Open letter asking 37 WTO Members to declare themselves eligible to import medicines manufactured under compulsory license in another country,

under 31bis of TRIPS Agreement

Posted on April 7, 2020 by James Love

Background

In 2001, the World Trade Organization (WTO) began negotiations on the rules regarding patents and access to medicine. While several issues were clarified and resolved in the November 2001 "Doha Declaration on TRIPS and Public Health", the negotiations took nearly two more years to adopt on August 30, 2003, a decision that was a limited "waiver of the export restriction" on medicines and diagnostic tests manufactured under a compulsory license. The final resolution was complicated. Among the controversial features was the definition of an "eligible importing member", which allowed WTO members to declare themselves ineligible in some cases or in all cases. In 2017, this decision became a formal amendment to the TRIPS agreement. Today 37 members of the WTO are listed as ineligible to import medicines manufactured in another country under a compulsory license, including the governments of Australia, Canada, Iceland, Japan, New Zealand, Norway, Switzerland, the United Kingdom, United States, and the European Union, including the following member states: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden.

On April 7, 2020, more than 30 groups and three dozen experts on health, law and trade sent an open letter to those 37 WTO members, asking that "countries to notify the WTO that they have changed their policy and now

considers itself an eligible importing country, and in addition, to also use whatever legal means are available to revoke the opt-out as importing members, for goods manufactured under a compulsory license."

The letter follows, followed by comments from several of the persons signing the letter as individuals or through their groups.

April 7, 2020

Open Letter to Governments of Australia, Canada, Iceland, Japan, New Zealand, Norway, Switzerland, the United Kingdom, United States, and the European Union, including the following member states: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden

Re: Opt-out as Eligible Importer for TRIPS Article 31.bis, Even during an Emergency

Dear all,

We are writing to ask that your government reverse an earlier decision to voluntarily opt-out of a mechanism in the World Trade Organization (WTO) rules on patents that provides an exception for compulsory licensing rules, to enable WTO members to import drugs, vaccines or diagnostic tests manufactured under a compulsory license in another country.

The technical details can be complicated, particularly for those who are not experts on both intellectual property rights and WTO rules, but at its core, the issue is fairly simple. Until 2001, the WTO rules made compulsory licensing of patented inventions of limited use, by requiring,

in Article 31(f) of the TRIPS Agreement, that the sale of goods manufactured under a compulsory license be limited "predominantly for the supply of the domestic market."/1/

The restriction on exports had the practical effect of making it very difficult for a country with a small market or a lack of domestic manufacturing capacity to benefit from compulsory licensing. It also made goods manufactured under a compulsory license more expensive, by limiting the economies of scale that could be achieved by selling goods globally.

While there are some exceptions and possible workarounds of this restriction, the WTO recognized that Article 31(f) created an unwanted barrier regarding access to medical inventions, and in a series of actions from 2001 to 2017,/2/ enacted a new Article 31bis, which provided a new exception to the Article 31(f) restriction on exports.

Article 31(f) of the TRIPS Agreement is just 20 words. The new Article 31bis,/3/, which modified the restriction on exports, is more than 2,400 words, including all of its annexes and protocols, and has been criticized for its complexity and burdensome nature. Nonetheless, it provides a mechanism for countries to both export and import drugs, vaccines and diagnostic tests manufactured under a compulsory license. The ability of countries to import and export these technologies may prove critically important during the COVID-19 pandemic, as well as under future health emergencies.

During the negotiation, the United States and the European Commission led an effort to pressure higher income countries to opt-out of the agreement as importers.

The definition of an "eligible importing Member" in Article 31bis states that "it being understood that a Member may notify at any time that it will use the system in whole or in a

limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use."

The definition states further that "some Members will not use the system as importing Members/footnote 3/." The countries identified in footnote 3 were: "Australia, Canada, the European Communities with, for the purposes of Article 31bis and this Annex, its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States." Since the decision was adopted, some countries have joined the European Union, and the United Kingdom of Great Britain and Northern Ireland have left.

We are asking that your government notify the WTO that it has now decided that it will use the system in whole or in a limited way. Such a notification might be unqualified, or it might be limited to the case of national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use. In light of the current COVID-19 pandemic, which is wreaking havoc on global health and the global economy, it is obvious that it is not in any WTO member's interest that any member opts-out as an importer.

