# Topic

## Topic Overview

Resolved: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.

India and South Africa made a request similar to the resolution in October of 2020. That request was within the context of COVID-19 and related intellectual property protections. Member nations of the World Trade Organization – particularly developed nations – voted against that request saying that there was not enough evidence and decided to make a decision in 2021. The year is now 2021 and there has not yet been consensus. Notably, in May of this year, the Biden administration voiced support for a version of this waiver specifically about COVID vaccines. Other countries still have varied responses, but it seems that many other member nations might be closer to being on board now that the U.S. has voiced support. However, this is not where the topic ends, this is only the exigency for why the topic is being discussed now. It’s important to consider the broader implications of the resolution.

The resolution is about reducing intellectual property protections for medicines. Under the World Trade Organization, this has a lot to do with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). While this is particularly relevant with the COVID pandemic, it also applies to how the world will think about and handle medical and health crises in the future. There is a lot of precedence behind how this has been handled, and there have been different revisions throughout the year. This topic is about identifying whether or not we have struck the proper balance between intellectual property protections to encourage innovation while also balancing the need for access to medications.

On both the affirmative and negative within this file, be intentional in your argumentation and think about how the contentions interact. When you present the argument, you want them to strengthen each other without being dependent on each other in case your opponent is prepared with great offense on one of the contentions. For example, contention one for the negative case is about how current flexibilities within TRIPS is preferrable to the resolution. There are multiple reasons for this – saving the most lives, avoiding legal obstacles, it’s the best for involved parties, etc. But one of the reasons it’s preferrable is innovation itself. Therefore, strength in contention 2 makes contention 1 stronger. However, if the only clear reason that flexibilities within TRIPS is preferable is innovation, then the affirmative can answer your whole case with some solid offense on the innovation advantage. You want to diversify your voters and impacts between these advantages but also think of ways they can interact in productive and efficient ways.

## Further Readings

Donohue, T. J. (2021). Why Intellectual Property Protection Matters in the Time of Coronavirus. Retrieved October 11, 2021, from https://www.theglobalipcenter.com/why-intellectual-property-protection-matters-in-the-time-of-coronavirus/

Ilias, S. (2010, June 14). Intellectual Property Rights and Access to Medicines: International Trade Issues. Retrieved October 11, 2021, from https://www.everycrsreport.com/reports/R40607.html

Jaci McDole, S. E. (2021, April 29). Ten Ways IP Has Enabled Innovations That Have Helped Sustain the World Through the Pandemic. Retrieved October 11, 2021, from https://itif.org/publications/2021/04/29/ten-ways-ip-has-enabled-innovations-have-helped-sustain-world-through

Mossoff, A. (2021, September 17). The COVID-19 Intellectual Property Waiver: Threats to U.S. Innovation, Economic Growth, and National Security. Retrieved October 11, 2021, from https://www.heritage.org/economic-and-property-rights/report/the-covid-19-intellectual-property-waiver-threats-us-innovation

World Trade Organization. (2006, September 21). Pharmaceutical patents and the TRIPS Agreement. Retrieved from <https://www.wto.org/english/tratop_e/trips_W>

Thrasher, R. (1969, September 01). Why the TRIPS Waiver Should Include More than Just Vaccines: Global Development Policy Center. Retrieved October 11, 2021, from https://www.bu.edu/gdp/2021/06/07/why-the-trips-waiver-should-include-more-than-just-vaccines/

# Aff

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### Definitions

#### Intellectual Property Protections, or IPPs, offer international legal credit to knowledge creation

WIPO, no date

The World Intellectual Property Organization is one of the 15 specialized agencies of the United Nations. WIPO is the global forum for intellectual property (IP) services, policy, information and cooperation. “What is Intellectual Property?” published by World Intellectual Property Organization, WIPO, no date. Available here: (<https://www.wipo.int/about-ip/en/>) -AL

Intellectual property (IP) refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce.

IP is protected in law by, for example, patents, copyright and trademarks, which enable people to earn recognition or financial benefit from what they invent or create. By striking the right balance between the interests of innovators and the wider public interest, the IP system aims to foster an environment in which creativity and innovation can flourish.

#### TRIPS is a legal agreement under the World Trade Organization, aka WTO, specifically concerning medicine relating to patents and IPPs

WTO, 06

The World Trade Organization (WTO) deals with the global rules of trade between nations. Its main function is to ensure that trade flows as smoothly, predictably and freely as possible. “Pharmaceutical patents and the TRIPS Agreement” published by the World Trade Organization, 21 September 2006. Available here: (<https://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm>) -AL

The purpose of this note is to describe those provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) that relate to the standards of patent protection to be accorded to inventions in the area of pharmaceuticals.

To set this discussion in context, it is useful to recall three basic features of the TRIPS Agreement:

that, together with some 25 other legal texts, it is an integral part of the Agreement Establishing the World Trade Organization (and therefore subject to the WTO dispute settlement system);

that it covers not only patents but all the other main areas of intellectual property rights; and

that it lays down not only the minimum substantive standards of protection that should be provided for in each of these areas of intellectual property, but also the procedures and remedies that should be available so that rights holders can enforce their rights effectively.

### Value-Criterion

#### For today’s value, I offer human rights. The right to access health ought not be infringed upon by others, including other nations or legal agreements.

Campbell, 04

Tom Campbell - Centre for Applied Philosophy and Public Ethics Charles Sturt University USA. “Moral Dimensions of Human Rights” published by Issues in Business Ethics book series, 2004. Available here: (<https://link.springer.com/chapter/10.1007/1-4020-2361-8_2>) -AL

That human rights should have moral implications beyond the need to enact and conform to effective human rights laws is hardly surprising, given that the very concept of human rights is, at base, a moral one. Human rights are primarily a species of moral rights in that they highlight certain priority moral values that cannot be identified with any actual set of institutionalised rights and duties. Human rights can never, for instance, simply be equated with human rights law, either in its domestic or international manifestations. Because human rights derive from important human interests and needs, it is natural to expect legal protection of human rights. Indeed this itself may contribute to their moral influence in a society. Nevertheless, the import of human rights goes far beyond setting up and implementing laws and ought to impact on every aspect of policy and decisionmaking in private as well as public sector organisations. This gives new force to the significance of developing ethical cultures in organisations, a process that is already emerging in the increasing significance given to internal codes of ethics, ethical audits and open acknowledgment of the corporate social responsibility of management and boards of directors.

In this introductory chapter, I argue that when these distinctively moral dimensions of human rights are taken seriously in the governance and goal-setting of organisations, this does not involve simply taking on board institutionalised human rights in their existing state and legally oriented guise, but can be expected to lead to the articulation and deployment of specific human rights that, in form and content, relate to the particular situations and capacities, for good and evil, of different types of human organisation.

#### For today’s value criterion, I offer equitable health access.

Oliver and Mossialos, 04

Dr. Adam Oliver LSE Health and Social Care, London School of Economics and Political Science, London. Elias Mossialos, London School of Economics, UK. “Equity of access to health care: outlining the foundations for action” published by BMJ Journals, Journal of Epidemiology and Community Health, 2004. Available here: (<https://jech.bmj.com/content/58/8/655>) -AL

PRINCIPLES OF EQUITY

There is an enormous literature on equity in health and health care, written from every conceivable disciplinary perspective, and several principles of equity are commonly discussed.3,4 For example:

Equal access to health care for those in equal need of health care.

Equal utilisation of health care for those in equal need of health care.

Equal (or, rather, equitable) health outcomes (as measured by, for example, quality adjusted life expectancy).

Equal access for equal need requires conditions whereby those with equal needs have equal opportunities to access health care (that is, horizontal equity), and, as a corollary, those with unequal needs have appropriately unequal opportunities to access health care (that is, vertical equity). For various acceptable reasons (for example, varying individual preferences), those in equal need and with equal opportunities to access health care may not make an equal use of those opportunities. These acceptable reasons should not be confused with unacceptable reasons for differential use of health care. For example, some individuals (or groups of individuals) may be better informed and more adept at accessing—and making full use of—health care than others.

As is implied in the terminology, equal utilisation for equal need requires conditions whereby those who have an equal need for health care make equal use of health care. Compared with equal access for equal need, this equity principle therefore requires more proactive (and possibly very costly) efforts by policy makers, and would require that potentially acceptable reasons for unequal use of healthcare services (by those in equal need) be overridden. For example, differences in lifestyle preferences and/or levels of risk aversion may lead to differences in the utilisation of health care, but the principle of equal utilisation for equal need does not allow for these considerations.

The principle of achieving equal health outcomes (for example, mortality and morbidity measurements) is potentially highly undesirable because it would require too many restrictions on the ways in which people may choose to live their lives. However, the attainment of less unequal health outcomes (that is, more equitable health outcomes) may be a desirable policy objective, but the extent to which the focus of this article—that is, health care—influences average levels of, and differentials in, population health outcomes is limited.5 Other areas of fiscal and social policy, that impinge upon, for example, incomes, education, housing conditions, and nutrition, are potentially far stronger influences, perhaps in large part because they better tackle the fundamental determinants of health. Moreover, the extent to which health care (in particular, curative health care) is used as a vessel to redistribute health outcomes is morally contentious, because this action would require people who are already ill and have the same need for health care to be treated unequally (and in line with some factor that is exogenous to their health—for example, their level of income or educational attainment, among other possible factors).

Hence, in agreement with the seven Ministers of Health who met in Stockholm and London, we contend that equal access to health care for those in equal need is the most appropriate principle of equity for the healthcare policy maker to pursue, because (1) it is specific to health care and does not require that we discriminate between people who are already ill purely on the basis of factors that are exogenous to their health, and (2) it respects acceptable reasons for differentials in healthcare utilisation by those in equal need.

### Contention 1: Future Pandemics

#### I affirm the resolution which specifically solves for medical emergencies broadly and in the future as opposed to the inaccessible TRIPS flexibilities and currently proposed waiver

Lindsey, 21

Brink Lindsey is Vice President and Director of the Open Society Project at the Niskanen Center. Previously he was the Cato Institute's vice president for research. “Why intellectual property and pandemics don’t mix” publishing by Brookings Institute, 3 June 2021. Available here: (<https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/>) -AL

On May 5 the Biden administration announced that it would support waiving intellectual property protections for COVID-19 vaccines under the World Trade Organization’s Agreement on Trade-Related Intellectual Property Rights (TRIPS). Predictably, the move drew fiery condemnation from drug companies. In addition, many disinterested observers criticized the support for a TRIPS waiver as empty symbolism, arguing that vaccine patents are not the major obstacle hindering the currently flagging drive to make vaccines available around the world.

Waiving patent protections is certainly no panacea. What is needed most urgently is a massive drive of technology transfer, capacity expansion, and supply line coordination to bring vaccine supply in line with global demand. Dispensing with patents in no way obviates the need for governments to fund and oversee this effort.

