre.int
www.southcentre.int

Follow the South Centre's Twitter: South_Centre

ABSTRACT

The COVID-19 pandemic has already claimed more than 4.6 million lives and caused significant economic harm. The Coronavirus is still circulating to cause further damage. In this context, this research paper argues that Canada's political choices have restrained the equitable distribution of COVID-19 vaccines. Part I evaluates Canada's nationalistic approach of procuring COVID-19 vaccines more than its needs through secretly concluded pre-purchase agreements with brand-name pharmaceutical corporations as advised by a secretly born task force having clear ties with the vaccine industry. Part II examines Canada's wavering and non-committal position on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Waiver proposal. Canada's confusing position of 'not blocking' the TRIPS Waiver while not supporting it either lacks legal clarity. Part III analyses the Bolivia-Biolyse case which highlights clear contradictions between statements and actions of the Canadian government. Since March 2021, Biolyse Pharma has been hamstrung by the first step in Canada's Access to Medicines Regime (CAMR), where a preliminary requirement is that the COVID-19 vaccine must be added to Schedule 1 of the Canadian federal *Patent Act* before applying for an export-oriented compulsory licence. The Bolivia-Biolyse case is important as a test case for the CAMR system. The workability of this export-oriented compulsory licensing regime is critical for low- and middle-income countries in the Global South lacking the domestic capacity to manufacture COVID-19 vaccines. The Bolivia-Biolyse case is also important as Canada has argued at the World Trade Organization (WTO) that the TRIPS Waiver is not required because the existing mechanisms are working as intended.

La pandémie de COVID-19 a déjà fait plus de 4,6 millions de victimes et causé d'importants dommages économiques. Le coronavirus circule toujours et risque de causer davantage de dommages. Dans ce contexte, ce document de recherche soutient que les choix politiques du Canada ont freiné la distribution équitable des vaccins COVID-19. La première partie évalue l'approche nationaliste du Canada qui consiste à se procurer des vaccins COVID-19 au-delà de ses besoins par le biais d'accords de préachat conclus secrètement avec des sociétés pharmaceutiques de renom, sur les conseils d'un groupe de travail créé secrètement et ayant des liens évidents avec l'industrie du vaccin. La deuxième partie examine la position hésitante et non engagée du Canada sur la proposition de dérogation à certaines obligations de l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC). La position confuse du Canada, qui consiste à "ne pas bloquer" la dérogation ADPIC, sans pour autant la soutenir, manque de clarté juridique. La troisième partie analyse le cas Bolivia-Biolyse qui met en évidence des contradictions claires entre les déclarations et les actions du gouvernement canadien. Depuis mars 2021, Biolyse Pharma est paralysée par la première étape du Régime canadien d'accès aux médicaments (RCAM), dont l'une des exigences préliminaires est que le vaccin COVID- 19 doit être inscrit à l'annexe de la Loi fédérale sur les brevets du Canada avant toute demande de licence obligatoire axée sur l'exportation. L'affaire Bolivia-Biolyse est importante car elle permet de tester le système du RCAM. L'applicabilité de ce régime de licence obligatoire axé sur l'exportation est essentielle pour les pays du Sud à revenu faible ou intermédiaire qui n'ont pas la capacité nationale de fabriquer des vaccins COVID-19. L'affaire Bolivia-Biolyse est également importante car le Canada a argumenté à l'Organisation mondiale du commerce (OMC) que la dérogation ADPIC n'est pas nécessaire car les mécanismes existants fonctionnent comme prévu.

La pandemia de COVID-19 ha cobrado más de 4,6 millones de vidas y ha causado una crisis económica. La circulación continua del coronavirus va a generar mas daño. En este

contexto, este documento de investigación sostiene que las decisiones políticas de Canadá han contribuido a restringir la distribución equitativa de las vacunas contra el COVID-19. En la parte I se evalúa el enfoque nacionalista de Canadá de adquirir vacunas contra el COVID-19 por encima de sus necesidades a través de acuerdos de precompra celebrados en secreto con corporaciones farmacéuticas, bajo asesoramiento de un grupo de trabajo vínculado a la industria. La segunda parte examina la posición vacilante y no comprometida de Canadá respecto a la propuesta de exención de los derechos de propiedad intelectual bajo el Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (ADPIC). La confusa posición de Canadá de "no bloquear" la exención de los derechos de propiedad intelectual y al mismo tiempo no apoyarla, carece de claridad jurídica. En la Parte III se analiza el caso Bolivia-Biolyse, que pone de manifiesto las contradicciones entre las declaraciones y las acciones del gobierno canadiense. Desde marzo de 2021, la empresa Biolyse Pharma se ha visto obstaculizada en solicitar una licencia obligatoria orientada a la exportación de vacunas a Bolivia en el primer paso del Régimen de Acceso a los Medicamentos de Canadá (CAMR), en el que un requisito preliminar es que la vacuna COVID-19 debe ser añadida a la Lista 1 de la Ley Federal de Patentes de Canadá antes de la solicitud de licencia obligatoires. El caso Bolivia-Biolyse es importante como caso de prueba para el sistema CAMR. El buen funcionamiento de este régimen de licencias obligatorias orientadas a la exportación es fundamental para los países de ingresos bajos y medios del Sur global que carecen de la capacidad nacional para fabricar vacunas contra el COVID-19. El estudio de caso Bolivia-Biolyse también es importante dado que Canadá argumentó en la Organización Mundial del Comercio (OMC) que la exención del ADPIC no es necesaria porque los mecanismos existentes están funcionando según lo previsto.

TABLE OF CONTENTS

I. CANADA'S PROCUREMENT OF COVID-19 VACCINES 1

II. CANADA'S NON-COMMITTAL POSITION ON THE TRIPS WAIVER 4

III. THE BOLIVIA-BIOLYSE CASE 9

IV. CONCLUSION..... 17

I. CANADA'S PROCUREMENT OF COVID-19 VACCINES

Vaccine nationalism refers to the 'my country first' approach of some resourceful countries to secure priority access to doses of emerging COVID-19 vaccines for their populations through advance purchase agreements, adversely impacting equitable distributive outcomes for others.[1] Canada took a lead role in embracing vaccine nationalism. In its advanced market commitments, Canada signed deals with Novavax (76 million doses), Johnson & Johnson (38 million doses), and GlaxoSmithKline/Sanofi (72 million doses).[2] Canada concluded further private deals with Pfizer, Moderna and AstraZeneca.[3]

The Canadian government ordered the world's largest number of COVID-19 vaccine doses per capita.[4] Canada used its economic might to overbuy safe and effective doses to vaccinate each Canadian 5 times over.[5] While COVID-19 poses an equal threat to all countries, their economic resources to deal with the pandemic are not equal. Resource-constrained low- and middle-income countries in the Global South had the only option to wait to secure doses for their health professionals and the most vulnerable segments of their population. Canada fully exploited the global income inequalities to its immediate benefit but to further health inequities and access challenges for others.

The Canadian government paid a lot of lip service to the need for fairness, transparency and global solidarity, as cited below in Part II, but Canada's procurement practices do not seem to be driven by these values. Instead of taking a value-based global approach, Canada decided to take an approach of furthering health inequities through vaccine nationalism. A closer look reveals further ethical pitfalls in Canada's vaccine procurement practices.

In June 2020, the Canadian government secretly set up a COVID-19 Vaccine Task Force. The task force advised the Canadian government on prioritizing vaccine candidates for advanced market commitments. The task force was asked to advise on whether to conclude pre-purchase agreements with Johnson & Johnson, Moderna, GlaxoSmithKline/Sanofi and/or

---

[1] Advance purchase agreements are "legally binding contracts whereby one party, such as a government, commits to purchasing from a vaccine manufacturer a specific number or percentage of doses of a potential vaccine at a negotiated price if it is developed, licensed, and proceeds to manufacture". See Alexandra L. Phelan, Mark Eccleston-Turner, Michelle Rourke, Allan Maleche, and Chenguang Wang, "Legal agreements: barriers and enablers to global equitable COVID-19 vaccine access", *The Lancet,* Vol. 396, no. 10254 (September 2020), p. 800. Available from https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(20)31873-0.pdf (accessed September 27, 2020).

[2] Medical Xpress, "Canada secures deals for millions of COVID-19 vaccine doses", 31 August 2020. Available from https://medicalxpress.com/news/2020-08-canada-millions-covid-vaccine-doses.html (accessed 27 September 2020). See further Will Feur, "Canada to purchase 76 million doses of Novavax coronavirus vaccine, company says" *CNBC*, 31 August 2020. Available from https://www.cnbc.com/2020/08/31/canada-to-purchase-76-million-doses-of-novavax-coronavirus-vaccine-company-says.html (accessed 27 September 2020); Sarah Turnbull, "Canada signs deals for supply of Sanofi vaccine candidate, antiviral drug to treat COVID-19" *CTV News*, 22 September 2020. Available from https://www.ctvnews.ca/politics/canada-signs-deals-for-supply-of-sanofi-vaccine-candidate-antiviral-drug-to-treat-covid-19-1.5114927 (accessed 27 September 2020).

[3] Joel Lexchin, Barbara Mintzes, Lisa Bero, Marc-Andre Gagnon and Quinn Grundy, "Canada's COVID-19 Vaccine Task Force needs better transparency about potential conflicts of interest", *The Conversation*, 8 October 2020. Available from https://theconversation.com/canadas-covid-19-vaccine-task-force-needs-better-transparency-about-potential-conflicts-of-interest-147323 (accessed 17 September 2021).

[4] Saba Aziz, "Canadian medical students push for COVID-19 vaccine IP waiver", *Global News*, 5 May 2021. Available from https://globalnews.ca/news/7836510/covid-vaccine-patents-canada/ (accessed 17 September 2021).

[5] Jesse Whattam, "It's time for Canada to support the WTO TRIPS waiver", *The Monitor*, 6 May 2021 Available from https://monitormag.ca/articles/its-time-for-canada-to-support-the-wto-trips-waiver (accessed 17 September 2021).

