

COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

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This regular alert covers key regulatory EU developments related to the COVID-19 situation. It does not purport to provide an exhaustive overview of developments and contains no analysis or opinion.

LATEST KEY DEVELOPMENTS

Competition & State Aid

- Executive Vice-President and Competition Commissioner Margrethe Vestager addresses competition policy's role in supporting Europe's recovery
- EU General Court annuls third COVID-19-related State aid decision for inadequate reasoning
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Parliament adopts Resolution calling for temporary waiver on COVID-19 vaccine patents
- Latest Eurostat data A rise in exports, imports, and intra-euro area trade as compared to April 2020

Medicines and Medical Devices

 European Parliament adopts Resolution calling for temporary waiver on COVID-19 vaccine patents

Cybersecurity, Privacy & Data Protection

• EU Digital COVID Certificate signed into law

COMPETITION & STATE AID

Competition

Executive Vice-President and Competition Commissioner Margrethe Vestager addresses competition policy's role in supporting Europe's recovery (see here) On 15 June 2021, Commissioner Vestager spoke at the European Competition Day conference, hosted by the Portuguese Competition Authority. She focused, in particular, on the essential role of competition policy in supporting Europe's strong recovery.

Among the Commission's recent initiatives, Commissioner Vestager noted the recent <u>review of the Horizontal Block Exemption Regulations</u> and their guidelines. Stakeholder feedback had revealed opinions that these rules should be updated in view of digitalization and sustainability goals, and this process is now underway. Commissioner Vestager also expressed her view that the pandemic demonstrated that significant benefits can arise from firms cooperating in R&D or to increase production. To encourage pro-competitive cooperation, for example, the Commission plans to issue guidance on data sharing and data pooling agreements.

Commissioner Vestager also emphasized the <u>key role of enforcement</u>, particularly in view of the COVID-19 outbreak and the importance of keeping pharmaceutical markets competitive. In 2020, the Commission issued eight decisions amounting to EUR 370 million in antitrust and cartel fines (involving the pharmaceutical and other sectors).

On <u>merger control</u>, Commission Vestager noted the continued steady pace in the number of notifications and enforcement as compared to the preceding five years. The Commission's intervention rate during the pandemic has remained nearly identical to 2019 at just above 5% and includes, e.g., eighteen Phase 1 conditional approvals, seven Phase 2 approvals, and three ongoing Phase 2 investigations.

Among the Commission's new policy projects in merger control, Commissioner Vestager also mentioned the March 2021 Guidelines on expanding referrals under Article 22 of the EU Merger Regulation in cases where the transaction does not meet national merger control thresholds (Jones Day Commentary, "European Commission Expands Antitrust Reviews to Non-Reportable Transactions," April 2021, see <u>here</u>).

new investor, the insolvency proceedings were extended in April 2020,

State Aid

EU General Court annuls third COVID-19-related	On 9 June 2021, the General Court ("GC") annulled another decision of the European Commission, following Ryanair's challenge to State aid granted to German charter airline, Condor Flugdienst GmbH ("Condor"). This is the third
State aid decision for inadequate reasoning (see	COVID-19 related State aid decision annulled by the GC (see also Jones Day COVID-19 Update No. 49 of 2 June 2021).
<u>here</u>)	In April 2020, Condor received government cash injections through German State aid measures amounting to EUR 550 million (see <u>here</u>) to address the economic losses suffered by the airline due to COVID-19 travel restrictions.
	Condor, previously owned by Thomas Cook, filed for insolvency in September 2019. Following an aborted transaction to sell the company to a

