

BRUSSELS REGULATORY BRIEF: MARCH 2021

Date: 30 March 2021

European Regulatory / UK Regulatory Newsletter

By: Mélanie Bruneau, Giovanni Campi, Francesco Carloni, Antoine de Rohan Chabot, Nicolas Hipp, Alessandro Di Mario, Miguel A. Caramello Alvarez, Philip Torbøl

ANTITRUST AND COMPETITION

The European Commission Opens a New Investigation in the Pharma Sector

On 4 March 2021, the European Commission (Commission) has opened a formal investigation into alleged misuses of patent procedures and exclusionary disparagement of competing products by a pharma company for its blockbuster drug. The Commission will now assess whether this conduct constitutes an abuse of the company's dominant position in breach of Article 102 of the Treaty on the Functioning of the European Union.

In particular, following patent expiry in 2015, the pharma company may have artificially extended the market exclusivity of its blockbuster drug by strategically filing and withdrawing divisional patents, repeatedly delaying entry of its generic competitor.

The pharmaceutical company also may have pursued a campaign disparaging competing products to unduly hinder their use, primarily directed at healthcare institutions and professionals.

The initiation of a formal proceeding is a step in the Commission's investigation that could lead to the adoption of an infringement decision. In general, the duration of a formal investigation procedure will depend on the extent to which the companies concerned cooperate with the Commission and the exercise of their rights of defense.

It is worth noting that this is the first investigation at the EU level that concerns the misuse of patent procedures and exclusionary disparagement of competing products in the pharma sector. In 2012, the Italian Competition Authority fined a pharma company more than EUR 10 million for patent abuse. In 2017, the French Competition Authority fined another pharma company EUR 25 million for exclusionary disparagement.

This investigation confirms the Commission's intense scrutiny on the pharma sector. While the Commission acknowledges that it is legitimate for pharma companies to protect their intellectual property rights, certain patent-related practices aimed at delaying or blocking generics market entry will attract scrutiny. This is also the case of so-called pay-for-delay agreements, which have been in the spotlight of the Commission since 2008, when it launched its sector inquiry into the pharmaceutical industry. These agreements result in a restriction on the ability to market and a reverse payment from the originator company to the generic company (e.g., direct transfer of money, distribution agreements, side deals or a license). A number of pharma companies have been heavily fined by the Commission and national competition authorities for having adopted pay-for-delay agreements.

DIGITAL ECONOMY

European Commission Executive Vice-President Vestager Further Clarifies Relationship Between Digital Markets Act and National Rules

The question of the relationship between the Digital Markets Act (“DMA”) and competition rules at the EU and national levels has been one of the key aspects of the European Commission's DMA proposal.

Recital (9) of the DMA in this respect states that since the DMA aims at complementing the enforcement of competition law, it should be without prejudice to Articles 101 and 102 TFEU, to the corresponding national competition rules and to other national competition rules regarding unilateral behaviour. However, the application of the latter rules should not affect the obligations imposed on gatekeepers under the DMA and their uniform and effective application in the internal market.

In its [Q&A accompanying the DMA](#), the Commission further explained that the DMA complements the enforcement of competition law at the EU and national levels, and such relationships between regulation and competition enforcement already coexist in other sectors, such as energy, telecoms and financial services. The DMA addresses unfair practices by gatekeepers that either fall outside the existing EU competition control rules, or cannot always be effectively tackled by these rules because of the systemic nature of some behaviours, as well as the ex-post and case-by-case nature of competition law.

In a recent [speech](#), Executive Vice-President Vestager noted that there will be room for coexistence of the DMA alongside case-by-case competition law investigations. She mentioned that while such interventions should not be used for the same gatekeepers or services covered by the DMA, they could impose additional obligations on gatekeepers, where this is warranted.

On this note, Vestager concluded that a proper consultation and coordination mechanism should be set-up with national competition authorities in the framework of the DMA, to make the most of this complementarity with competition law enforcement.

EDPB and EDPS Adopted a Joint Opinion on the Data Governance Act

The European Data Protection Board (EDPB) and European Data Protection Supervisor (EDPS) adopted a [joint opinion on the proposal for a Data Governance Act](#) (DGA). The DGA aims to promote the availability of public sector data for reuse and sharing of data among businesses. The DGA also seeks to enable the use of data for altruistic purposes.

EDPB and EDPS noted the need to ensure that the wording of the DGA clearly states that this act will not affect the level of protection of individuals' personal data. With respect to the reuse of personal data held by public sector bodies, the EDPB and EDPS recommend aligning the DGA with existing rules on the protection of personal data laid down in the GDPR and with the Open Data Directive. As for data altruism, it should be organised in such a way that it allows individuals to easily give, but also withdraw, their consent.

