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Establishing protocols for intellectual property rights of pharmaceutical companies during a public health crisis

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Introduction

During the COVID-19 pandemic, the significance of access to intellectual property has been re-emphasized. This is particularly true for two areas of importance: public health and educational/cultural involvement. Although this covers two independent domains of intellectual property rights (IPR) – patent and copyright – each with its own set of access hurdles, the common underlying link is their complex relationship with access in the public interest.

The function of IPR during the current pandemic has received a lot of attention. Much of the discussion has centered on how we can and should use open movements and existing public interest procedures to enable access to IPR-protected subject matter. While they are crucial to consider, it is also necessary to place access restrictions in their larger context. As a result, we can see how the IPR hurdles encountered during the present pandemic reflect larger, pre-existing access barriers.

Definition of Key Terms

Access

Access to subject-matter can be impacted by both IPR and non-IPR parameters. These parameters naturally shape which public(s) are able to access and reuse subject-matter, or not.

Epidemic

The CDC defines an epidemic as a sudden increase in the amount of cases of a particular disease or condition in a specific geographical location. Epidemics can occur when cases of an already prevalent disease (like a virus) spike rapidly, when an area that wasn't previously exposed to the disease experiences an outbreak, or when people previously not susceptible to infection suddenly start getting sick from it. Pandemic refers to an epidemic that has spread over several countries or continents, usually affecting many people.

Intellectual Property

Intellectual property rights (IPR) have been defined as ideas, inventions, and creative expressions based on which there is a public willingness to bestow the status of property. IPR provides certain exclusive rights to the inventors or creators of that property, in order to enable them to reap commercial benefits from their creative efforts or reputation.

Publics

In IPR theory, there are two categories of publics. The first is the "broader" public, which is defined as society or the entire community in a specific jurisdiction. The second public referred to would be subject-matter users or consumers. They are sometimes referred to as the "immediate" public, as they are the ones who are most affected by short-term access restrictions and incurs leveraging fees.

TRIPS Agreement

The TRIPS Agreement, which came into effect on 1 January 1995, is to date the most comprehensive multilateral agreement on intellectual property

General Overview

IPR's are based on the idea of limiting access to subject matter. This enables innovators and creators (hence referred to as "makers") to restrict and leverage subject-matter access during the

relevant term and subject to the limits of protection. When the subject-matter is valuable enough to be in demand, leveraging access often takes the form of payment to the rightsholder. In theory, the ability to leverage access is intended to incentivize creators to develop important topic matter. This short-term restriction is deemed to best benefit the public's long-term interests (i.e., society or the community at large) because it will result in more subject-matter being generated and disseminated.

Prohibitive IPR criteria are removed, reduced, or modified through open motions. Open movements, on the other hand, are not usually designed or shaped by the same regulatory systems that have shaped the IPRs. They have indeed evolved as a grassroots response to rigid regulatory and statutory frameworks. Because open movements are supposed to map onto, but evolve outside of, the IPR regulatory framework, they are better described as IPR private ordering tactics.

There are several levels or forms of access to IPR-protected subject-matter within these schemes. In practice, there is a difference between access to physical materials and access to their digital versions, especially when it comes to copyright. Even where IPR access has been obtained, there is a conflict between the physical and digital materials, even if they are not fully separate. When you buy a physical copy of an in-copyright book, you almost never get access to the digital version. Lack of access to physical resources, education sites, libraries, and heritage institutions heightened the public's need for digital access, as well as the creation of new digital assets to maintain connectedness, due to pandemic-related constraints. Multiple licenses are required to access identical materials published in different forms under IPR systems that handle such materials differently.

Ebola

Ebola virus disease (EVD) is a severe disease caused by Ebola virus, a member of the filovirus family, which occurs in humans and other primates. The disease emerged in 1976 in almost simultaneous outbreaks in the Democratic Republic of the Congo (DRC) and in what is now south Sudan (then still Sudan). Between 1979 and 1994 no cases or outbreaks were detected, however since that time outbreaks have been recognised with increasing frequency (see table below). The largest outbreak to date took place in West Africa between March 2014 and June 2016, affecting primarily Guinea, Liberia and Sierra Leone. Over 28,000 cases were recorded.

