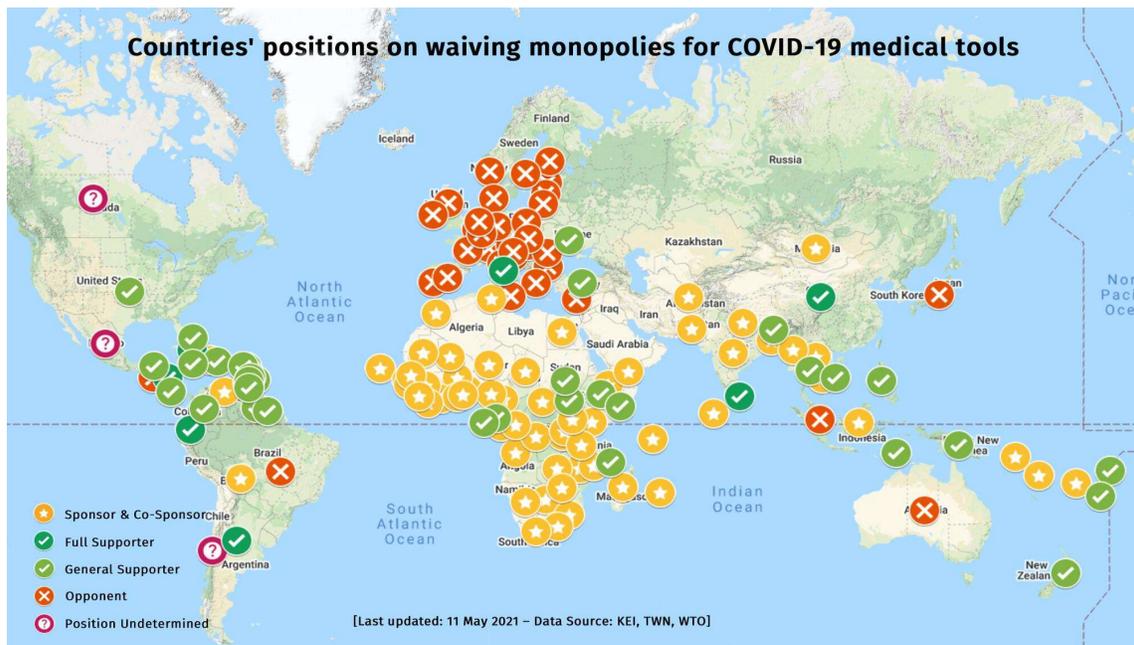


## Factsheet

On 2 October 2020, India and South Africa submitted a [proposal](#) to the World Trade Organization (WTO): in view of the global extent of the Covid-19 pandemic the call for the temporary suspension of Covid-19 related intellectual and patent rights on vaccines and technology needed to produce them. Doing this, they refer to [Article IX](#) of the WTO Agreement, where it states that such a waiver is permitted in “exceptional circumstances”.<sup>1</sup> The US, UK, EU, Switzerland and some other industrialized nation-states oppose this proposal and this seemed to be the end of it since the WTO normally decides consensually.

The proposal gained already more than half of the WTOs member states, here an overview:<sup>2</sup>



The proposal is also supported by many UN Bodies such as the UNESCO, World Health Organization and UNAIDS, and influential NGOs.<sup>3</sup> A breakthrough happened when US President Biden agreed to no longer oppose this debate, one day later, the influential Bill & Melinda Gates Foundation followed that lead.<sup>4</sup>

<sup>1</sup> World Trade Organization (April 1994) Marrakesh Agreement Establishing the World Trade Organization. Retrieved 19 February 2021 from [https://www.wto.org/english/docs\\_e/legal\\_e/04-wto\\_e.htm#articleIX](https://www.wto.org/english/docs_e/legal_e/04-wto_e.htm#articleIX) and [https://www.wto.org/english/res\\_e/publications\\_e/ai17\\_e/wto\\_agree\\_art9\\_jur.pdf](https://www.wto.org/english/res_e/publications_e/ai17_e/wto_agree_art9_jur.pdf)

<sup>2</sup> <https://www.msf.org/countries-obstructing-covid-19-patent-waiver-must-allow-negotiations>