Although focusing on these immediate constraints is vital, we cannot confine our attention to the short term. First of all, the COVID-19 pandemic is far from over. Although Americans can now see the light at the end of the tunnel thanks to the rapid rollout of vaccines, most of the world isn’t so lucky. The virus is currently raging in India and throughout South America, overwhelming health care systems and inflicting suffering and loss on a horrific scale. And consider the fact that Australia, which has been successful in suppressing the virus, recently announced it was sticking to plans to keep its borders closed until mid-2022. Criticisms of the TRIPS waiver that focus only on the next few months are therefore short-sighted: this pandemic could well drag on long enough for elimination of patent restrictions to enable new vaccine producers to make a positive difference.

Furthermore, and probably even more important, this is almost certainly not the last pandemic we will face. Urbanization, the spread of factory-farming methods, and globalization all combine to increase the odds that a new virus will make the jump from animals to humans and then spread rapidly around the world. Prior to the current pandemic, the 21st century already saw outbreaks of SARS, H1N1, MERS, and Ebola. Everything we do and learn in the current crisis should be viewed from the perspective of getting ready for next time.

#### IPPs’ method of incentivizing innovation should be rejected in the context of pandemics

Lindsey, 21

Brink Lindsey is Vice President and Director of the Open Society Project at the Niskanen Center. Previously he was the Cato Institute's vice president for research. “Why intellectual property and pandemics don’t mix” publishing by Brookings Institute, 3 June 2021. Available here: (<https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/>) -AL

PUBLIC HEALTH EMERGENCIES AND DIRECT GOVERNMENT SUPPORT

For pandemics and other public health emergencies, patents’ mix of costs and benefits is misaligned with what is needed for an effective policy response. The basic patent bargain, even when well struck, is to pay for more innovation down the road with slower diffusion of innovation today. In the context of a pandemic, that bargain is a bad one and should be rejected entirely. Here the imperative is to accelerate the diffusion of vaccines and other treatments, not slow it down. Giving drug companies the power to hold things up by blocking competitors and raising prices pushes in the completely wrong direction.

What approach to encouraging innovation should we take instead? How do we incentivize drug makers to undertake the hefty R&D costs to develop new vaccines without giving them exclusive rights over their production and sale? The most effective approach during a public health crisis is direct government support: public funding of R&D, advance purchase commitments by the government to buy large numbers of doses at set prices, and other, related payouts. And when we pay drug makers, we should not hesitate to pay generously, even extravagantly: we want to offer drug companies big profits so that they prioritize this work above everything else, and so that they are ready and eager to come to the rescue again the next time there’s a crisis.

#### Once IPPs are reduced, other issues can be resolved to save the most lives possible – we must rethink the global intellectual property system

Krishtel and Malpani, 21

Priti Krishtel, co-executive director at The BMJ and Rohit Malpani, a global health consultant. “Suspend intellectual property rights for covid-19 vaccines” published by The BMJ, 28 May 2021. Available here: (<https://www.bmj.com/content/373/bmj.n1344>) -AL

Key features

A successfully negotiated waiver would meet four important criteria. The waiver’s primary aim should be to save as many lives as possible. The Biden administration wants the waiver to focus on vaccines. This constraint should be removed. The original proposal applies to all medical technologies related to covid-19, including diagnostics, medicines, and ventilators. Many people are likely to become sick even if vaccination rates improve worldwide.

Secondly, negotiations should be completed quickly. Governments should make substantial progress ahead of the WTO meeting on 8 June 2021. Thirdly, any waiver should be straightforward, unambiguous, for a reasonable duration, and limit manufacturers’ ability to file legal challenges that impede access.

Finally, negotiating texts should be fully disclosed, with negotiations transparent to ensure all countries negotiate as equals. In the past, powerful nations have used their leverage to extract concessions from less powerful countries behind closed doors.14

Opponents of a waiver question whether manufacturers in lower income countries have the required capabilities. This argument was also made in the 1980s when Merck and GSK dominated the market for complex recombinant hepatitis B vaccines. It was discredited in 1997, when Indian manufacturer Shantha Biotechnics launched a vaccine that reduced the cost of a dose from up to $23 to just $1. Many millions of people worldwide have since been successfully immunised.15 Manufacturers in low and middle income countries are already critical to overall immunisation efforts worldwide: in 2018, they provided over half of the 2.4 billion vaccine doses procured by Unicef.16

Suppliers worldwide are gearing up to meet this moment. New mRNA vaccines are under development in India17 and China,18 and several companies in middle income countries are already manufacturing covid-19 vaccines.1920 WHO is establishing a technology transfer hub to support local production of mRNA vaccines.21 Although follow-on manufacturers can produce complex vaccines without support from holders of technology, sharing knowledge would save time and lives.

As we enter into a new era of global pandemics, we must fundamentally rethink the global intellectual property system. The ability to respond swiftly to global crises cannot be left to a handful of private companies in a few wealthy countries. We need a more cooperative global response to this and future public health emergencies.

### Contention 2: Global Equity

#### Vaccine distribution is woefully unequitable across the globe and vaccine knowledge isn’t publicly available even though it used public sources of funding

Krishtel and Malpani, 21

Priti Krishtel, co-executive director at The BMJ and Rohit Malpani, a global health consultant. “Suspend intellectual property rights for covid-19 vaccines” published by The BMJ, 28 May 2021. Available here: (<https://www.bmj.com/content/373/bmj.n1344>) -AL

Waivers are essential for global vaccine equity

The United States caught the world by surprise on 5 May 2021 when it announced its intention to support a World Trade Organization proposal that would temporarily waive intellectual property rights on covid-19 vaccines. While this move is encouraging, the Biden administration’s support is the first step of many required.1

Waiving intellectual property rights is essential to tackle serious inequity in the global distribution of covid-19 vaccines, whereby wealthy countries currently control the lion’s share of existing supplies. By the end of April, over 1.3 billion doses had been administered worldwide, but only 0.2% of vaccines had been given in low income countries.2

More than one year into the pandemic, the situation is at a low point globally. The average number of weekly deaths in April was over 36 000 in just India and Brazil,3 and variants are proliferating. Experts fear a devastating second wave across Asia and Africa.4

Voluntary action has not worked— whether timely sharing of doses with low and middle income countries or sharing knowledge through the World Health Organization. It’s time for mandatory rules and legal commitments that can help put an end to this pandemic.

The proposed intellectual property waiver is appropriate as vaccine manufacturers have relied heavily on publicly funded research into coronaviruses.5 Together, companies holding intellectual property rights are estimated to have benefited from government funding of around €93bn (£80bn; $110bn).6 The Moderna vaccine was funded almost exclusively by the US government.7

#### These inequities are encouraged by a system of private intellectual property which unfairly drives up prices while withholding needed medication

Krishtel and Malpani, 21

Priti Krishtel, co-executive director at The BMJ and Rohit Malpani, a global health consultant. “Suspend intellectual property rights for covid-19 vaccines” published by The BMJ, 28 May 2021. Available here: (<https://www.bmj.com/content/373/bmj.n1344>) -AL

A successfully negotiated intellectual property waiver would ensure manufacturers cannot block production or access to raw materials and finished products for covid-19 technologies worldwide. A waiver would also prevent companies from charging unaffordable prices while insulated from competition.

Lack of competition in the vaccines market has a long history. Previously, the two companies with a duopoly for the human papillomavirus (HPV) vaccine8 held patents that prevented competition. According to one estimate, low income countries paid up to 10 times the estimated cost of production for these vaccines.9 Millions of girls globally are still unable to access this critical protection against cervical cancer.

Similarly, Pfizer successfully enforced secondary patents on its pneumococcal vaccine through legal proceedings in India10 and South Korea,11 which delayed competition. Pneumonia remains the leading cause of death globally among children under 5 years old.12 Many middle income countries have low coverage because of the high price of the vaccine, often 5-10 times higher than the lowest price available globally.13

Inadequate access to essential vaccines is predictable in a system that prioritises monopolies—and this will repeat itself in the absence of an intellectual property waiver for covid-19 vaccines.

#### WTO’s prioritizing of protections for intellectual property has cost millions of lives

HRW, 21

Human Rights Watch (HRW) is an international non-governmental organization, headquartered in New York City, that conducts research and advocacy on human rights. “Sharing Knowledge, Technology Critical to Curb Covid-19” published by Human Rights Watch, 14 September 2021. Available here: (<https://www.hrw.org/news/2021/09/14/sharing-knowledge-technology-critical-curb-covid-19>) -AL

Most governments have also sidelined WHO technology sharing pools. The WHO first created a voluntary technology sharing pool for Covid-19 medical products in May 2020 that would have allowed the sharing of vaccine technology to promote faster production and distribution. However, only 41 governments have endorsed the pool. Most others including the US, UK, Germany, and many other EU member states and the European Commission have yet to signal their participation in the pool. None of these governments have used their influence or leverage to convince any of the pharmaceutical companies whose vaccines they have funded to join the technology pool.

The WTO is an intergovernmental organization that regulates and facilitates international trade between nations. Its promotion of trade and protection of intellectual property has historically taken priority over health, environment, or human wellbeing. This pattern has had lethal consequences during a pandemic by slowing a public response when at least 4.5 million lives have already been lost.

“The Covid-19 pandemic has shown the system needs a long-overdue course correction so that the WHO is empowered, and not undermined, by the WTO,” said Margaret Wurth, senior researcher at Human Rights Watch and a co-author of the paper. “Participating in WHO technology sharing platforms and temporarily waiving intellectual property rules are critical ways forward.”

## Other Cards (10)

### Extension: De-Coloniality

#### TRIPS is specifically a part of a process of deepening global inequalities beyond the pandemic

Sekalala et. al., 21

Sharifah Sekalala – Warwick Law School, University of Warwick, Coventry, UK. Lisa Forman – Dalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canada. Timothy Hodgson – International Commission of Jurists, Johannesburg, South Africa. Moses Mulumba – Center for Health, Human Rights and Development, Kampala, Uganda. Hadijah Namyalo-Ganafa – School of Law, Makerere University, Kampala, Uganda. Benjamin Mason Meier – Department of Public Policy, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA. “Decolonising human rights: how intellectual property laws result in unequal access to the COVID-19 vaccine” published by BMJ Global Health, 12 July 2021. Available here: (<https://gh.bmj.com/content/6/7/e006169>) -AL

The failure of TRIPS flexibilities

Although countries from the Global South have the option of engaging TRIPS flexibilities in the absence of a general waiver, they often do not do so because the process of using these flexibilities is often stacked against them, reproducing neocolonial dynamics. For instance, TRIPS allows states with limited manufacturing capacity to waive a patent for a limited duration so as to import essential medicines through a compulsory licence. However, in practice, this process is lengthy and complex, as it relies on ensuring that both the importing and exporting countries have enacted local laws that permit them to use TRIPS flexibilities. Further, the importing country needs to negotiate with the pharmaceutical company in order to establish a fair price, which is always tricky, but made significantly more difficult in a crisis. To date, this process has been used only once, when Rwanda obtained access to generic antiretrovirals through an importation agreement with the Canadian company Apotex. However, even in that context, although Rwanda notified the WTO Council of its intention to use the mechanism in July 2007, it took 15 months before it could import its first batch of antiretrovirals. Despite its strong support, the manufacturer Apotex felt that the process was too cumbersome to use again.36

This complexity has been heightened during the COVID-19 crisis due to the speed at which vaccines were manufactured, which has created a lack of transparency around the patent process.37 Thus, the Bolivian government, which is seeking to use TRIPS flexibilities through compulsory licences, recognises in their application that there is a lack of clarity around the exact extent of product and process patents for any of the existing COVID-19 vaccines due to inadequate information about manufacturing or regulatory processes in different countries.38 Additionally, many countries that have manufacturing capacity, such as those in the EU, have not sought to support countries in the Global South that want to use these flexibilities. In sum, cumbersome rules, political and economic pressures and a lack of transparency conspire to enable the Intellectual Property Regime (IPR) system to sustain and deepen global health inequities.

