C/2024/6049

11.10.2024

Summary of Commission Decision

of 6 September 2024

withdrawing decisions in cases M.10188 – Illumina / GRAIL (Art. 6(1)(c) decision and prohibition decision under Article 8(3)); M.10483 – Illumina / GRAIL (Art. 14 procedure); M. 10493 – Illumina / GRAIL (interim measures under Art. 8(5)(a)); M.10938 – Illumina / GRAIL (interim measures under Article 8(5)(c)); M.10939 – Illumina / GRAIL (restorative measures under Article 8(4)(a))

(notified under document number C(2024) 6433)

(Only the English version is authentic)

(Text with EEA relevance)

(C/2024/6049)

On 6 September 2024 the Commission adopted a Decision withdrawing its decisions in cases M.10188 – Illumina / GRAIL (Art. 6(1)(c) decision and prohibition decision under Article 8(3)); M.10483 – Illumina / GRAIL (Art. 14 procedure); M. 10493 – Illumina / GRAIL (interim measures under Art. 8(5)(a)); M.10938 – Illumina / GRAIL (interim measures under Article 8(5)(c)); and M.10939 – Illumina / GRAIL (restorative measures under Article 8(4)(a)) under Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings. [1] *A non-confidential version of the full Decision can be found in English on the website of the Directorate-General for Competition, at the following address: https://competition-cases.ec.europa.eu/search.*

1. THE PARTIES

(1) Illumina (United States) is a global genomics company that principally develops, manufactures, and commercialises NGS systems for genetic and genomic analysis, including sequencing instruments, consumables, and related services. Illumina's NGS systems are used in several applications, including oncology, where Illumina's NGS systems are used, inter alia, to develop and run tests to detect cancer and select therapies.

(2) GRAIL (United States) is a healthcare company that uses genomic sequencing and data science tools to develop blood-based cancer detection tests. In April 2021, GRAIL started a limited commercialisation of its flagship product 'Galleri', an early multi-cancer detection test, only in the United States. The United States Food and Drug Administration ('FDA') has, however, to date, not granted a more far-reaching pre-market approval for the product. GRAIL also has two additional pipeline products: (i) a diagnostic aid for cancer ('DAC') test, and (ii) a minimal residual disease ('MRD') test; each based on the same underlying platform as Galleri. GRAIL was founded by Illumina in 2015 before it was spun off in 2016.

2. SUMMARY

2.1. The Commission's administrative proceedings

(3) On 19 April 2021, the Commission adopted six decisions pursuant to Article 22(3) of the Merger Regulation (the 'Referral Decisions'), in which it accepted a referral request from France, joined by Belgium, Greece, Iceland, the Netherlands and Norway (the 'Referring Countries') to assess the proposed acquisition of GRAIL by Illumina (the 'Transaction') under the Merger Regulation [2]. The Transaction did not meet the turnover thresholds of the Merger Regulation, and was not notified in any Member State, but the Commission considered it to meet the criteria for referral under Article 22 of the Merger Regulation. In particular, the Commission found that the Transaction would affect trade within the internal market and threatened to significantly affect competition within the territory of the Referring Countries, and that a referral was appropriate because GRAIL's competitive significance was not reflected in its turnover.

[1] OJ L 24, 29.1.2004, p. 1.

[2] Case M.10188 – *Illumina / GRAIL*, Commission decisions of 19 April 2021 pursuant to Article 22(1) of Council Regulation No 139/2004 and Article 57 of the Agreement on the European Economic Area, C(2021) 2847 final, addressed to France; C(2021) 2849 final, addressed to Belgium; C(2021) 2848 final, addressed to Greece; C(2021) 2854 final, addressed to Iceland; C(2021) 2855 final, addressed to the Netherlands; C(2021) 2851 final, addressed to Norway, and correcting decision of 20 April 2021, C(2021) 2894 final, addressed to Iceland.

(4) On 22 July 2021, the Commission adopted a decision under Article 6(1)(c) of the Merger Regulation in which it found that the Transaction raised serious doubts as to its compatibility with the internal market and with the functioning of the EEA Agreement in relation to the vertical link arising from the Transaction between the supply of short-read next generation sequencing ('NGS') systems (upstream) and the development and supply of NGS-based cancer detection tests (downstream), and therefore decided to initiate proceedings.

(5) Following the implementation of the Transaction by the Parties, on 3 November 2021, the Commission notified to Illumina and GRAIL its decision ordering interim measures pursuant to Article 8(5)(a) of the Merger Regulation which had been adopted on 29 October 2021.

(6) On 6 September 2022, following an in-depth investigation, the Commission adopted a decision under Article 8(3) of the Merger Regulation finding that the Transaction is not compatible with the internal market and with the functioning of the EEA Agreement in relation to the vertical link arising from the Transaction between the supply of short-read NGS systems (upstream) and the development and supply of NGS-based early cancer detection tests (downstream).

(7) Following the adoption of the Article 8(3) decision, on 31 October 2022, the Commission notified to Illumina and GRAIL its decision pursuant to Article 8(5)(c) of the Merger Regulation which was adopted on 28 October 2022, in which the Commission concluded that the Transaction had been implemented and that the Transaction has been declared incompatible with the internal market, and imposed the continuation of interim measures on the Parties.

(8) In separate proceedings, on 12 July 2023, the Commission adopted a decision pursuant to Article 14(2) of the Merger Regulation, finding that both Illumina and GRAIL breached Article 7(1) of the Merger Regulation by implementing the Transaction prior to the completion of the Commission's in-depth investigation of the Transaction and imposing fines on Illumina and GRAIL.

(9) On 12 October 2023, the Commission adopted the Restorative Measures Decision, ordering measures to restore the situation prior to the implementation of the concentration pursuant to Article 8(4)(a) of the Merger Regulation. Illumina was ordered to dispose of GRAIL as a going concern on terms of disposal approved by the Commission. On 12 April 2024, the Commission approved under the Merger Regulation Illumina's plan to divest GRAIL following the restorative measures requiring Illumina to unwind its completed acquisition of GRAIL. On 24 June 2024, Illumina completed the spin-off of GRAIL.

2.2. **The proceedings before the EU courts**

(10) On 28 April 2021, Illumina sought the annulment of the Referral Decisions before the General Court of the European Union (Case T-227/21). On 13 July 2022, the General Court upheld the Referral Decisions, confirming the Commission's jurisdiction to examine the Transaction. On 22 September 2022, Illumina lodged an appeal against the judgment delivered by the General Court (Case C-611/22 P). On 30 September 2022, GRAIL also lodged an appeal against the judgment delivered by the General Court (Case C-625/22 P).

(11) On 3 September 2024, the Court of Justice of the European Union set aside the judgment of the General Court in Case T-227/21 and annulled the Referral Decisions.

2.3. **The withdrawal decision**

(12) It follows from the judgment of the Court of Justice of the European Union that the Commission had no jurisdiction to investigate the Transaction under the Merger Regulation.

(13) Consequently, since the Article 6(1)(c) Decision, the Article 8(3) Decision, the Article 8(5)(a) Decision, the Article 8(5)(c) Decision, the Article 14 Decision and the Article 8(4)(a) Decision were adopted on the basis that the Commission had jurisdiction to investigate the Transaction under the Merger Regulation, it is appropriate for the Commission to withdraw these decisions in view of the principle of good administration.

3. **CONCLUSION**

(14) For the reasons mentioned above, the Commission has withdrawn the decisions mentioned above.