Willkie IP COVID-19 Update: Government Activities Impacting Pricing, Supply, and Research and Development in the Pharmaceutical and Medical Supply Industries as of April 28, 2020

April 28, 2020

AUTHORS

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

The legislative and executive branches, including agencies such as the U.S. Food and Drug Administration, the National Institutes of Health, and the U.S. Department of Health and Human Services (FDA, NIH, and HHS, respectively), have enacted a variety of measures with the goal of controlling prices, increasing supply, and facilitating research and development of pharmaceuticals and medical products in response to the COVID-19 pandemic. This client alert has been updated to reflect the CARES Act and other new developments as of 9:00 am EST on April 28, 2020.

Efforts to Control Pricing

Pharmaceutical Pricing

The COVID-19 outbreak appears to be reigniting efforts to control costs in the U.S. prescription drug and healthcare market, particularly with respect to anticipated vaccines and treatments relating to COVID-19, as well as coverage for testing and treatment of uninsured patients or out-of-network health expenses.

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. The law provided that products purchased by the Federal Government with funds made available by this Act "shall be purchased in accordance with Federal Acquisition Regulation guidance on fair and reasonable pricing." The Families First Coronavirus Response Act was signed into law on March 18, 2020, and required private insurers to cover testing for COVID-19 without imposing cost-sharing (Section 6001).

The Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed into law on March 27, 2020, and provides $100 billion in relief funds to hospitals and other healthcare providers to support healthcare-related expenses or lost revenue attributable to COVID-19 and to ensure that uninsured Americans can get testing and treatment for COVID-19. For example, providers of COVID-19 diagnostics shall make their cash prices available on a public website, and out-of-network providers will be reimbursed based on those prices (Section 3202). Insurers are required to cover preventive services and vaccines for COVID-19 without any cost-sharing (Section 3203).

The HHS CARES page and General Distribution Portal are available at https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/index.html.

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 Trade Act 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 2020, the USTR 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. The comment period ends June 25, 2020. Comments submitted to date can be found at https://www.regulations.gov/ (enter "USTR-2020-0014" and hit Search).

Efforts to Increase Supply

Pharmaceutical Supply Chain

The COVID-19 pandemic has also highlighted the U.S. reliance on the foreign manufacture of various drug products and medical devices. Section 3101 of the CARES Act requires the Secretary of HHS to enter an agreement within 60 days with the National Academies of Science, Engineering, and Medicine to prepare a report on the security of the U.S. medical product supply chain. The report shall address and make recommendations concerning the supply of critical drugs and devices, the risks associated with reliance on such drugs and devices being sourced or manufactured outside the U.S., supply chain information gaps, and the potential economic impact of increased U.S. manufacturing.

The CARES Act also includes provisions meant to mitigate emergency drug shortages, such as prioritizing review of certain drug applications (Section 3111) and expanding the list of drugs for which manufacturers must notify the Secretary of a permanent discontinuance or an interruption of manufacture (Section 3112). The list of drugs now includes "any such drug that is critical to the public health during a public health emergency declared by the Secretary," including active pharmaceutical ingredients. The CARES Act adds a requirement for manufacturers of critical devices to report permanent discontinuances and interruptions as well, and expedites some inspections and reviews (Section 3121).

Defense Production Act

On March 18, 2020, the President invoked by Executive Order the Defense Production Act (DPA) 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."

Since then, the President has issued at least three orders under the DPA granting the Secretary authority to obtain resources from particular companies, two of which were related to ventilators on March 27, 2020 and April 2, 2020, and one of which was related to N-95 respirators on April 2, 2020. On April 3, 2020, the President also issued a Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use, which gives the Secretary authority to allocate to domestic use, as appropriate, certain "scarce or threatened materials" including: (a) N-95 Filtering Facepiece Respirators; (b) Other Filtering Facepiece Respirators (that offer protection from particulate materials at an N-95 filtration efficiency level); (c) Elastomeric, air-purifying respirators and appropriate particulate filters/cartridges; (d) PPE surgical masks; and (e) PPE gloves or surgical gloves.

From an IP perspective, contracts performed pursuant to orders under the DPA could conceivably 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 DPA. 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 under the DPA 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 April 27, 2020, the FDA has granted 48 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 was issued on April 24, 2020 and relates to digital pathology, is available here.

Limitations of Liability

In February 2020, 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." In addition, the CARES Act added respiratory protective devices to the list of Covered Countermeasures (Section 3103).

Efforts to Advance Research & Development

Guidance on Clinical Trials

In March 2020, 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 was updated on April 16, 2020 and is available here.

NIH 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. A number of NOSIs were issued on April 27, 2020, including one issued by the National Center for Advancing Translational Sciences focusing on the use of informatics solutions to diagnose COVID-19 cases and one issued by the National Heart, Lung, and Blood Institute to promote early phase clinical trials to evaluate new and existing COVID-19 interventions. Links to the NOSIs related to COVID-19 are available here and additional NIH COVID-19 information is 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, and CFTC and bank regulation. 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
hscheider@willkie.com

Dan Constantinescu
212 728 8549
dconstantinescu@willkie.com

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