PATENTS

Contractual solutions to overcome drug scarcity during pandemics and epidemics

Licensing provisions that obligate recipients of government funding to share relevant technology and know-how for scarce drugs during pandemics and epidemics can reduce shortages and overcome obstacles that intellectual property rights present.

The COVID-19 pandemic has highlighted problems regarding scarcity of lifesaving medicines[1]. Limited supplies of medicines often cannot satisfy surging demand during pandemics and large-scale epidemics. Intellectual property (IP) rights that incentivize the creation of new drugs also limit governments' ability to scale up production in a crisis[2]. Pharma companies' reluctance to share proprietary technology and know-how with third-party manufacturers further exacerbates this problem. For example, although Moderna received $2.5 billion in US government funding, it has refused to license out relevant mRNA technology to help alleviate vaccine shortages. Pfizer, Johnson & Johnson and other vaccine manufacturers have also resisted licensing their vaccines[3]. Governments currently lack the leverage to force cooperation from pharma companies, even when the companies receive significant taxpayer funding.

Limitations of current solutions

Proposed solutions for alleviating vaccine shortages revolve primarily around IP waivers or expanded compulsory licensing[4]. The Biden Administration and some public interest groups support a proposal under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement to permit member states to waive IP obligations for all COVID-19-related inventions[5]. The European Union has alternatively proposed loosening TRIPS' compulsory licensing provision to make it easier for countries to produce patented drugs without patent-holder consent[6].

These measures, however, have serious limitations. After more than a year, TRIPS members have failed to reach a consensus on an IP waiver. Moreover, even if they did, individual countries would need to amend their national laws to implement it. A waiver would also disrupt the financial expectations of pharma companies, which could undermine their willingness to develop drugs for future public health emergencies. Because of that, many governments are hesitant to agree to a TRIPS waiver.

In the short term, compulsory licensing cannot alleviate shortages of biologic medicines, including vaccines. TRIPS does not require IP holders to turn over the know-how needed to manufacture their inventions. Consequently, third-party manufacturers must recreate the relevant technology and gain regulatory approval for their versions of existing drugs. Although such reverse engineering works for small-molecule drugs like the antiviral remdesivir, it is insufficient to yield the necessary information about the products and manufacturing processes of biologics, including vaccines[7].

A proactive approach to mitigating drug scarcity

Instead of dealing with scarcity problems as pandemics or epidemics unfold, governments should plan proactively for pandemic-related drug shortages. We propose that they do so by tailoring government contracts used to fund medical research. When governments provide significant pandemic- or epidemic-related drug development funds, they could require funding recipients to produce resulting drugs in a quantity sufficient to meet public health needs. Companies that cannot meet this obligation would be required to license their technology and manufacturing expertise to third parties to scale up production quickly. More ambitiously, governments could include dormant licensing provisions in medical research funding agreements. Such provisions would be triggered only if a pandemic or epidemic is declared. We explore each proposed solution in turn.

Contractual provisions

At the emergence of an outbreak, governments often provide 'push funding' to pharma companies to help them quickly develop new drugs. For example, under Operation Warp Speed, the US government provided $18 billion to pharma companies to develop and manufacture COVID-19-related drugs[8]. However, governments often fail to secure promises from the funding recipients regarding alleviating scarcity. During the COVID-19 pandemic, governments consequently could not force funding recipients like Moderna to license out their technology.

Governments that provide outbreak-related push funding should require recipients to produce resulting drugs in sufficient quantity to meet public health needs. If a shortage exists, after a grace period, the government could compel the company to utilize 'out-licensing' — licensing of the relevant qualifying technology and manufacturing know-how to one or more third-party manufacturers. The contract would specify both the amount of compensation the company would receive and the penalty if the company refuses to cooperate. A company that is unwilling to agree to such terms would be free to decline the funding.

Some out-licensing already voluntarily occurs. In 2021, Johnson & Johnson allowed Merck & Co. to manufacture its vaccine in the United States under an agreement brokered by the Biden Administration[9]. However, pharma companies often delay or limit the use of third-party manufacturing. For example, Gilead Sciences' drug remdesivir was in short supply beginning in 2020, but it delayed out-licensing and limited the countries that could benefit from it. This has contributed to shortages of remdesivir in the United States and elsewhere[10].

Governments could use contractual provisions to address not just their own needs, but also those of low-income countries. They could require subsequently developed drugs to be sold at cost to WTO-designated Least-Developed Countries and at a discount to other low-income countries. They could also require companies to provide a minimum percentage of resulting drugs to lower-income countries, rather than merely to the highest bidders.

