

Rationale for Supporting Costa Rica's Proposal for Emergency COVID-19 Technology IP Pool for All Countries¹

Circumstances are urgent and require an urgent and smart global response.

The world is behind in developing and being able to supply the diagnostics, vaccines, therapeutics, medical devices, and other well adapted medical supplies [medical technologies] needed to respond to the COVID-19 pandemic which is sweeping across the globe. Although scientific and medical urgency are building, we need to ensure that the needed medical technologies will be developed and tested urgently, efficiently, and ethically with maximum degrees of open data, open science, and collaboration in the development stage and maximum degrees of universal and equitable access thereafter to all people in all countries. We therefore support the creation of a voluntary emergency Technology Intellectual Property Pool [TIPP] that will accelerate scientific discovery, technology development, proof of safety/efficacy/quality, and broad sharing of the benefits of scientific advancement and its applications in furtherance of the right to health. As proposed by Costa Rica,² the formation of TIPP would be coordinated in the first instance by the WHO after which operational implementation might be assigned to other coordinating entities. By in-licensing the broadest possible range of medically relevant intellectual property rights and data and by out-licensing those rights to all qualified producers, who can thereafter conduct follow-on research and produce priority medical technologies, the TIPP will result in greatly accelerated access and follow-on innovation of even better adapted products. Building on past proposals for benefit sharing and technology pooling during the SARS epidemic³ and for influenza preparedness⁴ and on the success of the Medicines Patent Pool in expanding affordable access to medicines tackling HIV, TB, and hepatitis C, not only will this pool save millions of lives by accelerating the response to this pandemic, but it will be a powerful demonstration of global solidarity and preparedness for future epidemic threats.

Open science and data sharing are needed from the earliest stages and should be built into funding agreements.

The genome of SARS-CoV-2 was made available openly and immediately,⁵ greatly accelerating initial stages of developing diagnostic tests and exploring new therapeutic compounds. Similarly, many scientists and clinicians are immediately sharing their early research data through open source publication.⁶ Researchers from multiple countries are collaborating on joint clinical trials, including through the WHO

¹ Prepared by Brook K. Baker, Senior Policy Analyst Health GAP (Global Access Project) and Professor Northeastern U. School of Law, with inputs from Charles Clift, Ellen 't Hoen, James Love and others.

² James, Love, *President and Minister of Health of Costa Rica ask WHO to create global pool for rights to COVID-19 related technologies*, KEI (March 23, 2020), <https://www.keionline.org/32556>.

³ Matthew Rimmer, *The Race to Patent the SARS Virus: The TRIPS Agreement and Access to Essential Medicines*, 5 Melbourne J. Int'l L. (2004), https://law.unimelb.edu.au/_data/assets/pdf_file/0007/1681117/Rimmer.pdf

⁴ WHO, PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK FOR THE SHARING OF INFLUENZA VIRUSES AND ACCESS TO VACCINES AND OTHER BENEFITS (2011), https://apps.who.int/iris/bitstream/handle/10665/44796/9789241503082_eng.pdf;jsessionid=FADD3EBD37834C516A92FEF43A8B1187?sequence=1

⁵ Institute Pasteur, *Whole Genome of novel coronavirus, 2019 nCoV, sequenced*, SCIENCE DAILY (Jan. 31, 2020) (reporting sharing by Chinese researchers on January 11-12, 2020), <https://www.sciencedaily.com/releases/2020/01/200131114748.htm>

⁶ Vasee Moortdhy, Ana Maria Henao Restrepo, Marie-Pierre Preziosi & Soumya Swaminathan, *Data Sharing for novel coronavirus (COVID-19)*, 98 BULL. WHO 150 (2020), <https://www.who.int/bulletin/volumes/98/3/20-251561.pdf>

SOLIDARITY trial,⁷ sharing epidemiological and medical course data, and in the development of medical guidelines for responding to the pandemic. These early exemplars of open science and data sharing now need to be applied through all stages of researching and developing COVID-19 medical technologies, including the stages now being undertaken by private enterprise. The world needs to share every success, every advance, and every false path and dry well so that research can be done with maximum speed to achieve the best results.

Much of the early research by universities, start-ups, major biopharmaceutical, and medical device companies is being funded by governments and charities. It is imperative that these funding agreements mandate open collaboration, open-source publication, and full data sharing while protecting identifying data of patients and human subjects.