<sup>3</sup> No open list of supporters is known, but this one is quite impressive: Fletcher, R. (10 November 2020) Médecins Sans Frontières – Nearly 100 World Trade Organization Members Could Support “Waiver” On IP For COVID Health Technologies. Retrieved 18 February 2021 from <https://healthpolicy-watch.news/moderna-and-pfizer-vaccine-trial-results-are-milestones-distribution-poses-new-challenges/> and Médecins Sans Frontières (MSF) Briefing Document (November 2020) India and South Africa proposal for WTO waiver from intellectual property protections for COVID-19-related medical technologies. Retrieved 19 February 2021 from [https://msfaccess.org/sites/default/files/2020-11/COVID\\_Brief\\_WTO\\_WaiverProposal\\_ENG\\_v2\\_18Nov2020.pdf](https://msfaccess.org/sites/default/files/2020-11/COVID_Brief_WTO_WaiverProposal_ENG_v2_18Nov2020.pdf)

<sup>4</sup> Regarding the US see <https://www.bbc.com/news/world-us-canada-57004302> Regarding the Bill & Melinda Gates Foundation see <https://www.devex.com/news/gates-foundation-reverses-course-on-covid-19-vaccine-patents-99810>

Supporters want to invoke yet another provision in Article IX, saying, that if no consensus can be achieved, a majority of three-quarters of the member states can pass such a decision.<sup>5</sup>

What are the arguments against the Indian and South-African Proposal? Most commonly, the following

- *“There are adequate flexibilities in the WTO framework since 2001.”* Yes, but they are very complex and technical. Moreover: In 2016 the [High-Level Panel on Access to Health Technologies](#) reported to the UN Secretary General that those flexibilities are inadequate for their intended purposes and, moreover, that governments face political and economic pressure when they try to apply those flexibilities. There are numerous indications that poor countries are not able to negotiate at eye level with pharmaceutical giants, and their refusal to be transparent about treaties suggests that they have things to hide.<sup>6</sup> Therefore, in reality the much-needed waiver and the existing TRIPS flexibilities are complementary.
- *“Compulsory Licensing is better.”* No, because (1) It applies only country-to-country and product-to-product and prohibits export to nations without production facilities. (2) It is such a complex and technical procedure that some countries are overtasked, which is why the EU offers help for implementation. (3) The waiver asked for by the Indian and African proposal includes generally related technology for diagnostics/testing, medication, and production as well as options for later possible vaccine modifications, so that no time is lost with complex and lengthy negotiations.<sup>7</sup>
- *“The COVAX fund as well as ACT-A and C-TAP will provide all that is needed”.* Nobody claims that all problems are resolved with the temporary waiving of patents. Of course, further transfer of technology and money is needed. But: “To achieve meaningful results in 2021, COVAX should have guaranteed funds in 2021 of US\$20–40 billion, which it would turn into firm agreements on expanded vaccine

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<sup>5</sup> More on the Indian-South African Initiative: Balino, S. (28 October 2020) As Second Wave of COVID-19 Sweeps the Globe, WTO Members Mull Options for Pandemic Response. Retrieved 18 February 2021 from <https://sdg.iisd.org/commentary/policy-briefs/as-second-wave-of-covid-19-sweeps-the-globe-wto-members-mull-options-for-pandemic-response/> and Balino, S. (21 December 2020) As Vaccine Roll-out Begins, WTO Members Intensify Debate Over Policy Solutions. Retrieved 18 February 2021 from <http://sdg.iisd.org/commentary/policy-briefs/as-vaccine-roll-out-begins-wto-members-intensify-debate-over-policy-solutions/> as well as World Trade Organization (April 1994) Marrakesh Agreement Establishing the World Trade Organization. Retrieved 19 February 2021 from [https://www.wto.org/english/res\\_e/publications\\_e/ai17\\_e/wto\\_agree\\_art9\\_jur.pdf](https://www.wto.org/english/res_e/publications_e/ai17_e/wto_agree_art9_jur.pdf)

