



Newsletter

Week XI - XII: 11th – 22nd March 2024

Contact us

@ENDesk

Jacques René
Zammit
Press Officer
+352 4303 3355

Monica Pizzo
Assistant
+352 4303 3366

Desk Email
Press.ENdesk@curia.europa.eu

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All times are 9:30
unless otherwise
stated.

Week XI – 11th to 15st March

Thursday 14th March

[Judgment in Case C-291/22 P D & A Pharma v Commission and EMA](#)

(Public health)

By its appeal, Debréguas et associés Pharma SAS (D & A Pharma) seeks the annulment of the judgment of the General Court of March 2, 2022, in Case T-556/20 D & A Pharma v Commission and EMA.

The contested judgment had dismissed their action seeking, *inter alia*, to annul Commission's implementing decision of July 6, 2020, refusing the application for marketing authorisation for the medicinal product for human use Hopveus - sodium oxybate under [Regulation \(EC\) No 726/2004](#).

The regulation seeks to guarantee high standards of quality and safety of medicines in the EU. It sets out procedures for authorising and supervising medicinal products for human and veterinary use and sets up the European Medicines Agency (EMA), responsible for providing scientific advice to the EU institutions and to the Member States in the field of medicinal products, concerning the authorisation and supervision of medicinal products.

EMA's Committee for Medicinal Products for Human Use (CHMP) is in charge of preparing opinions on the granting, variation, suspension or withdrawal of a marketing authorisation for a medicinal product for human use, in accordance with the regulation and pharmacovigilance.

On June 26, 2018, D & A Pharma submitted a conditional marketing authorisation application to the EMA for Hopveus under Commission Regulation (EC) No 507/2006, falling within the scope of Regulation No 726/2004. Hopveus, containing sodium oxybate as an active substance, is intended to combat alcohol dependence.

On October 17, 2019, the CHMP issued an unfavourable opinion on this application.

On October 29, 2019, D & A Pharma lodged a request for reconsideration of the CHMP's opinion.

Don't forget to check the diary on our website for details of other cases.

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For the purposes of that review, the CHMP convened an ad hoc group of experts. Following a further unfavourable opinion of the CHMP dated April 30, 2020, the European Commission, by the contested decision, again refused the application for conditional marketing authorisation, on the ground, *inter alia*, of the lack of demonstration of the efficacy of the Hopveus medicinal product.

[Background Documents C-291/22](#)

There will be a press release for this case.

Thursday 14th March

[Judgment in Case C-516/22 Commission v United Kingdom \(Supreme Court judgment\)](#)

(Arbitration Clauses - Member State Obligations - Brexit)

On 19 February 2020, before the end of the transitional period, the UK Supreme Court handed down the Micula v Romania judgment authorising the enforcement of an arbitral award made in the [ICSID](#) case of Ioan Micula, Viorel Micula and others v. Romania. In that award, Romania was ordered to pay compensation of approximately €178 million to Swedish investors for the premature termination of a regional investment aid scheme.

The UK Supreme Court's ruling came despite the fact that the Commission, which considered the compensation to be state aid incompatible with EU law, had prohibited Romania from paying it. Furthermore, a dispute concerning this Commission decision was pending before the Court of Justice.

In light of this judgment, in July 2022 the Commission brought an action against the United Kingdom before the Court of Justice for failure to fulfil obligations.

[Background Documents C-516/22](#)

There will be a press release for this case.

Thursday 14th March

[Judgment in Case C-46/23 Újpesti Polgármesteri Hivatal](#)

(Principles, objectives and tasks of the Treaties – Data protection)

In 2020, the municipal administration of Újpest (Hungary) decided to provide financial assistance to people made vulnerable by the COVID-19 pandemic. To this end, it has

asked the Hungarian Treasury and the Government Office of the Fourth District of Budapest-Capital to provide it with the personal data needed to verify the eligibility conditions for receiving the aid.

