


# Return of Benefit to Society of Publicly Funded Innovations to Combat COVID-19

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## Abstract

In response to the COVID-19 pandemic, significant public funds have been invested worldwide into the research, development, and manufacturing of pharmaceutical products to combat the novel coronavirus. Traditionally, intellectual property (IP) rights have been justified in the pharmaceutical sector because of the time and cost associated with drug discovery and development. However, if (a) the cost of research for COVID-19 related innovations have largely been subsidized by the public through public research grants; (b) the time for development has been significantly reduced through publicly funded initiatives; and (c) manufacturing has been de-risked through taxpayer funded advance purchase agreements, should IP rights be asserted on innovations that have largely already been paid for by the public? There needs to be clear legal and regulatory frameworks, informed by policy objectives such as principles of “responsible research and innovation” and “global public good,” to ensure that outcomes of publicly funded efforts can ultimately reach the intended public. Without any access and production conditions associated with the use of public efforts, worldwide supplies to medical solutions that benefited from these public initiatives can be frustrated. This article proposes a legal framework to address future access and availability problems to medical innovations that benefit from publicly funded initiatives.

## Keywords

return of benefit to society, responsible research and sustainable innovation, health policy and pandemic preparedness, legally supported framework for access and availability to healthcare, conditional access to publicly funded initiatives

### What Is Already Known About This Topic?

- Access and availability to COVID-19 related innovations, which have largely already been paid for by the public, are being hindered in part by intellectual property rights

### How Does Your Research Contribute to the Field?

- Because the current reactive proposals that attempt to achieve a better balance between public, private, and national interests have proven to be problematic and therefore unlikely to be useful for future pandemics, this

research proposes legally supported mechanisms that can be adopted in the future to ensure worldwide access and availability to innovations that benefited from public funds and initiatives

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### What Are Your Research's Implications Towards Theory, Practice, or Policy?

- The recommendations of this article incentivizes and places some pressure on industry to take a proactive effort to optimize their own manufacturing capacity and their licensing strategies to become an active responsible player in ensuring access and availability of medical solutions globally.

## Introduction

In response to the COVID-19 pandemic, significant public funds have been invested worldwide into the research and development of pharmaceutical products to combat the novel coronavirus. For example, €16 billion in pledges from international donors worldwide has been used to fund R&D to develop diagnostics, treatments, and vaccines for COVID-19.<sup>1</sup> The “Coronavirus Global Response” initiative was a truly global call to action for universal access to affordable solutions in the face of the pandemic.<sup>1</sup> In the spirit of openness, unity, and global cooperation, the World Health Organization (WHO) and its partners launched two publicly funded initiatives. First, the COVID-19 health technology access pool (C-TAP) is a voluntary initiative to support rapid collaborative research and development (R&D) efforts by removing legal barriers to existing or new innovations to enable the sharing of available knowledge.<sup>2</sup> Second, the Solidarity Trial is an international collaborative clinical trial effort to rapidly assess promising treatment options by enrolling patients in one single randomized trial, thereby reducing the time for clinical trials by 80%.<sup>3</sup> In addition to subsidizing the R&D process, advance purchase agreements (APAs) have been concluded by governments with industry using taxpayer monies to finance the upfront costs of manufacturing vaccines.<sup>4</sup>

However, as new innovations approached market readiness and the prospect of commercialization became a reality, intellectual property (IP) positions have been taken or are being used to secure financial interests, creating a layer of complexity to gain global access to much needed medical solutions. For example, Gilead received \$70 million in public federal funds to develop the use of remdesivir to treat COVID-19.<sup>5</sup> Remdesivir also benefited from the Solidarity Trials,<sup>6</sup> as well as NIH sponsored clinical trials,<sup>7</sup> leading to it being the first treatment option of COVID-19 to receive conditional marketing authorization by the European Medicines Agency through its accelerated approval procedures for promising potential COVID-19 treatments and vaccines.<sup>8</sup>

Gilead's existing patent on remdesivir,<sup>9</sup> which was originally developed to treat Ebola never made it to market, but now with its authorized use for the treatment of COVID-19, Gilead can enjoy exclusive rights to remdesivir in Europe under the name Veklury® until the expiry of its patent.

