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The U.S. Posture on Global Access to Medication & The Case for Change

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The year 2020 marks the 25th anniversary of including intellectual property rights within the larger agenda of trade. While the marriage between trade and intellectual property was always uncomfortable, COVID-19 exposed the flaws, failures and the inadequacy of the trade agenda to harmonise intellectual property rights, particularly for patents in pharmaceuticals. Typically, the United States through its questionable United States Trade Representative (USTR) process exposed the vulnerabilities of the intellectual property systems of the rest of the world. COVID-19 exposed the manner in which the so-called 'superior' intellectual property regime of the US left the country with a weak health-care system. Testing, cost of medical care, lack of treatment, lack of quick access to doctors are all barriers that generally place the United States as having one of the worst health care systems compared to other developed economies. The onset of COVID-19 merely exacerbated the existing flaws to expose these vulnerabilities.

At a general level, other governments seemed to have been better prepared and certainly seem to have responded better. For example, in early 2020 Canadian lawmakers passed a bill that would allow the issuance of

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compulsory licenses for medical products.[1] A compulsory license would allow the government to license the manufacturing of any treatment or medication or medical device that could help contain the spread of or treat COVID-19 to either a public agency or a generic drug maker. The license will allow the product to be available at a lesser cost because it will be free of the shackles of patent monopoly. The right to compulsorily license a patent to preserve public health was memorialised by the World Trade Organization's (WTO) agreement on Intellectual Property known as the Trade-Related Aspects of Intellectual Property Rights (TRIPS),[2] and later reiterated vide the Doha Declaration on Public Health.[3]

Similarly, Germany has taken actions to ensure that patents are not a barrier to public health or to its health care policy.[4] Meanwhile, developing countries like Costa Rica have reached out to the World Health Organization (WHO) to develop an IP pool to create an open licensing system that will create more access and affordability.[5] Other countries have either already taken or are gearing up to take the same or similar measures to create access to treatments and enable research or testing to facilitate a vaccine or a cure.[6]

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[1] An Act respecting certain measures in response to COVID-19, Bill C-13, 43rd Parliament §31 (2020).
[2] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 14, Apr. 15, 1994, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).
[3] World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002).
[4] Act on the Protection of the Population in the Event of an Epidemic Situation of National Importance, Federal Law Gazette, Pt. 1-14, Mar. 27, 2020.
[5] WHO COVID-19 Technology Access Pool, World Health Organization (Jun. 1, 2021, 11:30 am), https://www.who.int/initiatives/covid-19-technology-access-pool.
[6]International community rallies to support open research and science to fight COVID-19, World Health Organization (Jun. 1, 2021, 11:45 am), https://www.who.int/news/item/29-05-2020-international-community-rallies-to-support-open-research-and-science-to-fight-covid-19.

Notably, these actions are legal under the relevant international law, that is, the WTO's TRIPS Agreement.[7] Just like the compulsory licensing flexibility mentioned earlier, the TRIPS Agreement permits a range of negotiated flexibilities during a public health crisis to prevent intellectual property from becoming a barrier to public health by way of respecting sovereign rights of a nation to prioritise public interests (including access to healthcare) over intellectual property rights. Specifically, Article 31 of the TRIPS Agreement allows governments to issue compulsory licenses, permitting generic companies to produce copies of patented products under certain conditions, usually including the payment of royalties to the patent holder.[8] Other forms of flexibilities include price control of pharmaceuticals and importation of generic drugs manufactured from other countries. Many of these were used during the AIDS pandemic successfully by developing countries albeit with resistance from the United States.[9] Currently, while countries are considering either flexibilities or, alternatively, cooperative R&D solutions, the U.S. FDA, on March 23, 2020, surprised the world by granting Gilead's drug Remdesivir an Orphan Drug status for the treatment of COVID-19, on grounds this is a rare disease.[10] The orphan drug status essentially allows the maker of a patented drug about 7 additional years of market exclusivity.[11] The objective of the Orphan Drug Act, 1983, under which the status is granted, was to encourage research on treatments for diseases that impact a small

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[7] TRIPS Agreement, *supra* note 2.
[8] *Id.*
[9] Reed Beall and Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, PLOS MEDICINE (Jan., 2012). *See also,* YUGANK GOYAL, COMPULSORY LICENSING: PRACTICAL EXPERIENCES AND WAYS FORWARD 22 (Reto M. Hilty et. al., 2015).
[10] Designating an Orphan Product: Drugs and Biological Products, USFDA (Jun. 1, 2021, 12 pm), https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designating-orphan-product-drugs-and-biological-products.
[11] Patents and Exclusivity, FDA/CDER SBIA Chronicles (June 1, 2021, 12:30 pm), https://www.fda.gov/media/92548/download.