The Financial Times, a leading voice for the interests of shareholders and a robust proponent of trade, has itself called for compulsory licensing of patents on COVID-19 drugs or vaccines./4/ The rationale for such action was as follows:

> "Some will counter that domestic production is the only reliable source of supply. The virus has demonstrated the falsity of this: if the sole domestic factory is located in an area in lockdown its supply can disappear. Diversity of sources of supply, together with stockpiling for emergencies, is the safest policy. Another vital trade policy issue will arise in the near future: the licensing of drugs and vaccines effective against the virus. The world has an overwhelming interest in ensuring these will be

> universally and cheaply available. Fortunately, trade rules allow compulsory licensing. If necessary, it must be used."

Because of global supply chains, countries may need access to active pharmaceutical ingredients and other essential medical components, manufactured elsewhere but patent protected at home. They may also need access to finished products, if domestic supplies or manufacturing capacity are insufficient. It's totally irrational for any country, even a rich country, to keep its own hands tied to meet the COVID-19 needs of its population by voluntarily shutting itself off from patented ingredients, components, and essential medical products and supplies.

Moreover, it is not only irrational in the sense that the opting out works against the opting out countries' self-interest. Those who opt out (especially when they are rich countries with developed and relatively well funded health systems) do not only harm themselves but also harm other countries who are willing to use compulsory licenses. When they opt out they decrease the potential market for drugs, vaccines, medical devices, or diagnostic tests manufactured under a compulsory license in another country. As a result, manufacturers in countries who use compulsory licenses can expect to sell fewer quantities. This may prevent them from benefiting from economies of scale, which could mean they would have to charge higher prices or forego production altogether. Therefore, those rich countries should not only think about their own self-interest, but also should also consider their less wealthy neighbors.

The current WTO rules are flawed in several ways. One reform that clearly should be addressed immediately is for countries to notify the WTO that they have changed their policy and now consider itself an eligible importing country, and in addition, to also use whatever legal means are

available to revoke the opt-out as importing members, for goods manufactured under a compulsory license.

Sincerely (Organizations first, followed by individuals, both listed alphabetically).

Organizations

Access to Medicines Ireland
Asociacion por un Acceso Justo al Medicamento, Spain
AIDES (France)
ARAS – the Romanian Association Against AIDS
Asociación por un Acceso Justo al Medicamento, Spain
BEUC (Bureau Européen des Unions de Consommateurs)
Consumer Action (USA)
Consumer Association the Quality of Life-EKPIZO
Global Justice Now
Groupe Sida Genève
Health Action International (HAI)
Health Gap
Institute for Agriculture and Trade Policy
International Center for Technology Assessment
International Treatment Preparedness Coalition (ITPC)
KEI Europe
Knowledge Ecology International (KEI)
LWC Health
Médecins Sans Frontières Access Campaign
Prescrire
Public Citizen
Public Eye
Public Health Association of Australia
Public Health Association of New Zealand
Salaried Medical Specialists/ Toi Mata Hauora, New Zealand
Salud por Derecho
STOPAIDS
T1International

TransAtlantic Consumer Dialogue (TACD)
Treatment Action Group (TAG)
Union for Affordable Cancer Treatment (UACT)
Universities Allied for Essential Medicines (UAEM)
Vrijschrift Foundation
World Privacy Forum
Yolse

Individuals

Aidan Hollis, Professor of Economics, University of Calgary, Canada
Anupam Chander, Professor of Law, Georgetown University
Ariel Katz, Associate Professor at the Faculty of Law, University of Toronto, Canada
Benjamin Mason Meier, Associate Professor of Global Health Policy, University of North Carolina at Chapel Hill, USA
Brook K. Baker, Professor, Northeastern University School of Law, Senior Policy Analysis Health GAP
Christopher Jon Sprigman, Professor of Law, New York University School of Law
David Hammerstein, former Member of the European Parliament
Deborah Gleeson, Senior Lecturer in Public Health, La Trobe University, Australia
Elena Petelos, SRF in Public Health, Lecturer in EBM and EIP, CSFM, University of Crete, Greece
Ellen ‘t Hoen LLM PhD, Director, Medicines Law & Policy and University Medical Centre Groningen, the Netherlands
Fiona Macmillan, Professor of Law, Birkbeck, University of London
Frederick Abbott, Edward Ball Eminent Scholar Prof. of Law, Florida State University College of Law, USA
Graham Dutfield, Professor of International Governance, School of Law, University of Leeds, United Kingdom