A disadvantage of negotiating contractual provisions during a health crisis is cost. Governments will need to negotiate agreements quickly to address the crisis, and larger pharma companies will likely refuse funding if they find the conditions overly onerous. A better solution would be for governments to negotiate such assurances early, while the cost of obtaining them is relatively low. This could be achieved through the use of dormant licenses.

Dormant licenses

A dormant license provides a pre-negotiated contractual framework that applies only if an identifiable event occurs[11]. When governments fund medical research, they could include dormant licensing terms in funding agreements that activate if a pandemic or epidemic is formally declared. Once these terms are activated, the funding recipient would be obligated to license qualifying technology and manufacturing knowledge on a non-exclusive basis for the duration of the formal crisis period. Crucially, the funding contract should clearly identify the covered technology, provide a means to determine the beginning and end of the transfer period, and include guidelines for calculating royalties owed to the IP holder.

The government entity funding the relevant medical research would set terms before an outbreak occurred. A party seeking funding would either agree to the terms, negotiate them or forego funding. Under current practices, negotiations occur only after a public health crisis has emerged, when problems of scarcity are imminent. The proposed approach would facilitate bargaining by setting negotiations before an outbreak, before time constraints emerge. Early negotiation would likely be more cost efficient for governments, because terms would be agreed to before shortages are imminent.

A clearly identifiable trigger for activating the dormant license must be negotiated in advance. A formal declaration of a pandemic or epidemic from a mutually trusted health organization could serve this role, such as a declaration by a domestic health agency or a declaration of Public Health Emergency of International Concern by the World Health Organization[12]. The license could provide a grace period before execution and a phase-out period after the pandemic or epidemic is formally declared over.

While the dormant license is active, the IP holder could not refuse licensure of the specified drug or vaccine. Unlike other proposals, however, ours preserves most rights and compensates the IP holder. It provides governments with a means to calculate royalty rates during crisis-driven spikes in demand. A dormant license furthermore preserves the ethos of the patent bargain, while furthering the public health imperative of increasing the production of critically needed medicines.

To ensure the timely production of the medicine at issue, the proposed dormant license should encompass the transfer of know-how and other relevant forms of implicit or tacit knowledge. TRIPS and domestic IP laws lack mechanisms to compel such transfers[13]. Consequently, the dormant license should include, at minimum, financial penalties for non-compliance with the knowledge transfer provision. Although a penalty per se cannot guarantee that such a transfer would occur, it would help nudge companies toward compliance — a feature that is currently absent from existing frameworks governing the transfer of technology during pandemics and epidemics.

Our proposal offers benefits from a political economy perspective. The clear and automatic activation of licensing terms would help streamline the process of scaling up production. Unlike existing proposals, this framework reduces government intervention during the crisis period, when time is scarce due to competing demands.

This licensing framework can also be tailored. Governments may make funding conditional on the adoption of a dormant license only for medicines targeting neglected diseases, or for diseases caused by emerging pathogens. Or they could limit the framework to medicines likely to be needed during pandemics and epidemics. Countries could furthermore choose to work with each other to deal with scarcity on a broader scale. For example, a group of countries might jointly agree to adopt contractual provisions making pricing and supply assurances to lower-income countries, or even a segment thereof.

Conclusions

The COVID-19 pandemic illustrates how IP rights may hinder the swift production and dissemination of needed medicines. Current solutions have largely focused on altering IP rights after the fact, such as through a TRIPS waiver or expanded compulsory licensing. But such post-crisis solutions can be time consuming to implement, and they upend the settled expectations of pharma companies. Moreover, governments lack a legal basis for forcing IP rights holders to turn over the information needed to quickly replicate vaccines and other complex drugs.

By contrast, governments in high-income countries can leverage taxpayer funding for the research and development of medicine to address drug scarcity. We therefore propose that, when governments fund drug development after an outbreak begins, they require recipients to out-license know-how to third-party manufacturers in the event of a drug shortage, and pre-negotiate royalty terms. They should also extract guarantees on pricing and supply for low-income countries.

Better still, when funding new drug development, governments should utilize dormant licenses that activate when a health crisis is declared. By negotiating licensing terms before an outbreak, they can obtain a substantially lower price for such assurances and speed up their future response to drug shortages. ❐

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Author contributions

Both authors contributed equally to the work presented in the paper.

Competing interests

The authors declare no competing interests.