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UPDATE ON INTELLECTUAL PROPERTY-RELATED ISSUES IN THE RESPONSE TO COVID-19

To Our Clients and Friends:

This Alert reports on recent intellectual property law developments relating to the COVID-19 pandemic. First, we describe a new pilot program of the United States Patent and Trademark Office ("USPTO"), intended to help small businesses obtain expedited review of patent applications on products and processes related to the battle against COVID-19, and the agency's new platform listing COVID-19 related patents that are available for licensing. Second, we discuss the World Health Assembly's COVID-19 resolution calling on countries to rely on patent pooling mechanisms to help develop new technologies to fight the pandemic, and the response by the United States to sections of the resolution.

(1) Two USPTO Initiatives Relating to the Fight Against COVID-19

The COVID-19 Prioritized Examination Pilot Program: On May 14, 2020, the USPTO published a notice in the Federal Register setting forth the eligibility requirements for its previously announced "COVID-19 Prioritized Examination Pilot Program." That Pilot Program seeks to expedite the examination of patent applications that cover products or processes related to the fight against COVID-19. The program, which is restricted to applicants that qualify for either "small entity" or "micro entity" status (pursuant to 37 C.F.R. §§ 1.27 and 1.29), permits such entities to request prioritized examination of patent applications without paying the fees typically associated with such a request. (Notably, the "small entity" definition includes, among other things, "[a] university or other institution of higher education located in any country" and any Section 501(c)(3) organization that is exempt from taxation under Section 501(a) of the Internal Revenue Code). While the goal of the prioritized examination under the program "is to provide a final disposition within 12 months, on average, from the date prioritized status has been granted," the USPTO has stated that it will "endeavor to reduce" that timeframe to six months, if applicants respond within 30 days to "notices and actions" from the agency, once the applicant's initial request to have its patent applications be considered for prioritized examination has been approved.[1]

The pilot program will begin accepting requests for prioritized examination on July 13, 2020, and will continue "until such time as the USPTO has accepted a total of 500 requests."[2] To be eligible for the program, qualifying patent applicants must certify that at least one of the pending claims in the patent application(s) for which they seek expedited review is a product or process "subject to an applicable FDA approval for COVID-19 use." In addition, in what appears to be an effort to help ensure that the pilot program is limited to applicants seeking patents on more recent inventions, patent applications that claim the benefit of an earlier filing date of two or more U.S. non-provisional applications (or certain international applications) are ineligible for the program.

As early commentators have noted, small businesses that qualify for the program will need to carefully weigh its potential benefits against the potential risks of seeking prioritized examination of patent applications within what could be a very short timeframe, given that the program is currently limited to 500 requests. Although the program's offer of a cheaper and faster process to apply for patents on inventions like COVID-19 vaccines may be enticing to smaller businesses—especially since patents can help attract further capital—the pressure to get one of the program's limited slots could potentially lead to the filing of premature applications that require further experimental data and research in order to meet the requirements for patentability. Small businesses will therefore need to consider whether their inventions are ripe enough to mitigate the possibility that applying for a patent too early will create an unfavorable prosecution record that could impede subsequent renewed efforts to patent those inventions.

Patents 4 Partnerships: Earlier this month, the USPTO created the "Patents 4 Partnerships" program, which is a platform that allows patent holders (and owners of published patent applications) relating to COVID-19 technologies to list such patents and applications if they are available for licensing. The public can search the platform, including by keyword, issue date, and inventor name. As described by Andrei Inacu, Undersecretary of Commerce for Intellectual Property and Director of the USPTO, Patent 4 Partnerships "is a meeting place that enables patent owners who want to license their IP rights to connect with the individuals and businesses who can turn those rights into solutions for our health and wellbeing."

Patent holders may list their patents on the platform using the Platform Submission Page. As of May 26, 2020, the platform includes over 200 patents and published patent applications.

(2) The World Health Assembly's COVID-19 Resolution Calls for Voluntary Patent Pooling

During a virtual meeting last week, the World Health Assembly ("WHA") passed a resolution pressing for intensified efforts to control the pandemic and seeking equitable distribution of the technologies and products necessary to do so.[3] The resolution calls on international organizations "to work collaboratively at all levels to develop, test, and scale-up production" of "affordable diagnostics" and "vaccines for the COVID-19 response," referencing "existing mechanisms for voluntary pooling and licensing of patents in order to facilitate . . . affordable access to them, consistent with the provisions of relevant international treaties[.]" Existing mechanisms that can facilitate voluntary pooling and licensing of patents include the work of the U.N.-backed nonprofit "The Medicines Patent Pool." As reported in a prior alert, that Patent Pool gathers COVID-19 related patent information—such as on products that are tested in clinical trials to treat the virus—and makes that information accessible in a publicly available repository of patent data. The World Health Organization reports that the WHA resolution is co-sponsored by more than 130 countries.

The Resolution cautions that the cooperative efforts it advocates must all "respect" and "be consistent with" the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement") and the Doha Declaration on the TRIPS Agreement and Public Health ("Doha Declaration").[4] *See* Resolution at ¶¶ 4, 8.2, 9.8. In a written statement, the United States Department of State "endorse[d] the call in the resolution for all Member States to provide the WHO with timely, accurate, and sufficiently-detailed public health information related to the COVID-19 pandemic," but

"disassociate[d]" itself from a number of paragraphs in the resolution, including some relating to intellectual property. For example, the United States objected to paragraphs 4, 8.2, and 9.8 of the resolution. The United States "disassociates" from those paragraphs because the language in those paragraphs referencing the TRIPS Agreement and the Doha Declaration "does not adequately capture all of the carefully negotiated, and balanced, language" in the TRIPS Agreement and Doha Declaration. Likewise, the United States objected that those paragraphs "present[] an unbalanced and incomplete picture of that language at a time where all actors need to come together to produce vaccines and other critical health products." Finally, the United States emphasized that "[i]t is critical" that the "existing mechanisms for voluntary pooling" of patents referenced in the resolution "be narrowly tailored in scope and duration to the medical needs of the current crisis[.]"

We are continuing to monitor developments that may be of interest to businesses who hold, or seek to use, intellectual property rights.

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[1] COVID–19 Prioritized Examination Pilot Program, 85 Fed. Reg. at 28933 (May 14, 2020).

[2] *Id.*

[3] The WHA, which is comprised of delegations from all WHO Member States, acts as the WHO's decision-making body, principally determining the WHO's policies, and appointing the Director-General.

[4] At the risk of oversimplification, the TRIPS Agreement, which became effective on January 1, 1995, is a multilateral agreement that principally sets forth minimum standards of protection to be provided by Member countries to various types of intellectual property. The Doha Declaration of 2001 was adopted in response to growing concerns that patent-related terms under TRIPS Agreement could restrict access to affordable medicines in developing countries. The Declaration endeavored to allay those concerns by, for example, giving each Member the right to grant compulsory licenses (i.e., without the consent of patent holders) to the use of their patented inventions.

Gibson Dunn lawyers regularly counsel clients on the issues raised by this pandemic, and we are working with many of our clients on their response to COVID-19. For additional information, please contact any member of the firm's Coronavirus (COVID-19) Response Team. Please also feel free to contact the Gibson Dunn lawyer with whom you usually work, or the authors:

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