#### The Global North actively tries to impede the small access that the Global South has to developing vaccines by making TRIPS flexibilities inflexible and actively worsening neocolonial cycles

Entrenching inequalities between countries

The current global distribution of COVID-19 vaccines is largely dictated by power disparities and inequities in financial and other resources, with predominantly high-income countries contracting bilaterally with individual pharmaceutical companies (many in their own countries) for specific vaccines, leaving countries from the Global South facing inequitable vaccine access. Bilateral deals between states and pharmaceutical companies, whether completed by Global North or Global South states, significantly compromise the effectiveness and equity of the COVAX initiative, limited as it already is by the coercive influence, vested interests and participation of pharmaceutical companies and their host nations. The African Union, for example, endorsed the TRIPS waiver to relax WTO rules so that LMICs could create their own COVID-19 vaccines, but this collective effort across African countries faced resistance from Global North countries and pharmaceutical companies.

The IP system appears to have pushed countries in the Global South that may prefer not to be dependent on the charitable model of the COVAX scheme to join high-income countries in engaging directly with manufacturers to purchase COVID-19 vaccines. This has included African countries, despite the African Union’s criticism of the inequities resulting from IP law protections. This process has reproduced colonially entrenched power dynamics, in which poorer countries lack the bargaining power to obtain competitive rates and, consequently, typically end up paying far more than the wealthier, developed countries. More broadly, countries in the Global South are pressured into participating in global systems of trade that result in the exploitation of their own populations by unjust global economic systems and IP laws.39 The high cost of vaccines for countries from the Global South constitutes a large proportion of their health expenditure, and this comes at the expense of other health priorities.

In many cases, the only way in which Global South countries can purchase vaccines is to move themselves further into debt. Given the detrimental neocolonial implications of debt, with a long history of loan conditionalities through structural adjustment programmes, increasing debt to service health needs contributes to the worsening of inequalities between the Global North and Global South.40 These programmes may increase debt and undermine development in ways that limit the realisation of the right to health.41 The World Bank has set aside US$12 billion and has already disbursed loans of US$500 million for vaccines in low-income and middle-income nations;42 poorer nations, instead of servicing already depleted health systems, are forced to divert additional funds to servicing debt.

#### Voting in favor of reducing medical IPPs is part of a broader shift do de-colonize human rights issues

Sekalala et. al., 21

Sharifah Sekalala – Warwick Law School, University of Warwick, Coventry, UK. Lisa Forman – Dalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canada. Timothy Hodgson – International Commission of Jurists, Johannesburg, South Africa. Moses Mulumba – Center for Health, Human Rights and Development, Kampala, Uganda. Hadijah Namyalo-Ganafa – School of Law, Makerere University, Kampala, Uganda. Benjamin Mason Meier – Department of Public Policy, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA. “Decolonising human rights: how intellectual property laws result in unequal access to the COVID-19 vaccine” published by BMJ Global Health, 12 July 2021. Available here: (<https://gh.bmj.com/content/6/7/e006169>) -AL

Conclusion

As scholars and activists from the Global North and Global South who have been advocating for the full realisation of human rights throughout the pandemic, especially around access to essential medicines such as COVID-19 vaccines, we intend this article to contribute to a broader conversation on the need for the decolonisation of human rights in global health and to illustrate that human rights should be more emancipatory. Human rights require equality in access to vaccines, rather than the limited and ineffective charity currently made available in a glacial manner through initiatives like COVAX.

For Global South countries, the decolonisation of human rights in health is a potentially radical and transformative agenda, which would contribute to ensuring that vaccines are provided equitably, transparently, freely and universally at the point of access. It would contribute towards breaking the spell of regressive and inflexible application of patents acting as the over-riding consideration in all matters of vaccine production and distribution. The COVID-19 vaccination process is one of the greatest global health challenges of our time, and we must ensure that we use this moment to better conceptualise the ways in which we collectively think about the right to health of all people, everywhere.

### Extension: Global Equity

#### Amending TRIPS is key to global equity for COVID vaccines

Campos-Rudinsky, 21

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Conclusion

Building on the theoretical premise of global justice and applying it to the COVID-19 context, this article has discussed how the TRIPS regime makes it more difficult to achieve universal access to generic, affordable COVID-19 treatments—including potential vaccines. I have argued that, while patents can impose certain barriers to universal access to generic COVID-19 treatments, the TRIPS regime itself, in particular its article 31bis, could be an integral part of an equitable global solution to the pandemic. More specifically, I have argued that article 31bis, in allowing for a multilateral cooperative strategy predicated on complementary import and export of vital COVID-19 generic treatments, is of key importance to successful suppression of the pandemic. Such a cooperative strategy could involve, for example, some countries producing certain generic, affordable pharmaceutical products to treat COVID-19, and other countries producing other such products, all according to a multilateral complementary cooperative strategy, followed by the import and export of all these products among WTO member states. This division of labour, I suggest, illustrates what global solidarity and friendship among nations could look like during public health emergencies of international concern.

#### Thinking about medical knowledge and life-saving vaccines as a trade-able commodity has justified global inequities and lost lives

HRW, 21

Human Rights Watch (HRW) is an international non-governmental organization, headquartered in New York City, that conducts research and advocacy on human rights. “Sharing Knowledge, Technology Critical to Curb Covid-19” published by Human Rights Watch, 14 September 2021. Available here: (<https://www.hrw.org/news/2021/09/14/sharing-knowledge-technology-critical-curb-covid-19>) -AL

(New York) – Wealthy governments and pharmaceutical companies are undermining a rapid and equitable public health response to Covid-19 vaccines, therapeutic drugs, and tests, Human Rights Watch researchers said in a paper published ahead of a World Trade Organization (WTO) meeting this week. Human Rights Watch also released a video about the subject. Governments and companies should urgently share knowledge and technology to save lives, protect the right to health, and ensure everyone can benefit from scientific research, especially with the highly contagious Delta variant.

The paper, “COVID-19 Exposes Warped Global Health Power: The System Needs a Course Correction,” published on August 31, 2021 in the Business and Human Rights Journal, discusses how a handful of high-income countries that were lobbied by powerful pharmaceutical companies have stalled a proposal to temporarily waive global trade and intellectual property rules to expand access to lifesaving vaccines and other health care products. Drawing upon Human Rights Watch research and analysis on Covid-19 vaccine supply issues, it shows how governments have abdicated their responsibility to regulate pharmaceutical companies. Governments funding Covid-19 vaccine development with public money failed to condition these funds on affordability and sharing technology, leaving companies to decide how, when, and where they will manufacture, distribute, and price vaccines, Human Rights Watch said. Instead of sharing knowledge and technology, some governments are redistributing an inadequate amount of vaccines to poorer countries while letting companies set prices.

“Waiting for the benevolence of wealthy governments and pharmaceutical companies has dealt a deadly blow to basic rights,” said Aruna Kashyap, associate business and human rights director at Human Rights Watch and a co-author of the paper. “It’s unconscionable that wealthy governments are reducing life-saving health care to a tradeable commodity and using their power at the WTO to make the right to health subservient to pharma and trade interests.”

#### These inequalities run deep and aren’t getting solved – wealthy countries focus on boosters while the majority of low-income countries have not yet been vaccinated

HRW, 21

Human Rights Watch (HRW) is an international non-governmental organization, headquartered in New York City, that conducts research and advocacy on human rights. “Sharing Knowledge, Technology Critical to Curb Covid-19” published by Human Rights Watch, 14 September 2021. Available here: (<https://www.hrw.org/news/2021/09/14/sharing-knowledge-technology-critical-curb-covid-19>) -AL

Access to Covid-19 vaccines remains deeply unequal. Three-quarters of the more than 5 billion vaccine doses administered worldwide have gone to just 10 countries, according to the WHO. While some rich governments have begun distributing third “booster” shots, only two percent of Africa’s population is fully vaccinated. The director-general of the WHO has called for a moratorium on booster doses to enable vaccines to reach people who have yet to receive their first dose.

The pandemic has laid bare the dangers of having manufacturing capacity for life-saving vaccines concentrated in a few countries where governments have refused to prioritize and mandate intellectual property waivers and technology transfers for rapid diversified and global production. That has created deep inequities in access to the health products that can save lives.

Months-long debates at the WTO have left the WHO and public health authorities throughout the world in limbo. In May, the United States signaled that it would support negotiations on the text of the waiver proposal. But the European Commission, representing the European Union member states, Switzerland, and several other high-income governments have consistently stalled and blocked efforts to swiftly adopt the waiver. Negotiations resume in Geneva on September 14.

Meanwhile, shortages of vaccine supplies and inequitable vaccine distribution policies have led to vaccine inequity in a number of countries around the world, including India, Australia, Lebanon, Syria, Yemen, and Brazil.

The proposal to temporarily waive global trade and intellectual property rules, which has the support of over 100 governments, if adopted by the WTO, would signal that, in the context of the ongoing pandemic, providing life-saving health care comes first.

International law recognizes everyone’s right to benefit from scientific progress. Since the onset of the pandemic, United Nations human rights entities have repeatedly reiterated that states have an obligation to share the benefits of scientific research. Governments have obligations concerning international cooperation. They should refrain from actions that interfere, directly or indirectly, with the enjoyment of rights in other countries. This obligation extends to their actions in intergovernmental organizations like the WTO.

#### It was never about innovation and competitiveness because low-income countries were never given the chance to compete and were excluded from the benefits

Sekalala et. al., 21

Sharifah Sekalala – Warwick Law School, University of Warwick, Coventry, UK. Lisa Forman – Dalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canada. Timothy Hodgson – International Commission of Jurists, Johannesburg, South Africa. Moses Mulumba – Center for Health, Human Rights and Development, Kampala, Uganda. Hadijah Namyalo-Ganafa – School of Law, Makerere University, Kampala, Uganda. Benjamin Mason Meier – Department of Public Policy, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA. “Decolonising human rights: how intellectual property laws result in unequal access to the COVID-19 vaccine” published by BMJ Global Health, 12 July 2021. Available here: (<https://gh.bmj.com/content/6/7/e006169>) -AL

Introduction

The COVID-19 pandemic is one of the biggest health crises that the world has faced in the last century. While many COVID-19 vaccines have been rapidly developed, offering hope to billions, many countries face a herculean task in accessing them, in part because of restrictive intellectual property (IP) laws. This is because vaccine patents, which are a form of IP rights, lead to production monopolies that contribute to increased prices and decreased access. This injustice has been described as ‘vaccine apartheid’ because it creates stark disparities in vaccine access between countries in the Global North and those in the Global South, as well as between elites and others within countries.

