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COVID-19 & International Trade – Nation-State Responses to a Global Pandemic

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The COVID-19 pandemic has already had a catastrophic impact on international markets, with far reaching impacts on international trade that will be felt for years to come. In the short term, government authorities responsible for the regulation of global trade have been hobbled by the rapidly spreading pandemic and its resulting restrictions on their ability to work. Nevertheless, several early initiatives may serve as a harbinger of things to come, as regulators around the globe act to mitigate the impact of the pandemic on global supply chains and national security. This client alert provides information on the first visible impacts on and changes to export controls, tariffs, foreign direct investment regulations, and sanctions and respective enforcement.

1. The Immediate Impact: Export Restrictions on Medicine, Medical Devices and Personal Protective Equipment

On March 26, the G-20 Leaders issued a statement promising to work together to "facilitate international trade and coordinate responses in ways that avoid unnecessary interference with international traffic and trade," although many countries around the world have already taken steps to protect their supply of medicines and personal protective equipment ("**PPE**"). In the first week of March, France, Germany, Russia and the Ukraine prohibited the export of certain PPE. By mid-March, the French and German restrictions were replaced by broader European Union regulations prohibiting the export of PPE—regardless of origin—outside of the EU for six weeks. By late March, India—a nation that is central to the global production of hydroxychloroquine (a medicine under study as a potential COVID-19 treatment)—had prohibited exports of hydroxychloroquine as well as the export of ventilators, sanitizers and surgical masks due to domestic shortages.

The COVID-19 pandemic is the first major crisis to sweep the world since the United Kingdom announced its withdrawal from the European Union on January 31, 2020. While EU law is still in application in the UK during the transition period, late last year regulators in the United Kingdom limited the export of critical drugs to prevent shortages in the event of a no-deal Brexit. The UK prohibited the parallel export—here, the practice of buying medicines already on the market in the UK in order to sell them in the European Economic Area ("**EEA**")—of certain critical medicines currently being tested for efficacy in treating COVID-19.[1] On March 20, 2020, over 80 additional medicines used to treat patients in intensive care units were banned from parallel export from the UK in order to seek to ensure uninterrupted supply to NHS hospitals treating coronavirus patients. Included in this latest list of restrictions are medicines such as insulin, paracetamol, and morphine. The full list of medicines that cannot be parallel exported from the UK can be found here. The UK has guidance in place on parallel export and hoarding of restricted medicines. Parallel export of a restricted medicine risks violation of regulation 43(2) of the Human Medicines Regulations 2012 and potential enforcement action by the **Medicines and Healthcare products Regulatory Agency** ("**MHRA**").

China—which faced an early and devastating outbreak of COVID-19 and is also the primary source of most surgical masks globally—has not prohibited the export of PPE. Instead, in mid-March China exported medical supplies to assist Italy and Thailand, and in late March

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sent the first shipment of such supplies to the United States. Beijing has also been sending teams of medical experts to hotspots around the world to help combat the disease.

The United States has not imposed any immediate restrictions on the export of PPE, medicine or medical devices used to treat COVID-19, despite its own severe shortages nationwide and reports of large quantities of PPE being purchased by foreign buyers. Indeed, the United States has long depended upon imports of such materials, and efforts to obtain emergency supplies of face masks and other PPE from manufacturers in China were hobbled by the U.S. administration's efforts to label COVID-19 as the "Chinese" or "Wuhan" virus. Moving forward, the **U.S. Department of Commerce's Bureau of Industry and Security** ("**BIS**") has the authority to use the Export Administration Regulation ("**EAR**") Short Supply Controls (15 C.F.R. Part 754) to curtail the export of items that may become scarce as the COVID-19 crisis continues. For example, certain PPE controlled under ECCN 2B352 could be subjected to short supply controls that impose more stringent licensing requirements, prohibit the use of license exceptions that would otherwise apply, or restrict the availability of export licenses. BIS even has the flexibility to apply the short supply controls to certain PPE or other items that may be designated EAR99 and therefore currently subject to the least restrictive export controls. BIS can list those EAR99 items on which it wants to impose short supply controls, along with their Harmonized System-based Schedule B commodity numbers, as BIS has done for certain crude oil and petroleum products. These controls currently only apply to a handful of items unrelated to COVID-19—petroleum products, unprocessed western red cedar, and horses exported by sea for slaughter—but BIS could expand the category of short supply items relatively quickly.