<sup>6</sup> Impfstoff Poker: Wie die armen Länder leer ausgehen. ARD Weltspiegel (7 February 2021). Retrieved 18 February 2021 from <https://www.ardmediathek.de/daserste/video/weltspiegel/impfstoff-poker-wie-die-armen-laender-leer-ausgehen/das-erste/Y3JpZDovL2Rhc2Vyc3RlLmRlL3dlbHRzcGliZ2Vsl2Y1ODk4ZjgwLWY3YWYtNGJmMi1hM2FhLTQ2OGQxNDQwOGU5NA/>

<sup>7</sup> See, e.g., p. 4f. of Medicins Sans Frontiers (MSF) Access Briefing of 3 December 2020: WTO COVID-19 TRIPS Waiver Proposal: Myths, realities and an opportunity for governments to protect access to medical tools in a pandemic. Retrieved 18 February from <https://msfaccess.org/wto-covid-19-trips-waiver-proposal-myths-realities-and-opportunity-governments-protect-access>

production.”<sup>8</sup> So far, nothing indicates that this amount will be provided timely.<sup>9</sup> And even if money arrives: What, if no vaccine can be purchased? The new US Administration under President Biden promised only “donating ‘surplus’ vaccines ‘once there is a sufficient supply’ to meet domestic demand.”<sup>10</sup> Similar problems could be named with ACT-A and C-TAP, the latter opening the option for Big Pharma to voluntarily share patented information. But, as of 22 May, However, to date “no pharmaceutical companies have signed up”.<sup>11</sup>

- *“There is no adequate production and distribution infrastructure in poor countries.”* Not quite true. India already produces up to 60% of all global vaccines,<sup>12</sup> and on each continent exist WHO qualified vaccine producing facilities.<sup>13</sup> Big Pharma knows that, since they like to outsource their own production there, which also applies for the production of COVID 19 vaccines in places like India<sup>14</sup> and South Africa. Beyond that, existing facilities can vigorously modified and adapted with the help of developed countries and other donors once it is clear for which products. In Germany, BioNTech renovated a pharmaceutical facility within few weeks and started production ahead of envisaged deadline, similar reports exist from UK (repurposing a fish-processing plant) or the US (repurposing a Polaroid facility).<sup>15</sup> Furthermore, the Serum Institute in India is already the leading COVID-19 vaccine producer, thereby proving that production capacities outside the most-industrialized nations do exist and can be scaled up.
- *“IP issues did not obstruct the development, production, distribution... of vaccines.”* Not true. There is ample evidence that big pharmaceutical companies’ lawyers interfered when they believed that somebody else’s findings threaten own advantages or positions.<sup>16</sup>

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<sup>8</sup> Sachs, J. (12 February 2021) Priorities for the COVID-19 pandemic at the start of 2021: statement of the Lancet COVID-19 Commission. Retrieved 18 February 2021 from

<https://www.thelancet.com/action/showPdf?pii=S0140-6736%2821%2900388-3>

<sup>9</sup> By the end of 2020, merely 2 Billion USD were collected by 94 states, the EU and the Gates-Foundation. Covax-Übersicht: Arme Länder erhalten nur Bruchteil der weltweit verfügbaren Impfdosen (4 February 2021). Retrieved from <https://www.aerzteblatt.de/nachrichten/120819/Covax-Uebersicht-Arme-Laender-erhalten-nur-Bruchteil-der-weltweit-verfuegbaren-Impfdosen>. Not to forget: The pandemic affected the ability of public spending negatively and increased public debt. Hence, doubts are justifiable whether this amount will increase speedily.

<sup>10</sup> Williams, A. /Kuchler, H. (18 February 2021) US will not send vaccines to developing countries until supply improves. Retrieved 18 February 2021 from <https://www.ft.com/content/e00fe88e-263c-41da-9ac5-fdbbd71c928a>

<sup>11</sup> The Lancet (22 May 2021) What next for a COVID-19 intellectual property waiver?