In this article, we show that the existing application of IP law exacerbates already severe global and domestic inequalities and prevents many countries in the Global South from progressively realising the right to health for all of their people. This, in turn, amounts to a violation of states’ human rights obligations to respect, protect and fulfil the right to health. We suggest that the best way to address these structural global inequities is through a decolonised approach to human rights in global health. Decolonisation refers to the undoing of colonial rule over subordinate countries but has taken on a wider meaning as the ‘freeing of minds from colonial ideology’, in particular by addressing the ingrained idea that to be colonised was to be inferior. Decolonisation enables us to critique positions of power and dominant culture.1 In global health, decolonisation is a political tradition rooted in Global South struggles against colonisation, exploitative ‘development’ agendas, apartheid and access to public health, including inequity in access to essential medicines.2 Calls to decolonise global health are not new, and indeed they have gained urgency due to the power asymmetries illustrated by the COVID-19 crisis.3 4 In this paper, a ‘decolonial’ framing of human rights in global health enables us to focus on ways in which structural or systemic issues reproduce inequalities and, we hope, can help to galvanise more effective human rights struggles from below.5–8 In order to do so, we call for reparative redistributing of resources in global solidarity, shifting vaccine access from a charitable plea to a legal obligation, increasing manufacturing capacity in the Global South and clarifying human rights responsibilities of pharmaceutical corporations themselves.

International and domestic responses to COVID-19, including in respect of vaccine access, have been highly politicised.9 Thus, a decolonised approach allows us to consider ways in which the entire patent regime—and existing interpretations of international human rights law that defer to its applications—commodifies essential medicines, undermining universal health coverage. In this article, we illustrate how, beyond making essential medicines unaffordable for countries in the Global South, the commodification of vaccines is pushing countries into greater indebtedness and reproducing national inequalities through dual-track systems that discriminate against poorer and marginalised groups, thereby making it harder for these countries to achieve the realisation of the right to health for all.

The commodification of essential medicines is the consequence of the prevalent system of global capitalism that allows manufacturers and states to value financial profit over human life. In this paper, we define neocolonialism to mean that although many global South States are outwardly independent and sovereign in many respects, they remain beholden both to states in the Global North and increasingly to multinational corporations.9 This relationship is exemplified in the case of IP rights protections, which low and middle-income countries (LMIC) are pressured into adopting and respecting in order to enter into bilateral or regional free trade or investment agreements with high-income countries and/or receive investments and loans from global financial institutions.10

### Miscellaneous

#### Intellectual Properties actually reduce innovation – empirics from human genome research proves

Heidi L. Williams “Intellectual Property Rights and Innovation: Evidence from the Human Genome” published by the Journal of Political Economy. Available here: (<https://www-jstor-org.ezproxy.lib.utah.edu/stable/10.1086/669706?seq=1#metadata_info_tab_contents>) -AL

Intellectual property is a widely used policy lever for promoting innovation, yet relatively little is known about how IP on existing technologies affects subsequent innovation. The sequencing of the human genome provides a useful empirical context, generating variation in IP across a relatively large group of ex ante similar technologies. Across a range of empirical specifications, I find evidence that Celera’s IP led to reductions in subsequent scientific research and product development on the order of 20–30 percent.

A caveat to this interpretation of these results is that if innovation inputs are scarce, my estimates could reflect the substitution of innovative effort away from Celera genes toward non-Celera genes ðas opposed to a net decrease in total innovation over the set of all genesÞ. 24 Looking at a broad set of academic biomedical researchers, surveys by Walsh, Cho, and Cohen ð2005Þ and Walsh, Cohen, and Cho ð2007Þ suggest that some substitution is relevant: restricted access to tangible research inputsðincluding information, data, and softwareÞ appears to shift scientists’ research project choices. If substitution is relevant and researchers optimally choose their line of research in the absence of IP, quantifying the welfare costs of IP on cumulative innovation requires estimating the cost of distorting research toward suboptimal projects. If more socially valuable technologies are more likely to be held with IP, these welfare costs could be substantial.

While Celera’s gene-level IP did not depend on patent protection, the evidence in this paper is related to the ongoing legal controversy surrounding patents on human genes.25 Echoing the broader debate on patents, proponents argue that gene patents incentivize investment in gene-related technologies, while opponents argue that gene patents stifle subsequent product development and restrict patients’ access to gene related technologies.26To the best of my knowledge, there exists no direct evidence on how gene patents have affected subsequent product development. Moreover, the overall welfare consequences of gene patents—and patents more generally—depend on the trade-off between ex ante incentives for innovation, the ex post costs of restricting patients’ access to technologies, and any potential effects of IP on subsequent innovation. From a policy perspective, the evidence in this paper informs this gene patent debate by documenting that—at least for some forms of intellectual property—getting the incentives “right” for subsequent innovators is quantitatively important for encouraging subsequent scientific research and product development.

#### The decisions of wealthy nations and the use of IPPs impede all other nations abilities to respond to human lives lost and human rights abuses

HRW, 21

Human Rights Watch (HRW) is an international non-governmental organization, headquartered in New York City, that conducts research and advocacy on human rights. “Sharing Knowledge, Technology Critical to Curb Covid-19” published by Human Rights Watch, 14 September 2021. Available here: (<https://www.hrw.org/news/2021/09/14/sharing-knowledge-technology-critical-curb-covid-19>) -AL

States should not frustrate the efforts of other states to fulfill their human rights obligations, including when negotiating international agreements or participating in decisions as members of international organizations, such as by invoking intellectual property protections to slow vaccine distribution or production. In addition to violating their human rights obligations, obstructing a rapid health response is a huge setback to low- and middle-income countries’ ability to achieve the United Nations Sustainable Development Goals.

The pandemic has prompted discussions about an international pandemic treaty that will take place in the coming months. Any pandemic treaty should include human rights protections, including triggers for automatic intellectual property waivers and mandate greater transparency and accountability of global procurement efforts.

“We urgently need enforceable global health norms that de-commodify life-saving medical products and prioritize the health and safety of people instead of foot-dragging and equivocation,” said Kyle Knight, senior researcher at Human Rights Watch and the third co-author of the paper. “A powerful minority of wealthy governments has cynically prioritized their own and their companies’ interests while global infections and deaths soar.”

#### More than just vaccines should have IPPs reduced, broader medical IPPs should be reduced too

Thrasher, 21

Rachel Thrasher is a Researcher with the Boston University Global Development Policy’s Global Economic Governance Initiative. Ms. Thrasher received a JD and a Master’s degree in International Relations, both from Boston University. She works on policy issues related to trade and investment agreements, policy space for development, intellectual property and access to medicines and the climate impacts of trade and investment treaties. “Why the TRIPS Waiver Should Include More than Just Vaccines” published by the BU Global Development and Policy Center, 7 June 2021. Available here: (<https://www.bu.edu/gdp/2021/06/07/why-the-trips-waiver-should-include-more-than-just-vaccines/>) -AL

Nearly eight months after an initial proposal from India and South Africa, the United States surprised the world by making a public declaration of support for a Trade-Related Aspects of Intellectual Property (TRIPS) Waiver for COVID-19 vaccines at the World Trade Organization (WTO). Since then, proponents have been advocating for a waiver that is sufficiently broad in scope, coverage and duration to do the work of increasing equitable access to vaccines as well as other COVID-19 related products.

Unfortunately, the waiver still does not appear to have the global support needed to get past the WTO practice of consensus-based decision-making. The focus from G7 countries on donating doses and funding COVAX continues to keep vaccine access to a conversation about how much of their slice of pie rich countries are willing to give away, rather than expanding the pie altogether. And while the TRIPS Waiver is targeted at increasing vaccine production, the broader scope of the original proposal is cognizant of the complexity of this public health crisis by including other products that are crucial to the fight against the virus.

Arguments in favor of and against a TRIPS Waiver remain largely, and frustratingly, unchanged as the pandemic rages on. Opponents prioritize concerns that removing intellectual property protection during the pandemic will backfire and potentially make companies less likely to contribute to innovation during future pandemics. Supporters argue the COVID-19 pandemic is not the time to operate business-as-usual, where patents on tests, treatments and vaccines hinder access to critical products and put everyone at risk – “no one is safe until everyone is safe.”

WTO members should support a broad-scope TRIPS Waiver, applicable to a myriad of inventions and forms of intellectual property for two key reasons. First, millions more people are likely to contract COVID-19 and need treatment and care in the next few years, as the realities of vaccine production make it difficult to replicate in time to ramp up production in other countries quickly. Second, many products related to that treatment and care are potentially patent-protected, so a TRIPS Waiver could promote enhanced access to better care for sick people, even if the vaccines are not imminently available.

# Neg

## 1NC

#### I negate the resolution – Resolved: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.

### Value-Criterion

#### For today’s value, I offer utility. As the resolution is about the use of medicines, we should consider the extent to which medicines are used and can be effective for their given purposes

Savulescu et. al., 20

Julian Savulescu – Oxford Uehiro Centre for Practical Ethics, University of Oxford, Oxford, United Kingdom of Great Britain and Northern Ireland. Ingmar Persson – Oxford Uehiro Centre for Practical Ethics, University of Oxford, Oxford, United Kingdom of Great Britain and Northern Ireland; Department of Philosophy, Linguistics and Theory of Science, Gothenburg University, Gothenburg, Sweden. Dominic Wilkinson – Oxford Uehiro Centre for Practical Ethics, University of Oxford, Oxford, United Kingdom of Great Britain and Northern Ireland. “Utilitarianism and the pandemic” published by the journal, Bioethics, 20 May 2020. Available here: (<https://onlinelibrary.wiley.com/doi/full/10.1111/bioe.12771?af=R>) -AL

It might be said that what matters in the end is what action actually maximizes what is good for all rather than what action is expected to maximize what is good for all. But our best guide to what will actually happen is what is expected to happen on the best available evidence. So, when we decide what to do, we have to go by what is predicted to be best. This is true in most situations (although in some special cases we know that what is expected to be best is not what will actually be best4 ). The expected utility of an action is the sum of the products of the probability and value of each of the possible outcomes of that action.

#### As a value criterion, I offer practicality to consider the best predictions for maximized utility of the medicines in question by the resolution. Eliminating profitability from policymaking related to medical IPPs doesn’t reflect practical medical knowledge production

Bacchus 20

James Bacchus is a member of the Herbert A. Stiefel Center for Trade Policy Studies, the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida. “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines” published by the CATO Institute, 16 December 2020. Available here: (<https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines>) -AL

This view is myopic. Subordinating IP rights temporarily to pressing public needs during a pandemic or other global health emergency is one thing. Eliminating any consideration of “profitability” in all policymaking relating to “access to vaccines, essential tests and treatments, and all other medical goods, services and supplies” is quite another.17 To be sure, there is a superficial moral appeal in such a view. But does this moral appeal hold up if such a “human rights” approach does not result in meeting those urgent public needs?