Subsequently, the Hungarian Data Protection Authority ("the supervisory authority") found that both the Újpest administration and the Hungarian State Treasury and Government Office had violated rules of the [General Data Protection Regulation \(GDPR\)](#) and subsequently imposed a fine on them.

The supervisory authority noted that the Újpest administration had not informed the data subjects of the use of their data nor of its purpose, or of their data protection rights within the one-month time limit set by the Regulation. It also ordered Újpest's administration to delete the data of eligible individuals who had not applied for assistance.

The Újpest administration contested this decision, arguing that the supervisory authority does not have the power to order the deletion of personal data in the absence of a prior request to that effect from the data subjects.

[Background Documents C-46/23](#)

There will be a press release for this case.

Thursday 14th March

[Judgment in Case Case C-439/22 Commission v Ireland \(European Electronic Communications Code\)](#)

(Approximation of laws)

[Directive \(EU\) 2018/1972](#) establishing the European Electronic Communications Code ('the Directive') establishes a set of updated rules to regulate the internal market for very high capacity electronic communications (telecoms) networks, telecoms services, and associated facilities and services at EU level, including an efficient and effective management of the radio spectrum, spectrum authorizations and market access rules.

The directive had to be transposed and incorporated into the Member States' national law by December 21, 2020: all internal laws, regulations and administrative rules necessary to comply with the directive should be adopted and communicated to the Commission by that date (Article 124 of the Directive).

Having received no communication from Ireland, the Commission sent a letter of formal notice on February 3, 2021 and a reasoned opinion on September 23, 2021, requesting Ireland to comply with it by November 23, 2021. A new deadline, following Ireland's request for extension, was set for February 23, 2022.

On July 5, 2022, the Commission lodged the present action for failure.

[Background Documents C-439/22](#)

There will be an Info Rapide for the case (available on request).

Week XII – 18th to 22nd March

Wednesday 20th March

[Judgment in Case T-743/22 Mazepin v Council](#)

(Restrictive measures – Ukraine)

In March 2022, Nikita Dmitrievich Mazepin was included on the list of persons targeted by the restrictive measures adopted by the European Union following the Russian aggression against Ukraine.

In particular, his funds have been frozen and he has been banned from entering Member States. His inclusion on this list is based on his association with his father - Mr Dmitry Arkadievich Mazepin - an influential businessman who provides a substantial source of income to the Russian government. According to the Council, Dmitry Mazepin was the main sponsor of his son's activities as a racing driver with the Haas Formula 1 team.

In three consecutive series of decisions in September 2022, March 2023 and September 2023, the Council extended the restrictive measures against Nikita Mazepin until 15 March 2024.

Taking the view that these decisions were vitiated by an error of assessment by the Council, Mr Nikita Mazepin asked the General Court of the European Union to annul them.

[Background Documents T-743/22](#)

There will be a press release for this case.

Thursday 21st March

[Judgment in Case C-61/22 Landeshauptstadt Wiesbaden](#)

(Charter of Fundamental Rights – Data protection)

A German citizen challenges before a German court the refusal of the town of

Wiesbaden to issue him with a new identity card without the insertion of his fingerprints.

The German court asks the Court of Justice to verify the validity of the [Regulation \(EU\) 2019/1157](#) on strengthening the security of identity cards of Union citizens and of residence documents issued to Union citizens and their family members exercising their right of free movement. The EU regulation requires two fingerprints to be inserted in the storage medium of identity cards.

[Background Documents C-61/22](#)

There will be a press release for this case.

Thursday 21st March

[Judgment in Case C-10/22 LEA](#)

(Culture)

LEA is a collective management organisation governed by Italian law and authorised to mediate copyright in Italy. Jamendo, a company incorporated under Luxembourg law, is an independent copyright management entity which has been operating in Italy since 2004.

LEA has asked the Court of Rome to order Jamendo to cease its copyright intermediation activities in Italy. Under Italian law, this activity is reserved exclusively for the Italian Society of Authors and Publishers and the other collective management bodies referred to therein, such as LEA, while independent management entities are excluded from this field.