2. International Trade Regulator Responses

United States

In the United States, most federal agencies with export control or sanctions enforcement authority are continuing to operate, albeit under an expectation of delay in light of widespread teleworking arrangements in force throughout the U.S. federal government.

The **U.S. Trade Representative** ("**USTR**") plays a key role in the trade regulatory process, having already exempted Chinese PPE from duties, including tariffs recently imposed on Chinese imports under Section 301 of the Trade Act of 1974. Additionally, USTR announced on March 20, 2020 that it would open a new comment period for the public to suggest additional items that should be exempt from the Section 301 tariffs on Chinese imports due to the spread of the coronavirus. Last week a bipartisan group of senators on the Senate Finance Committee warned the Trump administration against trying to implement a new trade deal with Canada and Mexico too quickly in light of the novel coronavirus outbreak's impact on U.S. business. The senators issued a letter to U.S. Trade Representative Robert Lighthizer to back off the White House's apparent plan to bring the U.S.-Mexico-Canada Agreement into force by June 1, 2020.

BIS is also active with respect to the export controls that apply to vaccine development. BIS currently controls the export of certain pathogens, viruses, vaccines, medical products, diagnostic kits, personal protective equipment, and equipment for handling biological materials under Categories 1 and 2 of the Commerce Control List ("**CCL**"). Notably, certain viruses (including the SARS-related coronavirus associated with the 2002-2003 SARS outbreak) typically are classified as bio-agents and toxins on the CCL, imposing certain restrictions on the manner in which samples and vaccines may be exported as well as certain types of foreign direct investment. However, BIS has issued guidance clarifying that SARS-CoV-2, the virus that causes COVID-19, is not currently subject to the controls of these categories, removing a potential impediment to international collaboration on the development of a vaccine and treatments. To further facilitate the provision of important medical equipment to countries or end-users facing

shortages during the pandemic, BIS could relax the broad licensing requirements for items classified under Categories 1 and 2 or implement additional favorable licensing policies. Alternatively, BIS could impose new, more strict licensing requirements on exports of these items or impose less favorable licensing policies—helping to ensure those items remain available for domestic use.

Additionally, BIS can use the 0Y521 series Export Control Classification Numbers ("ECCNs") to quickly impose unilateral export controls on previously uncontrolled items (e.g., SARS-CoV-2) if BIS determines the item a "significant military or intelligence advantage" or determined there are "foreign policy reasons" supporting restrictions on its export. A license would be required to export items controlled under the 0Y521 series to any destination, except Canada, and exporters would be prohibited from relying on exceptions to this license requirement that might otherwise be available. Although these controls would only last one year—which may be sufficient to manage response to COVID-19—they could be moved to a more permanent ECCN before their expiration. Interestingly, this rarely used export controls tool may be top-of-mind for U.S. regulators. The Trump administration recently used the 0Y521 series to control AI-enabled geospatial imagery analysis software in response to an imminent national security concern.

The **U.S. Department of the Treasury's Office of Foreign Assets Control** ("**OFAC**"), which administers United States sanctions programs, provided new guidance clarifying the scope of general licenses (regulatory exemptions) which authorize the supply of medicine, medical devices, and other humanitarian goods to assist Iran in coping with its severe outbreak of COVID-19. OFAC also maintains relatively broad general licenses permitting the export of medicine and medical devices to other sanctioned jurisdictions, including the Crimea Region of Ukraine and Venezuela, as well as general licenses permitting nongovernmental organizations to provide medical aid to North Korea and Syria and to allow certain humanitarian aid and medical research collaborations with Cuba. These licenses and licensing policies may be relied upon to provide medicine and medical devices as the pandemic spreads. We are also aware that OFAC is currently reviewing on an expedited basis several COVID-19 related Specific License requests for shipment of goods and services that are not otherwise covered by the general exemptions. Senior OFAC leadership have indicated that the agency continues to operate at full pace. Despite broad work-at-home mandates, certain OFAC personnel responsible for enforcing sanctions must operate from secure office locations, limiting their ability to function remotely for the duration of the crisis. This may explain the agency's recent spate of designations since the coronavirus crisis began, suggesting that at least the targeting unit at the agency—charged with identifying sanctions targets and compiling dossiers to designate them—has continued its mission at a similar intensity as before the crisis hit. In fact, on March 31, against the backdrop of both recently increased sanctions and legal pressure against the Maduro regime and a likely significant expansion of COVID-19 cases in Venezuela, the Trump Administration offered the Maduro regime a significant reduction in sanctions in exchange for moving towards a transition government with the opposition.

