



People over Patents: How Governments are Preparing to Make COVID-19 Medicines Accessible

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As COVID-19 spreads around the world, more governments are taking steps to make sure future COVID-19 medicines will be affordable and available to all. This document surveys the steps some governments have taken to ensure that intellectual property (IP) does not pose a barrier to COVID-19 medicine access. It focuses on national policies.

So far these governments are streamlining processes for the government use and compulsory licensing of patented inventions. These mechanisms allow governments to authorize additional suppliers of a patented invention without the consent of the patent holder, typically in exchange for payment of a reasonable royalty.¹ In addition to increasing medicine supply, compulsory licensing and government patent use generate generic competition and significantly lower prices. Generic competition transformed access to HIV treatment, saving millions of lives.² Non-voluntary patent licensing has since been used to increase access to medicines for hepatitis C and cancer.³

In response to COVID-19, Germany, France, Canada and Indonesia have adopted new non-voluntary patent licensing policies. Several have taken steps to license patents, with Chile and Ecuador calling for licenses and Israel issuing a license for a candidate COVID-19 treatment.

Table 1: Survey of National IP Developments Related to COVID-19

Status	Legislative and Policy Changes	Government Use and Compulsory Licenses
Adopted	Canada France Germany Indonesia	Israel
Proposed	Brazil United States	Chile Ecuador

¹ Compulsory Licensing of Pharmaceuticals and TRIPS, WORLD TRADE ORGANIZATION (Last accessed July 27, 2020). https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm. Government patent use refers to the case when a license is for public, non-commercial use.

² A History of the Access to Medicines Movement in South Africa, STANDING UP FOR OUR LIVES (Last accessed July 27, 2020). <https://standingupforourlives.section27.org.za/> (detailing the history of the South African access to medicines movement).

³ The TRIPS Flexibilities Database, MEDICINES LAW AND POLICY (Last accessed July 27, 2020). <http://tripsflexibilities.medicineslawandpolicy.org/>.

LEGISLATIVE AND POLICY CHANGES

Adopted

Canada

Canada has simplified its government patent use procedure for public health emergencies. Whereas the Commissioner of Patents previously had discretion over whether to grant license applications, new legislation requires that the Commissioner authorize all applications from the Minister of Health related to public health emergencies.⁴ The law now provides that “The Commissioner shall, on the application of the Minister of Health, authorize the Government of Canada and any person specified in the application to make, construct, use and sell a patented invention to the extent necessary to respond to the public health emergency described in the application.”⁵ The law also eliminates the requirement for the government to negotiate with the patent holder.

Licenses under this new provision will be granted for a period of one year or until the Minister of Health notifies the Commissioner that the license is no longer needed, whichever is shorter. Commissioners cannot grant licenses under the new provision after September 30, 2020.

France

France has adopted a sweeping measure on access to Covid-19 medical tools. Article L.3131-15 allows the Prime Minister to “take any measures to make available to patients appropriate medicines for the eradication of the health disaster.”⁶ During legislative discussions on the provision, the Minister of Health noted that he was open to the possibility of compulsory licensing and noted that “overly complex mechanisms waste time.”⁷ France has since limited its state of health emergency, so it is not immediately clear whether the provisions still apply.⁸

Germany

Germany has recently empowered its Ministry of Health to authorize government use of patents in cases where the lower chamber of Parliament (Bundestag) finds there is a national epidemic. The Ministry of Health can order that an invention “shall be used in the interest of public welfare or in the interest of the security of the Federal Republic of Germany.”⁹ The government is required to notify the patent holder before the invention is used. The patent holder cannot prohibit the use of the invention, but only seek equitable remuneration.

⁴COVID-19 Emergency Response Act, STATUTES OF CANADA 2020 (March 25, 2020). <https://wipolex.wipo.int/en/text/565518>.