With the belief that medicines should be “public goods,” there is literally no support in some quarters for the application of the WTO TRIPS Agreement to IP rights in medicines. Any protection of the IP rights in such goods is viewed as a violation of human rights and of the overall public interest. This view, though, does not reflect the practical reality of a world in which many medicines would simply not exist if it were not for the existence of IP rights and the protections they are afforded.

Technically, IP rights are exceptions to free trade. A long‐​standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID-19 is but the latest global occasion for this ongoing discussion.

### Definitions

#### Intellectual Property Protections, or IPPs, offer international legal credit to knowledge creation

WIPO, no date

The World Intellectual Property Organization is one of the 15 specialized agencies of the United Nations. WIPO is the global forum for intellectual property (IP) services, policy, information and cooperation. “What is Intellectual Property?” published by World Intellectual Property Organization, WIPO, no date. Available here: (<https://www.wipo.int/about-ip/en/>) -AL

Intellectual property (IP) refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce.

IP is protected in law by, for example, patents, copyright and trademarks, which enable people to earn recognition or financial benefit from what they invent or create. By striking the right balance between the interests of innovators and the wider public interest, the IP system aims to foster an environment in which creativity and innovation can flourish.

#### TRIPS is a legal agreement under the World Trade Organization, aka WTO, specifically concerning medicine relating to patents and IPPs

WTO, 06

The World Trade Organization (WTO) deals with the global rules of trade between nations. Its main function is to ensure that trade flows as smoothly, predictably and freely as possible. “Pharmaceutical patents and the TRIPS Agreement” published by the World Trade Organization, 21 September 2006. Available here: (<https://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm>) -AL

The purpose of this note is to describe those provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) that relate to the standards of patent protection to be accorded to inventions in the area of pharmaceuticals.

To set this discussion in context, it is useful to recall three basic features of the TRIPS Agreement:

that, together with some 25 other legal texts, it is an integral part of the Agreement Establishing the World Trade Organization (and therefore subject to the WTO dispute settlement system);

that it covers not only patents but all the other main areas of intellectual property rights; and

that it lays down not only the minimum substantive standards of protection that should be provided for in each of these areas of intellectual property, but also the procedures and remedies that should be available so that rights holders can enforce their rights effectively.

### Contention 1: Current Flexibilities Solve Better

#### There is flexibility already built into the TRIPS agreement for medical crises

Bacchus 20

James Bacchus is a member of the Herbert A. Stiefel Center for Trade Policy Studies, the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida. “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines” published by the CATO Institute, 16 December 2020. Available here: (<https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines>) -AL

Balancing IP Rights and Access to Medicines Not New to WTO

This waiver controversy comes nearly two decades after the end of the long battle in the multilateral trading system over access to HIV/AIDS drugs. At the height of the HIV/AIDS crisis at the turn of the century, numerous countries, including especially those from sub‐​Saharan Africa, could not afford the high‐​priced HIV/AIDS drugs patented by pharmaceutical companies in developed countries. Having spent billions of dollars on developing the drugs, the patent holders resisted lowering their prices. The credibility of the companies, the countries that supported them, and the WTO itself were all damaged by an extended controversy over whether patent rights should take precedence over providing affordable medicines for people afflicted by a lethal disease.

Article 8 of the WTO Agreement on the Trade‐​Related Aspects of Intellectual Property Rights (the TRIPS Agreement) provides that WTO members “may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health … provided that such measures are consistent with the provisions of this Agreement.” In similar vein, Article 7 of the TRIPS Agreement provides that the “protection and enforcement of intellectual property rights” shall be “in a manner conducive to social and economic welfare.”6 It can be maintained that these two WTO IP rules are significantly capacious to include any reasonable health measures that a WTO member may take during a health emergency, such as a pandemic. Yet there was doubt among the members during the HIV/AIDS crisis about the precise reach of these provisions.

As Jennifer Hillman of the Council on Foreign Relations observed, ordinarily the “inherent tension between the protection of intellectual property and the need to make and distribute affordable medicines” is “resolved through licensing, which allows a patent holder to permit others to make or trade the protected product—usually at a price and with some supervision from the patent holder to ensure control.”7 But, in public health emergencies, it may be impossible to obtain a license. In such cases, “compulsory licenses” can be issued to local manufacturers, authorizing them to make patented products or use patented processes even though they do not have the permission of the patent holders.8

After years of debate, WTO members clarified in the Doha Ministerial Declaration in November 2001 that each WTO member “has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”9 In August 2003, WTO members followed up on the 2001 declaration by adopting a waiver that allows poorer countries that do not have the capacity to make pharmaceutical products—and thus cannot benefit from compulsory licensing—to import cheaper generic drugs from countries where those drugs are protected by patent.10 In such a case, both the importing and exporting countries are excused from what would otherwise be their obligations under the TRIPS Agreement. This waiver was transformed into an amendment in the WTO IP rules in 2017.11

Compulsory licensing of medicines is not popular with private drug manufacturers because it is a derogation from the customary workings of market‐​based capitalism. However, as these actions by WTO members in 2001, 2003, and 2017 illustrate, compulsory licensing is not a derogation from the balance struck by the members of the WTO between protecting IP rights and ensuring access to essential medicines. Rather, it is a crucial part of that balance. The balance struck in the WTO treaty includes the option of compulsory licensing during health emergencies.

#### Current flexibilities should be proven insufficient before taking other measures – that’s best for the interests of both global access to health and continuing innovation of medical technology

Bacchus, 20

James Bacchus is a member of the Herbert A. Stiefel Center for Trade Policy Studies, the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida. “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines” published by the CATO Institute, 16 December 2020. Available here: (<https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines>) -AL

Does a Novel Virus Present Novel Issues?

Now comes the COVID-19 crisis. In the debate over the proposed COVID-19 waiver, mostly we have heard the usual arguments, all of them reminiscent of the HIV/AIDS debate. The pharmaceutical companies in the global vaccine chase have been quick to express their opposition to the proposed waiver of IP rights for the pandemic’s duration. They have warned that allowing their COVID-19 vaccines to be copied without their permission through recourse to compulsory licensing “would undermine innovation and raise the risk of unsafe viruses.”12

The reaction of most nongovernmental health organizations and other global advocacy groups to these arguments is summed up in the Access Campaign’s response: “Since the start of the pandemic, pharmaceutical companies have continued with their ‘business‐​as‐​usual’ approaches either by maintaining rigid control over their proprietary IP rights or by pursuing secretive and monopolistic commercial deals and excluding countries affected by COVID-19.”13

What we have not heard in the waiver debate is any clear explanation from waiver advocates of why they believe that the right to compulsory licensing that they already possess will prove insufficient to ensuring access to COVID-19 vaccines.

In requesting a broad waiver of IP rights to COVID-19 vaccines, India and South Africa maintained that “many countries especially developing countries may face institutional and legal difficulties when using flexibilities available” under existing WTO rules. They also noted that a “particular concern for countries with insufficient or no manufacturing capacity” is that the 2017 amendment that permits countries that produce generic medicines under compulsory license to export all of those medicines to least‐​developed countries that lack their own manufacturing capabilities will lead to a “cumbersome and lengthy process.”14

India and South Africa did not offer any further explanation or any evidence to support these assertions. In an effort at an explanation, two Canadian university professors contended, “The TRIPS flexibilities are important policies but they are not perfect. Rules allowing compulsory licensing apply only on a case‐​by‐​case and product‐​by‐​product basis. This slows down the ability of countries to scale up production of needed COVID-19 products.”15 But this is advocacy, not evidence. At the time, this point was purely prospective; it was a prejudgment before any COVID-19 vaccine had been given final approval or reached the market.

Before such a sweeping waiver of IP rights is taken up, it should first be demonstrated that the option of compulsory licensing and other flexibilities under the current trade rules will not suffice. At this point, the developed countries that have opposed the waiver are correct. There is no evidence of the need for such a waiver. Action by the WTO should be contemplated only if, and when, the current flexibilities in WTO rules prove to be inadequate. Should that happen, any such action should be no broader than necessary to address the global medical need.

At the heart of this emerging trade debate is a belief by many people worldwide that all medicines should be “global public goods.” There is little room in such a belief for consideration of any rights to IP. As one group of United Nations human rights experts expressed: “There is no room for … profitability in decision‐​making about access to vaccines, essential tests and treatments, and all other medical goods, services and supplies that are at the heart of the right to the highest attainable standard of health for all.”16

#### IPP’s are not the issue in accessing COVID medicines and technologies, but the debate itself creates the worst outcomes for developed countries, developing countries, and victims of COVID themselves

Bacchus 20

James Bacchus is a member of the Herbert A. Stiefel Center for Trade Policy Studies, the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida. “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines” published by the CATO Institute, 16 December 2020. Available here: (<https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines>) -AL

In a sign of their increasing frustration with global efforts to ensure that all people everywhere will have access to COVID-19 vaccines, several developing countries have asked other members of the World Trade Organization (WTO) to join them in a sweeping waiver of the intellectual property (IP) rights relating to those vaccines. Their waiver request raises anew the recurring debate within the WTO over the right balance between the protection of IP rights and access in poorer countries to urgently needed medicines. But the last thing the WTO needs is another debate over perceived trade obstacles to public health.

Unless WTO members reach a consensus, the multilateral trading system may be further complicated by a delay like that in resolving the two‐​decades‐​old dispute between developed and developing countries over the compulsory licensing and generic distribution of HIV/AIDS drugs. A new and contentious “North‐​South” political struggle definitely would not be in the interest of the developed countries, the developing countries, the pharmaceutical companies, or the WTO. Certainly it would not be in the interest of the victims and potential victims of COVID-19.

Background

In early October 2020, India and South Africa asked the members of the WTO to waive protections in WTO rules for patents, copyrights, industrial designs, and undisclosed information (trade secrets) in relation to the “prevention, containment or treatment of COVID-19 … until widespread vaccination is in place globally, and the majority of the world’s population has developed immunity.”1 India and South Africa want to give all WTO members freedom to refuse to grant or enforce patents and other IP rights relating to COVID-19 vaccines, drugs, diagnostics, and other technologies for the duration of the pandemic.

In requesting the waiver, India and South Africa have argued that “an effective response to the COVID-19 pandemic requires rapid access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need.” They have said that “as new diagnostics, therapeutics and vaccines for COVID-19 are developed, there are significant concerns, how these will be made available promptly, in sufficient quantities and at affordable prices to meet global demand.”2

Later in October, the members of the WTO failed to muster the required consensus to move forward with the proposed waiver. The European Union, the United States, the United Kingdom, and other developed countries opposed the waiver request.3 One WTO delegate, from the United Kingdom, described it as “an extreme measure to address an unproven problem.”4 A spokesperson for the European Union explained, “There is no evidence that intellectual property rights are a genuine barrier for accessibility of COVID‐​19‐​related medicines and technologies.”5 In the absence of a consensus, WTO members have decided to postpone further discussion of the proposed waiver until early 2021.