number of patients – treatments with small markets.[12] That big pharma has misused the orphan drug provision to extend the exclusivity for known and patent-expired drugs has been reported extensively. When Remdesivir was granted the orphan drug status, KEI reported that Gilead developed Remdesivir using at least $79 million in U.S. government funding after the Ebola crisis to deal with future potential pandemics.[13] The backlash that resulted caused Gilead to announce that it will "waive all benefits associated" with the designation.[14] That the United States is not actively working to provide access, and instead considers regulatory and patent related exclusivities is appalling. Gilead's lack of public responsibility notwithstanding, the FDA's actions seemed completely dissociated with the ground realities. On March 26, 2020, the US recorded the highest number of COVID-19 cases. To provide a background, orphan drugs are meant to treat what is termed as an orphan disease, which are defined as diseases that affect fewer than 200,000 patients, for which, typically there is minimal incentive to innovate a new drug given the smaller market size. Getting the orphan drug status helps a drug that is otherwise available in the market to become exclusive to treat the identified orphan disease/condition. The exclusivity that ensues from the orphan classification helps a drug to avoid market competition by getting the orphan status. Giving Remdesfavir orphan status to treat COVID-19 is ironic considering that during that month the US was recording close to 3,000 patients a day. Thus, the orphan drug status to

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[12] Matthew Herder, *What Is the Purpose of the Orphan Drug Act*, PLOS MED (Jan., 2017).
[13] Kathryn Ardizzone, *Role of the Federal Government in the Development of Remdesivir*, KEI BRIEFING NOTE (2020), https://www.keionline.org/wp-content/uploads/KEI-Briefing-Note-2020_1GS-5734-Remdesivir.pdf.
[14] Gilead Sciences Statement on Request to Rescind Remdesivir Orphan Drug Designation, Gilead – Company Statements (Jun. 1, 2021, 12:45 pm), https://www.gilead.com/news-and-press/company-statements/gilead-sciences-statement-on-request-to-rescind-remdesivir-orphan-drug-designation.

Remdesfavir showcases how the FDA completely altered the incentive structure meant for getting the orphan status.

The FDA's actions, comports with the global trade posture of the U.S. which can be faulted for not appreciating the importance of public health for the globe and for other countries. In the face of a mounting COVID-19 outbreak, with the possibility of a shortage of medical equipment and supplies, the U.S. Trade Representative Robert Lighthizer, defended the trade posture with China which resulted in a shortage of medical supplies such as gloves and masks.

More importantly, it is true that historically the United States has actively worked against access to medication around the globe.[15] Be it with HIV, AIDS or SARS, when parts or all of the world has faced outbreaks of infectious diseases, the U.S. has ignored the multilateral systems and unilaterally used the powers of the Trade Act to oppose the fair use of negotiated flexibilities.[16]

To provide a background, the Trade Act, 1974 under Section 301 unilaterally authorises the office of the United States Trade Representative (USTR) to identify and pursue countries perceived as denying adequate and effective protection of intellectual property (IP) rights or fair and equitable market access to U.S. industries or entities that rely on IP protection.[17] Every year, USTR releases the Special 301 Report accusing various countries of having inadequate IP policies, and many of the alleged violations focus on

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[15] Aswathy Asok, *Compulsory Licensing For Public Health And USA's Special 301 Pressure: An Indian Experience*, JOURN. OF IPR 24, 125-131 (Sep.-Nov. 2019).
[16] JAKKRIT KUANPOTH, COMPULSORY LICENSING: PRACTICAL EXPERIENCE AND WAYS FORWARD 22 (Reto M. Hilty, et. al., 2015).
[17] 19 U.S.C § 2242; §182 of the Trade Act of 1974.

pharmaceutical patent protection.[18] Once identified, USTR applies direct and indirect pressure through trade negotiations and preference systems in order to win policy changes favored by U.S. IP-owning stakeholders in the identified countries. USTR seeks IP policy changes by amending laws, providing regulatory exclusivities, or directing the way specific laws are implemented. These changes typically fall in line with the expectations of the USTR without fully appreciating local realities, and target the TRIPS-based flexibilities that provide for access to medications. Laws and amendments made in other countries to ensure access to medication form a huge part of the Special 301 Report, such that developing countries typically assert that USTR works to take away negotiated TRIPS flexibilities to provide access to medication. The U.S. Special 301 Report routinely promotes levels of intellectual property protection that exceed what is required by the TRIPS Agreement, termed now as TRIP-Plus provisions.

The COVID-19 crisis makes it imperative for all countries to fully use TRIPS flexibilities. Thus, while internally the U.S. will have to reconsider much of the currently prevailing health-care systems, not much has been said about how COVID-19 could affect the role of the USTR on the issue of pharmaceutical patenting and trade. In order to show the extent to which USTR has targeted the use of TRIPS flexibilities in the Special 301 Report, we reviewed countries that have used TRIPS flexibilities in the past to tackle different health crisis such as AIDS, SARS, Zika, etc. In gist, we specifically examined reactions of the USTR when a country used TRIPS flexibilities by considering the subsequent placement of that country on the Special 301 Lists and the reason for the placement.