	resulting in further costs for Condor.
	In annulling the decision, the GC set out its view that the Commission had not provided inadequate reasons for approving the aid measure, and in particular, did not establish the direct causal link between (i) Condor's flight disruptions due to the COVID-19 travel restrictions and (i) the costs arising from the prolonged insolvency period, which were included in calculating Condor's damages due to the pandemic.
	Nevertheless, the GC temporarily suspended the effects of the annulment of the decision pending the adoption of a new Commission decision.
	The GC deemed that in light of the serious disturbance to the economy caused by the COVID-19 pandemic, calling into question such aid would have particularly damaging consequences for the German economy.
	Since 1 May 2020, Ryanair has brought a total of 21 appeals against Commission decisions authorizing State aid granted by Member States to the benefit of national air carriers.
	As of 19 May 2021, the GC had rejected six of those appeals. As of 4 June 2021, Ryanair had brought three appeals against the GC rulings before the European Court of Justice.
European Commission approves new and amended Member State measures to support the economy (see <u>here</u> and <u>here</u>)	Since the onset of the coronavirus outbreak, the Commission has adopted a significant number of State aid measures under Article 107(2)b, Article 107(3)b and under the Temporary Framework.
	The most recent measures adopted to support the economy and companies affected by coronavirus outbreak include:
	• €1.5 million Slovenian scheme to support potato farmers affected by the coronavirus outbreak.
	 €800 million Italian scheme to support companies affected by the coronavirus outbreak, as well as development and production of coronavirus-relevant products.
	• €170 million Finnish scheme to support uncovered fixed costs of companies affected by the coronavirus outbreak.
	 €25 million Italian scheme to support audio-visual production companies affected by the coronavirus outbreak.
	• €200 million extension of Spanish scheme to support access to high- speed broadband services in underserved areas with funds from the Recovery and Resilience Fund (RRF).
	• €385 million Dutch scheme to support organizers of events affected by the coronavirus outbreak.
	• €30 million Greek guarantee scheme to support SMEs active in the construction sector affected by the coronavirus outbreak.
	• €10.6 million Estonian scheme to support companies active in cultural and sport sectors in context of the coronavirus outbreak.
	• €1.5 million Estonian scheme to support operators of experience centres and operators of buildings used for events affected by the coronavirus outbreak.

TRADE / EXPORT CONTROLS		
European Parliament adopts Resolution calling for temporary waiver on COVID- 19 vaccine patents (see <u>here</u>)	On 10 June 2021, the European Parliament adopted a Resolution, with 355 votes in favor, 263 against and 71 abstentions, calling for negotiations on a temporary waiver of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") in relation to patents on products aimed at combating and preventing COVID-19. The temporary waiver is aimed at boosting production and ensuring global access to affordable COVID-19 vaccines.	
	The vote followed a Parliamentary debate in late May on the waiver that was proposed initially by South Africa and India to the WTO in October 2020 (<i>see also Jones Day COVID-19 Update No. 48 of 26 May 2021</i>).	
	Notably, the Resolution's export-related aspects also address the following:	
	 urges the Commission, with regard to export restrictions, to engage with vaccine-producing countries towards eliminating trade barriers and to replace the EU's own export authorization mechanism for COVID-19 vaccines and raw materials (introduced for the first time by Regulation (EU) 2021/111, as subsequently extended) with export transparency requirements; and 	
	 calls on the US and the UK to abolish their export ban on vaccines and raw materials necessary to produce vaccines. 	
	For further details on the Resolution, please see below Section on Medicines.	
Latest Eurostat data – A rise in exports, imports, and intra-euro area trade as compared to April 2020 (see <u>here</u>)	On 15 June 2021, the Commission published the latest Eurostat data on international trade.	
	The first estimate for <u>euro area* exports</u> of goods to the rest of the world in April 2021 was \in 193.8 billion, an increase of 43.2% compared with April 2020 (\in 135.3 billion). These statistics of last April were significantly impacted by Member State COVID-19 containment measures. <u>Imports</u> from the rest of the world stood at \in 182.8 billion, a rise of 37.4% compared with April 2020 (\in 133.0 billion).	
	As a result, the euro area recorded a \in 10.9 billion surplus in trade in goods with the rest of the world in April 2021, compared with + \in 2.3 billion in April 2020.	
	<u>Intra-euro area trade</u> rose to €178.9 billion in April 2021, an increase of 61.9% compared with April 2020.	
	For <u>extra-EU** exports</u> , in the period between January and April 2021, these rose to €688.1 billion (an increase of 7.8% compared with January-April 2020), and imports rose to €626.6 billion (an increase of 6.3% compared with January-April 2020). Furthermore, all Member States saw large increases in extra-EU exports except Cyprus (-17.7%) and Ireland (-0.3%). The highest increases were recorded in Slovakia (+120.6%) and Italy (+104.6%).	
	<u>Extra-EU imports</u> reflect a similar trend. In April 2021 compared to April 2020, all Member States increased their extra-EU imports, except Luxembourg (-5.3%). The highest increases were recorded in Malta (+160.4%), Estonia (+77.8%) and Slovenia (+71.2%).	

