TRIPS Waiver

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COVID-19 Medical Products: Global Context

Examples of Intellectual Property that can affect access

Medical products needed to deal with COVID-19	Type of IP protecting this technology
Test kits	• Trade secrets, patents
Masks	• Patents, Industrial Designs
Medicines to treat COVID-19	• Patent
Vaccines, mAbs	• Patent, trade secrets
Ventilators	• Control mechanisms etc - patents • (replacement) valves – patents, industrial designs, copyright (e.g. on the CAD file) • Software – copyright • Machining templates and quality assurance protocols etc – trade secrets
Artificial intelligence	• Algorithms – copyright and trade secrets • Patents • Dataset and training process – copyright, database rights and trade secrets

Current Tools Available:

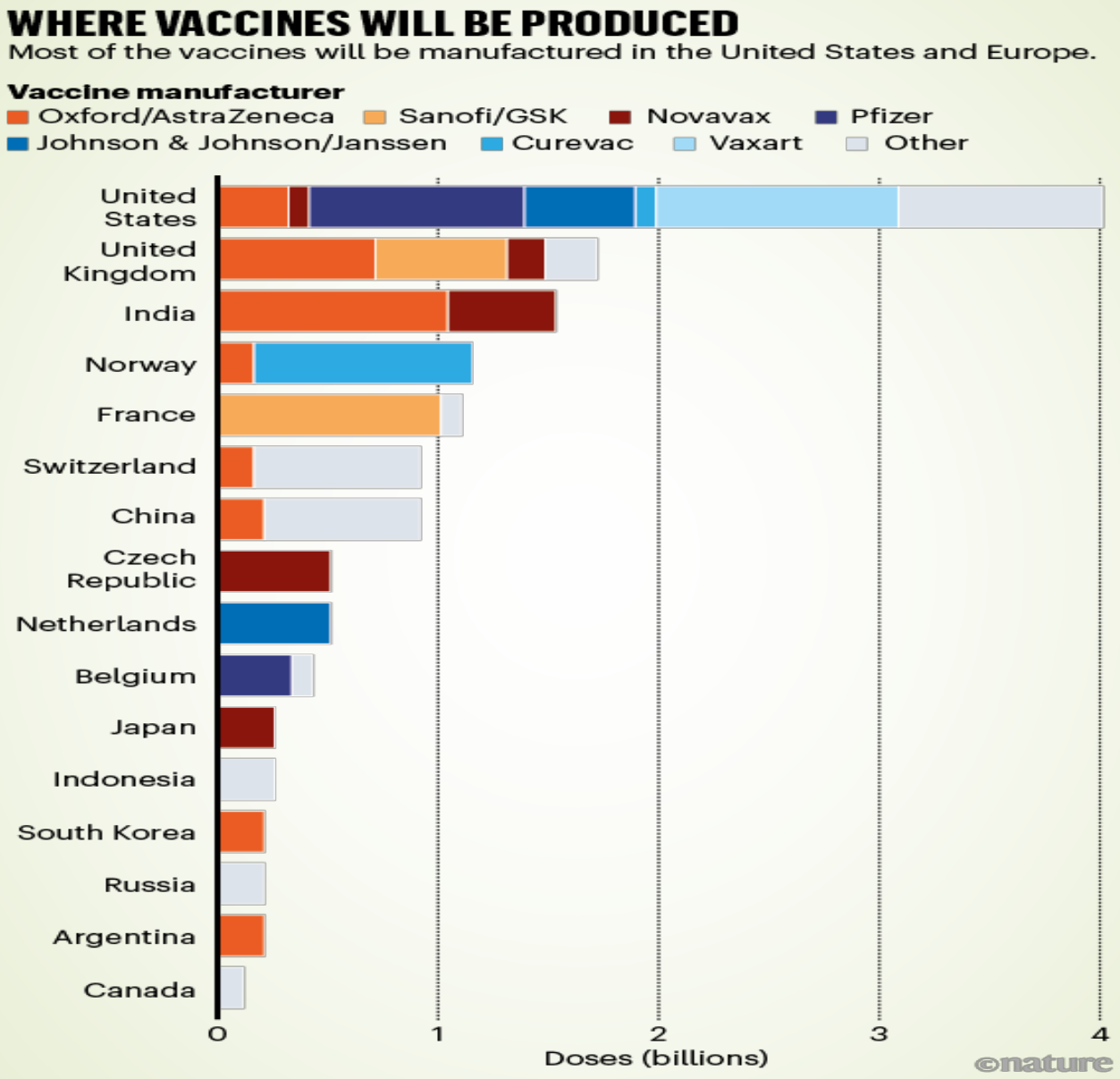
- TRIPS flexibilities e.g.
  - Compulsory licensing
  - Article 31*bis* mechanism, countries with insufficient manufacturing capacity. Several High Income countries have opted out from using the mechanism.
  - Article 73: security exception
  - Available but there are challenges in its use
  - Political pressure