A vaccine candidate that evoked protective immunological responses against Ebola in non-human primates was published in Nature in June 2005 by a Canadian researcher named Steven Jones and his

colleagues. Despite these encouraging results, human testing was not carried out at the time due to a lack of funding. Despite the fact that there had been 1,755 Ebola cases previous to 2014, no real efforts to create a vaccine for human use began until the present West African outbreak was underway, and the virus had spread to patients outside of Africa. Ebola killed over 11,000 people and devastated three countries in western Africa between 2013 and 2015. It took so long due to the simple reason that economic incentives for investing in medications and vaccines for diseases that predominantly affect the poor are insufficient, and humanitarian resources are limited.

Coronavirus

On May 5, 2021, the United States surprised the world by announcing its support for a World Trade Organization proposal that would temporarily waive intellectual property rights on covid-19 vaccinations. While this is a positive start, the Biden administration's support is only the first of many that must be taken. In order to address substantive unfairness in the worldwide distribution of covid-19 vaccinations, intellectual property rights must be waived. Currently, wealthier countries hold the lion's share of available supply. Over 1.3 billion doses of vaccine had been administered worldwide by the end of April, but just 0.2 percent of immunizations had been given to low-income countries. The situation has reached a low point globally after more than a year of the pandemic. In April, the average number of weekly deaths in India and Brazil was over 36 000, with variations aplenty. Experts are concerned about a disastrous second wave sweeping Asia and Africa, an issue that could be worse without the shring of information and IPRs.

Voluntary intervention, whether in the form of timely dosage sharing with low- and middle-income nations or knowledge sharing through the World Health Organization, has failed. It's past time for mandatory norms and legal obligations to help put a stop to the pandemic because vaccine producers have depended largely on publicly funded coronavirus research, the proposed intellectual property waiver is reasonable. Government support of roughly €93 billion (£80 billion; $110 billion) is projected to have helped enterprises with intellectual property rights. The US government provided practically all of the funding for the Moderna vaccine.`

Manufacturers would be unable to prevent manufacturing or access to raw materials and final goods for covid-19 technology if an intellectual property waiver was successfully agreed. A waiver would also keep businesses from charging exorbitant rates while keeping them out of competition. In the vaccines market, there has long been a lack of competition. Previously, patents restricted competition between the two businesses with a duopoly for the human papillomavirus (HPV)

vaccine. Low-income countries, according to one estimate, paid up to ten times the anticipated cost of production for these vaccines.

Patent Waiver

During a pandemic, every country should be able to produce its own vaccines. The effort to temporarily waive intellectual property (IP) protection on coronavirus vaccinations is based on this idea. More than 100 countries, as well as international institutions such as the World Health Organization and the United Nations AIDS charity, UNAIDS, have joined the campaign, which was started by India and South Africa. The purpose is to lower the hurdles to developing their own vaccines, especially for low-income countries.

The pharmaceutical industry, as well as most high-income countries, are now opposed to the concept. Instead, these governments have committed to sharing more of their own vaccines with low-income countries and to increasing funding for charitable vaccine distribution programs like COVAX. However, earlier this month, the US, Russia, and China came out in favour of an IP waiver on vaccinations, in a shock but positive development.

Because the United States is the world's largest market for pharmaceuticals, the significance of the US decision cannot be underemphasized. For decades, US governments have collaborated with industry, universities, and other research-intensive nations to establish — and enforce — intellectual property standards, most recently through the World Trade Organization (WTO), where the IP waiver proposal is currently being debated.

Even a few months ago, the concept of the US taking such a stance would have been inconceivable. Those countries still holding out, such as Japan, South Korea, the United Kingdom, and European Union member states, could hVE massive impact towards the good if they now follow suit.

