Public and private global organizations have responded like never before to try to develop ways to diagnose, treat and prevent COVID-19. Pharmaceutical companies have been working around the clock towards this common aim. The answers could lie in the drugs already on the market, those in development or completely new treatments—or a combination of all three. Is there still a place for intellectual property (IP)?

At the same time, governments around the world face immense pressure to ensure that tests, treatments and vaccines are delivered quickly, widely and cheaply to their own populations (first). Shortages of personal protective equipment (PPE) and intensive care medicines have made headlines, which will only grow as solutions are found. Many countries, facing global supply chains in an increasingly nationalist world, have restricted exports in an effort to protect their own. Is there still a place for free trade?

In this article, we consider some of the mechanisms that governments may seek to use to bypass patent rights and trading rules, comparing the UK, Germany, Austria, the Netherlands and the USA.

Bypassing patent rights

Governments grant patent rights to incentivize innovation. That incentive requires trust that those rights will be respected. Governments cannot simply take those rights away. Under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), they have agreed only to do so in limited circumstances, whether by granting compulsory licences or by permitting use in the services of the country.

In the UK, a compulsory licence cannot be sought until 3 years after the grant of a patent and a period of negotiation with the patent owner. This means that compulsory licences will only be relevant for older inventions which prove to be useful against COVID-19. It will still be necessary to show that demand is not being met on reasonable terms (for instance, where the patentee cannot achieve the necessary scale-up) or that exploitation of another patented invention involving an important technical advance is being hindered (which may affect platform technologies). For other inventions, particularly newer ones, we are more likely to see the
UK government relying on Crown use provisions, but again only if demand cannot be met.

In Germany, similarly, compulsory licences are only available when in the public interest and reasonable attempts to negotiate a licence have failed. The German government is more likely to rely on the new extended right introduced by the ‘coronavirus crisis package’ on 27 March 2020. That amended the Infection Protection Act to give the Federal Ministry of Health and downstream authorities the power to order the use of patents in the interest of public welfare during a national epidemic. Again, such orders are likely to be exceptional, and only if the right holder cannot meet supply and refuses to authorize others to do so.

The Austrian provisions on compulsory licensing are less restrictive than those in the UK and Germany, applying a broad public interest test and removing the need for prior negotiation in a situation of a ‘national emergency’ or ‘other circumstances of extreme urgency’. The scope and duration of the licence must be limited to the purpose that made the grant of the licence necessary.

Similarly, the Dutch Patents Act allows compulsory licensing in the public interest and allows the need for prior negotiation to be waived where this is incompatible with the urgency of the matter. Equally, the normal stay pending appeal can be waived due to urgency.

Finally, the USA has two key mechanisms it can seek to rely on: government use under Title 28, US Code § 1498, or march-in rights under the Bayh–Dole Act. To use the first in the pharmaceutical context, the government must show that the use is ‘by or for the United States’, that the drug receives the necessary regulatory approvals and that the right holder is compensated. Interestingly, the US government threatened to invoke section 1498 during the 2001 anthrax attacks if the patent owner of the antibiotic ciprofloxacin did not lower its prices. Ultimately, a deal was reached and the section was not invoked. The Bayh–Dole Act is of potentially broader scope, allowing the government to order patentees to grant licences where health and safety needs are not reasonably fulfilled, but of narrower application, as the government must have subsidized the research leading to the invention.

There are two other key restrictions on these routes to bypass patents: these measures are restricted territorially and they are restricted to patents.

First, these rules are for domestic use only—the TRIPS Agreement specifies that compulsory licences must be predominantly for the supply of the domestic market. This has long been a matter of public debate and led to amendment of the TRIPS Agreement to introduce a waiver to the restriction on exports of pharmaceutical products (Article 31bis). This waiver was aimed at the least-developed WTO members and those with insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question. Many developed countries (including the USA and the European Union (EU)) announced voluntarily that they would not use the system. That may be put to the test given the high proportion of active pharmaceutical ingredients made in China and India. Many developed countries may not have the manufacturing capability to fulfill the demand of their population and political statements about bringing manufacturing ‘home’ cannot build that capacity overnight.

Secondly, only patents are bypassed, not the other rights required to make a drug available. In particular, a large part of the cost of development of a drug is completion of the clinical trials to prove it is safe and efficacious. That data is confidential to the pharmaceutical company when submitted to the regulatory agencies, whether the US Food and Drug Administration (FDA), the European Medicines Agency (EMA) or the Medicines and Healthcare Products Regulatory Agency (MHRA). The regulatory agencies cannot rely on it to authorize competitor products for a number of years. Even with more flexible regulatory regimes introduced in response to COVID-19, this is likely to be a significant constraint on threats to bypass patent rights, at least for newer drugs.

A further twist arises from the degree of collaboration which has developed. Companies entering into global R&D agreements are already alive to the potential pitfalls associated with large-scale collaborations and the need to ensure that robust agreements and processes relating to ownership, rights of use, information-sharing and the protection of confidential information are in place. Responses to COVID-19, whether they work or not, may have important uses to improve public health in other ways. At the same time as responding to the urgent public health demand, companies will be thinking beyond that and putting in place procedures (possibly including information barriers) to monitor and, if necessary, document how information received through global initiatives has been used (and how it has not). Unfortunately, even after the immediate challenge has been overcome, we will still have other health issues to address. If non-COVID-19 IP rights are not protected and respected, we will not see the fruits of this creative collaboration proceed through development to market.

In sum, we are likely to see increasing public demand to ‘break patents’ and political showboating in response. However, governments are aware of the damage that can be caused to the longer-term incentives to develop new pharmaceuticals if they stop respecting the
of the transition period looming, that approach is likely rules may be unlikely during a crisis and with the end come sick. While the enforcement of free movement 19, as well as those required to care for patients who be-
which are regarded as potential treatments for COVID-
from the UK or hoarded. This extends to medicines updated lists of medicines that cannot be exported place. In the UK, the government publishes regularly 
regulation which for a number of weeks restricted 
goods remain low.

Bypassing free trade

The right to free movement of goods is one of the four fundamental freedoms in the Treaty on the Functioning of the European Union (the others being capital, people and services). The EU prohibits export quotas (or measures with equivalent effect) between Member States unless they can be justified on specific grounds, such as the protection of human health and life. The COVID-19 pandemic has put the free movement of goods sorely to the test. The shortage of PPE and intensive care medicines has sparked mutual suspicion among states and has led to an increase in trade protectionism globally, as nations place their focus on their own nationals’ health.

The COVID-19 pandemic has brought extremely challenging times in a whole range of ways. It is impossible not to have your spirits lifted by the creativity and collaboration with which we are tackling the pandemic on a global basis, including the WHO’s Access to COVID-19 Tools Accelerator and the Coronavirus Global Response Initiative. As well as solving the immediate problem, all this energy is likely to produce a panoply of solutions to other problems.
However, the current environment also presents serious challenges to our systems of patent protection and free trade. Many of those who have sought change to those systems for years are pressing that case now. These systems have developed for good reasons and, by and large, have supported a broad range of improvements to public health. Improvements are always possible—more innovation, more access, lower cost. But knee-jerk reactions are unlikely to realize those improvements and are much more likely to jeopardize the use of current and future innovation, at a time when we can expect the creative flow to be at its maximum. That would be a real public health disaster.