### Contention 2: Innovation

#### IPPs are key to innovation and vaccine development – COVID proves

Barroso, 21

José Manuel Barroso is a professor and Gavi Board Chair. “Intellectual Property and COVID-19 vaccines” published by Gavi, the Vaccine Alliance, 3 August 2021. Available here: (<https://www.gavi.org/vaccineswork/intellectual-property-and-covid-19-vaccines>) -AL

Moreover, intellectual property is an important part of vaccine development and critical for innovation; without which it is questionable that we would end up where we are today with 17 COVID-19 vaccines already in use, 105 in clinical trials and further 184 vaccine candidates in pre-clinical development. However, given that global demand for these vaccines is several times larger than the total annual global supply for all vaccines, we clearly need to do everything in our power to increase manufacturing capacity. That is why COVAX has been a strong supporter of encouraging manufacturers to share not just intellectual property with other manufacturers but also this all-important technical know-how.

This kind of technology transfer is one of the reasons we have managed to get the kinds of volumes of doses we have seen so quickly. But we need more. And if we are to be prepared for the next pandemic preparedness, we need to increase global manufacturing capacity too, particularly in regions with low manufacturing capacity. And while COVAX supports any measures that increase the sharing of intellectual property, encouraging the further use of technology transfers is the best way to ensure there is adequate supply, without removing the incentives for manufacturers to develop the vaccines we desperately need.

#### Incentives for innovation are a prerequisite to the very medical knowledge that saves lives, and also economic growth

Bacchus 20

James Bacchus is a member of the Herbert A. Stiefel Center for Trade Policy Studies, the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida. “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines” published by the CATO Institute, 16 December 2020. Available here: (<https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines>) -AL

The primary justification for granting and protecting IP rights is that they are incentives for innovation, which is the main source for long‐​term economic growth and enhancements in the quality of human life. IP rights spark innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.”18 The knowledge from innovations inspired by IP rights spills over to inspire other innovations. The protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know‐​how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor is the creation of knowledge, which adds enormously to “the wealth of nations.” Digital and other economic growth in the 21st century is increasingly ideas‐​based and knowledge intensive. Without IP rights as incentives, there would be less new knowledge and thus less innovation.

In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus preventing the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.19

As Stephen Ezell and Nigel Cory of the Information Technology and Innovation Foundation wrote, “A fundamental fault line in the debate over intellectual property pertains to the need to achieve a reasoned balance between access and exclusive rights.”20 This fault line is much on display in the WTO rules on IP rights. These rules recognize that “intellectual property rights are private rights” and that rules and disciplines are necessary for “the provision of effective and appropriate means for the enforcement of trade‐​related intellectual property rights.”21 Yet, where social and economic welfare is at stake, WTO members have sought to strike a balance in these rules between upholding IP rights and fulfilling immediate domestic needs.

#### While not solving the problem at hand, reducing IPPs would also harm future patients – it’s not theoretical, look to the future of mRNA medicine

Shah and Patel, 21

Sandip Shah, a visiting professor at Rutgers, is founder and president of Market Access Solutions, which develops strategies to optimize patient access to life-changing therapies. Deep Patel works at Market Access Solutions. “Guest Column: Waiving IP rights means waving goodbye to future medical breakthroughs” published by The World Link, 15 September 2021. Available here: (<https://theworldlink.com/opinion/columnists/guest-column-waiving-ip-rights-means-waving-goodbye-to-future-medical-breakthroughs/article_b20ac848-14cb-11ec-aed7-ff728285c94b.html>) -AL

The Biden administration recently announced that it would back a proposal by South Africa and India at the World Trade Organization to nullify American innovators' intellectual property rights for COVID-19 vaccines.

While the proposal's adoption would not increase the number of global vaccine doses available, it would dissuade investment in innovation - effectively inhibiting the next generation of medical breakthroughs and hurting patients in the process.

To understand the importance of intellectual property, look no farther than the COVID-19 vaccines developed by Moderna and Pfizer-BioNTech. They discovered that by taking advantage of the body's own molecular devices, mRNA can teach our cells how to make a protein similar to that of a given pathogen - which triggers an immune response.

mRNA technology could create an entire new class of medicines. Once scientists have the genetic sequence of a targeted virus or disease, they can equip mRNA with the means to fend it off. This new approach of custom-made mRNA has the potential to address a host of diseases ranging from cancer and heart disease to Alzheimer's and multiple sclerosis.

Moderna and fellow biotech firm Merck, for instance, have seen promising results for an mRNA-based therapeutic vaccine to treat cancer. Each treatment arms mRNA with a unique code to fight the particular mutations in an individual patient's tumor cells.

These experimental vaccines and therapies could soon help millions of Americans live longer, healthier lives. That is, if our innovative ecosystem maintains the incentives necessary to fund them.

Pharmaceutical research and development is inherently risky. Most experimental treatments and vaccines meet dead ends, despite the billions of dollars invested.

Intellectual property protections help assure innovators that they have exclusive rights to their medical inventions for a period of time.

Without that sense of security, innovation would come to a standstill. Investors would have to expend resources elsewhere as development ventures - even those pursuing new applications for technology as promising as mRNA - simply won't be financially feasible to pursue.

That's precisely why it's so concerning that the Biden administration has decided to support the intellectual property waiver that South Africa and India are pushing.

Administration officials likely felt pressured by the waiver's proponents, who claim that stripping protections is necessary to ramp up global vaccine access. But there's no evidence in support of that.

Giving away intellectual property rights will not expand supply because the real bottleneck lies with the logistical challenges of scaling up production. It takes time to retrofit manufacturing facilities so that they are capable of safely and effectively producing high-tech vaccines. Not to mention there is a worldwide shortage of the vaccines' essential raw materials.

The WTO proposal is not a policy option to adopt and abandon when it inevitably proves ineffective in achieving its purported aim. There are real-world consequences of continuing down this path. If intellectual property is no longer protected, patients can say goodbye to future treatments and cures.

Those who recognize the value of American innovation can - and must - push back on this disastrous proposal before it's too late.

## Other Cards (10)

### IPPs/Patents aren’t the problem

#### Germany says no to waivers in favor of future innovation – the problem is capacity and quality, not patents

Reuters, 21

Reuters is an international news organisation owned by Thomson Reuters. It employs around 2,500 journalists and 600 photojournalists in about 200 locations worldwide. Reuters is one of the largest news agencies in the world. “Germany rejects U.S. proposal to waive patents on COVID-19 vaccines” published by Reuters, 6 May 2021. Available here: (<https://www.reuters.com/business/healthcare-pharmaceuticals/germany-opposes-us-plan-waive-patents-covid-19-vaccines-2021-05-06/>) -AL

BERLIN, May 6 (Reuters) - Germany on Thursday rejected a U.S. proposal to waive patent protection for COVID-19 vaccines, saying the greatest constraints on production were not intellectual property but increasing capacity and ensuring quality.

President Joe Biden on Wednesday voiced support for a waiver in a sharp reversal of the U.S. position, and his top trade negotiator, Katherine Tai, swiftly backed negotiations at the World Trade Organization.

The German government stood behind the goal of a worldwide supply of COVID-19 vaccines, a government spokeswoman said, adding however that the main factors in vaccine production are capacity and quality standards, and not patents.

"The protection of intellectual property is a source of innovation and must remain so in the future," the spokeswoman said in a statement.

She said Germany supported the COVAX initiative, with the aim of ensuring that as many people in the world as possible have access to vaccines, adding that discussions were continuing at the WTO.

The WTO said in April that of 700 million vaccines administered around the world, only 0.2% had been in low-income countries. A recent surge of infections in India, the world's second most populous country, has underlined the point.

The European Union is willing to discuss a proposal to waive intellectual property rights for COVID-19 vaccines, European Commission President Ursula von der Leyen said on Thursday, as drugmakers fought their ground.

#### The issue is supply of materials – vaccines are different from drugs, they can’t be mass-produced even if the patents are removed

Barroso, 21

José Manuel Barroso is a professor and Gavi Board Chair. “Intellectual Property and COVID-19 vaccines” published by Gavi, the Vaccine Alliance, 3 August 2021. Available here: (<https://www.gavi.org/vaccineswork/intellectual-property-and-covid-19-vaccines>) -AL

During a pandemic, no one is safe until everyone is safe. So, from the very beginning of this global crisis, it was clear that we didn’t just need vaccines, we needed vaccinations and lots of them. Far more, in fact, than manufacturers and distribution networks were capable of producing and delivering to people before the pandemic. The colossal and imperative challenge of meeting this global need has created huge moral and legal predicaments that will be essential for us to solve, not just to end this current pandemic, but also to ensure we are more prepared for the next.

During a pandemic supply bottlenecks of essential medical products are almost inevitable, but with COVID-19 this has been further exacerbated by governments hoarding doses and imposing export bans.

To protect their citizens, for example, governments have been forced to strike a balance between the immediate protection of their populations, through domestic vaccination programmes, and their indirect protection, by ensuring the rest of the world has vaccines too by supporting the global vaccination effort spearheaded by COVAX. A similar moral and legal predicament also concerns the intellectual property of these vaccines, and one which at first glance appears to place the legal rights of companies to protect their patents in direct conflict with the rights of people to lead healthy lives by ensuring there are enough vaccine doses to go around.

Equitable and fair access to COVID-19 vaccines is the founding principle of COVAX, which was created to ensure that no one misses out on protection because they cannot afford to pay. Without COVAX that would be the reality for at least half the world’s populations, those people living in the 92 lower-income economies. But through the Gavi COVAX Advance Market Commitment, it has removed the financial barriers by pooling resources and collective purchasing power, and is now in a position to deliver an initial 1.5 billion doses, funded largely by donors, to people in these countries by the beginning of next year.

Achieving this has involved lining up an enormous number of complex pieces, from supporting the scientific development of a large number of vaccine candidates, raising the funded needed and then negotiating deals with manufacturers in an unprecedentedly competitive markets. And getting the vaccines out to people in the lowest resource settings has meant ensuring that all the logistical pieces were in place, from supply chain, cold storage, data systems, surveillance networks and trained health care workers, as well as all the important legal indemnity, liability and compensation safety nets too.

Getting this far was made possible because COVAX built on the pre-existing strengths of my organisation Gavi, the Vaccine Alliance, as well as its other three core partners, the Coalition for Epidemic Preparedness Innovations, the World Health Organization and UNICEF. But without a doubt we would have liked to have moved faster, and next time we will need to.

Besides raising the funds needed, for what has effectively become the world’s largest and most complex vaccine deployment ever, the single biggest obstacle has been supply. Even before vaccines were available, when the scientific community were racing to develop them, we were always anticipating initial supply constraints. During a pandemic supply bottlenecks of essential medical products are almost inevitable, but with COVID-19 this has been further exacerbated by governments hoarding doses and imposing export bans, not just on the vaccines themselves, but also on many of the vital components and materials needed to make them.