- Voluntary licensing
  - its voluntary, terms determined by IP holder (e.g. allow supply only to some countries, lock in generic manufacturers on certain terms etc.)
  - unaccountable non-transparent VL that excludes many manufacturers and countries from supply
  - WHO's Covid-19 Technology Access Pool – to date no company has endorsed the C-TAP. In fact, pharmaceutical companies have objected to participation.

- **Current tools are insufficient**

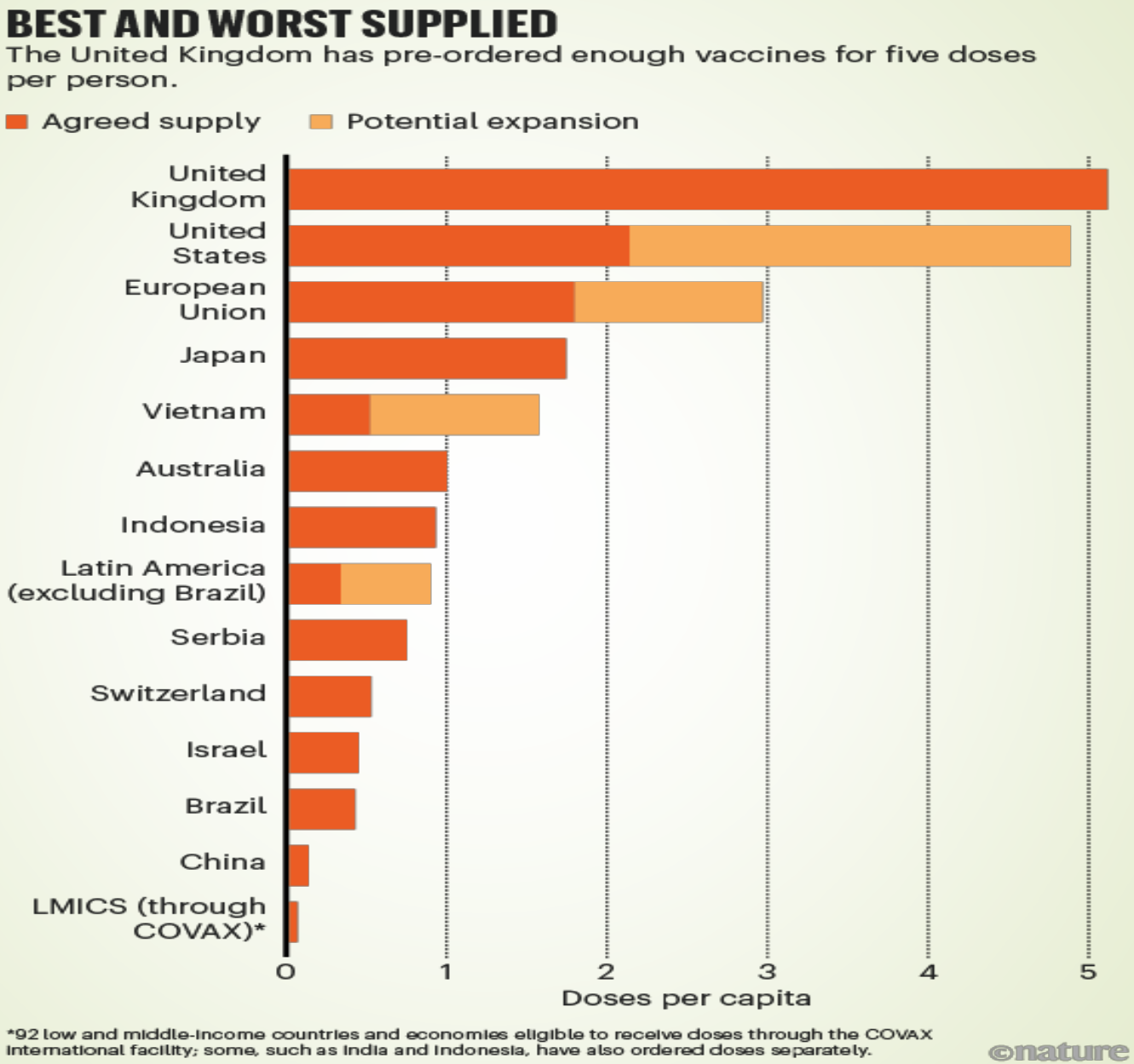
- **Example: Remdesivir**
  - new experimental COVID-19 anti-viral drug, (Developed for Ebola but unsuccessful). (Previously thought to improve recovery time by a bit but now considered to be ineffective. But still a useful case study of behavior of Big pharma)
  - Estimated that Gilead received at least US$70.5 million in public funding
  - Gilead holds primary patents on the drug in more than 70 countries that may block generic entry until 2031….allowing control of production and supply, and charge their prices.
  - signed VLs with select generic companies from Egypt, India and Pakistan, to market generic versions of the drug in 116 countries and 11 territories.
  - Terms of license unknown.
  - Capacity of these companies to supply other countries unknown. Excludes supply to half of world population including some with manufacturing capacity
  - In June – announced that supply of RDV all booked by US right up to Sept. EU and UK paid US$74 mill for 30 000 treatments.
  - priced at US$2,340 for a five-day treatment course for most countries in their "commercial" market
  - Countries outside of VL, where patent is not a barrier, and manufacturing capacity exists – (e.g. Bangladesh), already manufacturing remdesivir ($65 per vial)