On March 26, the **U.S. Customs and Border Protection** ("**CBP**") revoked a proposal to allow companies more time to pay import duties during the coronavirus outbreak. Less than a week after CBP told importers that it would consider delaying tariff payments on a case-by-case basis, the agency issued a new bulletin indicating that no further requests for delayed payment would be accepted. The CBP's earlier announcement regarding potential tariff payment delays drew criticism from the U.S. steel industry, which has been among the most forceful advocates for aggressive enforcement of U.S. trade laws. President Donald Trump has publicly dismissed the idea of tariff reduction as part of his coronavirus strategy, while White House trade adviser Peter Navarro has floated an executive order that will strengthen "Buy American" government procurement rules for drugs and medical devices as a means of reducing the government's reliance on imports.

Europe

In the EU, at the **EU Commission** level, offices are broadly closed and all employees in

non-critical functions have been ordered to work from home as of March 16, 2020. So far, this has not had a substantial impact on pending license applications, as EU sanctions and specifically EU (member state) export controls are administered and enforced on a member state level.

At the member state level, the impact of the virus on operations has differed from country to country as—despite alignment efforts—each member state has been impacted by COVID-19 in different ways (with the devastation in Italy and Spain at the extreme end) and states have been reacting to the pandemic on their own schedules and pursuing their own policies (ranging from severe lock-downs in some countries to more limited approaches taken by others, such as Sweden and the Netherlands). Generally, working from home is not common in many EU member states and thus a certain adjustment period, including related delays on any types of license applications, should be expected.

United Kingdom

On March 20, 2020, the **UK Joint Export Control Unit** issued a Notice regarding export license handling during the pandemic. The British government will continue to process export control licenses, but applications for strategic export licenses have been identified as business-critical operations for the Department for International Trade. The compliance/inspection program will continue, but site audits will be now conducted remotely.

3. Foreign Direct Investment Regulations: Protecting National Security in a Pandemic

Numerous countries have strengthened their foreign direct investment ("**FDI**") controls in an effort to better protect against national security risks—most recently with respect to the use and development of sensitive technologies and data. In the coming weeks and months—especially if depressed asset prices spur increased interest in cross-border transactions—we expect regulators around the globe to turn to these restrictions in an effort to protect domestic companies necessary to combat the spread of the virus. Foreign direct investment regulations—already robust in many major recipients of foreign direct investments, and nascent in many other states—may be used to fend off acquisitions from foreign firms. Critically, as much of the western world imposes strict lockdown measures, China has made moves to restart economic activity, raising concerns that distressed foreign assets could be acquired by Chinese companies without appropriate checks and balances. For example, the Australian government indicated last week that all proposed foreign investments into Australia will be reviewed as the government seeks to protect distressed Australian assets from the economic aftermath of the pandemic.

United States

The national security risks associated with the coronavirus pandemic may implicate the **U.S. Committee on Foreign Investment in the United States** ("**CFIUS**" or the "**Committee**"), an interagency group that is empowered to block or condition foreign acquisitions of U.S. companies involved in manufacturing necessary treatments or supplies. Proposed foreign acquisitions of U.S. drug manufacturers may require CFIUS review, and CFIUS review requirements may impact bankruptcy proceedings with respect to the sale of distressed U.S. assets. Furthermore, CFIUS is authorized to review national security risks associated with the foreign acquisition of U.S. companies involved in the production of high-priority goods. Depending on the extent and duration of the pandemic in the United States, CFIUS may use its authority to prevent the sale of key U.S. suppliers to foreign buyers.