Multiple forms of intellectual property rights are needed in the TIPP and regulatory barriers will need to be addressed.

The TIPP should be open to the broadest possible range of relevant intellectual property rights, including patent rights, manufacturing know-how, cell-lines, technology blueprints and specifications, copyright, software rights, clinical trial data, regulatory rights, research rights, and data rights. Simply put, no exclusive rights should stand in the way of governments' and the global community's response to the COVID-19 pandemic. Although previous patent pools have historically focused primarily on securing patent rights, the TIPP will need to accumulate and distribute all the rights, including traditional trade secret and confidential business information rights, that are needed for generic, biosimilar, vaccine and other medical technology producers to accelerate access to market.

In this regard it is important to emphasize the need to incentivize and fast-track registration and emergency access to the new medicines and medical technologies in all countries. Access to regulatory data and removal of data and registration-related market exclusivities will eliminate some barriers, but countries will also need to ensure that qualified producers can quickly bring the medical technologies to market in their countries.

Access rights need to be hardwired at the earliest stages of funding agreements for medical technology R&D and include rights to follow-on IP granted to funded entities.

One of the best ways to guarantee universal and equitable access to COVID-19-related medical technologies would be to immediately build in obligations to license all relevant IP to the TIPP via new government and charitable funding agreements. Those agreements could also include "reach-through" provisions that require that follow-on IP resulting from the fruits of funded research would also be licensed. However, there is also an existing treasure-trove of intellectual property rights already "owned" by university and research institute researchers, by start-ups, and by major biopharmaceutical and medical device companies. Some of those rights are founded in part on research funding previously supplied by governments and charities, and those right holders could be convinced to volunteer in-licensing of the fruits of funded research into the TIPP. Nonetheless, other proprietary IP rights are not strongly tethered to public funding. Therefore, private industry will need to be convinced to step forward and join the TIPP. Fortunately, there are already several positive examples of drug companies and device

⁷ Kai Kupferschmidt & Jon Cohen, *WHO launches global megatrial of the four most promising coronavirus treatments*, SCIENCE (March 22, 2020), <https://www.sciencemag.org/news/2020/03/who-launches-global-megatrial-four-most-promising-coronavirus-treatments>

manufacturers stepping up to share IP and to thereby accelerate and expand access. See Box. Unfortunately, there are already negative examples as well. See Box 2.

Box 1 – Positive Examples	Box 2 – Negative Examples
<p>The UK ventilator maker, Smiths Group, has announced that it is making its intellectual property and know-how on one of its lightweight ventilators available for other manufacturers so that they can expand production as part of a coordinated attempt to tackle a shortage of life-saving medical equipment needed treat the most serious cases of coronavirus infection.⁸</p> <p>AbbVie has announced the expansion of its license with the Medicines Patent Pool to allow generic production of its medicine lopinavir/ritonavir without restriction to all countries. Should lopinavir/ritonavir prove effective in treating COVID-19, multiple MPP licensees will thereby be able to greatly expand supply, including in high-income countries.</p>	<p>After volunteers in Northern Italy 3D-printed an out-of-stock ventilator valve that cost \$11,000 for \$1, the original manufacturer, Intersurgical, is reported to have made legal threats for alleged patent infringement, though Intersurgical has denied making threats.⁹ Access to the 3-D printer software file would have allowed copycat production elsewhere for the same valve.</p> <p>Efforts to insert a pricing restraint obligation in the first U.S. coronavirus bill were unsuccessful after lobbying from industry trade associations. There are external and internal pressures on drug companies to see the coronavirus pandemic as a profit-making opportunity.¹⁰</p> <p>Gilead sought and received designated orphan drug status, with 7 extra years of market exclusivity for potential COVID-19 treatment, remdesivir.¹¹</p>

Licenses granted to generics, biosimilar producers, and other producers will mobilize, expand, and use all available domestic and foreign capacity that is vital to the rapid dissemination of needed medical technologies to all without export restrictions.