Novavax.[6] Canada signed private deals with all these corporations after having a meeting with the task force.[7]

The task force was born in secrecy and worked in obscurity as an advisory body for over two months until Canada signed several pre-purchase deals to procure COVID-19 vaccines. Outside experts were denied an opportunity to offer feedback or suggestions as the proceedings of the task force were not made public. As noted by Amir Attaran, "[i]f you take high-stakes decisions secretly behind closed doors, you end up in a dead end after bad decisions are made."[8]

On August 5, 2020, Navdeep Singh Bains, then Minister of Innovation, Science and Industry, officially announced the creation of the task force. Later, names of members were disclosed but their relationships with vaccine developers or disclosures of conflicts of interest were kept secret. Instead of tasking an independent and impartial panel, the Canadian government asked bureaucrats to monitor and enforce the task force members' observance of avoiding conflicts of interest.[9] The government finally released the conflicts of interest declarations of the task force members in October 2020 subsequent to negative publicity and media outcry.[10] The Canadian government admitted in a statement that it was aware of the task force members' conflicting interests: "In the interest of ensuring the COVID-19 Therapeutics Task Force (CTTF) includes the leading experts in therapeutics development and production in Canada, the deliberate decision was made to include individuals who may have a real or perceived conflict of interest."[11]

Dr. Joanne Langley, the co-chair of the task force, declared that Dalhousie University, her employer, had collaborated in the past with GlaxoSmithKline and Sanofi on clinical trials. She had personally collaborated with Sanofi scientists on research projects and had worked as a consultant with Sanofi.[12] She currently holds a $700,000 research chair in pediatric vaccinology, funded by GlaxoSmithKline and the Canadian Institutes of Health Research, at Dalhousie University.[13] She is also registered as one of the principal investigators on a phase-three clinical trial of another vaccine candidate.[14] The other co-chair, Mark Lievonen, served Sanofi for 17 years as Chief Executive Officer (CEO) and still owns shares in the corporation.[15] He is currently serving as a director of two other pharmaceutical companies.[16] Michel De Wilde, a member of the task force, previously served as a vice-president of research and development for Sanofi.[17]

---

[6] Lexchin, and others, "Canada's COVID-19 Vaccine Task Force needs better transparency about potential conflicts of interest".
[7] Ibid.
[8] Tom Blackwell, "Disband conflicted, secretive task force behind flawed COVID-19 vaccine effort, MPs told", *National Post*, 17 February 2021. Available from https://nationalpost.com/news/politics/disband-conflicted-secretive-task-force-behind-flawed-vaccine-effort-mps-told (accessed 17 September 2021).
[9] Amanda Connolly, "Canadians can now see conflicts of interest declared by COVID-19 vaccine task force", *Global News*, 22 September 2020. Available from https://globalnews.ca/news/7351016/covid-19-vaccine-task-force-conflicts-of-interest-disclosures/ (accessed 17 September 2021).
[10] Blackwell, "Disband conflicted, secretive task force behind flawed COVID-19 vaccine effort, MPs told".
[11] Government of Canada, "Declaration of Interests Protocol for the COVID-19 Therapeutics Task Force", (2021). Available from https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/hn01782.html. (accessed 17 September 2021).
[12] Lexchin, and others, "Canada's COVID-19 Vaccine Task Force needs better transparency about potential conflicts of interest".
[13] Tom Blackwell, "Federal task force co-chair advised on COVID vaccine despite possible conflict of interest", *National Post*, February 20, 2021. Available from, https://nationalpost.com/news/politics/gsk-chair-professor-was-allowed-to-advise-on-gsk-vaccine-highlighting-task-force-criticisms (accessed 17 September 2021).
[14] Ibid.
[15] Lexchin, and others, "Canada's COVID-19 Vaccine Task Force needs better transparency about potential conflicts of interest".
[16] Ibid.
[17] Connolly, "Canadians can now see conflicts of interest declared by COVID-19 vaccine task force".

Canada should consider revamping the task force as a considerable number of its members, including both co-chairs, have a real or perceived conflict of interest. These members, having clear ties with the brand-name pharmaceutical industry, cannot be expected to offer any suggestions that conflict with the corporate interests of patentee corporations. It is reasonable to suppose that these members might have warm feelings toward commercial entities from which they have derived significant financial benefits. Some of the problems with Canada's political choices, discussed in the subsequent parts of this paper, may be rooted in this issue of conflict of interest of the task force.

II. Canada's Non-Committal Position on the TRIPS Waiver

Patents, which are considered the strongest form of intellectual property protection, provide the desired tool to manufacturers of pharmaceutical drugs and vaccines to dominate the market and derive maximum profits by excluding others. Patents are private exclusive rights that allow patent holders to control whether, and on what terms, the protected items can be used by third parties. Patent protection conflicts with reverse-engineering and manufacturing of pharmaceutical drugs and vaccines if such activities are carried out without the right holder's consent.

It can be foreseen that most of the developing countries will have to wait for several years to have widespread access to COVID-19 vaccines if a business-as-usual approach is adopted in terms of enforcing intellectual property protections. As noted by Dr. Patricia Ranald, "[r]ich countries are first in line to negotiate with [patentee] companies, but even Australia has experienced delays in supply. Most low-income countries will not have access to vaccines until 2023 or later."[18] India and South Africa, along with other developing countries, proposed in October 2020 that certain Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) rules should be waived for COVID-19 for a limited time to remove intellectual property barriers to widespread vaccination across the globe.[19] The goal of this proposal is to free up scientific knowledge, technology and unused resources and capacity to scale the manufacturing of vaccines and other necessary products to suppress the pandemic.

The support for the TRIPS Waiver has been increasing over time. In May 2021, United States (US) President Joe Biden announced his support for the proposal. Spain and New Zealand immediately followed suit and got on board with the TRIPS Waiver.[20] In June, France committed to backing the proposal.[21] On September 8, Australia announced its support for waiving COVID-19 related intellectual property protections. "We continue to work constructively in Geneva to do everything we can to expand the production of vaccines globally because we need everyone across the globe to get access to a vaccine ultimately if we are to be safe," said Australia's Trade Minister Dan Tehan.[22] If a country like the US, which pushes norms and standards for pharmaceutical patents and has been a champion of the pharmaceutical industry in bilateral and multilateral negotiations, can shift its position on the TRIPS Waiver, it is unfortunate that Canada is still reluctant and undecided on the issue of providing greater vaccine equity.

---

[18] Paul Karp and Elias Visontay, "Australia to support vaccine waiver after months of pressure from human rights groups", *The Guardian*, 8 September 2021. Available from https://amp.theguardian.com/society/2021/sep/08/australia-to-support-vaccine-waiver-after-months-of-pressure-from-human-rights-groups (accessed 17 September 2021).

[19] World Trade Organization, Waiver from Certain Provisions of The TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, Communication from India and South Africa, Council for Trade-Related Aspects of Intellectual Property Rights, 2 October 2020.

[20] Bernardo De Miguel, "Spain backs Biden's proposal for vaccine patent waivers", *EL PAIS*, 7 May 2021. Available from https://english.elpais.com/spanish_news/2021-05-07/spain-backs-bidens-proposal-for-vaccine-patent-waivers.html, (accessed 17 September 2021. See further Thomas Manch, "New Zealand to support effort to waive Covid-19 vaccine patents, after United States backs WTO bid", *Stuff,* 6 May 2021. Available from https://www.stuff.co.nz/national/health/coronavirus/125048729/new-zealand-to-support-effort-to-waive-covid19-vaccine-patents-after-united-states-backs-wto-bid (accessed 17 September 2021).

[21] Alex Baldwin, "France backs COVID-19 vaccine IP waiver", *Life Science Preview*, 14 June 2021. Available from https://www.lifesciencesipreview.com/news/france-backs-covid-19-vaccine-ip-waiver-4482 (accessed 17 September 2021).

[22] Stephen Dziedzic, "Australia to support waiving intellectual property rights for COVID-19 vaccines", *ABC News*, 8 September 2021. Available from https://www.abc.net.au/news/2021-09-08/australia-waive-intellectual-property-covid-vaccines/100445094?utm_campaign=news-article-share-next-actions-0&utm_content=twitter&utm_medium=content_shared&utm_source=abc_news_web (accessed 17 September 2021).

The pressure on the European Union (EU) will increase to support the waiver proposal if Canada decides to back the proposal. It is important to note here that the EU has brought a counterproposal to review the compulsory licensing system proposing that "the exporting member using the system may provide in a single notification a list of all countries to which vaccines and medicines are to be supplied by the exporting member".[23] The proposal does not address various other problems associated with using the Article 31bis mechanism as repeatedly highlighted by a number of studies.[24] The EU proposal is not a viable alternative to the TRIPS Waiver proposal. Canada should also not side with the EU vis-à-vis the counterproposal.

Canada has been non-committal and has a wavering position on the TRIPS Waiver proposal. There have been contradictions and inconsistencies in the position of Trudeau's government. Trudeau at times said that he is very keen on supporting international access to medicines, but other times he seemed unwilling to follow through with concrete actions. "We understand how important it is to get vaccines to the most vulnerable around the world and we will keep working for that," he said in May 2021.[25] He emphasized that "this pandemic will not end anywhere unless it ends everywhere".[26] "I can assure you Canada is not interfering or blocking anything and is very much working for a solution that benefits everyone," he added.[27] Trudeau also said that "we must urgently ensure that vaccines will be distributed according to a set of transparent, equitable and scientifically sound principles. Where you live should not determine whether you live, and global solidarity is central to saving lives and protecting the economy".[28]

On May 7, Mary Ng, Canada's Minister of Small Business, Export Promotion and International Trade, stated that "[t]he Government of Canada remains committed to working with all international partners to reach a rapid and just end to the COVID-19 pandemic."[29] "We remain committed to finding solutions and reaching an agreement that accelerates global vaccine production and does not negatively impact public health," she added.[30] She reiterated that "Canada has always been, and remains, a strong advocate for equitable access to vaccines and medical supplies around the world."[31] It is disappointing that all these virtue signalling and benevolent statements have been followed by a sheer lack of commitment. Canada's confusing position of 'not blocking' the TRIPS Waiver lacks legal clarity. As the World Trade

---

[23] Nirmalya Syam, "EU Proposals regarding Article 31bis of the TRIPS Agreement in the Context of the COVID-19 Pandemic", Policy Brief No. 100 (Geneva, South Centre, 2021). Available from https://www.southcentre.int/policy-brief-100-august-2021/.