The United States recently expanded the scope of transactions subject to CFIUS review, imposing mandatory filing requirements in certain narrow circumstances. As we described here, in February 2020 the Committee implemented new regulations formally expanding

its authority pursuant to the 2018 Foreign Investment Risk Review and Modernization Act ("**FIRRMA**"). Notably, the expanded CFIUS regulations impose a mandatory filing requirement for certain non-controlling investments in life sciences companies that produce, design, test, manufacture, fabricate or develop "critical technologies" used in connection with the biotechnology industry. Critical technologies include items on the CCL that are controlled agents and toxins covered by 7 CFR part 331, 9 CFR part 121, or 42 CFR part 73, including the earlier strain of SARS-CoV. As such, foreign investments in U.S. companies working with the novel coronavirus may trigger a mandatory CFIUS filing requirement if the U.S. company manufactures, tests, develops or produces other bio agents classified on the CCL. CFIUS has taken action against several life sciences and biotechnology firms in recent years, including a proposed transfer of the U.S. operations of a German pharmaceutical company as a part of the German parent company's sale to a Chinese investor in 2018. As a result of the Committee's refusal to clear the originally proposed transaction, the German parent company divested its U.S. operations to an undisclosed U.S. buyer in order to continue with the acquisition.

EU Foreign Investment Screening Process

The president of the EU Commission, Ursula von der Leyen, noted that if Europe is to be as strong after the crisis as it was before, it "must take preventive measures now … to protect [its] security and…economic sovereignty." She appealed to EU member states to "make full use of the necessary instruments."

So far only half of EU member states have comprehensive screening processes for takeovers of strategically important companies. The EU Commission has called on the remaining EU member states to establish similar regulations as permitted by the Regulation on Establishing a Framework for Screening of Foreign Direct Investments into the European Union—which we have discussed in detail here.

Below, we elaborate on recent developments in Germany, the EU's leading exporter and likely bellwether for bloc-wide developments with respect to such restrictions and controls—which we assess will likely be catalyzed by the COVID-19 crisis.

3.1. German Foreign Investment Control

Like many other companies around the world, the German-based biopharmaceutical company CureVac is currently in the process of researching and developing a vaccine against the novel coronavirus. In mid-March, it was reported that U.S. President Trump attempted to secure the exclusive rights to CureVac's work and use the possible vaccine only for the United States. The company immediately rejected allegations about offers of an acquisition or an exclusive contract with the United States. However, the fact that the company's CEO Daniel Menichella was replaced on March 11, 2020 shortly after he had met with Trump and other members of the U.S. administration's coronavirus taskforce at the White House fueled speculation that an acquisition could in fact be imminent.

This incident sparked a heated debate in Germany, leading CureVac's majority shareholder Dietmar Hopp (the co-founder of software firm SAP) to state: "Once we … succeed in developing an effective vaccine against the coronavirus, it should reach, protect and help people not only regionally but in the spirit of solidarity around the world."

Germany's Federal Secretary of Economic Affairs, Peter Altmaier, praised CureVac's decision and emphasized, "Germany is not for sale." In this context, various German politicians have referred to Germany's foreign trade law, under which the federal government can examine takeover bids from non-EU "third countries" if national or European security interests are deemed to be at stake. After company valuations in Europe's largest economy have been markedly reduced by the coronavirus pandemic, political leaders have made clear that Germany will protect domestic firms from foreign takeovers. As the state premier of Bavaria, Markus Söder, put it: "If most of Bavaria's

and Germany's economy ends up in foreign hands once this crisis is over … then it's not only a health crisis but a profound alteration of the global economic order."

Judging from the strong reactions by political leadership, COVID-19 will certainly have a profound impact on Germany's rules on foreign direct investment which the German government was already in the process of tightening.

3.1.1. Status Quo of the German Foreign Investment Control Process

Under the German rules governing the foreign investment control process[2], the German Federal Ministry for Economic Affairs and Energy ("**BMWi**" or the "**Ministry**") may, among other things, review, restrict or prohibit the acquisition of a direct or indirect interest of 25 percent or more of the voting rights of a domestic company by a foreign investor if the transaction poses a threat to the public order or security in the Federal Republic of Germany. The law expressly identifies domestic companies such as operators of critical infrastructures (including energy, IT, telecommunications, transport, health, water, food, finance and insurance sectors to the extent they are critical to the proper functioning of the community), operators of telecommunication systems and providers of surveillance technology and equipment, cloud computing services, providers of telematics services and components as well as media companies as businesses the acquisition of which may be deemed a threat to the public order or security.

The German foreign investment control process provides for even stricter rules if the domestic company develops and modifies software that is sector-specifically used for operating any of the above-mentioned critical infrastructures.[3] In those cases, the acquisition is already subject to the German foreign investment control process if the foreign investor acquires ownership of 10 percent or more of the voting rights of such German company and the transaction must be reported to the Ministry.