Without any legally supported mechanisms to ensure access to innovations and associated production conditions that benefited from public funds and open collaborative research efforts such as C-TAP and the Solidarity Trials, worldwide supplies to much needed medical solutions that benefited from these public health initiatives to respond rapidly to the pandemic can be frustrated. Based on lessons learned from the emergency responses and actions initially taken as an immediate reaction to the COVID-19 pandemic, it is clear that any future preparedness plan absolutely requires clear legal and regulatory frameworks, informed by policy objectives such as principles of “responsible research and innovation”<sup>10</sup> and “global public good”<sup>11</sup> to ensure that publicly funded outcomes can ultimately reach the public. This will require pharmaceutical companies to permit worldwide production if they are unable to produce sufficient quantities to meet global demand, while still being remunerated with fair and reasonable royalties without giving up their IP rights.

In the context of the COVID-19 pandemic, open and collaborative research and development efforts to accelerate the discovery of solutions have proven in theory and in practice to be successful as long as interests of the participants in the innovation process are aligned. However, as private rights and commercial realities diverge from previously shared common good considerations, problems associated with access and availability to adequate supplies to much needed public health solutions start to arise. This paper will explore “the good, the bad, and the ugly” of the open and publicly funded strategies in response to the COVID-19 pandemic and conclude with legally supported recommendations that can be adopted in the future to mitigate against the very real access and availability problems we are currently facing.

### “The Good”

C-TAP was launched by the WHO as a platform to pool data, knowledge, and IP for existing or new COVID-19 solutions to enable open sharing of science access to information necessary to develop new technologies to combat COVID-19.<sup>2</sup> The promise of C-TAP is to ensure that “the latest and best science benefits all of humanity...and made universally available” to accelerate discovery of innovations through open science.<sup>2</sup> Participants are invited to contribute patents on a voluntary basis to the Medicines Patent Pool (MPP), a United Nations initiative aimed at facilitating development and increasing access to essential medicines globally, and in particular, to low and middle income countries.<sup>12</sup> Patent

pools are essentially agreements for licensing patents to a centralized entity for the purpose of sharing IP to other innovators. As the holder of these voluntary licenses, MPP has a pooled resource of patent protected innovations which innovators can then negotiate access to the pooled patent rights to develop new or follow-on innovations. Patent holders who grant licenses to MPP are therefore entitled to royalty revenues from successful innovations developed as a result of having access to the pooled patent rights.

Patent pools have generally been recognized as a key open innovation tool to make sure the fruits of publicly funded collaborative research and development efforts can be distributed quickly globally.<sup>13</sup> The potential benefit offered by patent pools makes sense in view of the European Patent Office's estimate that USD\$20 billion are spent every year to develop innovations and technologies that have already been developed elsewhere,<sup>14</sup> highlighting the exorbitant cost of duplication arising from the lack of sharing. Equally discouraging is the finding that over 85% of research funds, equivalent to USD\$100 billion per year globally, are wasted per year due in large part to selective non-publication and poor reporting of information that should otherwise be publicly available, leading to ineffective uptake and application of research and findings.<sup>15</sup> Failure to share and mobilize existing knowledge has been recognized by the research community as one of the key sources of waste in the innovation process.<sup>16</sup>

### *"The Bad"*

Because the pooling of IP rights under C-TAP is voluntary, even for those who received public funding to conduct COVID-19 related R&D, C-TAP cannot be used to ensure fair and reasonable access to solutions developed in part from taking advantage of publicly funded open and collaborative efforts. Opponents to the pooling of IP rights, even in the case of a public health emergency, argue that IP based incentives continue to be necessary for pharmaceutical companies to make upfront investment risks to develop new medical innovations that have no guarantee of success.<sup>17</sup> The concern that demand could outstrip supply should not be addressed through undermining the legal certainty offered by the existing IP framework.<sup>17</sup> The pharmaceutical industry has expressed a commitment to ensure "equitable distribution" and affordable access to therapeutics and vaccines and they should therefore continue to be able to exercise their own discretion when negotiating licensing arrangements on terms they believe will achieve the desired social outcome.<sup>18</sup>

Traditionally, IP rights have been justified in the pharmaceutical sector because of the time and cost of drug discovery and development.<sup>19</sup> However, if the cost of research associated with COVID-19 related innovations has largely been borne and subsidized by the public through public research grants and the time for development has been significantly reduced through open and collaborative efforts,

how can pharmaceutical companies justifiably assert IP on innovations as a private asset that in fact has largely already paid for by the public?