Finally, with respect to supervision, EDPB and EDPS consider that data protection authorities should be designated as the main competent authorities to monitor and supervise compliance with the DGA.

European Commission Adopts Data Collection Rules for Vehicles' CO2 Emissions and Fuel Consumption

On 4 March 2021, the Commission adopted a new [Implementing Regulation](#) requiring all new vehicles in the EU to be equipped with a device that records fuel consumption.

The data will be harvested by manufacturers when vehicles are brought in for repairs and by authorities, when vehicles go through occasional specialized assessments. This information will be gathered from new vehicles sold as of March 2021 and be reported to the European Environment Agency (EEA) as of April 2022.

According to the text of the Regulation, *“the monitoring and reporting of data on passenger cars and light commercial vehicles registered in the Union are essential for the functioning of the CO2 emission performance standards set out in [Regulation \(EU\) 2019/631](#) [on setting CO2 emission performance standards for new passenger cars and for new light commercial vehicles]”*. This data allows for the monitoring of the gap between the approval through a certificate of conformity, by the relevant national authority and actual CO2 emissions. The data will also provide for a better appreciation of how vehicles perform under real-world driving conditions, which will therefore help ensure that CO2 emission reduction targets remain achievable.

The European Community Whole Vehicle Type Approval (ECWVTA), or certificate of conformity, is the process used to ensure that motor vehicles on the market meet environmental, safety and security standards. In 2017, the Commission replaced the certificate of conformity assessment with the Worldwide Harmonised Light Vehicle Test Procedure (WLTP), which has now been replaced by the on-board fuel consumption measurement devices. The collection of live data is the first implementing measure adopted under the [CO2 emissions standards](#) that entered into force on 1 January 2020.

The obligation to equip vehicles with on-board devices does not apply to certain small volume manufacturers, but it does not prevent these manufacturers from delivering data if they wish to do so.

Car manufacturers, EU Member States and the Commission must guarantee that the gathering and recording of the information is done in accordance with the standards of the general data protection Regulation (GDPR). As such, vehicles' owners have the option to oppose the collection of the data.

Starting in December 2022, the Commission will publish the aggregated data every year in order to exemplify the difference between the former WLTP process and real-world CO2 emissions for each manufacturer's fleet of new vehicles.

The European Commission Publishes its Communication 2030 Digital Compass: The European Way for the Digital Decade

On 9 March 2021, the Commission published its [Communication '2030 Digital Compass: the European way for the Digital Decade'](#), which sets out the Commission's vision and targets for a digital transformation of Europe by 2030.

This Communication builds on the 2020 Strategy on Shaping Europe's Digital Future that remains the underlying framework, but it also takes into account the radical changes brought by the COVID-19 pandemic, which has massively accelerated the use of digital tools, demonstrating their benefits while exposing the vulnerability of the digital space.

The Commission outlines a Digital Compass to translate the EU's digital ambition into targets to be achieved by 2030. The Digital Compass will be proposed in the form of a policy programme to be adopted by co-decision of European Parliament and Council. This Digital Compass will include:

- Concrete targets to reach the Commission's vision along four “cardinal points” measured at EU and national level;
- A governance structure, including annual reporting by the Commission to the European Parliament and Council on the progress towards the Digital Decade;
- Monitoring of digital principles; and
- A mechanism to organise Multi-Country Projects for building Europe's digital transition in critical areas.

Key elements of the Digital Compass include:

- A digitally skilled population and highly skilled digital professionals, which foresees that at least 80% of all adults should have basic digital skills, and that 20 million Information Communications Technology specialists should be employed in the EU;
- Secure, performant and sustainable digital infrastructures: all European households should be covered by a Gigabit network, all populated areas should be covered by 5G, 10,000 climate neutral highly secure edge nodes should be deployed in the EU, and Europe should have its first quantum computer;
- Digital transformation of businesses: at least three out of four companies should use cloud computing services, big data and Artificial Intelligence, and more than 90% SMEs should reach at least basic level of digital intensity; and
- Digitalisation of public services, including that all key public services should be available online, all citizens will have access to their e-medical records, and 80% of all citizens should use an eID solution.

The Commission also proposes to develop a framework of digital principles such as access to high quality connectivity, to sufficient digital skills, to public services, to fair and non-discriminatory online services, and in general to ensure that the same rights that apply offline can be fully exercised online. The Commission proposes to monitor whether Europeans feel that their digital rights are respected.

The EU will also work to promote its digital agenda within international organisations and through strong international digital partnerships. Combining EU internal investments with the significant funding available under the new external cooperation instruments will allow the EU to work with partners around the world in achieving common global objectives.