As a result, the global distribution of these vaccines has been far from equitable. Many wealthy countries have already vaccinated more than half their population, while in low-income countries less than 1% of people have received their first jab. So, even though there are now 17 vaccines available and more than three billion doses have been administered, millions of people most at risk, such as frontline health and social care workers, and vulnerable people, are still not protected.

The solution to this problem, quite simply, is that we need more vaccines. This has led to many people, and some governments, to call for the waiving of patents for COVID-19 vaccines, to boost global capacity by allowing third-party manufacturers to produce more doses than proprietary manufacturers would be capable of by themselves.

It’s easy to see the logic and certainly there has been precedent for such moves, for example with the production of HIV/AIDS antiviral drugs. But vaccines are very different from drugs. Unlike most drugs, which can be relatively easily mass produce, vaccines are inherently biological products, and so extraordinarily complex to make. Some COVID-19 vaccines involve hundreds of individual components, as many as 50,000 discrete production steps and dozens of quality control checks, all of which requires vital know-how that does not come with a patent. For one manufacturer to produce a vaccine developed by another it’s not enough to share intellectual property, you also need knowledge transfer.

#### Reducing IPPs is empty symbolism – it does nothing to solve our global pandemic

Lindsey, 21

Brink Lindsey is Vice President and Director of the Open Society Project at the Niskanen Center. Previously he was the Cato Institute's vice president for research. “Why intellectual property and pandemics don’t mix” publishing by Brookings Institute, 3 June 2021. Available here: (<https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/>) -AL

On May 5 the Biden administration announced that it would support waiving intellectual property protections for COVID-19 vaccines under the World Trade Organization’s Agreement on Trade-Related Intellectual Property Rights (TRIPS). Predictably, the move drew fiery condemnation from drug companies. In addition, many disinterested observers criticized the support for a TRIPS waiver as empty symbolism, arguing that vaccine patents are not the major obstacle hindering the currently flagging drive to make vaccines available around the world.

Waiving patent protections is certainly no panacea. What is needed most urgently is a massive drive of technology transfer, capacity expansion, and supply line coordination to bring vaccine supply in line with global demand. Dispensing with patents in no way obviates the need for governments to fund and oversee this effort.

### Extensions

#### Current flexibilities in the TRIPS agreement are best to balance global health and maintain incentives for innovation

Bacchus 20

James Bacchus is a member of the Herbert A. Stiefel Center for Trade Policy Studies, the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida. “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines” published by the CATO Institute, 16 December 2020. Available here: (<https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines>) -AL

Conclusion

The solution is not another impassioned and prolonged multilateral impasse inside the WTO. The solution is multilateral action in international institutions and international endeavors outside the WTO. It is the slow pace and the uncertain success in those other global arenas that have led developing countries to seek a waiver from the WTO. Rather than continuing to press for an unnecessary WTO waiver, they should redouble their combined efforts to reach solutions in those other arenas. And the United States, the European Union, the United Kingdom, and other developed countries should do more to work with them toward that end.

In no event should IP rights become legal obstacles to ensuring early access to affordable medicines for everyone in the world during a pandemic that has already killed more than a million people worldwide and threatens to kill millions more. But also, in no event should WTO members act in ways that would eliminate the incentives that are essential to inspire the innovations that make new medicines possible.

The right balance in the WTO trade rules on IP is a balance that provides all countries with sufficient flexibility to protect IP rights while also promoting access to life‐​saving medicines.22 For COVID-19 medicines, there is no proof at this time that this balance does not exist. Maintaining this balance must remain the aim of the WTO, and it must be the aim of every endeavor of multilateral cooperation in the fight to end this pandemic.

#### IPPs are key to long-term innovation incentives

Lindsey, 21

Brink Lindsey is Vice President and Director of the Open Society Project at the Niskanen Center. Previously he was the Cato Institute's vice president for research. “Why intellectual property and pandemics don’t mix” publishing by Brookings Institute, 3 June 2021. Available here: (<https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/>) -AL

THE NATURE OF THE PATENT BARGAIN

When we take the longer view, we can see a fundamental mismatch between the policy design of intellectual property protection and the policy requirements of effective pandemic response. Although patent law, properly restrained, constitutes one important element of a well-designed national innovation system, the way it goes about encouraging technological progress is singularly ill-suited to the emergency conditions of a pandemic or other public health crisis. Securing a TRIPS waiver for COVID-19 vaccines and treatments would thus establish a salutary precedent that, in emergencies of this kind, governments should employ other, more direct means to incentivize the development of new drugs.

Here is the basic bargain offered by patent law: encourage the creation of useful new ideas for the long run by slowing the diffusion of useful new ideas in the short run. The second half of the bargain, the half that imposes costs on society, comes from the temporary exclusive rights, or monopoly privileges, that a patent holder enjoys. Under U.S. patent law, for a period of 20 years nobody else can manufacture or sell the patented product without the permission of the patent holder. This allows the patent holder to block competitors from the market, or extract licensing fees before allowing them to enter, and consequently charge above-market prices to its customers. Patent rights thus slow the diffusion of a new invention by restricting output and raising prices.

The imposition of these short-run costs, however, can bring net long-term benefits by sharpening the incentives to invent new products. In the absence of patent protection, the prospect of easy imitation by later market entrants can deter would-be innovators from incurring the up-front fixed costs of research and development. But with a guaranteed period of market exclusivity, inventors can proceed with greater confidence that they will be able to recoup their investment.

For the tradeoff between costs and benefits to come out positive on net, patent law must strike the right balance. Exclusive rights should be valuable enough to encourage greater innovation, but not so easily granted or extensive in scope or term that this encouragement is outweighed by output restrictions on the patented product and discouragement of downstream innovations dependent on access to the patented technology.

#### Reducing IPPs won’t solve and will ruin incentive structures to solve future pandemics

Mossoff, 21

Adam Mossoff is Visiting Intellectual Property Fellow in the Edwin Meese III Center for Legal and Judicial Studies at The Heritage Foundation. “The COVID-19 Intellectual Property Waiver: Threats to U.S. Innovation, Economic Growth, and National Security” published by The Heritage Foundation, 17 September 2021. Available here: (<https://www.heritage.org/economic-and-property-rights/report/the-covid-19-intellectual-property-waiver-threats-us-innovation>) -AL

Conclusion

The IP waiver is an example of a solution in search of a problem. There is zero evidence that IP rights have impeded or otherwise hampered the distribution of any vaccines. The evidence is to the contrary: IP rights prompted the investment of billions of dollars over several decades in research and development, encouraged the creation of a knowledge infrastructure within the biopharmaceutical sector, and served as the foundation for innumerable commercial and information-sharing agreements that made possible an unprecedented health care response to the COVID-19 pandemic.58

By wiping out international commitments to the protection of IP rights, including patents and trade secrets, the IP waiver violates the primary maxim in healthcare, “first, do no harm.” The best way to end the COVID-19 pandemic, as well as other scourges and future pandemics, is to continue recognizing, supporting, and respecting IP rights like patents and trade secrets—the legal engines that have driven medical innovations for the past century.

### Miscellaneous

#### IPP reductions wouldn’t solve – it would only lead to vaccine nationalism and economic turmoil

Lopez, 21

Ian Lopez is a senior reporter at Bloomberg Law. “China Will Steal U.S. Vaccine IP Via Waiver, GOP Senators Say” published by Bloomberg Law, 9 May 2021. Available here: (<https://news.bloomberglaw.com/ip-law/china-will-steal-u-s-vaccine-ip-via-waiver-gop-senators-say>) -AL

Senate Republicans are calling on top Biden administration officials to walk back support of an international plan to waive Covid-19 vaccine IP protections, calling the decision a “giveaway” to China and India that will only promote “vaccine nationalism.”

Countries like China that regularly steal U.S. intellectual property began urging the World Trade Organization to waive IP rights “almost immediately after these vaccines were proven to work,” Sens. Thom Tillis (R-N.C.) and Tom Cotton (R-Ark.) wrote in a Wednesday letter to Commerce Secretary Gina Raimondo and U.S. Trade Representative Katherine Tai.

“These nations are falsely claiming that granting such a waiver would speed the development of new vaccine capacity. Nothing could be further from the truth,” they said in the letter, obtained by Bloomberg Law. Senators Chuck Grassley (R-Neb.), Mike Lee (R-Utah), and Dan Sullivan (R-Alaska) are among the letter’s backers, according to a Republican staffer.

The letter comes amid a heightening debate over whether the U.S.'s backing of a waiver would help expedite global vaccine manufacturing and distribution.

“It is not surprising that China, India, and South Africa want to steal our intellectual property and medical technology,” the senators wrote. “What is surprising is that an American president, especially one who claims to be a ‘jobs’ president, would force American companies to give their medical technology and manufacturing processes to foreign adversaries like China.”

A proposal before the WTO—set out by South Africa and India last year and supported by dozens of other countries—would waive obligations on the protection of IP rights for the duration of the pandemic.

‘America’s Interests Last’

Key to the debate is whether patents and other IP are an obstacle to global Covid-19 immunization.

Proponents of the waiver plan—which include some Democrats and nonprofits—say it’s a step in the right direction, and, taken with other steps like increased manufacturing capacity, could help with faster world vaccination. U.S. support could help get other countries on board with global distribution while spurring efforts to ramp up vaccine production capabilities in nations struggling to immunize their populations, proponents say.

Opponents say it’s bad for innovation and does little to get vaccines to those in need while opening the door to IP theft from competing countries. Among those in the latter camp are Tillis, who led a legislative effort to strengthen patent rights; former U.S. Patent and Trademark Office Director Andrei Iancu; and Sen. Chris Coons (D-Del.), who has previously criticized the idea of waiving rights around Covid-19 vaccines.

“The reason why there are not enough vaccine doses at this time is simple: the supply chain lacks the technological capacity,” the letter said. “At best, all The President’s giveaway to China and India and others will do is to foster uncoordinated vaccine nationalism, as countries jump in to try to coerce technology transfer and manufacturing locally.”

Tai earlier this month announced the Biden administration’s support of the IP waiver, following pressure from a group of more than 100 House Democrats, led by Rep. Jan Schakowsky (D-Ill.). Piecemeal IP licensing agreements can’t keep pace with the scope and speed of the pandemic, while temporarily waiving rights could promote technology access and sharing for vaccine production without spurring trade sanctions, they argue.

House Republicans quickly followed suit, writing their own letter to Tai in opposition.

The senators in their letter posed a series of questions over the details and economic impact of waiving vaccine IP rights.

They called for a list and descriptions of all U.S. meetings with foreign officials about the waiver plan. They also asked if the Biden administration is considering waiving domestic IP enforcement, and whether support of the waiver is “premised on China, Russia, South Africa, India, or any other nation state supporting other foreign policy priorities of the Administration,” according to the letter.

“Simply put, the Biden Administration’s support for a TRIPS waiver puts America’s interests last and China’s interests first,” the senators said.