### *The Ugly*

At the World Health Assembly held in May 2020, the concept of "vaccine nationalism" was discussed to describe the growing trend of countries prioritizing the health interests of their own citizens at the expense of others.<sup>20</sup> Early examples of such behavior raised alarm bells<sup>5,21</sup> while more recent examples of vaccine hoarding<sup>22,23</sup> and preventing the export of vaccines<sup>24,25</sup> appear to confirm the fear that vaccine nationalism is a real threat.

Collectively, these actions suggest a pattern of behavior where larger countries leverage their significant national resource to secure limited supplies of medical innovations at the expense of poorer countries. As the WHO Director-General stated very poignantly, it is natural that countries want to protect their own citizens first, but in order for vaccines to be effective, they must be used effectively, which means we need to vaccinate some people in all countries rather than all people in some countries.<sup>26</sup> If governments worldwide continue to take nationalistic approaches to secure the public health of their own people first without sufficient regard to other countries, then the fight for access will get ugly. Health experts speculate there will be a global supply shortage for 12–18 months if countries continue on the path of hoarding.<sup>22,23</sup> The concept of openness and collaborative research and development will forever be undermined if the trust, solidarity, and goodwill between nations are broken if a global public good approach is not ultimately taken.

The COVID-19 pandemic has brought global attention to the often overlooked but critical issue of inequalities in access to healthcare.<sup>27</sup> Although the COVAX plan developed by the WHO attempts to provide global access to vaccines,<sup>28</sup> recent reports indicate that COVAX is falling short of its vaccine distribution goals.<sup>29</sup> Despite the laudable objectives of the COVAX plan, as long as production capabilities and capacities are limited by proprietary rights, countries in need of access to vaccines will have to rely on the wealthy countries (who have bought more than enough vaccines for their own population) to distribute doses to countries in need. Moving forward, this cannot be an acceptable or sustainable way from a health equity perspective to distribute vaccines in the future.

## **Discussion**

Based on the previous geopolitical struggles over vaccines in response to the avian flu and swine flu pandemics,<sup>30</sup> the world has already experienced and witnessed how a fragmented approach to the distribution of medical solutions will simply prolong global recovery. The reality of the current situation is that we have only been able to reactively respond to the

problem of access and to navigate the complex IP and trade secret landscape of COVID-19 related innovations,<sup>31</sup> each with its advantages and disadvantages.

The idea of APAs for governments to finance the upfront costs for the production of vaccines in exchange for a guaranteed minimum number of dosages was supposed to be a mutually beneficial way to address the issue of access in view of IP rights and innovation incentives.<sup>4</sup> APAs also mean that public funds go into paying for the manufacturing, as well as the R&D process of medical solutions, which further puts into question the traditional argument in favor of strong IP positions to offset the significant financial outlay for the drug discovery and development process. However, as seen in Europe with APAs, this “guaranteed access” to a minimum number of dosages does not address the manufacturing capacity problem.<sup>32</sup> Essentially, the argument is if the number of promised dosages cannot be made fast enough despite reasonable best efforts, stronger contractual obligations and the threat of legal action and penalties will not resolve the problem.

Compulsory licenses are available as an option for governments to authorize the manufacturing and sale of patent protected medicines by third parties. However, compulsory licenses are often seen as extraordinary measure because of their potential negative impact on innovation.<sup>33</sup> They are an important policy instrument that can be used to improve access to much needed pharmaceutical products, particularly in least developed and developing countries,<sup>34</sup> but in practice, there is much legal uncertainty and feasibility challenges surrounding compulsory licenses, which makes them rarely used. There is the added complexity that even if a compulsory license is granted for the patent rights, there is no automatic or corresponding compulsory waiver of the associated data and marketing exclusivities granted by the regulatory authorities.<sup>35</sup> Furthermore, because compulsory licenses are primarily for domestic use purposes only, they also do not solve the problem for countries that do not have the manufacturing capacity or infrastructure to produce sufficient quantities of medicine for its own domestic use.<sup>36</sup> Because many countries have opted out of the ability to issue a compulsory license for importing patent treatments manufactured elsewhere,<sup>37</sup> compulsory licenses may not be a sufficient tool to ensure timely global access.