The Court of Rome asks the Court of Justice whether the [Directive 2014/26/EU](#) on collective management of copyright can be compatible with the legislation of a Member State excluding in a general and absolute manner the possibility for independent management bodies established in another Member State to provide their services in the first Member State.

[Background Documents C-10/22](#)

There will be a press release for this case.

Thursday 21st March

[Judgment in Case C-76/23 Cobult](#)

(Transport)

An air passenger booked a flight from Fortaleza (Brazil) to Frankfurt am Main with a scheduled connection in Lisbon operated by TAP Air Portugal (TAP). This connecting flight was cancelled.

To obtain reimbursement for the cancelled flights, TAP offers its passengers two alternatives: a) either immediate reimbursement in the form of travel vouchers by completing an online form, or b) reimbursement in another form, such as a sum of money, provided that the passenger first contacts its customer service department, which will examine the facts.

The conditions of acceptance specify that if the passenger chooses a refund in the form of a travel voucher, a cash refund of the ticket is excluded. The passenger requested a refund in the form of a travel voucher, which he immediately received by email.

Two months later, he transferred his rights to the consumer association Cobult, which asked TAP to refund the price of the cancelled flight in cash within 14 days. When TAP refused to make the refund, Cobult took the case to the German courts.

The Frankfurt am Main Regional Court is questioning the interpretation of the relevant regulation, that is to say [Regulation \(EC\) No 261/2004](#) establishing common rules on compensation and assistance to passengers in the event of denied boarding and of cancellation or long delay of flights. More specifically the notion of "signed agreement of the passenger", which is necessary to be able to resort to reimbursement by travel vouchers.

[Background Documents C-76/23](#)

There will be a press release for this case.

Thursday 21st March

[Opinion Joined cases C-778/21 P Commission v Front Polisario and C-798/21 P Council v Front Polisario, Joined cases C-779/21 P Commission v Front Polisario and C-799/21 P Council v Front Polisario and Opinion C-399/22 Confédération paysanne \(Melons and tomatoes from Western Sahara\)](#)

(External relations – International agreements – Agriculture and Fisheries)

In 2021, the European Commission and the Council appealed against judgments of the General Court (Case [T-279/19](#) and Joined Cases [T-344/19](#) and [T-356/19](#)). In 2019, the Polisario Front asked the Court of First Instance to annul the Council decisions approving the conclusion of agreements between the European Union and Morocco. The agreements in question were a partnership agreement on sustainable fisheries

between the EU and Morocco and an amendment to the Euro-Mediterranean Association Agreement on the arrangements applicable to imports into the EU of agricultural products originating in Morocco.

The Polisario Front had requested the annulment of these decisions on the grounds that, by approving the disputed agreements without the consent of the people of Western Sahara, the Council had violated its obligations under EU and international law. According to this move, the territory of Western Sahara does not belong exclusively to Morocco: any international agreement applicable to the territory of Western Sahara and adjacent waters should be made with the consent of the people of Western Sahara as they are directly and individually concerned.

The Court upheld the claims of the Polisario Front and annulled the decisions relating to the disputed agreements. Following this annulment, the Commission and the Council, for their part, asked the Court to set aside the judgments of the Court of First Instance, which had allegedly committed several errors of law, as regards both the admissibility of the action and its merits.

On the one hand, the Commission and the Council maintain that the Court of First Instance disregarded the provisions of the Treaty by recognising that the Polisario Front not only has the capacity to bring an action before the courts of the European Union, but also that it is directly and individually concerned by the disputed agreements. On the other hand, they claim that the Court of First Instance erred in law in holding that the Polisario Front can invoke the principle of self-determination and the principle of the relative effect of treaties, in particular as regards the concept of 'consent' of the people of Western Sahara.

[Background Documents C-778/21 P and C-798/21 P](#)

[Background Documents C-779/21 P and C-799/21 P](#)

[Background Documents C-399/22](#)

There will be one press release for these cases.