Howard Knopf, Macera & Jarzyna LLP, Ottawa, Canada
Irene Calboli, Professor of Law, Texas A&M University School of Law
James Andrew Elliott, Canada. T1International Trustee
Jan De Maeseneer, Professor Emeritus, Department of Public Health and Primary Care, Ghent University, Belgium.
Jane Kelsey, Professor of Law, The University of Auckland, New Zealand
Jerome H. Reichman, Bunyan S. Womble Professor of Law, Duke Law School
Joel Lexchin MD, Professor Emeritus, School of Health Policy and Management, Faculty of Health, York University, Toronto ON, Canada
Jordan Jarvis, MSc, DrPH Candidate, London School of Hygiene & Tropical Medicine, UK; Research Affiliate, MAP-Centre for Urban Health Solutions, St. Michael's Hospital, Toronto, Canada
Joseph Stiglitz, University Professor, Columbia University, and recipient of the Sveriges Riksbank Prize in Economic Sciences in Memory of Alfred Nobel 2001
Julia Reda, former Member of the European Parliament
Ken Shadlen, Professor of Development Studies and Head of Department, Department of International Development, London School of Economics and Political Science (LSE)
Kristine Husøy Onarheim, MD, PhD., Institute for Global Health, University College London and Bergen Centre for Ethics and Priority Setting, University of Bergen
Margo A. Bagley, Asa Griggs Candler Professor of Law, Emory University School of Law, Faculty Fellow, Emory Global Health Initiative (EGHI), Collaborator, Harvard University Global Access in Action (GAiA) Program
Matthew Herder, Associate Professor, Faculties of Medicine & Law, Dalhousie University, Canada
Michael A. Geist, Professor, University of Ottawa, Faculty of

Law
Myra J. Tawfik, Professor of Law, EPICentre Professor of IP Commercialization and Strategy, University of Windsor, Canada
Pascale Chapdelaine, Associate Professor, University of Windsor Faculty of Law. Ontario, Canada
Prudence Stone, PhD. CEO at Public Health Association of New Zealand
Richard Laing, Professor, Department of Global Health, Boston University School of Public Health
Rochelle Dreyfuss, Pauline Newman Professor of Law, NYU School of Law and Arthur Goodhart Visiting Professor in Legal Science University of Cambridge
Ronald Labonté, FCAHS, HonFFPH, Professor and Distinguished Research Chair in Globalization and Health Equity, School of Epidemiology and Public Health, University of Ottawa, Canada
Ruth Lopert, Adjunct Professor, Dept of Health Policy and Management, George Washington University
Sean Flynn, American University Washington College of Law
Shyamkrishna Balganesh, Professor of Law, University of Pennsylvania Law School.
Suerie Moon, Global Health Centre, Graduate Institute of International and Development Studies, Geneva, Switzerland
Susan K. Sell, Professor, School of Regulation and Global Governance, College of Asia and the Pacific, Australian National University
Thiru Balasubramaniam, Member of the Coordination Committee, European Alliance for Responsible R&D and Affordable Medicines
Trudo Lemmens (LicJur, LLM bioethics, DCL), Professor and Scholl Chair in Health Law and Policy, Faculty of Law, University of Toronto, Canada

Professor Dr. Uma Suthersanen, Chair in International Intellectual Property Law Centre for Commercial Law Studies, Queen Mary University of London
Yannis Natsis, Management Board member, European Medicines Agency

Footnotes

1. Article 31(f) states: “any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.” https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_oth.pdf

2. William New. “It’s Official: TRIPS Health Amendment In Effect, First Ever To A WTO Agreement,” January 23, 2017, INTELLECTUAL PROPERTY WATCH, https://www.ip-watch.org/2017/01/23/official-trips-health-amendment-effect-first-ever-wto-agreement/

3. WTO ANALYTICAL INDEX, TRIPS Agreement – Article 31bis (Practice) https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_bis_oth.pdf

4. THE EDITORIAL BOARD: Coronavirus must not destroy an open world economy – The global health emergency makes trade more important, not less, March 27, 2020. https://www.ft.com/content/4a3bf282-701c-11ea-9bca-bf503995cd6f

ANNEX, definition of “eligible importing Member”

https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_bis_oth.pdf

(b) “eligible importing Member” means any least-developed country Member, and any other Member that has made a

notification/2/ to the Council for TRIPS of its intention to use the system set out in Article 31bis and this Annex ("system") as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system as importing Members/3/ and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency

(footnote original) 2 It is understood that this notification does not need to be approved by a WTO body in order to use the system.

(footnote original) 3 Australia, Canada, the European Communities with, for the purposes of Article 31bis and this Annex, its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States.

Additional commentary

Tuesday, 7 April 2020

Joseph Stiglitz, University Professor, Columbia University, and recipient of the Sveriges Riksbank Prize in Economic Sciences in Memory of Alfred Nobel 2001
"Life should always be put before profits, and never more so than in the midst of a pandemic. The WTO should not have rules that deliberately create barriers to importing needed drugs, whether it's rich countries or poor; and especially so because those rules limit the ability of firms to achieve efficient economies of scale. The opt-out provision in Article 31bis is protectionism at its worst—where it is lives that may be lost as a result–and something clearly not in the interests

of any country, large or small, importer or exporter, during the COVID-19 crisis."