Deferral of exclusivity rights means IP and data and market exclusivities remain intact but will not be enforced for a period of time. Even before the proposed COVID IP waivers in the US and the EU,<sup>38,39</sup> Moderna had agreed not to enforce its patent for the course of the pandemic.<sup>40</sup> But what determines how long the deferral will be and what conditions trigger the reinstatement of exclusivity rights? When is the pandemic considered over? And if the pandemic is truly over before the exclusivity rights are reinstated, what incentive is there if the return of exclusivity rights does not give industry sufficient benefits? The legal uncertainty

makes this option conceptionally interesting but practically hard to balance and implement with a significant risk of stifling innovation.

### *Recommendations—Preparing for the Future*

Looking forward to the future, what lessons can we learn from the COVID-19 pandemic so that we are better prepared to proactively manage future pandemics with legally supported mechanisms to ensure essential medicines can be rapidly and widely distributed worldwide? The European Council’s resolution calling for an international treaty on pandemics has largely garnered general support for the identified incentives and benefits.<sup>41</sup> Although conceptually sensible and commendable, it remains to be seen whether it is likely that states can reach an agreement for a legally binding and meaningful international treaty that encompasses all the identified principles to structure and coordinate collective actions on how to deal with a global public health threat. Of course, there is precedent of a successful global health treaty with the WHO Framework Convention on Tobacco Control,<sup>42</sup> but that treaty deals with very different issues a pandemics treaty sets out to address, particularly with respect to the challenges of healthcare disparities and inequities to access and availability of medical solutions. Whether international law is an effective tool or solution to address and manage global health care challenges remains to be seen.

Two of the main bottlenecks to enable global distribution of treatments include (1) IP and proprietary positions that restrict who can and has the necessary know-how to manufacture medical solutions worldwide; and (2) global shortage of required materials (i.e., glass vials, active pharmaceutical ingredients, temperature control units) to manufacture the solutions. Incorporating a licensing provision to a trusted centralized authority, triggered only under strict prescribed circumstances **as a condition** to receive public funding or to participate in publicly funded open and collaborative initiatives, will ensure benefits supported by the public will actually reach the public. The license to IP and proprietary know-how will be granted to a trusted centralized authority, such as the MPP, to authorize production by countries with manufacturing capabilities **if and only if** the IP holder is unable to produce sufficient quantities to meet global demand. If innovators want to take advantage of public funding and initiatives to accelerate R&D of new innovations in order to remain competitive with competitors who do take advantage of these public initiatives, then they must agree to this “compulsory voluntary license.” The Medical R&D Treaty concept which attempted to provide for a global framework to support medical innovation<sup>43</sup> falls short of including this “compulsory voluntary license,” which will ensure the original IP holder still receives financial compensation from markets they are not able to supply adequately but they will have to share the revenue with the third-party manufacturer. Export restrictions should likewise be removed



to ensure the medical solutions can be made available to countries without their own manufacturing infrastructure. The production capacity of the IP holder therefore cannot be held captive by national or private interest if mechanisms for alternative manufacturing are made available as a condition for having received public financial support or expedited access to clinical trials or regulatory approval. IP holders will still be entitled to receive fair and reasonable royalties for production in markets they cannot service, administered by way of a trusted international organization that understands and will consider the market and economic realities of the pharmaceutical industry.

## Conclusion

In response to a global pandemic, there must be legally supported mechanisms to ensure the pharmaceutical industry and national interests cannot be used to undermine the ability to rapidly and widely distribute essential medicines worldwide. Although commercial interests of industry need to be recognized to incentivize innovation, private profits should not be subsidized by public funds that supported the development of essential medical solutions. Nor should global public health be at the mercy of national interests and companies who refuse to cede manufacturing control if they are unable to produce sufficient quantities to meet global demand. The proposed recommendations do not require IP holders to abandon or waive their IP rights. However, if innovators want to remain competitive with competitors who do take advantage of these public initiatives, they have a choice to make. The intent of the “voluntary compulsory license” is to incentivize and put some pressure on industry to take the proactive effort to optimize their own manufacturing capacity and their licensing strategies if they do not want manufacturing control taken away from them. This places some onus on industry to become an active responsible player on matters of global public health if they wish to take advantage of public collaborative efforts to accelerate their innovation efforts.

## Summary of Recommendation

Include compulsory voluntary license of IP and associated know-how as a condition to receiving public funds or participating in publicly funded initiatives for global common good, triggered if and only if IP holders fail to optimize their manufacturing capacity and licensing strategies to meet global public health needs.

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