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[18] Special 301, Office of the United States Trade Representative (Jun. 1, 2021, 12:05 pm), https://ustr.gov/issue-areas/intellectual-property/Special-301.

To do this, we used the most comprehensive source of data on the use of TRIPS flexibilities — the TRIPS Flexibilities Database — compiled by Medicines Law and Policy.[19] It contains examples of use of compulsory licenses, patent exceptions, parallel imports, LDC transition provisions by countries and outlines the flexibility used in order to access generic medicines. The database is one of the more comprehensive set of data on use of flexibilities. The list does not claim to be exhaustive, but it contains many instances of use of these flexibilities and thus helps to make the correlation between the use of flexibilities and reaction of the USTR. There are a total of 79 countries in the database. Some countries have used TRIPS flexibilities more than once, and the database includes each instance of a country's use of flexibilities.

In reviewing countries that have used TRIPS flexibilities and subsequent (re)actions of the USTR through Special 301 listings with a keen eye on the access to medication question, we found the following:

First, we found that 93% of people living in countries that used flexibilities are from countries that were placed on a Special 301 List the year after their government issued a compulsory license.

The countries that are included in the Special 301 Report are often large markets. China, India, Indonesia and Brazil are on the Special 301 Lists each year. Based on the most recent World Bank data, 4.5 billion people live in the non-African countries that used TRIPS flexibilities, and 4.2 billion them live

[19] The TRIPS Flexibility Database, Medicines Law & Policy (Jun. 1, 2021, 12:07 pm), http://tripsflexibilities.medicineslawandpolicy.org/.

in countries that were listed in the Special 301 Report the year after they first used or planned to use a TRIPS flexibility – or 93%.[20]

Second, the world's total population is 7.5 billion people. Considering the population of the countries that have been placed on the Special 301 list for having included TRIPS flexibilities, a whopping 56% of the world's population today live in countries that were placed on a Special 301 List the year after their government used (or planned to use) a TRIPS flexibility.

Thus, directly or indirectly, the USTR's actions has affected access to medication for over half of the world's population outside of the United States.

Third, 61% of the (non-African) countries that used TRIPS flexibilities were included on the Special 301 List of the immediately following year. Importantly, the report generally has not included Sub-Saharan African countries for reasons related to intellectual property and healthcare. A Presidential Executive Order, 13155, issued by the U.S. in 2000, which was a fall-out considering the AIDS crisis and its devastating effect on Africa, stated that "the United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy" used by Sub-Saharan African countries to fight HIV/AIDS. The Executive Order was a by-product of negotiation by the African Union after AIDS ravaged the continent in early 2000s.

Notably, out of the 79 countries in the TRIPS Flexibilities Database, 41 are located in Sub-Saharan Africa. Out of the remaining 38 (non-Sub-Saharan

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[20] The most recent publicly available World Bank population data is from 2018. The World Bank databank does not include statistics on Taiwan, so here we use UN data for the same year, compiled by Worldometer.

African) countries, 23 were included on one of the Special 301 Lists the year following their use of a TRIPS flexibility. That amounts to 61%. That is, all of these 38 countries had considered seriously, or, issued or, begun the process of issuing (a) compulsory license(s) for a medicine. It is notable that USTR rarely uses the explicit term "compulsory license" when identifying countries as having inadequate intellectual property protection. USTR will often pair specific grievances with other, vague complaints about a list country's intellectual property landscape. For instance, even in the 2019 Special 301 Report, along with specific complaints about India USTR noted that IPR protection concerns remained about India due to inadequate laws and ineffective enforcement – which really could pertain to anything but was essentially a fall out from the one compulsory license India issued to cover Bayer's Nexavar in 2012. But, each of these notations of the USTR have historically prevented access to medication. Also, with countries like India, a one-time use of TRIPS flexibility has resulted in Special 301 mention for several years such that it becomes a deterrent for the country to use that or another flexibility again.

The table below highlights countries that used TRIPS Flexibilities and Placement on Special 301 Lists. Importantly, the table highlights how unilateral PWL status, arguably in violation of the World Trade Organization's multilateral dispute settlement process, ensues from the Office of the USTR, as a consequence of sovereign national action which was in comport with negotiated TRIPS flexibilities. Importantly, countries like India have been featured with PWL status, which needed to comply with the State of Administrative Action submitted to ensure compliance with the multilateral dispute settlement process as outlined in the opinion in *Special*

301-310 of the Trade Act, 1974.[21] Nevertheless, it is important for readers to know that one violation typically ensues in several years of featuring – most often, unfairly in the Special 301 report by the USTR such as with India.