Although competition between medical technology producers has almost always resulted in lower prices and increased supply, the special advantages of facilitating competitive sources of supply in response to the COVID-19 pandemic are three-fold. First and foremost, the exponential pace of coronavirus infection is so threatening that we must do everything possible to mobilize existing supply capacity to speed tests, vaccines, medical, and devices to people-in-need as soon as possible. Second, we desperately need abundant and redundant sources of supply so that stockouts and supply interruptions traceable to a single-source producer do not grind the pandemic response to a halt. Third, many countries will be able to mobilize existing local capacity to meet some or all of their supply needs, building supply chain security

⁸ <https://uk.reuters.com/article/uk-health-coronavirus-britain-ventilator/uks-smiths-makes-ventilator-available-to-other-producers-idUKKBN2180IG>

⁹ <https://www.techdirt.com/articles/20200317/04381644114/volunteers-3d-print-unobtainable-11000-valve-1-to-keep-covid-19-patients-alive-original-manufacturer-threatens-to-sue.shtml>

¹⁰ Sharon Lerner, *Big Pharma Prepares to Profit from Coronavirus*, THE INTERCEPT (March 13, 2020), <https://theintercept.com/2020/03/13/big-pharma-drug-pricing-coronavirus-profits/>; See Fang, *Banks Pressure Health Care Firms to Raise Prices on Critical Drugs, Medical Supplies for Coronavirus*, THE INTERCEPT (march 19, 2020), <https://theintercept.com/2020/03/19/coronavirus-vaccine-medical-supplies-price-gouging/>

¹¹ <https://seekingalpha.com/news/3554448-gileads-remdesivir-wins-orphan-drug-status-for-coronavirus>

for the future and allowing additional global capacity to be used to meet the needs of countries with insufficient local capacity.

While we expand supply, we also have to guard against nationalistic responses that hoard medical supplies and limit exports of needed ingredients and medical technologies to other countries.¹² Although we cannot have a first-come, higher-payer system, we also cannot tolerate a system that prioritizes the needs of producer countries to the detriment of countries that have become highly dependent on global supply chains for essential medical technologies, including those needed in the COVID-19 response.

Emergency needs require an emergency response from governments, WHO, and others.

Although working on the details of the TIPP and its licenses will take time, we have no time to delay in approving the broad outlines of the proposed TIPP. If we let the ordinary course of events and the commercial imperatives of biomedical-R&D-as-usual prevail, we will have a tangle of IP rights that will tie the pandemic response in knots for months if not years. Already countries including Israel, Chile, and Ecuador are considering compulsory licenses for COVID-19 medical technologies because they sense they will be at the end of the line in gaining needed supplies unless effective voluntary measures are adopted. A comprehensive, voluntary mechanism organized by the WHO that addresses all IP barriers, that facilitates open and collaborative R&D and data sharing, and that mobilizes all available manufacturing capacity to meet needs in every country is desperately needed in these desperate times. Shared needs require shared responsibility and shared resources – millions of lives literally hang in the balance.

¹² Aitor Hernandez-Morales, *Germany confirms that Trump tried to buy firm working on coronavirus vaccine*, POLITICO (March 15, 2020), <https://www.politico.eu/article/germany-confirms-that-donald-trump-tried-to-buy-firm-working-on-coronavirus-vaccine/>; Hannah Ellis-Petersen, *India bans medicines export after supplies hit by coronavirus*, THE GUARDIAN (March 4, 2020) (since reversed), <https://www.theguardian.com/world/2020/mar/04/india-limits-medicine-exports-coronavirus-paracetamol-antibiotics>; <https://www.theguardian.com/world/2020/mar/04/india-limits-medicine-exports-coronavirus-paracetamol-antibiotics>; Chad P. Brown, *EU limits on medical gear exports puts poor countries and Europeans at risk*, PETERSON INSTITUTE FOR INTERNATIONAL ECONOMICS – TRADE AND INVESTMENT POLICY WATCH (March 19, 2020) <https://www.piie.com/blogs/trade-and-investment-policy-watch/eu-limits-medical-gear-exports-put-poor-countries-and>; *UK bans parallel export of key drugs to protect supplies*, REUTERS (March 23, 2020), https://www.reuters.com/article/us-health-coronavirus-britain-medicines/uk-bans-parallel-exports-of-key-drugs-to-protect-supplies-idUSKBN2171Z8?utm_campaign=pharmalittle&utm_source=hs_email&utm_medium=email&utm_content=85110708&hsenc=p2ANqtz-9GulXB2OHxgqG0AP0WzdZ2pjAoeEvYeUCJyIOZSKKSZrAmERuJgLMER9NvxDWABdaHkkDkgjnyCQinR70i-YobF9y5qw&hsmi=85110708