One of the most serious issues concerning IP waivers is that they give competitors a shortcut to expensive technologies. Companies also claim that IP relief will not speed up vaccine production because materials are in low supply and building capacity from the ground up can take many years. Furthermore, many who oppose the waiver say that current WTO regulations already allow countries to seek for "compulsory licensing" to overrule IP during emergencies. Bolivia, for example, is currently requesting permission from the WTO to use this technology to produce Johnson & Johnson's COVID vaccine. However, in a draft paper on the waiver idea, a group of patent law

scholars in the United Kingdom point out that compulsory licenses are exceedingly complex and time-consuming to obtain.

Major Parties Involved

World Trade Organisation (WTO)

Prior to the creation of the World Trade Organization in 1995, individual countries were free to determine their own patent laws. This position has now changed. All WTO members must enact patent legislation that complies with the Agreement on Trade-Related Aspects of Intellectual Property Rights, which includes the adoption of patent protection for pharmaceuticals. The TRIPS Agreement was negotiated by the WTO's developed countries on the idea that obligatory protection for pharmaceutical products and procedures would provide the essential incentives for sustained pharmaceutical research.

Developing countries and Least Developed Countries, on the other hand, contended that passing TRIPS-compliant patent laws would limit the production and supply of low-cost generic pharmaceuticals by their domestic pharmaceutical industries or by pharmaceutical industries in other developing countries. As a result, the price of drugs may rise to the point where they are no longer affordable to their people.

USA

The United States has expressed its support for a proposed temporary waiver of intellectual property rights on COVID-19-related drugs that was considered at a WTO General Council meeting on May 5–6, reversing its previous opposition to the waiver.

A growing tide of international opposition, primarily from developing nations, is thought to be behind this shift in policy, claiming that wealthy countries' vaccine monopolies are obstructing both equal supply and the US government's attempt to fight China and Russia's "vaccine diplomacy."

UK

According to the Guardian, the UK government is discussing a plan to waive Covid-19 vaccine patents in order to encourage vaccine production in poor and middle-income nations.

The conversations take place as pressure mounts on the United Kingdom and other European countries to join the United States in backing the World Trade Organization plan (WTO).

Covid-19 could tear across the world's poorest countries, causing in a "moral and public health disaster" equivalent to the original catastrophically inadequate global response to the Aids pandemic in the 1980s and 1990s, according to Michael Weinstein, founder of the Aids Healthcare Foundation (AHF).

Lady Sheehan, who sits on the UK's all-party parliamentary group on vaccinations for all, welcomed the fact that Britain was in talks, but stressed: "Time is of the essence. Given what we are seeing in India and the risk to the UK and other countries, with potentially dangerous variants emerging, the government has a moral duty to act to create conditions to ramp up global supply – but also enlightened self-interest should dictate it too."

The UK government stated that it provided money for the AstraZeneca vaccine, which was manufactured at scale and through manufacturing partnerships around the world at a cheap cost to poor and middle-income countries.

"We are talking constructively with the US and other WTO members on the Trips waiver issue," a spokesperson said, "but we need to act now to grow production and distribution worldwide."

European Commission

140 MEPs wrote to the European Commission earlier this month, pushing it to embrace the idea for a temporary derogation to address vaccine disparity. Meanwhile, 400 academics, politicians, and charities have written to Boris Johnson, encouraging him to follow the lead of the United States.

Parliament proposes that negotiations begin for a temporary waiver of the WTO TRIPS Agreement on patents to improve global access to affordable COVID-19-related medical products and to address global production constraints and supply shortages in a resolution passed with 355 votes in favour, 263 votes against, and 71 abstentions. MEPs also highlight the dangers that an indefinite TRIPS Agreement waiver poses to research funding, particularly for researchers, investors, developers, and clinical trials.