⁵ *Id.*

⁶ Pochart, Francois, et al. Compulsory Licenses Granted By Public Authorities; An Application In The COVID-19 Crisis, KLUWER PATENT BLOG. (April 24, 2020). http://patentblog.kluweriplaw.com/2020/04/24/compulsory-licenses-granted-by-public-authorities-an-application-in-the-covid-19-crisis-in-france-part-2/?doing_wp_cron=1595533025.0941770076751708984375#_ftn3.

⁷ *Id.* The same article also allows the government to requisition goods and services, and impose temporary price controls.

⁸Rose, Michel. France Will End Coronavirus Emergency Health Powers On July 10, REUTERS (June 10, 2020).

<https://www.reuters.com/article/us-health-coronavirus-france/france-will-end-coronavirus-emergency-health-powers-on-july-10-idUSKBN23HOW0>; Article L3131-15, LÉGIFRANCE (July 9, 2020).

https://www.legifrance.gouv.fr/affichCodeArticle.do;jsessionid=B0142FB0B7FAA062714A571025D4CE0A.tplgr38s_2?idArticle=LEGIARTI000042103698&cidTexte=LEGITEXT000006072665&categorieLien=id&dateTexte=20200710.

⁹Mussman, Thomas and Pross, Rospatt Osten. Update on Patent-Related Measures in Germany in View of Corona Pandemic, KLUWER PATENT BLOG (April 2, 2020). http://patentblog.kluweriplaw.com/2020/04/02/update-on-patent-related-measures-in-germany-in-view-of-corona-pandemic/?doing_wp_cron=1595534220.6007499694824218750000.

On March 25, 2020, the Bundestag found that there is a national epidemic, empowering the Ministry of Health. Orders will expire when the Bundestag finds there is no national epidemic, or on March 31, 2021.¹⁰

Indonesia

Refining the scope of its existing licensing authority, Indonesia has adopted a new implementing regulation in response to COVID-19.¹¹ This regulatory guidance allows the government, in part, to authorize government use of patents for pharmaceutical products that are expensive or required to overcome significant disease, and constitute a global public health emergency. Government officials must file an application with the Minister of Law and Human Rights to authorize government use of a patent, describing the invention and the governmental need. The final approval comes from the President.¹²

Proposed

Brazil

Members of the National Congress have proposed an accelerated, automatic compulsory licensing mechanism. The mechanism would streamline the existing mechanism, which is limited in scope and complex to administer. It would require automatic non-voluntary licensing of patents for medical technologies whenever there is a public health emergency declaration by Brazilian authorities or the World Health Organization, including for COVID-19.¹³ It would also require the patent holder to share “all information necessary and sufficient for the effective reproduction of the protected objects.” The license would be valid for the duration of the public health emergency. The royalty would be fixed at 1.5% of the sale price to the government.

United States

The U.S. has an expansive government patent use statute.¹⁴ Members of Congress have introduced legislation that would go further, and *require* the Secretary of Health and Human Services issue open, nonexclusive licenses for excessively priced COVID-19 medicines across the entire market.¹⁵ It would also require the Secretary to waive marketing exclusivities, and allow the Secretary to access and use confidential information, including know-how.¹⁶ The Secretary can terminate the licenses “only if the

¹⁰ Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG), § 5 Epidemische Lage von nationaler Tragweite, https://www.gesetze-im-internet.de/ifsg/_5.html.

¹¹ Ambrizal, Melinda and Ratanaprayul, Wongrat. Indonesia Adjusts Compulsory Licensing Guidelines in Preparation for Eventual COVID-19 Vaccine, TILLEKE & GIBBINS (July 23, 2020). <https://www.tilleke.com/resources/indonesia-adjusts-compulsory-licensing-guidelines-preparation-eventual-covid-19-vaccine> (Presidential Regulation No. 77/2020 regarding Procedures of Patent Implementation by the Government).

¹² *Id.* “[P]harmaceutical and biotechnology products that are deemed expensive, or are necessary to overcome a disease that could cause a large number of deaths or significant disabilities in the short term and that constitutes a global public health emergency.”; Tata Cara Pelaksanaan Paten Oleh Pemerintah, REPUBLIK INDONESIA, (2020) <https://tinyurl.com/yxhl414d>.