Thursday 21st March

[Opinion Joined cases C-611/22 P Illumina v Commission and C-625/22 P Grail v Commission and Illumina](#)

(Competition – Concentrations between undertakings – Referral request)

The EU system of merger control – governed by the [Merger Regulation](#) – is primarily based on the turnover of the merging companies. Some provisions in that regulation, by way of exception, empower the Commission to review mergers not meeting the turnover thresholds in question, when cases are referred to it by the Member States' authorities and, as the case may be, after being invited to do so by the Commission.

In the present case the Court is being essentially asked whether Article 22 of the Merger Regulation enables the Commission to review a merger referred to it by some Member State's authorities, where the latter lack any competence to review it, since the merger in question falls below the thresholds set out in their national legislation on merger control.

The merger involves the acquisition of sole control of Grail LLC, a company that develops blood tests for the early detection of cancer, by Illumina Inc. – a US-based company marketing sequencing- and array-based solutions for genetic and genomic analysis. Since the merger did not have a European dimension, due to the low turnover of the parties as defined by the Merger Regulation, it was not notified to the Commission. Additionally, since it did not fall within the scope of national merger control rules it was not notified to EU and EEA member states.

Following a complaint relating to the concentration and following exchanges with Member State Competition Authorities, the Commission received a referral request from the French Competition Authority asking it to examine the concentration at issue. Through an information letter, the Commission had informed Illumina and Grail of the referral request, stating that the concentration at issue could not be implemented.

By its judgment in *Illumina v Commission* (T-227/21), the General Court dismissed the action by Illumina challenging the Commission's decisions concerning the proposed merger.

Illumina and Grail have appealed this judgment.

[Background Documents C-611/22 P and C-625/22 P](#)

There will be one press release for this case.

HEARINGS OF NOTE*

Court of Justice

Monday 11th March: 14:30 – Case [C-15/24 PPU Stachev](#) (Fundamental rights – Charter of Fundamental Rights – Area of Freedom, Security and Justice – Judicial cooperation in criminal matters)

Tuesday 12th March: 09:30 – Joined Cases [C-146/23 Sąd Rejonowy w Białymstoku and C-374/23 Adoreiké](#) (Fundamental rights – Charter of Fundamental Rights – Principles, objectives and tasks of the Treaties)

Thursday 14th March: **09:00** – Case [C-134/23 Elliniko Symvoulio gia tous Prosfyges](#) (Area

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of Freedom, Security and Justice – Border checks)

Monday 18th March: **15:00** – Case [C-240/23 Herbaria Kräuterparadies II](#) (Agriculture and Fisheries)

Tuesday 19th March: 09:30 – Case [C-248/23 Novo Nordisk \(VAT - Contributions paid under a legal obligation\)](#) (Taxation)

Thursday 21st March: 14:30 – Case [C-118/23 Getin Holding and Others](#) (Economic policy)

General Court

Tuesday 12th March: 09:30 – Case [T-797/22 Ordre néerlandais des avocats du barreau de Bruxelles and Others v Council](#), Case [T-798/22 Ordre des avocats à la cour de Paris and Couturier v Council](#) and Case [T-828/22 ACE v Council](#) (Restrictive measures – Ukraine)

Thursday 14th March: 09:30 – Case [T-692/20 Iliad Italia v Commission](#) (Competition)

Thursday 14th March: 09:30 – Case [T-398/21 Ryanair and Ryanair Sun v Commission](#) (State aid)

Wednesday 20th March: 09:30 – Case [T-587/22 Crown Holdings and Crown Cork & Seal Deutschland v Commission](#) and Case [T-589/22 Silgan Holdings and Others v Commission](#) (Competition)

Friday 22nd March: 09:30 – Case [T-72/22 Interneto žiniasklaidos asociacija and Others v Commission](#) (State aid)

* This is a non-exhaustive list and does not include all the hearings over the next two weeks.