- **Monoclonal Antibodies (mAbs)**
- Biologic drugs
- Broad applicability – can be used as therapeutic or prophylactic
- Expected to be highly effective
- clinical data of most advanced mAbs expected in Sep 2020
- 70 mAb candidates are currently in development for treatment and prevention of COVID-19
- **Immediate need will far exceed available manufacturing capacity**
- **Competition to lock up capacity is intense**– e.g., BARDA (US Biomedical Advanced Research and Development) reserved up to 1.2M doses of Regeneron mAb for the U.S. market and VIR secured contracts with 2 contract manufacturing organization
- **Developing countries access limited** – e.g., ~80% of global mAbs produced globally are used in HIC. Also see vaxmap.org



Also see:
http://vaxmap.org/

Source:
https://www.nature.com/articles/d41586-020-02450-x



Source: https://www.nature.com/articles/d41586-020-02450-x

- Covax Facility:
  - Led primarily by Gavi (vaccine alliance), decisions taken by Gavi
  - Entering into agreements with manufacturers to pre-book supply for vaccines within portfolio (presently 9 candidates).
  - Self-financing countries (HIC & UMIC) can pre-book 10-50%, paying upfront & providing guarantees
  - LMICs – cost sharing. Vaccine allocation – 3% first phase, up to 20%
  - Developed countries – mostly relying on bilateral deals for supply
  - There are issues of equity, transparency, accountability, and skepticism whether the facility will deliver in view of bilateral deals, and ability of manufacturers to deliver
  - Aim 2 billion doses by end of 2021 (vaccinating 1 billion people (500 mill –LMICs)). **Very short term plan.**
  - No commitment to sharing IP, know-how and technology transfer.

