Compulsory Patent Licensing in Response to COVID-19: Recent International Developments

Can a government authorize the production of a COVID-19 vaccine without the consent of the patent holder? The answer is likely yes, depending on which country you are in.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provides a mechanism for member states to authorize themselves or third parties to produce a patented product without the express consent of the patent holder through the grant of compulsory licenses.

In response to the COVID-19 pandemic, several countries have already taken steps to facilitate compulsory licensing. In March, Canada[1], Germany[2] and France[3] amended their laws to make it easier to issue compulsory licenses, Ecuador[4] and Chile[5] passed resolutions to encourage the use of compulsory licenses, and Israel issued a compulsory license to import from India a generic version of AbbVie's patented product Kaletra for the treatment of coronavirus patients, which has since then been proven to be an ineffective treatment.[6]

More recently, on the basis of national security, Pharmasyntez, a Russian pharmaceutical company, is seeking a compulsory license from the Russian government to manufacture a generic version of Gilead's patented COVID-19 drug remdesivir without Gilead's consent.[7]

A compulsory license, however, may not always be necessary. Following Israel's issuance of the compulsory license for Kaletra, in an official company statement, AbbVie announced its intention to dedicate to the public its intellectual property related to Kaletra[8], and in October 2020, Moderna announced that while "the pandemic continues, Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic"[9].

Whether reliance on compulsory licenses will be necessary in order to ensure access to COVID-19 vaccines remains to be seen. However, the use of compulsory licenses should be carefully considered, as patent protection is one of the main economic incentives to innovate, particularly in the pharmaceutical field, where the average cost of bringing a drug to market is estimated to be close to 1.3 billion dollars.[10]

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[1] https://laws-lois.justice.gc.ca/eng/AnnualStatutes/2020_5/

[2] https://www.gesetze-im-internet.de/ifsg/index.html?_sm_au_=iVVvns5WHQ11sMDPvMFckK0232C0F

[3] https://www.legifrance.gouv.fr/codes/id/LEGIARTI000042103698/2020-07-11/

[4] **https://www.keionline.org/wp-content/uploads/ES-Ecuador-CL-resolution.pdf**

[5] **https://www.keionline.org/wp-content/uploads/resolucioncoronavirus.pdf**

[6] **https://www.reuters.com/article/us-health-coronavirus-israel-drug-idUSKBN216237**

[7] **https://www.reuters.com/article/us-health-coronavirus-russia-remdesivir/russian-firm-seeks-to-produce-covid-19-drug-remdesivir-without-patent-idUSKBN27I0QH**

[8] **https://news.bloomberglaw.com/pharma-and-life-sciences/abbvie-to-allow-use-of-intellectual-property-for-coronavirus**

[9] https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19

[10] **https://www.biospace.com/article/median-cost-of-bringing-a-new-drug-to-market-985-million/**

"March-In" Rights in the Era of COVID-19: An Unlikely Scenario for Remdesivir

As the total number of COVID-19 deaths in the U.S. is expected to climb to between 180,000 to 200,000 by September 5, 2020[1][2], there currently are no FDA-approved vaccines or drugs to prevent or treat COVID-19. However, the FDA has granted emergency use authorizations to some products for use in certain patients with COVID-19, including to Gilead for its investigational antiviral drug remdesivir[3].

On August 4, 2020, a bipartisan group of 34 state attorneys general (AGs) asked the U.S. government to exercise its march-in rights under the Bayh-Dole Act and license Gilead's remdesivir to third-party manufacturers in order to scale up production and lower the price of the drug, or allow states to do so.[4] The AGs argued that the U.S. government should exercise its march-in-rights because the price of remdesivir is too high and because Gilead "has benefited from millions of dollars of public funding, including a $30-million NIH-funded clinical trial," and "is unable to assure a supply of remdesivir sufficient to alleviate the health and safety needs of the country."[5]

The AGs' request that the U.S. government exercise its march-in rights under the Bayh-Dole Act, however, does not appear to be tethered to the law.

Under the Bayh-Dole Act, in specific circumstances, the U.S. government has the right to "march-in" and either grant licenses, or require the patent holder/licensee to grant licenses, to third parties

under federally funded patents.[6] The U.S. government may exercise its march-in rights if it determines that action is necessary because the patent holder or licensee:

- has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention;
- is not reasonably satisfying health or safety needs;
- is not reasonably satisfying regulatory requirements for public use; or
- has violated the U.S. industry preference provisions of 35 U.S.C § 204.[7]

If the U.S. government decides to exercise its march-in rights, the decision may be appealed to the U.S. Court of Federal Claims, and with respect to items (1) and (3) above, march-in rights may not be exercised until all appeals or petitions are exhausted.[8]

Despite having the authority, the U.S. government has never exercised its march-in rights. In its response to a 1997 petition requesting that the NIH exercise it march-in rights, the NIH noted its unwillingness "to influence the marketplace for the benefit of a single company, particularly when such actions may have far-reaching repercussions on many companies' and investors' future willingness to invest in federally funded medical technologies,"[9] and, with respect to drug pricing, in response to a 2004 petition, the NIH noted that "because the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be altered if prices on such products were directed in any way by NIH, the NIH agrees with the public testimony that suggested that the extraordinary remedy of march-in is not an appropriate means of controlling prices."[10]

Given the fact that: (a) march-in rights are limited to federally funded patented inventions (and it is not clear to what extent federal funds contributed to the development or remdesivir[11]), (b) the Bayh-Dole Act is not triggered by high drug prices, (c) the NIH's unwillingness to exercise its march-in rights, particularly because it does not want to disincentivize innovation and does not believe that the Bayh-Dole Act should be used to control drug prices, and (d) the patent holder/licensee has the ability to appeal the U.S. government's decision to exercise its march-in rights, and some instances march-in rights may not be exercised until all appeals or petitions are exhausted, it seems unlikely that the Bayh-Dole Act will be invoked in response to the AGs' request that the U.S. government exercise its march-in rights.

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[1] According to the Centers for Disease Control and Prevention (CDC) COVID Data Tracker, as of August 21, COVID-19 has claimed 173,490 lives. **https://www.cdc.gov/covid-data-tracker/#cases**

[2] https://www.cdc.gov/coronavirus/2019-ncov/covid-data/forecasting-us.html#anchor_1587397564229

[3] https://www.gilead.com/purpose/advancing-global-health/covid-19

[4] https://www.oag.ca.gov/system/files/attachments/press-docs/Remdesivir%20Letter%2020200804.pdf

[5] https://www.oag.ca.gov/system/files/attachments/press-docs/Remdesivir%20Letter%

2020200804.pdf

[6] 35 U.S.C. §203(a).

[7] 35 U.S.C. §203(a).

[8] 35 U.S.C. §203(b).

[9] Harold Varmus, Director, NIH, Determination in the Case of Petition of CellPro,Inc., August 1, 1997,

https://web.archive.org/web/20070102183356/http:/www.nih.gov/icd/od/foia/cellpro/pdfs/foia_cellpro39.pdf.

[10] Elias A. Zerhouni, Director, NIH, In the Case of Norvir Manufactured by Abbott Laboratories, Inc., July 29, 2004,

https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf.

[11] https://www.statnews.com/pharmalot/2020/05/08/gilead-remdesivir-covid19-coronavirus-patents/