Country	First Year Using TRIPS Flexibility	Placed on a Special 301 List the Following Year?[22]	Type of Flexibility	Flexibility Executed	Population
Argentina	2005	Yes	Art 31	No	44,494,502
Belarus	2005	Yes	Art 31	Yes	9,485,386
Brazil	2001	Yes	Art 31	Yes	209,469,333
Canada	2007	Yes	Art 31 bis	No	37,058,856
Chile	2018	Yes	Art 31	Pending	18,729,160
China	2005	Yes	Art 31	Yes	1,392,730,000
Colombia	2014	Yes	Art 31	Pending	49,648,685
Ecuador	2003	Yes	Art 31 bis	No	17,084,357

[21] United States – Sections 301-310 of the Trade Act of 1974, World Trade Organization, WT/DS152/14 (Feb. 28, 2000).

[22] Many of these countries were on the Priority Watch List *before* using the TRIPS flexibility for various reasons. For example, India was on the PWL for not amending the patent statute from 2005. In 2005, India amended its patent statute to conform to TRIPS but was *again* featured in the Special 301 list as a consequence for using negotiated flexibilities ***several times***.

Guatemala	2005	Yes	Art 31	-	17,247,807
India	2008	Yes	Art 31	No	1,352,617,328
Indonesia	2004	Yes	Art 31	Yes	267,663,435
Italy	2005	Yes	Art 31	Yes	60,431,283
Korea	2002	Yes	Art 31	No	51,635,256
Malaysia	2003	Yes	Art 31	Yes	31,528,585
Pakistan	2006	Yes	Art 31	Yes	212,215,030
Peru	2013	Yes	Art 31	Pending	31,989,256
Philippines	2005	Yes	Art 31	Yes	106,651,922
Romania	2015	Yes	Art 31	Pending	19,473,936
Russia	2018	Yes	Art 31	Yes	144,478,050
Taiwan (Chinese Taipei)	2005	Yes	Art 31	Yes	23,726,460
Tajikistan	2005	Yes	Art 31	Yes	9,100,837
Thailand	2006	Yes	Art 31	Yes	69,428,524
Ukraine	2004	Yes	Art 31	Yes	44,622,516
Albania	2004	No	Par 7	Yes	2,866,376
Azerbaijan	2011	No	Art 31	Yes	9,942,334

Cambodia	2005	No	Par 7	Yes	16,249,798
Cuba	2004	No	Art 31	Yes	11,338,138
Georgia	2006	No	Art 31	Yes	3,731,000
Germany	2016	No	Art 31	Yes	82,927,922
Guyana	2005	No	Art 31	Yes	779,004
Haiti	2005	No	Par 7	Yes	11,123,176
Honduras	2005	No	Art 31	Yes	9,587,522
Mongolia	2007	No	Art 31	Yes	3,170,208
Myanmar	2005	No	Art 31	Yes	53,708,395
Nepal	2007	No	Par 7	Yes	28,087,871
Norway	2018	No	Art 31	No	5,314,336
Papua New Guinea	2007	No	Art 31	Yes	8,606,316
United Kingdom	2015	No	Art 31	Pending	66,488,991

Within the U.S., COVID has exposed the lacunas of a health care system that is inaccessible to many Americans. Even when accessible, the bureaucracy of a system that is completely privatised makes both access and affordability a rigorous exercise. COVID-19 will necessarily raise questions about the flaws of the healthcare system in the United States.

Along the same vein, COVID-19 raises important issues about innovation and access to health care globally. The world will be forced to consider whether the IP maximalist rhetoric of trade and innovation that has been used by USTR and the WTO to undermine public health, is, in turn, creating a worse barrier to public health. COVID-19 has also increased the significance of finding an integrated solution that includes the access question into the larger debate on trade and innovation. It has highlighted that a public health crisis in one part of the world can affect the globe, global trade, and all that the U.S. and the WTO stands for in unimaginable ways. COVID-19 has underscored the need for a balance between innovation and access.

For the U.S., COVID-19 has undermined the carefully constructed rhetoric that stronger IP – stronger than what is required by WTO – is needed to drive innovation, and therefore trumps concerns over pricing and access to healthcare. As the U.S. struggles with the global pandemic, access to healthcare and affordability of medication seem to be the one paradigm that can alleviate much of the national and global concerns, including those that involve trade. Lack of medications either because of lack of research or, access, can catapult what could be a national public health issue into an international crisis or a pandemic

While as a nation we consider different long-term solutions, the role of the USTR via-a-vis the use of public health flexibilities should be up for a serious debate nationally. Not just within the United States but at the level of the World Trade Organization too, which turned a blind eye to the unilateral pressure the U.S. imposes indirectly after agreeing to a system that requires multilateral dispute resolution. COVID-19 perhaps, is a call to reset the dial and look at trade with a dose of realism.