#### Reducing IPPs threatens global competitiveness, economic growth, innovation, and national security

Mossoff, 21

Adam Mossoff is Visiting Intellectual Property Fellow in the Edwin Meese III Center for Legal and Judicial Studies at The Heritage Foundation. “The COVID-19 Intellectual Property Waiver: Threats to U.S. Innovation, Economic Growth, and National Security” published by The Heritage Foundation, 17 September 2021. Available here: (<https://www.heritage.org/economic-and-property-rights/report/the-covid-19-intellectual-property-waiver-threats-us-innovation>) -AL

The COVID-19 pandemic, as well as growing economic and strategic competition from China and other traditional competitors such as Russia, have made innovation, economic growth, and national security top policy concerns. All three are threatened by the Biden Administration’s support for the proposed intellectual property (IP) waiver at the World Trade Organization (WTO). The Biden Administration should retract its support for the continuing negotiations of the IP waiver, and, if it fails to do so, then Congress should refuse to enact any implementing legislation of this waiver of the international commitment to honor the protection of IP rights.

Commentary about the proposed IP waiver at the WTO originally focused on its theft of patents for vaccines and other medical treatments for the COVID-19 virus.1

As Heritage Foundation Research Fellow James Roberts explained recently, the IP waiver would facilitate the global theft of the patents that made possible the private investments necessary in creating new technologies like the mRNA vaccines that were invented and mass produced in unprecedented time.2

The IP waiver would obliterate international protection for patent rights while leaving unaddressed the real problems that are impeding global distribution of vaccines to those who still need these vital medicines—problems such as eliminating the trade restrictions prohibiting international distribution of vaccines and creating distribution and transportation infrastructures in the developing world necessary to distribute the vaccines in those countries.3

If the U.S. continues to support and ultimately implement domestically the IP waiver, this would threaten far more destructive consequences than just its impact on patents and the innovation spurred by this key legal tool in the U.S. innovation economy. The IP waiver threatens many forms of IP rights, such as justifying the coerced disclosure of the trade secrets in the vital technical know-how used in creating the cutting-edge mRNA vaccines. This not only destroys the economic value and competitive advantage represented by these trade secrets—and the billions in investments that made them possible—but once this information is disclosed, it is impossible to recover it as a valuable trade secret.

The IP waiver raises broad concerns about innovation policy, economic policy, and even national security. The U.S. should oppose the IP waiver. Failing this change in foreign policy by the Biden Administration, Congress should refuse to implement the IP waiver domestically if the Biden Administration continues to pursue another disastrous foreign policy initiative on the heels of the debacle of the Afghanistan withdrawal.

#### IPPs are key to investment in research and develop of medicine and vaccines

Mossoff, 21

Adam Mossoff is Visiting Intellectual Property Fellow in the Edwin Meese III Center for Legal and Judicial Studies at The Heritage Foundation. “The COVID-19 Intellectual Property Waiver: Threats to U.S. Innovation, Economic Growth, and National Security” published by The Heritage Foundation, 17 September 2021. Available here: (<https://www.heritage.org/economic-and-property-rights/report/the-covid-19-intellectual-property-waiver-threats-us-innovation>) -AL

The Threat to U.S. Innovation, Economic Competitiveness, and National Security

Commentators have long recognized in the context of patents that failing to protect innovation properly destroys the promise of IP rights.18

People will not invest the billions required to create a new drug or vaccine—and to create the follow-on technologies and the commercial production and distribution chains necessary to distribute this drug in the health care market to patients—if the fruits of their productive labors are not secured to them. People easily recognize this moral principle in the context of a farmer investing a year of valuable labor to plant, grow, harvest, and then distribute a crop—and it applies equally to the modern biotech or pharmaceutical company that creates, develops, produces, and distributes a new drug.

Disclosure of Trade Secrets. The threat to innovation is magnified exponentially in the context of forced disclosures of trade secrets that protect valuable technical know-how—the inventions and commercial information created through the productive labors of scientists and businesspersons. In contrast to a trade secret, a patent is a public document that fully discloses all relevant information about the invention so that someone skilled in the technical field can make and use the invention protected by the patent. Judges and scholars have long identified this as the quid pro quo of the patent system: The inventor receives a time-limited property right in a new and useful invention, and in exchange for this property right, society receives public disclosure of the invention.19

(Today, the U.S. patent term is 20 years from date of filing of the patent application, a global standard in patent term achieved through the harmonization brought about by TRIPS.20

A trade secret is an entirely different matter altogether. Valuable technical or commercial information that is actively kept secret is protected under trade secrets law.21

Reverse engineering or independent discovery are permissible for commercially valuable information protected under trade secrets law.22

The law prohibits only piracy of the trade secret—the wrongful acquisition of the information through theft or other improper means.23

The law strongly protects trade secrets because once they are publicly disclosed, the proverbial cat is out of the bag. There is no way to take back the knowledge; as the popular Internet meme puts it, “there’s no way to unsee” what one has seen. Following disclosure, the trade secret is lost as a commercial asset that gave its owner a competitive advantage in the marketplace. Thus, the law strongly protects trade secrets.

For example, the federal government recently enacted the Defense of Trade Secrets Act of 2016 to make it easier for trade secret owners to seek legal relief in federal court.24

This law was enacted partly in response to the growing threat posed by industrial espionage from foreign actors, such as China. Recent bipartisan legislation has been proposed to protect even more IP rights—including trade secrets—from theft by Chinese companies and government officials.25

The original policy debate about the IP waiver focused on the removal of the international enforcement mechanisms for patent protections. This is one reason why the CEO of Moderna, one of the creators of one of two mRNA vaccines for COVID-19, said that he “didn’t lose sleep” after the announcement by the Biden Administration that it would support the IP waiver proposal by India and South Africa at the WTO.26

He told reporters, “There is no idle mRNA manufacturing capacity in the world. You cannot go hire people who know how to make mRNA—those people don’t exist…. When we hire people that come from traditional pharma, we have to train them in the art of mRNA.”27

Id. (emphasis added).

He knows the real value in the mRNA vaccines—the value in the mRNA platform itself—is in the technical know-how that has evolved over the two decades that it has taken for mRNA technology to be researched and developed.

But his dismissive reaction was premature because the advocates for the IP waiver understood from the get-go that this was not about weakening or eliminating patent protections for vaccines, drugs, or other medical treatments for COVID-19. Of course, the evisceration of international respect for patent rights is one aspect of the IP waiver; there are certainly some patents on some drugs that foreign companies or governments would benefit from appropriating, such as the patent on Remdesivir, the first drug approved by the FDA to treat severe respiratory symptoms caused by COVID-19.28

However, if this effort was only about patent rights, then India and South Africa would have sought only an automatic mandate under Article 31 of TRIPS for immediate compulsory licensing for all patents covering COVID-19 medical treatments (what was achieved almost two decades ago for the AIDS pandemic).29

That is not the true goal of the IP waiver, nor is it what it states in its text.

The Real Reason. The IP waiver is a complete waiver from international protections provided by the TRIPS agreement for a period of at least three years for any “health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19.” This covers the technical know-how and other trade secrets that have been created by the scientists at Moderna, BioNTech, Pfizer, and all other companies licensed to make and sell mRNA vaccines.

In sum, the IP waiver would eliminate international commitments to and enforcement mechanisms for IP rights, including trade secrets. The IP waiver would not be automatically implemented in the U.S., but the Biden Administration, after supporting the IP waiver at the WTO, would very likely push for domestic implementation of its goals, such as the disclosure of trade secrets. Over 100 Congressional Democrats lobbied the Biden Administration to support the IP waiver before the Administration announced its support on May 5, 2021, and they will also push aggressively for domestic legislation to implement in the U.S. the goals of the IP waiver.30

#### IPPs around mRNA medicine are especially relevant – reductions of IPPs would be a huge blow to the U.S.’s global economic competitiveness

Mossoff, 21

Adam Mossoff is Visiting Intellectual Property Fellow in the Edwin Meese III Center for Legal and Judicial Studies at The Heritage Foundation. “The COVID-19 Intellectual Property Waiver: Threats to U.S. Innovation, Economic Growth, and National Security” published by The Heritage Foundation, 17 September 2021. Available here: (<https://www.heritage.org/economic-and-property-rights/report/the-covid-19-intellectual-property-waiver-threats-us-innovation>) -AL

The Economic and National Security Concerns About the IP Waiver

Last, the waiver’s policy concerns go far beyond the subsidization of tens of thousands of labor hours and billions in investments to create the knowledge necessary to produce safe and effective mRNA vaccines. The mRNA technology is a platform technology—a technological discovery that has applications that go far beyond the current COVID-19 pandemic. Companies have begun investigating how to develop more mRNA vaccines to address viral scourges that have killed millions of humans around the globe.45

With incredible medical cures ranging from cancer to HIV to malaria, the mRNA platform is the invention that may fulfill the full promise of the biotech revolution that began in the U.S. almost four decades ago.46

Unauthorized Use by Global Competitors. If implemented domestically to the degree demanded by its advocates, the IP waiver would promote the disclosure of technical know-how in the mRNA platform to countries throughout the globe, including to China and Russia. As economic and strategic competitors—expressed in both words and deeds over many years—it is highly unlikely that China or Russia would respect the requirement in the IP waiver that these trade secrets be used only for COVID-19 medical treatments and only for three years or the length of the pandemic, whichever is longer.

Unauthorized Transfer to Global Competitors. Even if China or Russia are prohibited somehow from directly receiving the technical know-how, there is nothing that would stop other countries or individuals in other countries from transferring the information to them after the direct disclosure and training by U.S. scientists in the technical know-how of how to produce mRNA vaccines. Again, once a trade secret is disclosed, it is lost by its owner to the world; information is transmissible as easily as it takes for digital signals to traverse the cables that carry international Internet traffic or as easily as it is for people with the knowledge in their heads to travel from one country to another country.

Preventing trade secret misappropriation is a difficult endeavor within a single jurisdiction, and identifying or tracking information back to the original act of misappropriation can be onerous and costly for private companies seeking renumeration or other legal relief. On an international scale between nation-states, even with the threat of WTO trade sanctions, it may prove nearly impossible to catch malefactors—or even simply prove the unauthorized transfer by any reasonable measure of evidence.

Any prohibitions or sanctions for unauthorized transfers of technical know-how in implementing U.S. legislation would represent oratory proclamations at best, tantamount to the Biden Administration’s demand in August 2021 that the Taliban create a “united, inclusive and representative” government in Afghanistan.47

Simply put, U.S. laws have no control over actions undertaken in foreign jurisdictions by foreign citizens. Ultimately, any forced disclosure of the technical know-how in the mRNA biotech platform simply requires that Congress and U.S. officials have blind faith that China, Russia, or other countries will use these disclosed trade secrets solely for purposes of producing only vaccines and other medical treatments only for COVID-19. This reflects an astonishing level of naïveté in international politics—especially when dealing with a well-established economic and strategic competitor like China that has blatantly stolen hundreds in billions in U.S. IP or a country like Russia that has engaged in cyberattacks on U.S. institutions, illegally invaded Ukraine, and annexed the Crimea in 2014.48