In the coming months the Commission will start a consultation process on the digital principles and will engage on specific elements of the Communication during 2021, including the compass framework with specific targets and governance, with the Member States, the European Parliament, regional, economic and social partners, businesses and citizens. Building on this consultation, the Commission aims to achieve decisive progress with the other institutions on a Declaration of Digital Principles by the end of 2021 and propose a Digital Policy Programme in the third quarter of 2021.

ECONOMIC AND FINANCIAL AFFAIRS

IOSCO Calls for Globally Consistent, Comparable, and Reliable Sustainability Disclosure Standards

On 24 February 2021, the International Organization of Securities Commissions (IOSCO) published a [press release](#) following a Board meeting in which it discussed the progress made over the past year by its Sustainable Finance Task Force.

In this context, IOSCO identified three priority areas for improvement in sustainability-related disclosures by companies and asset managers, namely: (i) to encourage progress towards globally consistent application of a common set of international standards for sustainability-related disclosures across jurisdictions; (ii) to promote comparable metrics in companies' sustainability-related disclosures and standardization of narrative information; and (iii) to drive international consistency of sustainability-related disclosures.

Against this backdrop, IOSCO pledged to work with the International Financial Reporting Standards (IFRS) Foundation Trustees and other stakeholders to advance these priorities. In more detail, IOSCO's engagement with the IFRS will focus on: (i) establishing a Sustainability Standards Board (SSB); (ii) encouraging the SSB to leverage the content of existing sustainability-related reporting frameworks; and (iii) encouraging a "building blocks" approach for the establishment of a global sustainability reporting system.

Overall, the press release reiterates IOSCO's commitment to facilitate comparable high-quality international standards that provide the content that capital markets need, within a transparent standard-setting architecture with a robust and inclusive governance structure.

European Supervisory Authorities Deliver Advice to the European Commission on Disclosures From Financial and Non-Financial Undertakings Under Article 8 of Taxonomy Regulation

On 1 March 2021, the European Supervisory Authorities (ESAs) – i.e., the European Banking Authority (EBA), the European Securities and Markets Authority (ESMA) and the European Insurance and Occupational Pensions Authority (EIOPA) – issued their advice to the European Commission on the content, methodology and presentation of the key performance indicators (KPIs) that non-financial and financial undertakings are required to disclose under Article 8 of the Taxonomy Regulation. Even though the three supervisory authorities provided separate advice, their respective responses have been coordinated in order to ensure consistent proposals.

In more detail:

- The ESMA [recommendations](#) define the KPIs disclosing how, and to what extent, the activities of businesses that fall within the scope of the Non-Financial Reporting Directive (NFRD) qualify as environmentally sustainable under the Taxonomy Regulation.
- The EBA [advice](#) concerns: (i) what information banks and investment firms subject to the NFRD should disclose on how their financial or broader commercial activities align with economic activities identified as environmentally sustainable in the Taxonomy Regulation; (ii) which financial or commercial activities should be included/excluded; (iii) what alternative indicators would achieve the same purpose if turnover, OpEx and CapEx are not considered appropriate; (iii) what KPIs are best suited to disclose the necessary information for banks and investment firms; and (iv) whether the green asset ratio (a key performance indicator to show if a company is transitioning from financing fossil fuels to renewable energy) should be adapted to include taxonomy-related disclosures.

- The EIOPA [proposals](#) consider whether the mandatory ratios of non-financial undertakings, as set out in the Taxonomy Regulation, are relevant and appropriate to depict insurance and reinsurance activities or whether they need to be translated to the most appropriate and comparable KPIs for insurers and reinsurers.

As for next steps, the European Commission will now consider the advice received from the ESAs and is expected to adopt by 1 June 2021 the delegated act specifying the content, presentation and methodology of the information to be disclosed by financial and non-financial undertakings subject to the NFRD. Once the European Commission has adopted the delegated act, the European Parliament and the Council of the EU will then have four months to object, which can be extended by another two months.

KEY CONTACTS



MÉLANIE BRUNEAU
PARTNER

BRUSSELS
+32.2.336.1940
MELANIE.BRUNEAU@KLGATES.COM



GIOVANNI CAMPI
GOVERNMENT AFFAIRS ADVISOR

BRUSSELS
+32.2.336.1910
GIOVANNI.CAMPI@KLGATES.COM



FRANCESCO CARLONI
PARTNER

BRUSSELS, MILAN
+32.2.336.1908
FRANCESCO.CARLONI@KLGATES.COM



ANTOINE DE ROHAN CHABOT
COUNSEL

BRUSSELS
+32.2.336.1941
ANTOINE.DEROHANCHABOT@KLGATES.COM

This publication/newsletter is for informational purposes and does not contain or convey legal advice. The information herein should not be used or relied upon in regard to any particular facts or circumstances without first consulting a lawyer. Any views expressed herein are those of the author(s) and not necessarily those of the law firm's clients.