“Wealthy nations representing just 13 percent of the world’s population have already cornered more than half (51 percent) of the promised doses of leading COVID-19 vaccine candidates. …
Even in the extremely unlikely event that all five vaccines succeed, nearly two thirds (61 percent) of the world’s population will not have a vaccine until at least 2022.”

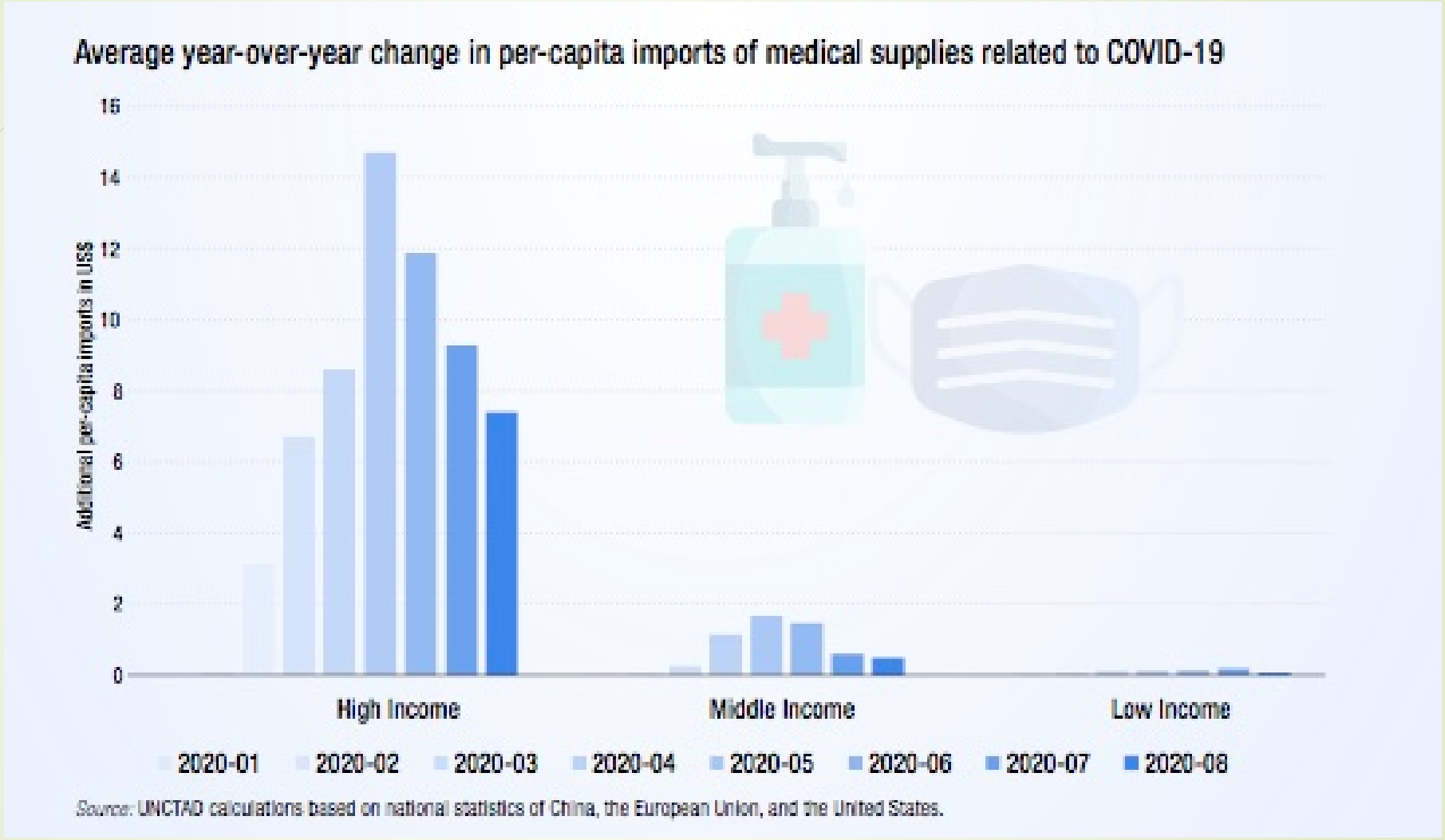
Oxfam analyzed the deals that pharmaceutical corporations and vaccine producers have already struck with nations around the world for the five leading vaccine candidates currently in phase 3 clinical trials, based on data collected by Airfinity.
https://www.oxfam.org/en/press-releases/small-group-rich-nations-have-bought-more-half-future-supply-leading-covid-19