[24] See, for instance, Carlos M. Correa, "Supplying pharmaceuticals to countries without manufacturing capacity: Examining the solution agreed upon by the WTO on 30th August," *Journal of Generic Medicines,* vol. 1, No. 2 (January 2004), p. 117. Matthew Rimmer, "Race Against Time: The Export of Essential Medicines to Rwanda" *Public Health Ethics,* vol. 1, No. 2 (May 2008). Muhammad Zaheer Abbas and Shamreeza Riaz, "WTO 'Paragraph 6' System for Affordable Access to Medicines: Relief or Regulatory Ritualism?," *Journal of World Intellectual Property* vol. 21, No. 1–2 (November 2017), pp. 32–51; Alexandra Nightingale, "WTO 'Paragraph 6' System for Affordable Medicine: Time for Change?," *Intellectual Property Watch,* 11 November 2016.

[25] Saba Aziz, "Canadian medical students push for COVID-19 vaccine IP waiver", *Global News*, 5 May 2021. Available from https://globalnews.ca/news/7836510/covid-vaccine-patents-canada/ (accessed 17 September 2021).

[26] John Paul Tasker, "Trudeau non-committal on waiving intellectual property rights for COVID-19 vaccines", *CBC News*, 7 May 2021. Available from https://www.cbc.ca/news/politics/canada-waiving-intellectual-property-rights-1.6017776 (accessed 17 September 2021).

[27] Ibid.

[28] Joel Lexchin, "Canada is virtue signalling while waffling on global access to COVID-19 vaccines", *The Conversation*, 11 May 2021. Available from https://theconversation.com/canada-is-virtue-signalling-while-waffling-on-global-access-to-covid-19-vaccines-160685 (accessed 17 September 2021).

[29] Mary Ng, Minister of Small Business, Export Promotion and International Trade, Canada, "Statement by Minister Ng on intellectual property waiver for COVID-19 vaccines", Global Affairs Canada, Ottawa, 7 May 2021. Available from https://www.canada.ca/en/global-affairs/news/2021/05/statement-by-minister-ng-on-intellectual-property-waiver-for-covid-19-vaccines.html (accessed 17 September 2021).

[30] Ibid.

[31] Ibid.

Organization (WTO) works by consensus, legally speaking, Canada will keep blocking the proposal until it agrees to support it.

Instead of having a clear and consistent position on waiving intellectual property protections, Trudeau's government tends to say different things to different players. Canada's ambassador to the US Kirsten Hillman stated that "[o]ur position [on the TRIPS Waiver] is to discuss this with our allies, to discuss this with our WTO partners, and to make sure that we proceed in a way that is going to achieve the goals of ensuring the continued development of these vaccines."[32] Mary Ng said that Canada "firmly believes in the importance of protecting IP, and recognizes the integral role that industry has played in innovating to develop and deliver life-saving COVID-19 vaccines".[33] At the WTO, Canada has insisted for evidence, to be convinced of the need for the TRIPS Waiver, that intellectual property rights pose a genuine barrier to accessing COVID-19 vaccines.[34] At home, Canada acted swiftly, without waiting for the evidence to accumulate, to equip itself with legal tools to temporarily override intellectual property rights.

On March 24, 2020, Canada, which already provided a compulsory licensing mechanism under its national patent laws, rushed to amend its Patent Act (Bill C-13 entitled the *COVID-19 Emergency Response Act*) to make it faster and simpler for the government to utilize the compulsory licensing option in response to the current pandemic.[35] The legislative changes were made in the blink of an eye and received Royal Assent the very next day on March 25, 2020. The amended law empowers the Commissioner of Patents 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".[36] On a simple application to the patent office, the government or anyone it authorizes can obtain a compulsory licence for one year.[37] The amended law allows the government to defer negotiations for remuneration or compensation. The new provision s19.4 clarifies that the grant of a compulsory licence - even when the patent-holder is capable of making, using, and selling the patented invention – is "not an infringement of the patent".[38]

It is important to note that this legislative change was made very early in the pandemic when less than 30 people had died in Canada due to COVID-19. Canada proactively anticipated access problems without waiting for real-world patent barriers to arise. There was no evidence of any specific barriers, but Canada swiftly proceeded with putting in place precautionary measures to deal with any potential challenges.

---

[32] Sarah Turnbull, "Canada inches closer to waiving intellectual property rights on vaccines, amid political pressure", *CTV News*, 6 May 2021. Available from https://www.ctvnews.ca/politics/canada-inches-closer-to-waiving-intellectual-property-rights-on-vaccines-amid-political-pressure-1.5417078 (accessed 17 September 2021).
[33] Tasker, "Trudeau non-committal on waiving intellectual property rights for COVID-19 vaccines".
[34] MSF Access Campaign, "Why Canada should support the WTO waiver to expand access to COVID-19 medical technologies", 1 May 2021. Available from https://msf-access.medium.com/why-canada-should-support-the-wto-waiver-to-expand-access-to-covid-19-medical-technologies-9ecdcc0f81ab (accessed 17 September 2021).
[35] Ed Silverman, "A Canadian bill would make it easier to issue compulsory licenses for Covid-19 products", *Pharmalot*, 25 March 2020. Available from https://www.statnews.com/pharmalot/2020/03/25/canada-compulsory-license-coronavirus-covid19/ (accessed 17 September 2021).
[36] House of Commons of Canada, Bill C-13, An Act respecting certain measures in response to COVID-19, Parliament of Canada, Part 12. Available from https://www.parl.ca/DocumentViewer/en/43-1/bill/C-13/third-reading.
[37] Colleen M. Flood, Vanessa MacDonnell, Jane Philpott, Sophie Thériault, and Sridhar Venkatapuram, eds., *Vulnerable: The Law, Policy and Ethics of COVID-19* (University of Ottawa Press, 2020). Available from https://ruor.uottawa.ca/handle/10393/40726.
[38] Canada, Patent Act, s. 19.4(7).

It is also important to note that Canada's legislative change in response to the COVID-19 pandemic was meant for a limited time only. No authorizations under s19.4 could be issued after September 30, 2020. Canada, therefore, understands the importance of temporarily waiving or suspending intellectual property rights in an emergency situation for its own domestic use. It only needs to understand that the TRIPS Waiver calls for a similar flexibility to all WTO Members to address similar barriers at the international level.

The TRIPS Waiver proposal has enjoyed some political support in Canada. In May 2021, sixty Canadian Members of Parliament (MPs), cutting across party lines, wrote to Trudeau to express their support for the TRIPS Waiver. They wrote, "[s]imply, we need to eliminate all potential barriers to the timely access of affordable Covid-19 medical products, including vaccines and medicines, and scale up the manufacturing and supply of essential medical products."[39] In May, Conservative leader Erin O'Toole said, while speaking to reporters, that "[c]onservatives would support a temporary suspension of IP rules to help get vaccines as quickly around the world as possible."[40] He also wrote a letter to Trudeau urging him to support the waiver proposal. "It is vital that developed countries do more to support vaccination of developing countries," he wrote.[41] Previously, in December 2020, MP Daniel Blaikie wrote a letter to Mary Ng to convey New Democratic Party's support for the waiver proposal:

> There is no doubt that COVID-19 requires a coordinated global response and the ability to produce the vaccine in a timely way for distribution is an essential component of that response. Without such a waiver, profit-driven pharmaceutical companies will be in a position to dictate vaccine pricing to governments, as well as other important logistical considerations essential to swift and effective domestic responses to the pandemic across the world.[42]

The Canadian government, however, has argued at the WTO that the TRIPS Waiver is not required because the existing flexibilities in the current TRIPS Agreement, like export-oriented compulsory licensing mechanism, are sufficient to address supply problems faced by poorer countries.[43] Canada has asked low- and middle-income countries to demonstrate the difficulties of using the existing mechanisms.[44] On one hand, Canada has asserted that the existing mechanisms are working as intended without any difficulties while on the other hand, Trudeau's government stonewalled Biolyse Pharma's legitimate attempt to use the CAMR mechanism in response to COVID-19. These contradictions make it hard to comprehend Canada's position on the TRIPS Waiver.

The COVID-19 pandemic has already claimed more than 4.6 million lives and caused significant economic harm.[45] The virus is still circulating to cause further damage. Resource-poor countries, scrambling for access to more doses, cannot be left at the mercy of the optional goodwill of the half a dozen or so vaccine developers. In this context, Canada's position on the TRIPS Waiver conflicts with its human rights obligations. Canada has signed and ratified

---

[39] Anirudh Bhattacharyya, "Canadian MPs ask Trudeau to drop opposition to TRIPS waiver", *Hindustan Times*, 7 May 2021. Available from https://www.hindustantimes.com/world-news/canadian-mps-ask-trudeau-to-drop-opposition-to-trips-waiver-101620361257163.html (accessed 17 September 2021).
[40] Tasker, "Trudeau non-committal on waiving intellectual property rights for COVID-19 vaccines".
[41] Ibid.
[42] Doctors Without Borders Canada, WTO COVID-19 TRIPS Waiver Briefing Note (2021).
[43] Government of Canada, "Item 15 – Waiver from certain provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19", Intervention by Canada, December 10, 2020. Available from https://www.international.gc.ca/world-monde/international_relations-relations_internationales/wto-omc/2020-12-10-TRIPS-ADPIC.aspx?lang=eng (accessed 4 September 2021).
[44] Doctors Without Borders Canada, WTO COVID-19 TRIPS Waiver Briefing Note (2021), p. 4.
[45] World Health Organization, WHO Coronavirus (COVID-19) Dashboard. Available from https://covid19.who.int (accessed 4 September 2021).

the International Covenant on Economic, Social and Cultural Rights (ICESCR).[46] The Committee on Economic, Social and Cultural Rights emphasized that "pandemics are a crucial example of the need for scientific international cooperation to face transnational threats".[47] "All State parties should, as a matter of urgency, adopt special, targeted measures, including through international cooperation, to protect and mitigate the impact of the pandemic," it added.[48] By overlooking its human rights obligations in the middle of a pandemic, Canada might not be choosing to stand on the right side of history.