The most important way to scale and speed up global production in the long run, according to MEPs, is voluntary licencing (when the vaccine developer decides to whom and under what conditions the patent can be licensed to enable manufacturing), know-how, and technology transfer to countries

with vaccine-producing industries. MEPs want the EU to "quickly reduce export obstacles and replace its own export authorisation procedure with export transparency standards" to ease manufacturing bottlenecks. They argue that the United States and the United Kingdom should "immediately eliminate their export prohibition on vaccines and raw materials." Only a fraction of the 11 billion doses required to immunize 70 percent of the world's population have been manufactured.

Timeline of Key Events

Date	Description of event
May 5 th, 2021	Katherine Tai, the US representative at the World Trade Organization, announced US support for a waiver on intellectual property for COVID vaccines on 5 May.
May 31 st, 2021	Despite Washington's support, a settlement on an intellectual property waiver for COVID-19 vaccines at the World Trade Organization (WTO) remained no closer to acceptance on Monday, owing to predicted scepticism about a fresh draft.

UN involvement, Relevant Resolutions, Treaties and Events

- In an effort to accelerate vaccine manufacturing, the UN health director has been pressing states involved in World Trade Organization (WTO) negotiations over intellectual property rights to suspend patent regulations for those vaccines designated for emergency use.
- The US had previously refused to waive restrictions, but Katharine Tai, the US Trade Representative, issued a thorough statement on Wednesday explaining why the Biden Administration was altering its position.
- “This is a worldwide health crisis, and the COVID-19 pandemic's unique circumstances necessitate extraordinary measures,” she stated. “While the government believes strongly in intellectual property protections, it supports the waiver of such protections for COVID-19 vaccinations in the interest of resolving the pandemic. We will fully participate in text-based WTO negotiations, which are required to achieve this.”

Possible Solutions

Four crucial requirements would be met if a waiver was successfully obtained. It should be the primary goal of the waiver to save as many lives as possible. The waiver, according to the Biden administration, should be focused on vaccines. This restriction should be lifted. The original plan covers all covid-19-related medical technologies, including diagnostics, medications, and ventilators.

Due to the fact that vaccine producers have depended largely on publicly funded coronavirus research, the proposed intellectual property waiver is reasonable.Government support of roughly €93 billion (£80 billion; $110 billion) is projected to have helped enterprises with intellectual property rights. The US government provided practically all of the funding for the Moderna vaccine. Any waiver should be clear, explicit, and for a reasonable period of time, and it should restrict manufacturers' ability to pursue legal challenges that obstruct access. Manufacturers would be unable to prohibit production of covid-19 technology or access to raw materials and final products if an intellectual property waiver was successfully agreed. A waiver would also keep corporations from charging unsustainable pricing while keeping them out of the market. Powerful nations have in the past used their power to force concessions from weaker states behind closed doors.

In terms of incentives it is important that there is a development of systematic incentives for investment in vaccines and medications that treat diseases that disproportionately afflict the world's

poor and for which there are insufficient financial incentives for optimal levels of research and development should receive more attention. In this context, innovative funding mechanisms such as advance market pledges, rewards, challenges, and public-private partnerships have a lot of promise.

More coordination between humanitarian funding institutions is needed to ensure that few funds are directed to the most pressing issues. This goal might be achieved with the support of an institution committed to the rigorous identification and surveillance of global-health concerns, as well as a ranking system that prioritizes the most serious of those threats. More efforts should be made to ensure that the benefits of humanitarian aid may be used to meet unmet needs on a long-term basis. Those that receive humanitarian research funds should make sure that the treatments and vaccinations that result are available to those who need them the most. It would also assist if recipients of humanitarian R&D funding were more transparent and collaborated. Once viable vaccinations and treatments have been produced, wealthier countries' governments should acquire and stockpile enough vaccines and drugs to ensure that they can be distributed quickly in areas where outbreaks occur.

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Appendix or Appendices

i. This article talks about the importance of waiving the intellectual property rights. https://www.bmj.com/content/373/bmj.n1344

ii. Article which gives detailed overview of the implication of IPR in the pharmaceutical industry https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3217699/