UNCTAD Global Trade Update Oct 2020

"Nevertheless, the increase in supply of COVID-19 related products has been largely to the benefit of wealthier countries. There is substantial evidence that **middle- and low-income countries have been largely priced out from access** to COVID-19 related products. Despite efforts to facilitate access to COVID-19 supplies3, trade statistics show that only a tiny fraction of the additional world production of COVID-19 related supplies have reached low income countries.

Since the onset of the pandemic, **each resident of high-income countries has benefited, on average, from an additional US$10 per month of imports of COVID-19 related products.4 This number is much lower for middle income countries- at about US$1, and lower still for low income countries – a mere US$0.10.** In other words, per capita imports of the medical goods essential to mitigate the COVID-19 pandemic have been about 100 times larger in high income countries in comparison to low income countries. While it should be expected that the increase of per capita imports of COVID-19 products would be larger for wealthier countries, **the sheer difference is staggering**.5

A vaccine appears to be the most promising way to assuage the pandemic and revive the global economy. Still, for any recovery to be truly global and inclusive, it is important for the vaccine to be affordable and widely available. **The ongoing initiatives to make vaccines available in developing countries may not be sufficient.**



https://unctad.org/system/files/official-document/ditcinf2020d4_en.pdf

Submission by India & South Africa (co-sponsored by Eswatini & Kenya):

Waiver From Implementing, Applying & Enforcing Specific Parts of TRIPS

The Waiver Proposal (IP/C/W/669) is available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True

- **Legal Basis:** paragraphs 1, 3 and 4 of Article IX of the WTO Agreement

- **Scope:** implementation and application of ***Sections 1 (Copyright), 4 (Industrial Designs), 5 (Patents), and 7 (Protection of Undisclosed Information) of Part II of the TRIPS Agreement*** and ***enforcement*** of these sections under Part III of TRIPS (which is on enforcement) ***in relation to prevention, containment and treatment of COVID-19.***

- **Duration:**
  - Specific duration to be determined. Proposal states: until widespread vaccination is in place globally, and the majority of the world's population has developed immunity

- **Least Developed Countries**
  - Does not affect LDC rights to extension under Article 66.1 of TRIPS
  - Would benefit LDCs.

What will a Waiver Achieve?

- Main idea: Recognition at WTO level countries have the option of freedom to operate by suspending implementation and enforcement of relevant IP for purpose of containing COVID-19.
- avoid procedural and administrative delays in addressing IP barriers.
- with the Waiver, the waived IPRs (e.g. patents, industrial designs, test data protection, copyright) relating to the prevention, containment and treatment of Covid-19 need not be implemented, applied or enforced nationally
- Allows international collaboration with respect to development, production (including technology transfer) and supply of needed medical products.