[46] Amnesty International, "Re: Canada's Human Rights Obligations on Global Access To COVID-19 Vaccines", 28 July 2021 (TG AMR 20/2021.1865), p. 1.
[47] United Nations Committee on Economic, Social and Cultural Rights, Statement on the coronavirus disease (COVID-19) pandemic and economic, social and cultural rights", E/C.12/2020/1, p. 5, para. 23.
[48] Ibid., p. 3, para. 15.

III. THE BOLIVIA-BIOLYSE CASE

Bolivia is a developing nation facing the challenges of poverty, inequality and precarious work as its labour market is dominated by informal work.[49] The informal sector, with no unemployment insurance, represents 77% of the occupied population or 2.5 million households.[50] The labour market structure in this small South American country, with a population of around 11 million, is too fragile to manage the shocks of an emergency. Bolivia, having a weak health system, was not prepared for a health emergency.[51] The COVID-19 crisis strained the healthcare system in Bolivia and further weakened its fragile economy.[52] As of this writing in mid-September 2021, an average of 302 new cases of COVID-19 are being recorded in the country per day and there have been more than 18,600 virus-related deaths since the start of the pandemic.[53] At one point, Bolivia was recording more than 2000 confirmed cases per day.[54]

Bolivia has staggeringly low rates of vaccination as doses of vaccines are coming too slowly.[55] Bolivia lacks the manufacturing capacity to produce its own vaccines. One of the policy options available to Bolivia is to make use of the export-oriented compulsory licensing mechanism provided under Article 31bis. To address vaccine supply shortages, Bolivia self-identified as a country wishing to purchase COVID-19 vaccines from Biolyse Pharma and made a general notification to the WTO in February 2021.[56] Bolivia intends to purchase up to 15 million doses of COVID-19 vaccines from Biolyse Pharma subject to the grant of a voluntary licence by Johnson & Johnson (J&J) - the patentee company based in New Jersey, USA - or the grant of an export-oriented compulsory licence under the CAMR system.

In March 2021, Biolyse Pharma, a Canada based manufacturer of sterile injectable medicine, publicly stated its intent, rather eagerness, to help bridge the supply gap by fabricating and exporting COVID-19 vaccines to Bolivia and other low- and middle-income countries.[57] Biolyse Pharma is a fully certified current Good Manufacturing Practices/ Good Laboratory Practices (cGMP/GLP) biologics manufacturing facility having some of the largest bioreactors in Canada.[58] The generic drug company has equipped itself with the capabilities to manufacture certain COVID-19 vaccine candidates.[59] Claude Mercure, Manager at Biolyse Pharma, stated that the company has the facilities and equipment and "fill-and-finish capability".[60] "We

---

[49] Calla Hummel, Felicia Marie Knaul, Michael Touchton, V Ximena Velasco Guachalla, Jami Nelson-Nuñez, Carew Boulding, "Poverty, precarious work, and the COVID-19 pandemic: lessons from Bolivia", *The Lancet,* vol. 9, No. 5 (May 2021), p. 579. Available from https://doi.org/10.1016/S2214-109X(21)00001-2.

[50] Milenka Figueroa Cárdenas and Carlos Gustavo Machicado, "COVID-19 in Bolivia: On the path to recovering development", #COVID19/ Policy Documents Series, No. 22 (United Nations Development Programme Latin American and the Caribbean, 2020).

[51] Hummel, and others, "Poverty, precarious work, and the COVID-19 pandemic: lessons from Bolivia", p. 579.

[52] Ibid.

[53] Reuters, COVID-19 Tracker, Bolivia. Available from https://graphics.reuters.com/world-coronavirus-tracker-and-maps/countries-and-territories/bolivia/ (accessed 4 September 2021).

[54] United Nations Children's Fund, UNICEF Bolivia COVID-19 Situation Report No. 2 (2020).

[55] Helen Lock, "Bolivia Could Unlock New Access to Life-Saving COVID-19 Vaccines — But Needs Canada to Grant a License." *Global Citizen,* 2 August 2021. Available from https://www.globalcitizen.org/en/content/bolivia-canada-patents-covid-19-vaccines-trips/ (accessed 4 September 2021).

[56] Ibid.

[57] Arianna Schouten, "Canada based Biolyse Pharma Seeks to Manufacture COVID-19 Vaccines for Low-Income Countries, may test Canada's compulsory licensing for export law", *Knowledge Ecology International,* 12 March 2021. Available from https://www.keionline.org/35587 (accessed 4 September 2021).

[58] Executive Director - General of the Center for Supply and Provision (CEASS), "Terms of Reference", *Ministry of Health and Support*, 11 May 2021, p. 2. (Official document on file with the author).

[59] Ibid., p. 2.

[60] Stephen Buranyi, "The world is desperate for more Covid vaccines – patents shouldn't get in the way", *The Guardian*, 24 April 2021. Available from https://amp.theguardian.com/commentisfree/2021/apr/24/covid-vaccines-patents-pharmaceutical-companies-secrecy (accessed 4 September 2021).

basically have the equipment. We have large bioreactors here that could deal with industrial production," he said.[61] The company claims to have the potential to produce up to approximately 200,000 doses of COVID-19 vaccine per week.[62]

On March 3, 2021, Biolyse Pharma wrote a letter to J&J to request a voluntary licence. Biolyse requested a licence to manufacture and sell Ad26.COV2.S vaccine (hereafter the COVID-19 vaccine) in Canada, and to export it to WTO Members that authorize the export under Article 31bis of the TRIPS Agreement.[63] J&J rejected the request for a voluntary licence and refused to negotiate.[64] Claude Mercure said that Biolyse Pharma would have preferred to work collaboratively with J&J, "but this type of vaccine is based on a widely used technology and could be reverse engineered".[65] Anyway, a collaborative approach could be helpful in avoiding the additional burden of clinical trials, if a compulsory licence is granted, as these trials push up the cost and cause delays.

J&J's refusal to collaborate was unfortunate. The patentee company's one-shot vaccine is the best solution for low- and middle-income countries because you vaccinate only once and cover more population. More importantly, as compared to Pfizer and Moderna's mRNA vaccines, J&J's viral-vector vaccine is manufactured by using less complex technologies reducing the transition time for generic manufacturers. Several generic manufacturers licensed to produce Russia's Sputnik V are also finding it hard to produce the second dose, which has a different composition, in large quantities.[66] Countries in the Global South, lacking mRNA options and struggling with low yields for the second dose production of Sputnik V, largely rely on J&J's cooperation to license its viral-vector vaccine. More than 30 generic manufacturers in the Global South, outfitted for Sputnik V, can quickly transition to J&J vaccine to scale up manufacturing if authorized. So far, J&J has partnered with only one company in the Global South, Biological E, based in Hyderabad, India.[67] Even in this single collaboration, "the decision on where they [vaccine doses manufactured under this partnership] will be exported, and at what price, is under the purview of J&J completely".[68]

With J&J refusing to license voluntarily, the alternate option for Biolyse Pharma is to seek a compulsory licence under CAMR. The first step in using CAMR is to get the product added to Schedule 1, which is a list of patented pharmaceutical products that are eligible for export under the regime. Schedule 1 can be amended by the Governor-in-Council. This regulatory step is incumbent on the recommendation of the Minister of Innovation, Science and Industry and the Minister of Health.[69] On March 23, 2021, Biolyse Pharma requested the Minister of

---

[61] Elana Gordon, "A Canadian company challenges vaccine rules to increase access", *PRI Organization*, 1 April 2021. Available from https://www.pri.org/stories/2021-03-31/canadian-company-challenges-vaccine-rules-increase-access.

[62] Executive Director - General of the Center for Supply and Provision (CEASS), "Terms of Reference", *Ministry of Health and Support*, 11 May 2021, p. 2. (Official document on file with the author).

[63] Johnson and Johnson, "Re: Johnson & Johnson/ Janssen/Crucell License Request related to Ad26.COV2.S Vaccine", 3 March 2021. (Licence request letter on file with the author). See further Schouten, "Canada based Biolyse Pharma Seeks to Manufacture COVID-19 Vaccines for Low-Income Countries, may test Canada's compulsory licensing for export law."

[64] Zachary Brennan, "How to manufacture Covid-19 vaccines without the help of J&J, Pfizer or Moderna? Biolyse sees the difficulties up close", *Endpoints News,* 17 May 2021. Available from https://endpts.com/how-to-manufacture-covid-19-vaccines-without-the-help-of-jj-pfizer-or-moderna-biolyse-sees-the-difficulties-up-close/ (accessed 4 September 2021).

[65] Gordon, "A Canadian company challenges vaccine rules to increase access".

[66] Amy Maxmen, "The fight to manufacture COVID vaccines in lower-income countries" *Nature,* 16 September 2021. Available from https://www.nature.com/articles/d41586-021-02383-z (accessed 19 September 2021).

[67] See Mint, "J&J working with Telangana-based Biological E to manufacture Covid-19 vaccine" 19 May 2021. Available from https://www.livemint.com/companies/news/jj-working-with-telangana-based-biological-e-to-manufacture-covid-19-vaccine-11621387220068.html (accessed 19 September 2021).

[68] Amy Maxmen, "The fight to manufacture COVID vaccines in lower-income countries".

[69] Patent Act R.S.C., 1985, c. P-4 (Canada), Section 21.03(1).

Health and the Minister of Innovation, Science and Industry to recommend to the Governor-in-Council to add the COVID-19 vaccine to Schedule 1 of the Patent Act.[70]

The procedure to amend Schedule 1 is fraught with challenges and uncertainties. The Canadian government has stonewalled the process and has not provided any clear answer to Biolyse Pharma's queries about adding the COVID-19 vaccine to the list. The process to amend Schedule 1 lacks transparency and certainty. As highlighted by Arianna Schouten:

> The CAMR website [states] that 'as of April 2006, an advisory committee was being established and a website will be created'. The purpose of this advisory committee is to advise the Ministry of Health and Ministry of Industry on their recommendations to the Governor in Council with respect to amending Schedule 1.[71]

Moreover, the 2007 Report on the Statutory Review of CAMR categorically stated that to make sure "this process [of amending Schedule 1] takes place in an informed and transparent manner, CAMR calls upon the Ministers of Industry and Health to establish an expert committee by May of 2008, to advise them on what drugs should be eligible for export under the regime".[72] Unfortunately, no such expert committee has been established to ensure transparency in amending Schedule 1.