* The <u>euro area</u> (EA19) includes Belgium, Germany, Estonia, Ireland, Greece, Spain, France, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Austria, Portugal, Slovenia, Slovakia and Finland.

** The <u>EU</u> (European Union) includes Belgium, Bulgaria, Czechia, Denmark, Germany, Estonia, Ireland, Greece, Spain, France, Croatia, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, the Netherlands, Austria, Poland, Portugal, Romania, Slovenia, Slovakia, Finland and Sweden.

MEDICINES AND MEDICAL DEVICES

European Parliament adopts Resolution calling for temporary waiver on COVID-19 vaccine patents (see <u>here</u>) On 10 June 2021, the European Parliament adopted a Resolution, with 355 votes in favor, 263 against and 71 abstentions, calling for negotiations on a temporary waiver of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") in relation to patents on products aimed at combating and preventing COVID-19. The temporary waiver is aimed at boosting production and ensuring global access to affordable COVID-19 vaccines.

Notably, towards accelerating vaccine production and promoting greater transparency, the Resolution also calls for the following:

- an urgent increase of international investment and coordination for the scaling up of production of critical vaccine inputs;
- increased transparency and the disclosure of future Advance Purchase Agreements ("APAs") to be signed by the European Commission and pharmaceutical companies for the purchase of COVID-19 vaccines and particularly with regard to next generation vaccines;
- the Commission's engagement with the private sector and incentivizing pharmaceutical companies to voluntarily share their technologies and know-how (at low cost to low- and middle-income countries); and
- the active mapping of companies, including sub-contractors, with the necessary know-how to transfer technology and pairing them with companies with idle production facilities.

For further details on the Resolution, please see above Section on Trade/Export Controls.

CYBERSECURITY, PRIVACY & DATA PROTECTION

EU Digital COVID
Certificate signed
into law (here)On 14 June 2021, the Regulation on the EU Digital COVID Certificate was
officially signed into law by the Presidents of the European Parliament, the
Council, and the Commission.This follows the Parliament's approval, in plenary session, of the Regulation
on 9 June 2021 (see here), followed by the Council's official adoption on 11
June 2021.A statement by the Commission highlights the objectives of the EU Digital
COVID Certificate, including the right to free movement. The Certificate will
be available in either digital or paper format, containing a QR code, and will
be issued by national authorities free of charge.

The Certificate will certify whether a person has been vaccinated against COVID-19, has a recent negative test result, or has recovered from the infection. In practice, these will be three distinct certificates (i.e., proof of vaccination, testing, or recovery).

In addition, any processing of personal data will have to comply with the General Data Protection Regulation. Certificates will be verified offline and personal data will not be retained.

The Commission also recalled that the technical backbone of the system, the "EU Gateway", was already implemented on 1 June 2021.

The EU Gateway enables verification of the digital signatures contained in the QR codes of all COVID certificates, without the processing of personal data (see also Jones Day COVID-19 Update No. 49 of 2 June 2021).

The Regulation will apply for 12 months as of 1 July 2021. 13 Member States are already issuing EU Digital COVID Certificates.

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