James Love, Director, Knowledge Ecology International
"In 2003, the WTO concluded a negotiation to correct a known flaw in the TRIPS agreement. The ability to benefit from a compulsory license on a patent depends upon the ability to obtain a product from a competitive supplier, such as, in the case of medicine, a company that sells generic versions. It won't always be the case that a supplier capable of manufacturing a good is located in your own country, and even if one exists, it may not be able to meet local demand, or operate efficiently. Access to know-how is often important, particularly when time is of the essence. Economies of scale are not some minor issue you can forget after your first economics class. If you want cheap affordable drugs, vaccines and tests, being able to export and import is part of the solution. It is absolutely a scandal that 37 members of the WTO have made themselves ineligible to import, even in cases of health emergencies. This needs to be fixed, for the current pandemic, and for the next health crisis, which will surely follow someday."

Thiru Balasubramaniam, Member of the Coordination Committee, European Alliance for Responsible R&D and Affordable Medicines
"In 2005, the well-seasoned trade negotiators from the European Union abdicated their responsibility to their populace when they opted out of trade rules that would permit the importation of medicines issued under a compulsory license. In the midst of the Covid-19 pandemic, this lack of foresight could have devastating consequences. To remedy this protectionist lapse of reason, the European Union should notify the World Trade Organization of its intention to use the Article 31bis system as an eligible importing member, and revoke its decision to opt-out as an

importing member, for goods manufactured under a compulsory license."

Brook K. Baker, Senior Policy Analyst Health GAP (Global Access Project)
"Even rich countries should have foreseen that they might face crises like COVID-19 and might lack sufficient access to patent-protected active pharmaceutical ingredients, final formulations of medicines, and many other health products and components in the global supply chain that they could not produce domestically, even if they were to issue a compulsory or government use license. Although they were shortsighted 17 years ago into signing onto a US/EU demand to opt out of the Article 31 bis production-for-export solution, they can reverse that error now by revoking this ill-considered decision that might otherwise bar them from getting needed quantities of life-saving health products to prevent catastrophic deaths and economic collapse in their countries."

Pierre Chirac, Publication Manager, Prescrire
"In the next weeks and months, we expect medicines and vaccines to be able to fix this deadly pandemic; national IP laws should not be an obstacle to them."

Rochelle Dreyfuss, Pauline Newman Professor of Law, NYU School of Law and Arthur Goodhart Visiting Professor in Legal Science University of Cambridge
"The rapid spread of COVID-19 from country to country and continent to continent demonstrates the fundamental interconnectedness of the world's citizenry. In truth, no country can go it alone. We can no longer countenance a trade-off between global health and private wealth. The time has come to revise the international legal regime and national policies to ensure that everyone everywhere has access to essential medical technologies."

Patrick Durisch, Health Policy Expert, Public Eye

“As a small country, Switzerland would be wise to reverse its regrettable past decision to opt-out of TRIPS Art. 31bis mechanism as importing WTO member country. This would clearly be in the national interest as it provides an additional card to be played in such uncertain times should domestic access to affordable COVID-19 technologies be hampered.”

Graham Dutfield, Professor of International Governance, School of Law, University of Leeds, United Kingdom

“No country, however wealthy, can afford to tie its hands in the face of a global pandemic. Compulsory licensing is an essential policy tool for access to medicines, especially in emergencies requiring swift action, and must be fully available for all countries, and not for some.”

James Andrew Elliott, Canada. T1International Trustee

“Now is not the time for half-measures. Countries must use every available tool to beat this pandemic. This includes fully leveraging all rights available to countries under international law. As a citizen of Canada and the world I fully support the open letter on WTO TRIPS Article 31bis. I will also be encouraging my elected officials to act to ensure universal access to COVID 19 testing, treatment, and an eventual vaccine, both domestically and internationally.”

Sean Flynn, Professorial Lecturer and Director, Program on Information Justice and Intellectual Property, American University Washington College of Law

“It should be shocking that the US, under the Bush administration’s watch, would bow to pharmaceutical industry pressure and give up its right to import medicines and other critical patented technologies in an emergency. The emergency is here. If COVID saps our ability to produce necessary products in this country, we need the

right to import from where they can be made."