Representatives for Biolyse Pharma had meetings with officials of the Canadian government's Innovation, Science and Economic Development (ISED) program, Health Canada and the Canadian Intellectual Property Office to discuss the process of adding the COVID-19 vaccine to Schedule 1.[73] They met close to 30 different high-level officials but still have no straight answer on how to start the process.[74]

It is hard to understand the Canadian government's rationale for not adding COVID-19 vaccines to Schedule 1. The underlying purpose of the CAMR system is "to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics".[75]

Instead of explaining the procedure in a straightforward manner, the Canadian government has tried to create new barriers for Biolyse Pharma by adding formalities that are not even required under the Canadian regime. For instance, a spokesperson for the Canadian government's ISED program stated:

> It is important to note that adding a COVID vaccine to Schedule 1 would not allow a compulsory licence for the production and export of these vaccines. A company seeking authorization under Canada's Access to Medicines Regime must be able to manufacture the drug and conduct necessary trials to establish

---

[70] Brigitte Kiecken (President Cooperation Biolyse Pharma), "Reference: Request for adding Ad 26.COV2.S as a patented medicine under Scheme 1 of the Patent Act for export to low income or medium income countries", 23 March 2021. (Official document on file with the author).
[71] Schouten, "Canada based Biolyse Pharma Seeks to Manufacture COVID-19 Vaccines for Low-Income Countries, may test Canada's compulsory licensing for export law".
[72] Government of Canada, *Report on the Statutory Review of Sections 21.01 to 21.19 of the Patent Act - Canada's Access to Medicines Regime* (2007).
[73] Jacquelyn LeBel, "Biolyse suggests Health Canada lacks urgency over its task to produce COVID-19 vaccines for export." *Global News,* 8 April 2021. Available from https://globalnews.ca/news/7743371/biolyse-covid-19-vaccines-health-canada-johnson-and-johnson/ (accessed 4 September 2021).
[74] Brennan, "How to manufacture Covid-19 vaccines without the help of J&J, Pfizer or Moderna? Biolyse sees the difficulties up close".
[75] Patent Act R.S.C., 1985, c. P-4 (Canada), Section 21.01.

> that the drug meets Canadian safety and efficacy requirements before authorization would be granted.[76]

Before adding the COVID-19 vaccine to Schedule 1, the Canadian government has questioned the capability of Biolyse Pharma to manufacture safe and efficacious COVID-19 vaccines. John Power, a spokesperson for the federal Minister of Innovation, Science and Industry Francois-Philippe Champagne, stated that "vaccine production is a complex process dependent on securing access to needed equipment, production inputs, technical expertise and know-how, as well as a range of other considerations".[77] As noted by John Fulton, the Executive Vice-President of Biolyse Pharma, the Canadian government's implied position is that "for having a product listed on Schedule 1, a third party company like Biolyse must first demonstrate that it can manufacture a competing version of the product and have obtained a Notice of Compliance (NOC) from Health Canada".[78]

It appears that the Canadian government has doubted that Biolyse Pharma has the potential or capability to reverse engineer and manufacture the COVID-19 vaccine. Even if that is true, it does not provide a legal ground for not amending Schedule 1. There were already products on Schedule 1 when CAMR received royal assent in May 2004. None of the products was at any stage of development by any generic manufacturer. This position of the Canadian government to question the vaccine manufacturing capability of Biolyse Pharma before amending Schedule 1 has no legal basis. This interpretation of CAMR is flawed and against the Canadian government's original policy rationale.

Schedule 1 has been amended three times in the past.[79] In none of these instances "was there any indication that a company stood poised to enter the market with a generic version of these drugs".[80] As noted by John Fulton, "I didn't experience this in 2006 when we asked to have Tamiflu [Oseltamivir] added to the list of drugs. We didn't provide any kind of studies, any kind of bioequivalence. We just started the process by asking to have this bird flu drug added to the list of drugs on Schedule 1."[81] For eligibility on Schedule 1, it could not have been the Canadian government's original policy rationale to require a participating generic drug company to produce the product and obtain an NOC from Health Canada.[82]

Such a requirement is unrealistic and unjustifiable. Claude Mercure questioned the practicality of this cumbersome requirement: "They are asking that we invest $10 million and that we prove that we can receive the approval of the Ministry of Health before putting the vaccine on the list of authorized drugs."[83] John Fulton expressed similar concerns in his open letter to Canada's Minister of Innovation, Science and Industry:

---

[76] Ibid.
[77] Geoffrey York, "Canadian company wins COVID-19 vaccine deal with Bolivia – and WTO support", *The Global Mail*, 11 May 2021. Available from https://www.theglobeandmail.com/world/article-canadian-company-wins-covid-19-vaccine-deal-with-bolivia-and-wto/ (accessed 4 September 2021).
[78] John R. Fulton, "Re: DAY #101 Time for Canada to show leadership in global effort to vaccinate developing countries." *Bioniagara,* 11 June 2021.Available from http://bion.ca/day101/#101 (accessed September 4, 2021).
[79] Schedule 1 was amended in August 2005 to add Apo-TriAvir to the list as requested by Apotex Inc. In September 2006, oseltamivir phosphate was added to Schedule 1 as requested by Biolyse Pharma. Schedule 1 was amended again in May 2015 to add three more products (tenofovir disoproxil and two combination drugs containing tenofovir disoproxil) to the list as requested by Teva Canada Limited. See Arianna Schouten, "Canadian Experience with Compulsory Licensing under the Canadian Access to Medicines Regime", KEI Briefing Note, 31 March 2021, pp. 4-7.
[80] Fulton, "Re: DAY #101 Time for Canada to show leadership in global effort to vaccinate developing countries".
[81] Policy Alternatives, "Global Vaccine Inequity: COVID-19 and Canada's Access to Medicines Regime", 28 June 2021. Available from https://www.youtube.com/watch?v=GXJkvFlwm3g (accessed September 4, 2021).
[82] Fulton, "Re: DAY #101 Time for Canada to show leadership in global effort to vaccinate developing countries".
[83] Edna, "Bolivia wants to import COVID-19 vaccines from Canada", *News in 24* (2021). Available from https://news.in-24.com/news/56887.html (accessed 4 September 2021).

> [This requirement] places the onus on the third-party manufacturer to assume all the risk associated with reverse engineering a competing version of a patented drug and undertaking all of the clinical work needed to secure an NOC, with no guarantee that it will actually be added to Schedule 1 by the time the company is in a position to export it to a needy developing country. In what universe would any company – even the most altruistically minded – roll the dice in this manner when there is no indication that the Government harbours the same altruism toward the less fortunate of this world?[84]

The CAMR process includes a Health Canada review of the application, but this step is after getting the product added to Schedule 1. Having the relevant product added to Schedule 1 is a prerequisite condition for the Health Canada review. Once Schedule 1 is amended, drug submissions may be submitted by the applicant for the regulatory review by Health Canada, which can be completed either before or after making an application for a compulsory licence.[85] The Commissioner of Patents and the generic manufacturer are notified once Health Canada has approved the product. The Commissioner can make a determination on the application for a compulsory licence only once Health Canada approves the pharmaceutical product in question.[86] Biolyse Pharma is willing to use its commercially reasonable efforts to obtain the requisite Health Canada regulatory approvals to manufacture and export the COVID-19 vaccine.[87]

On May 10, 2021, Bolivia made a specific notification of intent to the WTO as a would-be importing country of the COVID-19 vaccine.[88] Bolivia announced its agreement with Biolyse Pharma on May 11, 2021. Bolivia wishes to import low-cost COVID-19 vaccines to strengthen the country's efforts in fighting the COVID-19 pandemic. Bolivia is interested in buying up to fifteen million doses of the COVID-19 vaccine from Biolyse Pharma at around the cost of manufacturing, at approximately US $3.00 to US $4.00 per dose.[89] According to Benjamin Blanco, a Bolivian trade official, "the move could help the impoverished Andean nation speed up a slow vaccination process".[90]

Rogelio Mayta, Bolivia's Foreign Minister, said that he anticipates a "complicated bureaucratic process".[91] Biolyse Pharma has a long way to go before it has all the approvals and authorizations to start the production line. The CAMR mechanism overall is an ignored and broken system making it extremely hard to pursue a compulsory licence. As noted by Arianna Schouten:

> On the CAMR contact website, they provide two phone numbers. The first number provided is invalid and out of service and when calling and leaving a message for the second number, there was no response. Additionally, the compulsory licence application forms are not readily available. Applicants are directed to call the Canadian Intellectual Property Office (CIPO) to gain access to the forms. Yet the only contact numbers provided are general CIPO phone

---

[84] Fulton, "Re: DAY #101 Time for Canada to show leadership in global effort to vaccinate developing countries".
[85] Schouten, "Canadian Experience with Compulsory Licensing under the Canadian Access to Medicines Regime", p. 2.
[86] Ibid., p. 3.
[87] Executive Director - General of the Center for Supply and Provision (CEASS), "Terms of Reference", *Ministry of Health and Support*, 11 May 2021, p. 2. (Official document on file with the author).
[88] Policy Alternatives, "Global Vaccine Inequity: COVID-19 and Canada's Access to Medicines Regime".
[89] Executive Director - General of the Center for Supply and Provision (CEASS), "Terms of Reference", *Ministry of Health and Support*, 11 May 2021, p. 3. (Official document on file with the author).
[90] Allison Martell, "Bolivia signs J&J vaccine deal with a twist - it needs WTO patent waiver", *Reuters,* 11 May 2021. Available from https://www.reuters.com/world/americas/bolivia-signs-jj-vaccine-deal-with-twist-someone-else-would-make-it-2021-05-11/ (accessed 4 September 2021).
[91] York, "Canadian company wins COVID-19 vaccine deal with Bolivia – and WTO support".

