Willkie IP COVID-19 Update: Government Activities Impacting Pricing, Supply, and Research & Development in the Pharmaceutical and Medical Supply Industries

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AUTHORS

Michael W. Johnson | Heather M. Schneider | Dan Constantinescu | Zachary S. Travis

The legislative and executive branches, including agencies such as the FDA, NIH, and HHS, have enacted a variety of measures with the goal of controlling prices, increasing supply, and facilitating research & development of pharmaceuticals and medical products in response to the COVID-19 pandemic. Proposals on one of the stimulus measures that were excluded from the version signed into law could have affected IP rights in these industries, and the invocation of the Defense Production Act might do so as well. Given the focus on IP in drug pricing discussions even before the COVID-19 pandemic, we envision more discussion of IP rights as further policies are enacted in response to the pandemic.

Efforts to Control Pricing

Pharmaceutical Pricing

The COVID-19 outbreak appears to be reigniting efforts to control costs in the U.S. prescription drug market, particularly with respect to anticipated vaccines and treatments relating to COVID-19. The Coronavirus Preparedness and Response Supplemental Appropriations Act, which was signed into law on March 6, 2020, allocated $8.3 billion in emergency funding, including $3.1 billion to develop and purchase vaccines, therapeutics, and diagnostics, among other uses. An additional $300 million was also reserved specifically for products purchased under the law, including “vaccines,

therapeutics, and diagnostics" in the event "additional funds are necessary." The law provides that products "shall be purchased in accordance with Federal Acquisition Regulation guidance on fair and reasonable pricing." The law also provides that HHS "may" take legal measures to ensure that vaccines, therapeutics, and diagnostics developed with these funds "will be affordable in the commercial market," but "shall not take actions that delay the development of such products."

Some commentators see the language that HHS "may" take measures to ensure affordability while being prohibited from actions that delay development as a win for the biopharmaceutical industry. A number of Democrat lawmakers had sent a letter to the White House urging HHS "not to provide an exclusive license to any private manufacturer for a coronavirus vaccine or treatment in any government grants, contracts, or licensing arrangements." These lawmakers urged that "[p]roviding exclusive monopoly rights could result in an expensive medicine that is inaccessible, wasting public resources and putting public health at risk in the United States and around the globe." Some commentators have argued that adopting this suggestion would have essentially codified government "march-in" rights to force licensing. Opponents have expressed concerns that limiting patent rights would have a chilling effect on both investment and collaboration, and deter companies from taking risks with drug and vaccine development. As the COVID-19 outbreak continues and drugs targeting the virus get closer to commercialization, it is possible we will see additional legislative efforts to curb drug pricing related to COVID-19 or more generally.

Tariff Relief for Medical Supplies

On March 20, 2020, the U.S. Trade Representative's (USTR) office solicited public comments on potential additional modifications to the Section 301 China tariffs "in an effort to keep current on developments in our national fight against the coronavirus pandemic." The request for comments is intended to supplement the current exclusion process through which entities can formally request the exclusion of particular products from Section 301 tariffs. In March, the USTR has granted various requests for exclusions from Section 301 tariffs on imports of medical equipment from China, in anticipation of increased demand resulting from the COVID-19 outbreak. Excluded products include face masks, hand sanitizing wipes, surgical gowns, examination gloves, and the like. Considering that tariffs remain on various other medical items, including high-tech equipment and components for systems such as ultrasound machines, patient monitors, X-ray devices, defibrillators and electrocardiograms, the administration could grant additional tariff relief in the future, in an effort to lessen the impact of the COVID-19 outbreak on the economy and healthcare system. Jeff Emerson, a USTR spokesman, stated that "the U.S. Trade Representative will continue to issue decisions on pending requests on a periodic basis."

Efforts to Increase Supply

Pharmaceutical Supply Chain

Trump administration officials reportedly are working on an Executive Order that would seek to relocate medical supply chains from overseas to the United States. White House trade advisor, Peter Navarro, stated that "[t]he essence of the order . . . is to bring all of that home so that we don't have to worry about foreign dependency." This effort reflects growing unease with United States reliance on the foreign manufacture of pharmaceutical ingredients and drug products. Bi-partisan legislation was recently introduced in the Senate that would dedicate $100 million to develop U.S. drug production in order to reduce dependence on foreign nations. And bipartisan companion bills were introduced in the House and Senate that would give the FDA authority to identify sourcing locations for medical supplies and help to more quickly bring products to market should shortages exist. Reports estimate that about 72% of manufacturers of pharmaceutical ingredients supplying the United States are overseas, including 13% in China. The COVID-19 outbreak could stimulate changes through legislation and Executive Order that would require drug supply chains to return to the United States.