3.1.2. Current Proposals to Further Tighten the Rules on German Foreign Investment Control

Even before the COVID-19 crisis arose, similar to initiatives underway in the United States, Japan, UK, France and other European states, Germany had been contemplating enhanced scrutiny on foreign investors targeting domestic companies. On January 30, 2020, the BMWi published a draft bill to reform and tighten the rules governing the German foreign investment control process. This marks the third major reform of the German FDI rules in less than three years. Below are the most relevant amendments currently contemplated, and we expect that those amendments will be enacted quickly and potentially sharpened in light of COVID-19:

First, as noted above, the current test is whether the contemplated acquisition constitutes an actual threat to the public order or security of the Federal Republic of Germany. The draft bill proposes to enhance such scrutiny by lowering the requirements for the test and broadening the Ministry's scope of discretion by only asking whether the acquisition is likely to affect the public order or security of Germany.

Second, in accordance with Regulation (EU) 2019/452, which we have discussed in detail here, the draft bill also extends the scope of screening to include the public order or security of another EU Member State or of projects or programs of EU interest.

Third, so far the validity of most acquisitions subject to the current German FDI rules (except for acquisitions in the military or IT security sectors, for which stricter rules already apply) is subject only to the condition subsequent that the acquisition will not be prohibited by the Ministry. Under the newly proposed rules, any acquisition of voting rights in a domestic company that is required to be reported to the Ministry will be rendered invalid as long as it has not received written approval by the Ministry or the review deadline following

the proper reporting of the transaction has not expired. This change will have a major impact on both the certainty of deals and the timing of transactions going forward.

Fourth, the Ministry is planning to define a catalog of critical technologies, for which the reporting requirement as well as the lower 10 percent threshold will apply. Those critical technologies are reported to include artificial intelligence, robotics, semiconductors, biotechnology and quantum technology. This is part of the German government's attempt to retain Germany's technological preeminence.

4. Conclusion

Despite calls by some in the United Nations—specifically the UN High Commissioner for Human Rights, Michelle Bachelet—to re-evaluate trade restrictions in force against countries dealing with the COVID-19 pandemic, states have by and large not heeded these calls. Instead, they have responded to the crisis by not only closing their borders to visitors, but also by restricting exports of pharmaceuticals and medical equipment, and in some cases even expanding upon sanctions and other restrictions in place against states dealing with COVID-19. Further, measures have been undertaken or announced to support and protect their respective economies from damage due to COVID-19 or from foreign takeovers.

Heartening examples of German hospitals accepting COVID-19 patients from France appear to be the exceptions to what threatens to become the rule—unilateralism at all costs, every country for itself. Once the initial panic regarding the virus fades, we hope to see a return of cooperation, multilateral approaches, and solidarity to fight COVID-19 and its already devastating economic effects. For the time being, companies, specifically in the health care sector, should expect severe—and likely mounting—challenges to their international trade operations.

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[1] This restriction has been applied to chloroquine phosphate and lopinavir + ritonavir in all dosages, as well as to hydroxychloroquine in all dosages—medicines that are among the many which are currently under review as potential treatments for COVID-19. There are exceptions regarding the export of restricted medicines by UK distributors and drug companies if they were initially manufactured to be exported to non-domestic markets.

[2] For English translations of the German Foreign Trade and Payments Act and Foreign Trade and Payments Ordinance see: https://www.gesetze-im-internet.de/englisch_awg/ and http://www.gesetze-im-internet.de/englisch_awv/.

[3] For an English convenience translation of the Act on the Federal Office for Information Security defining the "critical infrastructures" see: https://www.bsi.bund.de/SharedDocs/Downloads/EN/BSI/BSI/BSI_Act_BSIG.pdf

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Gibson Dunn, its International Trade Practice Group and its dedicated COVID-19 support team, stand ready to support you in dealing with such challenges.

Authors: Ron Kirk, Judith Alison Lee, Adam M. Smith, Jose Fernandez, Stephanie Connor, Chris Timura, Samantha Sewall and R.L. Pratt (United States); Fang Xue (China); Michael Walther, Markus Nauheim, Richard Roeder (Germany); Patrick Doris and Steve Melrose (United Kingdom); and Nicolas Autet (France); with contributions from Anna Helmer, Karthik Ashwin Thiagarajan, and Prachi Jhunjhunwala (India, Russia, and the Ukraine).

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