> numbers, there is no specific compulsory licence contact number, enquiry form, or CIPO webpage.[92]

John Fulton highlighted similar issues: "CAMR sounds like a program, but when you go on the website, you get a disconnected phone number and you go to the list of drugs and it's a broken link. You think there should be somebody there with a budget running this program but it's really not a program."[93] There should be somebody in charge of CAMR that the participating generic companies can talk to and go back and forth with. It should not take companies months to work out who is the right person to talk to to trigger the process. If an entity within any government department has been tasked with coordinating and facilitating the use of the Canadian regime, they may have perhaps forgotten about their responsibility given the extremely rare use of the regime.

After nearly six months of effort, Biolyse Pharma has not been able to even get the CAMR process started. There are no signs of political will to consider Biolyse Pharma's request, especially if the COVID-19 Vaccine Task Force, rife with conflict of interest, keeps advising the Canadian government. It is not clear at the moment whether the COVID-19 vaccine will be added to Schedule 1 or how much time it will take to amend the list. Further delays are foreseen but unwarranted delays during a health emergency seriously undermine the public interest.

It is quite evident that the CAMR system is broken. The real cause of concern is that the system is broken in the favour of patentee corporations. As noted by Marc-Andre Gagnon, the Canadian regime "is perched with red-tape, so much that the big pharmaceuticals are very happy that this regime is not functional".[94] Further, brand-name corporations, profiteering on the pandemic, tend to pressure governments – in importing as well as exporting countries - not to use this regime. Justin Trudeau revealed that J&J "had warned him of potential production delays for their one-shot vaccine option".[95] It was a safe approach for the Canadian government to placate J&J and other patentee corporations keeping in view the forthcoming election. Matthew Herder views that "Canada [did] not want to alienate the lobby of the pharmaceutical giants. Ottawa surely [feared] that next dose deliveries will decrease if it attacks patents".[96] John Fulton had indicated that "we have an election coming up and they want the vaccines to keep flowing into Canada and every vaccine is equivalent to say three votes".[97] He had, however, questioned the political foresight of the Canadian government:

> You are fearful that adding COVID-19 vaccines to Schedule 1 will incur the wrath of the pharmaceutical industry and Canadians will punish you at the polls for being seen to put the health of people in developing countries ahead of their own. With the greatest of respect, I think this does a terrible disservice to the people of this country. Canadians have always prided themselves on seeing beyond their own immediate self-interest, especially in other's times of need. In our lifetimes, there has never been a greater need for anything globally than for these vaccines at this moment. Canadians understand this and will reward you for your faith in their character.[98]

---

[92] Schouten, "Canada based Biolyse Pharma Seeks to Manufacture COVID-19 Vaccines for Low-Income Countries, may test Canada's compulsory licensing for export law".
[93] Policy Alternatives, "Global Vaccine Inequity: COVID-19 and Canada's Access to Medicines Regime".
[94] Edna, "Bolivia wants to import COVID-19 vaccines from Canada ".
[95] Shelby Knox, "St. Catharines Pharmaceutical Company Wants To Help With Global COVID-19 Vaccine Rollout," *iHeartRadio,* 11 March 2021. Available from https://www.iheartradio.ca/610cktb/news/st-catharines-pharmaceutical-company-wants-to-help-with-global-covid-19-vaccine-rollout-1.14749000 (accessed 4 September 2021).
[96] Edna, "Bolivia wants to import COVID-19 vaccines from Canada".
[97] Policy Alternatives, "Global Vaccine Inequity: COVID-19 and Canada's Access to Medicines Regime".
[98] Fulton, "Re: DAY #101 Time for Canada to show leadership in global effort to vaccinate developing countries".

COVID-19 vaccines are not accessible to many people because of limited stocks and supply shortages. The Canadian government claims that it "is actively committed to a robust global effort to stop COVID-19 and address its devastating health, social and economic impacts on people across the world".[99] Biolyse Pharma should have been encouraged and supported to fully use its potential to manufacture and export the COVID-19 vaccine. As noted by James Love, "access [to COVID-19 vaccines] remains a challenge, particularly in developing countries. Biolyse has the unused capacity to manufacture vaccines at a time when it will take years to vaccinate everyone at risk".[100] John Fulton raised a valid question: "If a compulsory licence system can't work now, during a worldwide pandemic, what's it for? What's the use?"[101] "You pull the smoke alarm and the fire department is supposed to show up and you go downstairs and you look at the water is not even hooked up," he added.[102]

The Trudeau government argued at the WTO that "Canada believes that the concerns raised [about equitable access to vaccines] can be addressed through the TRIPS Agreement itself and the flexibilities it contains, chiefly the mechanisms outlined in Articles 31 and 31bis… [Canada observes], on the basis of concrete experience, that the system worked as intended."[103] Canada claims that "no regime-level weaknesses, obstacles or inefficiencies that would necessitate a waiver have yet been identified".[104] The Canadian government asserted to be "fully available and interested in hearing about concrete challenges faced by [WTO] Members in addressing the pandemic".[105] The actions of the Canadian government have not supported these assertions. Canada cannot claim that the CAMR system is functioning as intended while stonewalling the same process. As noted by Knowledge Ecology International (KEI), "[i]f Canada fails to expeditiously allow Bolivia to import vaccines manufactured by Biolyse under a compulsory licence, they would be directly contradicting their own statements at the WTO."[106]

Bolivia is not the only WTO Member seeking a compulsory licence under the Article 31bis system. Several other countries are interested in using the regime to address supply shortages of COVID-related health technologies. The Bolivian government's initiative is paving the way for other WTO Members to consider this legitimate policy option. As noted by Ana Santos Rutschman, "this [initiative] means that something that was mostly a theory or legal framework that went unused, suddenly becomes a possibility. We sometimes just need one, you know, one to lead the pack and then we can resort to this mechanism, which really has been underused".[107]

Two more countries - Antigua and Barbuda - have followed suit and notified the WTO of their intent to use the export-oriented compulsory licensing regime.[108] It will be frustrating for these countries if the export-oriented compulsory licensing mechanism remains unfunctional. As

---

[99] Government of Canada, "Item 15 – Waiver from certain provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*"*.
[100] Biolyse Pharma, "Canadian-pharma solution to aid worldwide COVID vaccine access", *Newswire,* 11 March 2021. Available from https://www.newswire.ca/news-releases/canadian-pharma-solution-to-aid-worldwide-covid-vaccine-access-831681238.html (accessed 4 September 2021).
[101] Brennan, "How to manufacture Covid-19 vaccines without the help of J&J, Pfizer or Moderna? Biolyse sees the difficulties up close".
[102] Policy Alternatives, "Global Vaccine Inequity: COVID-19 and Canada's Access to Medicines Regime".
[103] Government of Canada, "Item 15 – Waiver from certain provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*"*.
[104] Ibid.
[105] Ibid.
[106] Luis Gil Abinader, "Bolivia seeks to import COVID-19 vaccines from Biolyse, if Canada grants them a compulsory license", *Knowledge Ecology International,* 11 May 2021. Available from https://www.keionline.org/36119 (accessed 4 September 2021).
[107] Gordon, "A Canadian company challenges vaccine rules to increase access".
[108] Luis Gil Abinader, "Antigua and Barbuda notified the WTO of their intent to import products using compulsory licenses", *Knowledge Ecology International,* 7 June 2021. Available from https://www.keionline.org/36241 (accessed 4 September 2021).

noted by Bolivia's Ambassador Macdonal, "we have been advised by wealthier countries to look at using compulsory licensing with individual nations rather than rely on a TRIPS waiver, but so far it hasn't been successful. [The Canadian government officials] tell us it will take time to be granted, but they never say how long".[109] It would be extremely unfortunate if these countries are forced to remain dependent on a handful of patentee corporations and made to wait indefinitely for vaccine doses while allowing big corporations to profit on the pandemic.

There are allegations that Pfizer has bullied some South American countries seeking COVID-19 vaccine purchases from the pharmaceutical giant. According to a report of the Bureau of Investigative Journalism, Pfizer allegedly held Brazil and Argentina to ransom by demanding these countries to "put up sovereign assets as collateral to guarantee indemnity, as well as create a guarantee fund with money deposited in a foreign bank account".[110] There is a clear imbalance of bargaining power between those South American countries and big vaccine developers. If Brazil and Argentina are treated like this, one can imagine how smaller countries, like Bolivia, having no real alternatives, are negotiating with big corporations.

[109] Lock, "Bolivia Could Unlock New Access to Life-Saving COVID-19 Vaccines — But Needs Canada to Grant a License".
[110] Mattha Busby and Flávia Milhorance, "Pfizer accused of holding Brazil 'to ransom' over vaccine contract demands", *The Guardian,* 10 September 2021. Available from https://www.theguardian.com/global-development/2021/sep/10/pfizer-accused-of-holding-brazil-to-ransom-over-vaccine-contract-demands (accessed 14 September 2021).

IV. CONCLUSION

It can be seen that the Trudeau government is not politically inclined to the humanitarian needs of poorer countries and has been trying to hide behind the legislation. Instead of explaining the procedure to amend Schedule 1 in a straightforward manner, the Canadian government has created new barriers for Biolyse Pharma by adding unjustifiable formalities which are not even required under CAMR. After nearly six months of effort, Biolyse Pharma has not been able to even get the CAMR process started. There are no signs of political will to consider Biolyse Pharma's request to add the COVID-19 vaccine to Schedule 1.