¹³ Bill No. 1462, BRAZIL (2020) <https://www.statnews.com/wp-content/uploads/2020/04/brazil-cl-proposal-1.pdf>

¹⁴ 28 USC § 1498(a).

¹⁵ H.R. 7296 - MMAPP Act of 2020, <https://www.congress.gov/bill/116th-congress/house-bill/7296/text?q=%7B%22search%22%3A%5B%22Make+Medications+Affordable%22%5D%7D&r=1&s=4>. This follows an earlier letter sent by 46 Members of Congress urging the Secretary “not to provide an exclusive license to any private manufacturer for a coronavirus vaccine or treatment in any government grants, contracts, or licensing arrangements.”; See *also* House Democrats Demand Fair Drug Pricing For Taxpayer-Funded Coronavirus Vaccine or Treatment, PRESS RELEASE FROM THE OFFICE OF REPRESENTATIVE JAN SCHAKOWSKY (Feb. 20, 2020) <https://schakowsky.house.gov/media/press-releases/house-democrats-demand-fair-drug-pricing-taxpayer-funded-coronavirus-vaccine-or>.

¹⁶ *Id.*

circumstances which led to the granting of the open, nonexclusive license cease to exist and are unlikely to recur.”

COMPULSORY LICENSES AND GOVERNMENT USE

Granted

Israel

After failing to secure sufficient supply of an experimental COVID-19 treatment, Israel used the medicine patent under Section 104 of Israeli Patent Law.¹⁷ The government license allowed a pharmaceutical distributor, K.S. Kim International Ltd., to procure generic versions of Kaletra (lopinavir/ritonavir) from an Indian supplier for treating COVID-19 patients. Within days, the originator corporation AbbVie responded by announcing that it would no longer enforce patents on the drug *anywhere in the world*.¹⁸

Proposed

Chile

Referencing its right to health obligations, Chile’s lower house of Congress recently adopted a resolution calling for the Minister of Health to issue compulsory licenses for all patents on COVID-19 health technologies.¹⁹

Ecuador

A committee in Ecuador’s National Assembly passed a resolution asking the Minister of Health to grant compulsory licenses for medicines and products related to the COVID-19 pandemic for the duration of the public health emergency.²⁰ The request included access to test data.

¹⁷ Balasubramaniam, Thiru. Isreal Issues Compulsory License to Allow the Government to Import Generis Versions of Kaletra, KNOWLEDGE ECOLOGY INTERNATIONAL (March 23, 2020) <https://www.keionline.org/32503>.

¹⁸ AbbVie drops patent rights for Kaletra antiviral treatment, FINANCIAL TIMES (March 23, 2020) <https://www.ft.com/content/5a7a9658-6d1f-11ea-89df-41bea055720b>.

¹⁹ English translation of Chile “RESOLUTION FOR THE GRANTING OF NON-VOLUNTARY LICENSES REFERRED TO IN ARTICLE 51^o Nº 2 OF INDUSTRIAL PROPERTY LAW Nº 19.030 TO FACILITATE ACCESS AND AVAILABILITY OF MEDICINES AND TECHNOLOGIES FOR THE PREVENTION, TREATMENT AND CURE OF CORONAVIRUS COVID-19”, KNOWLEDGE ECOLOGY INTERNATIONAL (March 17, 2020) <https://www.keionline.org/chilean-covid-resolution>.

²⁰ Resolution to require the National Government to establish compulsory licenses and other measures to guarantee free and affordable access to pharmaceutical products and medical technologies in the Declaration of Sanitary Emergency due to the Coronavirus pandemic (COVID-19) and other variations, as well as biosafety protocols and instruments for health personnel, postgraduates and students of the Public Health System, KNOWLEDGE ECOLOGY INTERNATIONAL (March 20, 2020) <https://www.keionline.org/ecuador-CL-coronavirus-resolution>