Defense Production Act

On March 18, 2020, the President invoked by Executive Order the Defense Production Act to obtain "health and medical resources needed to respond to the spread of COVID-19, including personal protective equipment and ventilators." The Order also provides that "the Secretary of Health and Human Services may identify additional specific health and medical resources." The President, however, has yet to use the powers granted under the Act. Contracts performed pursuant to orders under the Defense Production Act might result in the unlicensed use of patented inventions, thus raising implications for IP holders and manufacturers alike regarding potential patent infringement liability. 28 U.S.C. § 1498, which addresses liability and remedies for patent owners when a patented invention is "used or manufactured by or for the United States," might apply to contracts performed pursuant to the Defense Production Act. Specifically, Section 1498 states that the patent owner's remedy in such circumstances "shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture." With respect to non-government entities, Section 1498 protects "the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government." Whether infringing conduct is deemed to be "for . . . and with the authorization or consent of the Government" depends on the circumstances and the specific provisions in any existing contract, and thus involved parties should review such matters carefully.

Emergency Use Authorizations

On February 4, 2020, the Secretary of HHS determined that there is a public health emergency that justifies the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19. As of March 23, 2020, the FDA has granted 13 emergency use authorization applications relating to diagnostic testing for COVID-19 to various entities, a list of which is available here. The FDA has also issued various policy guidances to help accelerate the availability of COVID-19 diagnostic testing and medical supplies. A current list of the FDA guidance documents, including the latest guidance, which issued on March 22, 2020 and relates to ventilators, is available here.

Limitations of Liability

In February, the Office of the Secretary of HHS issued a Declaration pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d) to provide liability immunity for activities related to medical countermeasures against COVID-19. The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of HHS to issue a Declaration to provide liability immunity to certain individuals and entities against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving "willful misconduct" as defined in the PREP Act. The Covered Countermeasures under this declaration are "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product." More information is available here.

Efforts to Advance Research & Development

Guidance on Clinical Trials

In March, the FDA issued guidance for industry, investigators, and Institutional Review Boards on the Conduct of Clinical Trials of Medical Products during the COVID-19 pandemic. Having recognized that clinical trial challenges may arise from quarantines, site closures, travel limitations, supply chain interruptions, or infection of site personnel or trial subjects, the FDA guidance provides "general considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice (GCP), and minimizing risks to trial integrity during the COVID-19 pandemic." The guidance is available here.

National Institutes of Health Grants

Starting in February, the NIH began issuing Notices of Special Interest (NOSI) offering urgent Competitive Revisions and Administrative Supplements to active grants to address various urgent research needs related to COVID-19. Competitive Revisions provide research sponsors with increased support in a current budget period for expansion of the project's approved scope or research protocol. Administrative Supplements provide additional funds during a current project period to provide for an increase in costs due to unforeseen circumstances. The latest NOSI was issued on March 19, 2020 by NIDA and identifies the following general area of interest "collecting and examining data on the risks and outcomes for COVID-19 infection in individuals suffering from substance use disorders." Links to the Notices of Special Interest related to COVID-19 are available here.

Willkie has multidisciplinary teams working with clients to address coronavirus-related matters, including, for example, contractual analysis, litigation, restructuring, financing, employee benefits, SEC and other corporate-related matters. Please click here to access our publications addressing issues raised by the coronavirus. For advice regarding the coronavirus, please do not hesitate to reach out to your primary Willkie contacts.

If you have any questions regarding this client alert, please contact the following attorneys or the Willkie attorney with whom you regularly work.

Michael W. Johnson
212 728 8137
mjohnson1@willkie.com

Heather M. Schneider
212 728 8685
hschneider@willkie.com

Dan Constantinescu
212 728 8549
dconstantinescu@willkie.com

Zachary S. Travis
212 728 8594
ztravis@willkie.com