Canada feared that patentee corporations would punish the government had it chosen to support TRIPS Waiver or allowed Biolyse Pharma to use CAMR. It is a real failure of leadership and foresight on the part of Trudeau's government. Their only consideration was to get re-elected by making sure Canada's own citizens are well supplied with COVID-19 vaccines. They needed to realize that we are all in this together. International solidarity and collaboration are the best approaches to tackle this pandemic. It is in our collective best interest that COVID-19 vaccines are distributed equitably across the globe. If low- and middle-income countries are left behind and a more infectious and dangerous variant comes in from these countries where people are not vaccinated, the short-term strategy of high-income countries may lead to long-term suffering and economic harm for fully immunized Canadians. It has been estimated that "each Canadian could lose as much as $2000 annually as a result of a COVID-19-induced recession worsened by unequal vaccine allocation".[111]

There are obvious contradictions in Canada's position on the TRIPS Waiver. On one hand, Canada has argued at the WTO that existing mechanisms are working as intended, while on the other, the government has stonewalled Biolyse Pharma's legitimate attempt to use the CAMR system to manufacture and export COVID-19 vaccines. To avoid international embarrassment, the Canadian government needs to consider amending Schedule 1 of the Patent Act without further delay. This research paper also calls upon Canada to reverse course at the WTO by publicly announcing its support for the TRIPS Waiver. Canada's strong support for the proposal can make a big difference in terms of paving the way for equitable distribution of COVID-19 vaccines. Resource-poor countries, scrambling for access to more doses, cannot be left at the mercy of the optional goodwill of major vaccine developers.

[111] Ronald Labonté, Mira Johri, Katrina Plamondon & Srinivas Murthy, "Canada, global vaccine supply, and the TRIPS waiver/ Le Canada, l'offre mondiale de vaccins et l'exemption ADPIC", *Canadian Journal of Public Health,* vol. 112 (2021), p. 544. Available from https://doi.org/10.17269/s41997-021-00541-4.

SOUTH CENTRE RESEARCH PAPERS

No.	Date	Title	Authors
1	November 2005	Overview of the Sanitary and Phytosanitary Measures in QUAD Countries on Tropical Fruits and Vegetables Imported from Developing Countries	Ellen Pay
2	November 2005	Remunerating Commodity Producers in Developing Countries: Regulating Concentration in Commodity Markets	Samuel G. Asfaha
3	November 2005	Supply-Side Measures for Raising Low Farm-gate Prices of Tropical Beverage Commodities	Peter Robbins
4	November 2005	The Potential Impacts of Nano-Scale Technologies on Commodity Markets: The Implications for Commodity Dependent Developing Countries	ETC Group
5	March 2006	Rethinking Policy Options for Export Earnings	Jayant Parimal
6	April 2006	Considering Gender and the WTO Services Negotiations	Meg Jones
7	July 2006	Reinventing UNCTAD	Boutros Boutros-Ghali
8	August 2006	IP Rights Under Investment Agreements: The TRIPS-plus Implications for Enforcement and Protection of Public Interest	Ermias Tekeste Biadgleng
9	January 2007	A Development Analysis of the Proposed WIPO Treaty on the Protection of Broadcasting and Cablecasting Organizations	Viviana Munoz Tellez and Andrew Chege Waitara
10	November 2006	Market Power, Price Formation and Primary Commodities	Thomas Lines
11	March 2007	Development at Crossroads: The Economic Partnership Agreement Negotiations with Eastern and Southern African Countries on Trade in Services	Clare Akamanzi
12	June 2007	Changes in the Governance of Global Value Chains of Fresh Fruits and Vegetables: Opportunities and Challenges for Producers in Sub-Saharan Africa	Temu A.E and N.W Marwa
13	August 2007	Towards a Digital Agenda for Developing Countries	Dalindyebo Shabalala
14	December 2007	Analysis of the Role of South-South Cooperation to Promote Governance on Intellectual Property Rights and Development	Ermias Tekeste Biadgleng
15	January 2008	The Changing Structure and Governance of Intellectual Property Enforcement	Ermias Tekeste Biadgleng and Viviana Munoz Tellez
16	January 2008	Liberalization of Trade in Health Services: Balancing Mode 4 Interests with Obligations to Provide Universal Access to Basic Services	Joy Kategekwa

17	July 2008	Unity in Diversity: Governance Adaptation in Multilateral Trade Institutions Through South-South Coalition-Building	Vicente Paolo B. Yu III
18	December 2008	Patent Counts as Indicators of the Geography of Innovation Activities: Problems and Perspectives	Xuan Li
19	December 2008	WCO SECURE: Lessons Learnt from the Abortion of the TRIPS-plus-plus IP Enforcement Initiative	Xuan Li
20	May 2009	Industrialisation and Industrial Policy in Africa: Is it a Policy Priority?	Darlan F. Marti and Ivan Ssenkubuge
21	June 2009	IPR Misuse: The Core Issue in Standards and Patents	Xuan Li and Baisheng An
22	July 2009	Policy Space for Domestic Public Interest Measures Under TRIPS	Henning Grosse Ruse – Khan
23	June 2009	Developing Biotechnology Innovations Through Traditional Knowledge	Sufian Jusoh
24	May 2009	Policy Response to the Global Financial Crisis: Key Issues for Developing Countries	Yılmaz Akyüz
25	October 2009	The Gap Between Commitments and Implementation: Assessing the Compliance by Annex I Parties with their Commitments Under the UNFCCC and its Kyoto Protocol	Vicente Paolo Yu III
26	April 2010	Global Economic Prospects: The Recession May Be Over but Where Next?	Yılmaz Akyüz
27	April 2010	Export Dependence and Sustainability of Growth in China and the East Asian Production Network	Yılmaz Akyüz
28	May 2010	The Impact of the Global Economic Crisis on Industrial Development of Least Developed Countries	Report Prepared by the South Centre
29	May 2010	The Climate and Trade Relation: Some Issues	Martin Khor
30	May 2010	Analysis of the Doha Negotiations and the Functioning of the World Trade Organization	Martin Khor
31	July 2010	Legal Analysis of Services and Investment in the CARIFORUM-EC EPA: Lessons for Other Developing Countries	Jane Kelsey
32	November 2010	Why the IMF and the International Monetary System Need More than Cosmetic Reform	Yılmaz Akyüz
33	November 2010	The Equitable Sharing of Atmospheric and Development Space: Some Critical Aspects	Martin Khor
34	November 2010	Addressing Climate Change through Sustainable Development and the Promotion of Human Rights	Margreet Wewerinke and Vicente Paolo Yu III
35	January 2011	The Right to Health and Medicines: The Case of Recent Negotiations on the	Germán Velásquez

		Global Strategy on Public Health, Innovation and Intellectual Property	
36	March 2011	The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries	Gurdial Singh Nijar
37	March 2011	Capital Flows to Developing Countries in a Historical Perspective: Will the Current Boom End with a Bust?	Yılmaz Akyüz
38	May 2011	The MDGs Beyond 2015	Deepak Nayyar
39	May 2011	Operationalizing the UNFCCC Finance Mechanism	Matthew Stilwell
40	July 2011	Risks and Uses of the Green Economy Concept in the Context of Sustainable Development, Poverty and Equity	Martin Khor
41	September 2011	Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing	Carlos M. Correa
42	December 2011	Rethinking Global Health: A Binding Convention for R&D for Pharmaceutical Products	Germán Velásquez and Xavier Seuba
43	March 2012	Mechanisms for International Cooperation in Research and Development: Lessons for the Context of Climate Change	Carlos M. Correa
44	March 2012	The Staggering Rise of the South?	Yılmaz Akyüz
45	April 2012	Climate Change, Technology and Intellectual Property Rights: Context and Recent Negotiations	Martin Khor
46	July 2012	Asian Initiatives at Monetary and Financial Integration: A Critical Review	Mah-Hui (Michael) Lim and Joseph Anthony Y. Lim
47	May 2013	Access to Medicines and Intellectual Property: The Contribution of the World Health Organization	Germán Velásquez
48	June 2013	Waving or Drowning: Developing Countries After the Financial Crisis	Yılmaz Akyüz
49	January 2014	Public-Private Partnerships in Global Health: Putting Business Before Health?	Germán Velásquez
50	February 2014	Crisis Mismanagement in the United States and Europe: Impact on Developing Countries and Longer-term Consequences	Yılmaz Akyüz
51	July 2014	Obstacles to Development in the Global Economic System	Manuel F. Montes
52	August 2014	Tackling the Proliferation of Patents: How to Avoid Undue Limitations to Competition and the Public Domain	Carlos M. Correa
53	September 2014	Regional Pooled Procurement of Medicines in the East African Community	Nirmalya Syam
54	September 2014	Innovative Financing Mechanisms: Potential Sources of Financing the WHO Tobacco Convention	Deborah Ko Sy, Nirmalya Syam and Germán Velásquez

55	October 2014	Patent Protection for Plants: Legal Options for Developing Countries	Carlos M. Correa
56	November 2014	The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for Access to Medicines	Sangeeta Shashikant
57	November 2014	Globalization, Export-Led Growth and Inequality: The East Asian Story	Mah-Hui Lim
58	November 2014	Patent Examination and Legal Fictions: How Rights Are Created on Feet of Clay	Carlos M. Correa
59	December 2014	Transition Period for TRIPS Implementation for LDCs: Implications for Local Production of Medicines in the East African Community	Nirmalya Syam
60	January 2015	Internationalization of Finance and Changing Vulnerabilities in Emerging and Developing Economies	Yılmaz Akyüz
61	March 2015	Guidelines on Patentability and Access to Medicines	Germán Velásquez
62	September 2015	Intellectual Property in the Trans-Pacific Partnership: Increasing the Barriers for the Access to Affordable Medicines	Carlos M. Correa
63	October 2015	Foreign Direct Investment, Investment Agreements and Economic Development: Myths and Realities	Yılmaz Akyüz
64	February 2016	Implementing Pro-Competitive Criteria for the Examination of Pharmaceutical Patents	Carlos M. Correa
65	February 2016	The Rise of Investor-State Dispute Settlement in the Extractive Sectors: Challenges and Considerations for African Countries	Kinda Mohamadieh and Daniel Uribe
66	March 2016	The Bolar Exception: Legislative Models and Drafting Options	Carlos M. Correa
67	June 2016	Innovation and Global Intellectual Property Regulatory Regimes: The Tension between Protection and Access in Africa	Nirmalya Syam and Viviana Muñoz Tellez
68	June 2016	Approaches to International Investment Protection: Divergent Approaches between the TPPA and Developing Countries' Model Investment Treaties	Kinda Mohamadieh and Daniel Uribe
69	July 2016	Intellectual Property and Access to Science	Carlos M. Correa
70	August 2016	Innovation and the Global Expansion of Intellectual Property Rights: Unfulfilled Promises	Carlos M. Correa
71	October 2016	Recovering Sovereignty Over Natural Resources: The Cases of Bolivia and Ecuador	Humberto Campodonico
72	November 2016	Is the Right to Use Trademarks Mandated by the TRIPS Agreement?	Carlos M. Correa
73	February 2017	Inequality, Financialization and Stagnation	Yılmaz Akyüz

