THE HILL

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We need to relax intellectual property rules to fight this viru

BY JAMES M. COOPER AND BASHAR MALKAWI, OPINION CONTRIBUTORS — 04/06/20 09:00 AM EDT
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Intellectual property (IP) — patent, copyright, trademark and industrial design — is the foundation for a thriving consumer society and a significant driver for economic growth. Most importantly for right now, it is the engine to help the globe out of the coronavirus pandemic. To fight this scourge, there is an urgent need for personal protection equipment for medical professionals, the deployment of safe and reliable testing, and the research, testing and rollout of a vaccine. To effectively do all that, governments around the world need to intervene to lessen IP restrictions in the short term and control spiraling prices.

With the shortage of CPAP hoods — to provide patients with oxygen — Italian doctors have been 3D-printing replacement parts, violating the patent on the machines. Medicines need to be replicated en masse to fight the pandemic. Data exclusivity among researchers is slowing down the development of vaccines to ward off COVID-19. We need to relax IP rules to allow companies — small, medium and large, domestic and foreign — to contribute to these efforts. Price controls may be called for.

First, about the machines such as ventilators: A patentable invention grants its inventor certain exclusive rights. These rights include preventing non-authorized making, using, offering for sale, or importing for these purposes patented products or processes. A process patent protects the method by which the product is made. Now is not the time to prosecute these patent infringement claims. The use of the Defense Production Act in the United States and legislative solutions in other countries is one step. Governments also should be acquiring the rights to

critical medical products and services to fight the coronavirus. We can divide up the spoils later.

Second, concerning much-needed medicine, we should consider compulsory licensing. The laws of many countries authorize granting a compulsory license for the services of the government for national defense, emergency, or public non-commercial use. However, certain conditions, sometimes onerous and time-consuming, must be met before a compulsory license will be granted. The interested party should first try to amicably negotiate a license with the patentee. In addition, the compulsory license shall be granted principally to supply the national market. When granted, a compulsory license should be non-exclusive. If the circumstances leading to the granting of a compulsory license cease to exist, compulsory license should be suspended.

Compulsory licensing can be used for COVID-19 tests and drugs to treat the disease. Issuing a compulsory license for drugs can fall under emergency circumstances exceptions in national laws. The use of such licenses prevents patent holders from using their rights in a manner that might restrict trade. In response to COVID-19, Canada passed amendments to speed the process of issuing compulsory licenses for medical products. And it does not have to be limited to medicines: Brazil suspended compulsory licensing for tubes and syringes. Rather than undergoing the usual process of haggling with a company over terms, these governments can simply issue a license and negotiate compensation later.

Third, data exclusivity is another area for quick action, because it can delay the introduction of generic competition for existing drugs. It is high time for pharmaceutical companies, scientists and medical associations to share data and transfer technology to treat COVID-19. Generic drug applications can be encouraged even if data submitted by a generic producer is based on data originally compiled by the brand-name producer. Extreme health issues can and should justify such extreme measures that violate IP rights.

Lastly, there is a need for price control measures. Over the years, drug prices have increased dramatically. Non-contagious diseases such as heart diseases, cancers and diabetes, are major causes of death. Now, with the COVID-19 outbreak, we are witnessing the unavailability of certain essential drugs in hospitals, which could lower per capita consumption of medicines. Several factors could contribute to an increase in prices of drugs, including inflation, currency values and high levels of patent protection.

Higher drug prices would put a strain on the public health system, and for those Americans without health insurance, higher prices would require significant out-of-pocket expenditure. During these difficult times, the government could rely on some forms of price controls on drugs. For example, the government can establish reference prices for drugs. Reference prices are set at only slightly higher levels than prices for generic drugs in order to encourage competition.

In addition, the government could create a cap on drug prices deemed excessive; drug prices should reflect a reasonable monetary return for the manufacturer on the cost of production. Moreover, the government can subsidize drugs indirectly by reimbursing patients who pay up front. Although these price controls yield lower revenue for drug firms and medical device manufacturers by preventing them from charging market-based prices, they address wider health policy considerations such as access and affordability.

We must recognize that corporations, and the scientists who work at them, are economic actors who want and deserve to be compensated for their efforts, investments, research and products that emerge. For example, it is estimated that the total cost of developing a drug, including the costs of capital and failed research and development efforts, hovers at $400 million. Without strong protection for these innovations, there will be no economic justification for investment.

But this is a different time — this is a global emergency. Millions of people will be infected with COVID-19 and require treatment, and hundreds of millions more need to be tested. And more than 7 billion people may need to be vaccinated once we find a way to protect humanity from this horrid pandemic. The niceties of IP law should not get in the way of our countries fighting it.

James M. Cooper is a professor of law at California Western School of Law in San Diego. He is a former member of the U.S. government delegation to the World Intellectual Property Organization Advisory Committee on Enforcement.

Bashar Malkawi is director of knowledge management at the H.H. Dubai's Ruler Court, Government of Dubai, Legal Affairs Department and a former dean of the University of Sharjah in the United Arab Emirates.

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