<https://www.thelancet.com/action/showPdf?pii=S0140-6736%2821%2901151-X>

<sup>12</sup> [Covid: India could play an important role in producing vaccines \(cnbc.com\)](https://www.cnbcm.com/india/covid-19/india-could-play-an-important-role-in-producing-vaccines)

<sup>13</sup> <https://extranet.who.int/pgweb/>

<sup>14</sup> Spinnery, L (14 February 2021) 'We took a huge risk': the Indian firm making more Covid jobs than anyone. Retrieved 18 February 2021 from <https://www.theguardian.com/global-development/2021/feb/14/we-took-a-huge-risk-the-indian-firm-making-more-covid-jobs-than-anyone>

<sup>15</sup> For Germany: BioNTech nimmt Produktion in Marburg auf (10 Februar 2021). Retrieved 18 February 2021 from <https://www.n-tv.de/wirtschaft/Biontech-nimmt-Produktion-in-Marburg-auf-article22350890.html> For UK [Government buys Benchmark's Braintree vaccine facility in a bid to beat Covid | The Fish Site](https://www.fishbase.org/news/government-buys-benchmark-s-braintree-vaccine-facility-in-a-bid-to-beat-covid) For US [Frank E. Arabi, MD auf Twitter: "RT @ElTorrelee: In mere months, Moderna transformed an old Polaroid factory in America into a state-of-the-art vaccine-production centre..." / Twitter](https://twitter.com/ElTorrelee/status/1354888888888888888)

<sup>16</sup> Statement of the Republic of South Africa to the WTO-TRIPS Council on 16 October 2020. Retrieved on 18 February 2021 from

- *“A waiver will dampen private investment into research and development.”* We are talking about a truly “exceptional situation”, calling for swift and effective action for the Common Good of All. And we must be mindful that Covid-19 related research and development was heavily subsidized with public money.<sup>17</sup> Several companies even received more than one billion US\$ in public subsidies.<sup>18</sup>
- *“Pharma companies release patents and licenses voluntarily.”* Some companies release indeed something (e.g. Moderna, AstraZeneca), but: (1) Release of some information on the vaccine does not suffice to produce it since also technology rights are involved. (2) Other companies do not release anything, which, given the complexity, may infringe patent rights even if companies in developing countries start working on those vaccines deemed to be available, endangering lawsuits.<sup>19</sup> (3) Time is of essence and we cannot wait until all relevant information is voluntarily and transparently available. How much profit is at stake illustrates the fact that BioNTech/Pfizer originally asked for 54 Euro – per single dose!<sup>20</sup>
- *“WTO always decides by consensus and never by vote. Let us try to secure consensus, if not at the TRIPS Council then at the General Council.”* True so far. But for everything exists a first time, and we think that the pandemic justifies this procedure. And: If there is little likelihood to find consensus at the TRIPS Council, there will be little likelihood to find it at the General Council. Meanwhile, people suffer and die.

**Clearly the Indian and South African initiative is the easiest, clearest, most transparent as well as the least complex approach to the pressing issue of speedy and comprehensive access of poor countries to Covid-19 vaccination and start the process of exponentially increase production and distribution of vaccines.**

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[https://www.twn.my/title2/intellectual\\_property/trips\\_waiver\\_proposal\\_wtotrips\\_6oct.htm](https://www.twn.my/title2/intellectual_property/trips_waiver_proposal_wtotrips_6oct.htm). MSF Access Briefing of 3 December 2020: WTO COVID-19 TRIPS Waiver Proposal: Myths, realities and an opportunity for governments to protect access to medical tools in a pandemic. Retrieved 18 February from <https://msfaccess.org/wto-covid-19-trips-waiver-proposal-myths-realities-and-opportunity-governments-protect-access>

<sup>17</sup> Allen, A. (November 2020) For Billion-Dollar COVID Vaccines, Basic Government-Funded Science Laid the Groundwork. Retrieved on 18 February 2021 from <https://www.scientificamerican.com/article/for-billion-dollar-covid-vaccines-basic-government-funded-science-laid-the-groundwork/>. Take Pfizer, who claims that they did not receive any government money: Their partner BioNTech, who did all the research in the cooperation of the two firms, received 375 Million Euros from the German government: BioNTech to Receive up to €375M in Funding from German Federal Ministry of Education and Research to Support COVID-19 Vaccine Program BNT162, Retrieved 19 February 2021 from <https://investors.biontech.de/news-releases/news-release-details/biontech-receive-eu375m-funding-german-federal-ministry/>