74	February 2017	Mitigating the Regulatory Constraints Imposed by Intellectual Property Rules under Free Trade Agreements	Carlos M. Correa
75	March 2017	Implementing Farmers' Rights Relating to Seeds	Carlos M. Correa
76	May 2017	The Financial Crisis and the Global South: Impact and Prospects	Yılmaz Akyüz
77	May 2017	Access to Hepatitis C Treatment: A Global Problem	Germán Velásquez
78	July 2017	Intellectual Property, Public Health and Access to Medicines in International Organizations	Germán Velásquez
79	September 2017	Access to and Benefit-Sharing of Marine Genetic Resources beyond National Jurisdiction: Developing a New Legally Binding Instrument	Carlos M. Correa
80	October 2017	The Commodity-Finance Nexus: Twin Boom and Double Whammy	Yılmaz Akyüz
81	November 2017	Promoting Sustainable Development by Addressing the Impacts of Climate Change Response Measures on Developing Countries	Martin Khor, Manuel F. Montes, Mariama Williams, and Vicente Paolo B. Yu III
82	November 2017	The International Debate on Generic Medicines of Biological Origin	Germán Velásquez
83	November 2017	China's Debt Problem and Rising Systemic Risks: Impact of the global financial crisis and structural problems	Yuefen LI
84	February 2018	Playing with Financial Fire: A South Perspective on the International Financial System	Andrew Cornford
85	Mayo de 2018	Acceso a medicamentos: experiencias con licencias obligatorias y uso gubernamental- el caso de la Hepatitis C	Carlos M. Correa y Germán Velásquez
86	September 2018	US' Section 301 Actions : Why They are Illegitimate and Misguided	Aileen Kwa and Peter Lunenborg
87	November 2018	Stemming 'Commercial' Illicit Financial Flows & Developing Country Innovations in the Global Tax Reform Agenda	Manuel F. Montes, Daniel Uribe and Danish
88	November 2018	Assessment of South-South Cooperation and the Global Narrative on the Eve of BAPA+40	Yuefen LI
89	November 2018	History and Politics of Climate Change Adaptation at the United Nations Framework Convention on Climate Change	Harjeet Singh and Indrajit Bose
90	December 2018	Compulsory Licensing Jurisprudence in South Africa: Do We Have Our Priorities Right?	Yousuf A Vawda
91	February 2019	Key Issues for BAPA+40: South-South Cooperation and the BAPA+40 Subthemes	Vicente Paolo B. Yu III

92	March 2019	Notification and Transparency Issues in the WTO and ' November 2018 Communication	Aileen Kwa and Peter Lunenborg
93	March 2019	Regulating the Digital Economy: Dilemmas, Trade Offs and Potential Options	Padmashree Gehl Sampath
94	April 2019	Tax Haven Listing in Multiple Hues: Blind, Winking or Conniving?	Jahanzeb Akhtar and Verónica Grondona
95	July 2019	Mainstreaming or Dilution? Intellectual Property and Development in WIPO	Nirmalya Syam
96	Agosto 2019	Antivirales de acción directa para la Hepatitis C: evolución de los criterios de patentabilidad y su impacto en la salud pública en Colombia	Francisco A. Rossi B. y Claudia M. Vargas P.
97	August 2019	Intellectual Property under the Scrutiny of Investor-State Tribunals Legitimacy and New Challenges	Clara Ducimetière
98	September 2019	Developing Country Coalitions in Multilateral Negotiations: Addressing Key Issues and Priorities of the Global South Agenda	Adriano José Timossi
99	September 2019	Ensuring an Operational Equity-based Global Stocktake under the Paris Agreement	Hesham AL-ZAHRANI, CHAI Qimin, FU Sha, Yaw OSAFO, Adriano SANTHIAGO DE OLIVEIRA, Anushree TRIPATHI, Harald WINKLER, Vicente Paolo YU III
100	December 2019	Medicines and Intellectual Property: 10 Years of the WHO Global Strategy	Germán Velásquez
101	December 2019	Second Medical Use Patents – Legal Treatment and Public Health Issues	Clara Ducimetière
102	February 2020	The Fourth Industrial Revolution in the Developing Nations: Challenges and Road Map	Sohail Asghar, Gulmina Rextina, Tanveer Ahmed & Manzoor Illahi Tamimy (COMSATS)
103	February 2020	Eighteen Years After Doha: An Analysis of the Use of Public Health TRIPS Flexibilities in Africa	Yousuf A Vawda & Bonginkosi Shozi
104	March 2020	Antimicrobial Resistance: Examining the Environment as Part of the One Health Approach	Mirza Alas
105	March 2020	Intersección entre competencia y patentes: hacia un ejercicio pro-competitivo de los derechos de patente en el sector farmacéutico	María Juliana Rodríguez Gómez
106	March 2020	The Comprehensive and Progressive Agreement for the Trans-Pacific Partnership: Data Exclusivity and Access to Biologics	Zeleke Temesgen Boru

107	April 2020	Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents	Carlos M. Correa
108	April 2020	Public Health and Plain Packaging of Tobacco: An Intellectual Property Perspective	Thamara Romero
109	May 2020	Non-Violation and Situation Complaints under the TRIPS Agreement: Implications for Developing Countries	Nirmalya Syam
110	May 2020	Estudio preliminar del capítulo sobre propiedad intelectual del acuerdo MERCOSUR – UE	Alejandra Aoun, Alejo Barrenechea, Roxana Blasetti, Martín Cortese, Gabriel Gette, Nicolás Hermida, Jorge Kors, Vanesa Lowenstein, Guillermo Vidaurreta
111	May 2020	National Measures on Taxing the Digital Economy	Veronica Grondona, Abdul Muheet Chowdhary, Daniel Uribe
112	June 2020	La judicialización del derecho a la salud	Silvina Andrea Bracamonte and José Luis Cassinerio
113	June 2020	La evolución de la jurisprudencia en materia de salud en Argentina	Silvina Andrea Bracamonte and José Luis Cassinerio
114	June 2020	Equitable Access to COVID-19 Related Health Technologies: A Global Priority	Zeleke Temesgen Boru
115	July 2020	Special Section 301:US Interference with the Design and Implementation of National Patent Laws	Dr. Carlos M. Correa
116	August 2020	The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic	Frederick Abbott
117	September 2020	Data in Legal Limbo: Ownership, sovereignty, or a digital public goods regime?	Dr. Carlos M. Correa
118	September 2020	Re-thinking Global and Local Manufacturing of Medical Products After COVID-19	Dr. German Velásquez
119	October 2020	TRIPS Flexibilities on Patent Enforcement: Lessons from Some Developed Countries Relating to Pharmaceutical Patent Protection	Joshua D. Sarnoff
120	October 2020	Patent Analysis for Medicines and Biotherapeutics in Trials to Treat COVID-19	Srividya Ravi
121	November 2020	The World Health Organization Reforms in the Time of COVID-19	German Velásquez
122	November 2020	Analysis of the Overcapacity and Overfishing Pillar of the WTO Fisheries Subsidies Negotiations	Peter Lunenborg

123	November 2020	The United Nations Declaration on the Rights of Peasants and Other People Working in Rural Areas: One Step Forward in the Promotion of Human Rights for the Most Vulnerable	Maria Natalia Pacheco Rodriguez and Luis Fernando Rosales Lozada
124	November 2020	Practical Implications of 'Vaccine Nationalism': A Short-Sighted and Risky Approach in Response to COVID-19	Muhammad Zaheer Abbas, PhD
125	December 2020	Designing Pro-Health Competition Policies in Developing Countries	Vitor Henrique Pinto Ido
126	December 2020	How Civil Society Action can Contribute to Combating Antimicrobial Resistance	Mirza Alas Portillo
127	December 2020	Revisiting the Question of Extending the Limits of Protection of Pharmaceutical Patents and Data Outside the EU – The Need to Rebalance	Daniel Opoku Acquah
128	February 2021	Intellectual Property in the EU–MERCOSUR FTA: A Brief Review of the Negotiating Outcomes of a Long-Awaited Agreement	Roxana Blasetti In collaboration with Juan I. Correa
129	March 2021	The TRIPS waiver proposal: an urgent measure to expand access to the COVID-19 vaccines	Henrique Zeferino de Menezes
130	April 2021	Misappropriation of Genetic Resources and Associated Traditional Knowledge: Challenges Posed by Intellectual Property and Genetic Sequence Information	Nirmalya Syam and Thamara Romero
118	June 2021	Repensando la fabricación mundial y local de productos médicos tras el COVID-19	Germán Velásquez
131	June 2021	TRIPS Flexibilities and TRIPS-plus Provisions in the RCEP Chapter on Intellectual Property: How Much Policy Space is Retained?	Vitor Henrique Pinto Ido
132	June 2021	Interpreting the Flexibilities Under the TRIPS Agreement	Carlos M. Correa
133	August 2021	Malaria and Dengue: Understanding two infectious diseases affecting developing countries and their link to climate change	By Mirza Alas
134	September 2021	Restructuring the Global Vaccine Industry	Felix Lobo
135	September 2021	Implementation of a TRIPS Waiver for Health Technologies and Products for COVID-19: Preventing Claims Under Free Trade and Investment Agreements	Carlos M. Correa, Nirmalya Syam and Daniel Uribe

International Environment House 2
Chemin de Balexert 7-9
POB 228, 1211 Geneva 19
Switzerland

Telephone: (41) 022 791 8050
E-mail: south@southcentre.int

Website:
http://www.southcentre.int

ISSN 1819-6926