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May 6, 2021 • Advisory • www.atllp.com

WILL A U.S.-BACKED TRIPS WAIVER FOR COVID-19 VACCINES ERODE TRADE SECRET PROTECTIONS FOR MRNA VACCINE PLATFORMS?

Following an expression of support by the Biden administration on May 5, momentum appears to be growing for a waiver of intellectual property protections for COVID-19 vaccines by the World Trade Organization (WTO). These protections, laid out in the WTO TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights), cover familiar forms of intellectual property including copyrights, trademarks and patents. But a fourth category of protections for "undisclosed information" may hold the most far-reaching implications for developers of new therapeutic platforms.

Under Article 39 of the TRIPS Agreement, undisclosed information protections extend to (a) trade secret information submitted to governments and government agencies, as well as (b) proprietary test and other data required by regulatory agencies for marketing approval of new medicines. In practice, these protections mean that chemistry, manufacturing and control (CMC) information relevant to the quality and consistency of new drugs or biologics can be evaluated by the U.S. Food and Drug Administration or the European Medicines Agency without becoming available to other drug makers, who could potentially use it to develop competing products. The risk of competition, and the sensitivity of CMC information disclosed to regulators, is heightened when that information is provided in support of first-in-class therapeutics such as the mRNA vaccines for COVID-19. The tools and processes used to manufacture the first-in-class product may be broadly relevant to other medicines developed on the same platforms. It is precisely this CMC information, however, that proponents of the TRIPS waiver seek to distribute more widely in order to catalyze production of vaccines for developing countries.

Thus, a broad waiver of protections for undisclosed information relating to COVID-19 vaccines may pose a risk to the future commercial potential of the mRNA therapeutic platforms used to develop the vaccines. That risk may be compounded by the simultaneous waiver of patent and other IP protections for these vaccines. Drug developers typically outsource the production of FDA and

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EMA approved medicines to contract development and manufacturing organizations (CDMOs). The CDMOs receive and use the same sensitive CMC information disclosed to regulators in order to produce the medicines they are hired to make, but developers are protected by the contracts they enter with their CDMOs, which (a) grant limited licenses under the developers' patent and other IP rights to allow CDMOs to manufacture the medicines, and (b) restrict the CDMOs' ability to disclose and use sensitive manufacturing information beyond what is necessary to meet their contractual obligations.

By waiving patent and other IP rights in parallel with undisclosed information protections, the WTO may empower manufacturing organizations to produce COVID-19 vaccines without the need to license any underlying patent or other IP rights from their developers. Developers of the vaccines, on the other hand, face the loss of both IP and contractual protections for their trade secret manufacturing information. If this CMC information is made available to manufacturing organizations without significant restrictions on its use, it is likely to remain accessible after the pandemic is over, giving recipients a leg up in developing mRNA vaccines for other indications that may compete with the COVID-19 vaccine developers' own products.

Article 39 of the TRIPS agreement is intended to "ensure effective protection against unfair competition" for developers of novel therapeutics. The challenge for the Biden administration is crafting a TRIPS waiver that will facilitate rapid vaccine production for the developing world while protecting vaccine developers from unfair competition once the pandemic is over.

Our Intellectual Property team is closely monitoring this news and will continue to share relevant updates. Please contact one of our attorneys for additional information.