<sup>18</sup> Wouter et al (February 2021) Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment. Retrieved on 19 February 2021 from <https://www.thelancet.com/action/showPdf?pii=S0140-6736%2821%2900306-8>

<sup>19</sup> Regarding the previous issues on the limitations of voluntary release: On the Moderna case see page 5 of MSF Access Campaign Briefing of 18 November 2020: India and South Africa proposal for WTO waiver from intellectual property protections for COVID-19-related medical technologies, Retrieved on 18 February 2021 from <https://msfaccess.org/india-and-south-africa-proposal-wto-waiver-ip-protections-covid-19-related-medical-technologies>. And page 4 of MSF Access Briefing of 3 December 2020: WTO COVID-19 TRIPS Waiver Proposal: Myths, realities and an opportunity for governments to protect access to medical tools in a pandemic. Retrieved 18 February from <https://msfaccess.org/wto-covid-19-trips-waiver-proposal-myths-realities-and-opportunity-governments-protect-access>

<sup>20</sup> BioNTech-Pfizer originally demanded €54 per vaccine dose (18 February 2021). Retrieved 18 February 2021 from <https://www.dw.com/en/biontech-pfizer-originally-demanded-54-per-vaccine-dose/a-56620748>

Saying that, it is important to call for technical and financial support to accompany the release of patents, since the availability of patents alone indeed does not produce any vaccines. Here, also the EUs promise at the G20 Global Health Summit in Rome (21 May 2021) to assist in establishing production facilities in Africa is a good step along that road.<sup>21</sup>

Talking about the Global Health Summit: Even though the summit did not support the waiving of patents, the question remains on the table. Big Pharma understood the sign of the times. The more support the temporary waiving of patents gains, the more “voluntary” offer they put on the table, e.g. by promising billions of COVID 19 doses by the end of 2022 at low costs.<sup>22</sup>

Looking ahead the coming months, we want to conclude with two quotes:

"If anyone should be given preference, let it be the poorest, the most vulnerable, those who so often experience discrimination because they have neither power nor economic resources," Pope Francis told the United Nations on 26 September 2020.<sup>23</sup>

The words of the pope should ring loud with those still obstructing both the temporary waiver and the voting mechanism: They are just the very same countries securing more vaccines for their own population than needed, putting the rest of the world on the waiting list!

Challenging times require bold moves. This is even known at the WTO, the main obstacle for further progress. WTO Secretary General Ngozi Okonjo-Iweala warned in one of her first interviews after her appointment, “vaccine nationalism” and reiterated: “No one is safe until everyone is safe.”<sup>24</sup>

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<sup>21</sup> “In addition to covering current vaccine needs, Team Europe will also invest to equip Africa to produce vaccines itself. Team Europe has launched an initiative to boost manufacturing capacity in Africa and access to vaccines, medicines and health technologies. The initiative, backed by €1 billion funding from the EU budget and European development finance institutions such as the European Investment Bank, will cover investments in infrastructure and production capacity, but also in training and skills, supply chains management, and regulatory framework.” [https://global-health-summit.europa.eu/about\\_de](https://global-health-summit.europa.eu/about_de)

<sup>22</sup> „Pharmakonzerne bangen um ihre Patente für Covid-19-Impfstoffe. Damit die Politik keine Rechte aussetzt, machen sie ein Angebot: Milliarden Dosen zum kleinen Preis für bedürftige Länder. Ob das reicht, ist keineswegs sicher.“, see <https://www.sueddeutsche.de/politik/gesundheitsgipfel-g20-impfstoff-beduerftige-1.5301421>

<sup>23</sup> Poor should get COVID-19 vaccine first, Pope Francis says (26 September 2020). Retrieved 18 February 2021 from <https://www.thejakartapost.com/life/2020/09/26/poor-should-get-covid-19-vaccine-first-pope-francis-says.html>

<sup>24</sup>Shalal, A. (16 February 2021) WTO chief Ngozi Okonjo-Iweala on vaccine nationalism: ‘No one is safe until everyone is safe’. Retrieved 18 February 2021 from <https://www.weforum.org/agenda/2021/02/world-trade-organisation-head-vaccine-nationalism-covid-19>

The previous reflects the current debate as of 22<sup>nd</sup> May 2021

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