- **Emerging patent disputes that may impact manufacturing and supply of medical products**
  - Pfizer-BioNTech, Regeneron sued for patent infringement with COVID-19 products https://www.fiercepharma.com/pharma/pfizer-biontech-regeneron-sued-for-infringement-allele-s-patent-their-covid-19-products;
  - Lawsuit reveals intellectual property is holding back production of CEPI- and Gates Foundation-funded COVID-19 vaccine candidate,https://twn.my/title2/briefing_papers/twn/Hammond.pdf;
  - Pandemic intellectual property dispute deepens as Inovio is countersued, leaving its COVID-19 candidate in limbo, https://twn.my/title2/briefing_papers/twn/Inovio%20countersued%20IP-COVID%20Jul%. 202020%20Hammond.pdf;
  - Patent dispute looms as a major complication for Moderna's COVID-19 vaccine, https://twn.my/title2/briefing_papers/twn/Moderna%20IP-COVID%20Aug%202020%20Hammond.pdf

State of Play

- TRIPS Council meeting: 15-16 October

- "Given this range of positions, the Council chair, Ambassador Xolelwa Mlumbi-Peter of South Africa, said that the **item would remain suspended** as members continue to consider the proposal. Requests for waivers concerning WTO agreements must be submitted initially to the relevant council for consideration. **After 90 days, the TRIPS Council has to submit a report to the Ministerial Conference. Given that the proposal was submitted on 2 October, the 90-day time-period expires on 31 December 2020.** The TRIPS Council meeting will be reconvened on the item of the waiver proposal as appropriate before that date, the chair said". https://www.wto.org/english/news_e/news20_e/trip_20oct20_e.htm

Supporters:

- **MSF:** *https://msfaccess.org/landmark-move-india-and-south-africa-propose-no-patents-covid-19-medicines-tools-during-pandemic;*
- **Drugs for Neglected Diseases initiative (DNDi)**; https://dndi.org/statements/2020/dndi-statement-india-south-africa-request-wto-waive-ip-rules-covid-19-health-tools/
- **UNITAID:** *https://unitaid.org/news-blog/unitaid-supports-call-for-intellectual-property-waivers-and-action-for-access-to-covid-19-products/#en;*
- **UNAIDS:**https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2020/october/20201015_waiver-obligations-trips-agreement-covid19
- **WHO :** https://twitter.com/drtedros/status/1317449471727407104?s=24 & https://www.thehindubusinessline.com/economy/who-lends-support-to-ip-waiver-proposal-from-south-africa-india/article32885984.ece
- **H.E. Archbishop Ivan Jurkovič, Permanent Observer of the Holy See**: https://nuntiusge.org/wp-content/uploads/2020/10/HOLY-SEE-Statement-WTO-TRIPs-Council-India-and-South-Africa-proposal-for-WTO-waiver-from-intellectual-property-protections-for-COVID-19-related-medical-technologies-1.pdf
- **More than 400 civil society organizations:** https://www.twn.my/announcement/signonletter/CSOLetter_SupportingWaiverFinal.pdf
- **Progressive International;** *https://progressive.international/blueprint/b6cf1166-724d-46de-884e-058f771562ff-covid-19-response-group-to-wto-ensure-equitable-and-affordable-access-to-all-covid-19-health-technologies/en*
- **South Africa-Affiliated Academics, Researchers and Teachers Letter to President Ramaphosa;** *http://infojustice.org/archives/42692*
- **Brazilian CSO** at https://www.uaem.org/carta_da_sociedade_brasileira (in English at https://drive.google.com/file/d/1IQmIohurO7GrT4V4BbMgL65vBCuBoQHi/view)
- **Chilean House of Representatives passes a Resolution** requesting the Government to support at the Trips Council the Indian and South Africa proposal; https://innovarte.org/chilean-house-of-representatives-passes-a-resolution-requesting-the-goverment-to-supoort-at-the-trips-council-the-indian-and-south-africa-proposal-regarding-a-waiver-ot-trips-obligation-to-fight-covid/