Michael Geist, Professor, University of Ottawa, Faculty of Law

"The COVID-19 global pandemic has placed the spotlight on how the shortsighted decision to opt-out of rules designed to facilitate access to life-saving drugs was a mistake that may cost lives. Those governments that voluntarily signed onto the restriction – including my own Canadian government – should swiftly rescind the opt-out before it is too late."

Tabitha Ha, STOPAIDS Advocacy Manager

"STOPAIDS urge the UK and other governments to reverse their previous opt-out as "eligible importers" under WTO rules on compulsory licensing. Equitable access to diagnostics, vaccines and medicines are essential for building resilient health systems that can effectively respond to COVID-19 and ongoing pandemics. Governments must reinforce their ability to import and export technologies that may be potentially useful in halting the spread of COVID-19 and saving lives in the UK and overseas."

David Hammerstein, former Member of the European Parliament

"In times of public health emergency affordable access to relevant technologies must take priority over intellectual property restrictions."

Dr Kieran Harkin, MRCPI, MICGP, Access to Medicines Ireland

"If Covid-19 is to teach us anything, it is that just as the public good cannot be left to the mercy of the market place, neither can public health be left to the mercy of the pharmaceutical industry."

Aidan Hollis, Professor of Economics, University of Calgary, Canada

“The Government of Canada has just revised the Patent Act for COVID-related needs, allowing a compulsory license to “make, construct, use and sell a patented invention.” What’s missing is the word “import”. If speed of response is critical, then let’s not close off our options, which should include importing. Requiring domestic production under a compulsory license is, moreover, anti-trade and contrary to the spirit of TRIPS.”

Ariel Katz, Associate Professor at the Faculty of Law, University of Toronto, Canada

When countries opt out of the flexibility explicitly recognizes in Article 31bis they do not only harm themselves. By opting out, they also decrease the potential market for products manufactured under a compulsory license in another country and therefore may prevent those producing them from achieving economies of scale, without which those products may only be available at higher prices or not at all. Therefore, those opting-out countries should not only think about their own self-interest, but also should also consider their less wealthy neighbours. The coronavirus does not recognize any legal limits to its global propagation. As all countries share the effort to combat the pandemic, countries should remove all laws that impede this collective effort.

Prof Jane Kelsey, Faculty of Law, The University of Auckland, New Zealand

“Whatever prompted our governments in 2003 to sign away our ability to access to medical supplies in an emergency, history is proving them wrong. They need to fix it now, not just for COVID-19 but permanently.”

Ruth Lopert, Adjunct Professor, Dept of Health Policy and Management, George Washington University

“Whether motivated by appeasement or hubris, it’s ironic

that in deciding to opt out, high income countries never anticipated the day they might themselves need 31bis."

Joel Lexchin MD, Professor Emeritus, School of Health Policy and Management, Faculty of Health, York University, Toronto ON, Canada

"It shouldn't take a crisis like COVID-19 to make people in power realize that compulsory licensing is a key factor in getting affordable medicines to people who need them."

Vanessa López, Co-founder and Executive Director, Salud por Derecho

"The TRIPS flexibilities are a response to shortages and high prices that governments must bear in mind now. The current context is unprecedented and the urgent priority is to safeguard the public interest and immediate attention to the population. Is not the time to enforce patents or data exclusive rights."

Dr. Burcu Kilic, Research Director, Access to Medicines, Public Citizen

"No government should be put in a position to choose between overprotecting patents and providing public access to treatments and vaccines. It's not too late to do the right thing. Possibly, there is no better time for countries to revisit their decision to op-out and declare themselves eligible importing countries. It is not time to discuss how to please Big Pharma, it is time to tackle this pandemic."

Monique Goyens, Director General, The European Consumer Organisation (BEUC)

"Governments must ensure that consumers have access to affordable vaccines, diagnostic tools and treatments. In times of a pandemic, the EU's Member States ought to make it possible to import these in order to avoid and mitigate any shortages."

Ellen 't Hoen LLM PhD, Director, Medicines Law &

Policy and University Medical Centre Groningen, the Netherlands

“‘Never say never’ – we said in 2003. I have never understood why any country would choose to paralyse itself, even in a medical emergency situation, the very moment when governments need to have maximum policy space to act.”

Ronald Labonté, School of Epidemiology and Public Health, University of Ottawa, Canada

“This will not be the last time we encounter something like COVID-19. Time finally to redesign the whole government/private sector/patent relationship for essential health care needs.”

Access to Medicine, Trade COVID-19, Patents and Health, WTO

WHO DIRECTOR-GENERAL REMARKS IN SUPPORT OF GLOBAL POOLING OF RIGHTS IN COVID-19 TECHNOLOGIES AND DATA, IN OPEN SCIENCE AND OPEN DATA

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