Op-Eds

- We can't let the WTO get in the way of a 'people's vaccine' https://www.theguardian.com/commentisfree/2020/oct/15/peoples-vaccine-coronavirus-covid-wto?ref=hvper.com
- The Indian/South African Proposal For a WTO Waiver On IP For COVID-19 Related Health Products – What It Means? https://healthpolicy-watch.news/77719-2/
- Avoiding patents for Covid-19 vaccines https://www.deccanherald.com/opinion/in-perspective/avoiding-patents-for-covid-19-vaccines-900688.html
- COVID-19 Crisis and WTO: Why India and South Africa's Proposal on Intellectual Property is Important https://thewire.in/law/covid-19-crisis-wto-intellectual-property-vaccine-public-health
- Simon Lester from Cato Institute "Who Will Get the Coronavirus Vaccines and When?": Waiving TRIPS Rules To Fight COVID-19 at https://ielp.worldtradelaw.net/2020/10/who-will-get-the-coronavirus-vaccines-and-when-.html.

Country Position

- **members who supported the proposal**, the vast majority of which were least developed and developing countries: Bangladesh, Sri Lanka, Pakistan, Venezuela, Honduras, Nepal, Nicaragua, Egypt, Indonesia, Argentina, Tunisia, Mali, Mauritius and Mozambique;
- **members who expressed their rejection** of the text, the vast majority of which were developed countries European Union, United States, Switzerland, Norway, Australia, Canada, Japan and the United Kingdom), joined by Brazil;
- **members waiting for instructions/need clarification & further meetings/general statements on A2M:** Tanzania (on behalf of Africa Group), Chad (on behalf of LDC Group); Nigeria, Philippines, Turkey, Ecuador, China, Thailand, Senegal, Jamaica, Colombia, Costa Rica, Chile and El Salvador.

- **Statements of proponents:**
  - India at https://pmindiaun.gov.in/public_files/assets/pdf/TRIPS_Agreemnet.pdf
  - South Africa at https://www.keionline.org/34235 introducing the proposal and rebuttal of some common developed country points.
  - See also South Africa, India strongly rebut arguments against TRIPS waiver https://www.twn.my/title2/wto.info/2020/ti201021.htm
  - Proposal for TRIPS waiver secures strong support from South https://www.twn.my/title2/wto.info/2020/ti201020.htm

- **Statements of Opposers:**
  - **UK:** https://www.gov.uk/government/news/uk-statement-to-the-trips-council-item-15
  - **Norway:** https://www.norway.no/en/missions/wto-un/nig/latest-news/trips1610/
  - **European Union:** https://www.keionline.org/34275

- **Common Points raised by developed countries:**
  - no indication that IPR issues have been a genuine barrier in relation to COVID-19 related medicines and technologies.
  - IP is an important incentive, with exceptions and flexibilities, it is part of the solution rather than a barrier.
  - Shift focus to "counterfeit" pharmaceutical products, tariffs and taxes, non-efficient and underfunded health care and procurement systems, lack of manufacturing capacity or materials.
  - Article31*bis* mechanism
  - Gavi's Covax Facility, funding provided to facility
  - TRIPS flexibilities are sufficient

- **STRATEGY: Possible actions**
  - PHM country circles to reach out nationally: ministry of health, trade, WTO missions. (Africa, Latin America, developed countries esp EU, Canada, NZ, Norway)
  - Reach out to leading personalities for op-eds, letters, appeal to governments
  - Getting endorsement of leading personalities, constituency.
  - International action (TBD)
  - Getting MPs/opposition parties/parliamentary support

- A briefing document by MSF on the Importance of Waiver from TRIPS Obligations, https://msfaccess.org/sites/default/files/2020-10/COVID_Brief_ProposalWTOWaiver_ENG_2020.pdf
- Recording of the Webinar on IP and Access to Covid Medical Products held on 8th October: https://www.youtube.com/watch?v=aL1VElxep4U. This webinar touches on how IP related barriers to access and on how trade secret (protected under Article 39 of the TRIPS Agreement) impacts sharing of knowledge and hence access.

Thank You

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