EUROPEAN COMMISSION
DG Competition

PUBLIC VERSION

Commission decision withdrawing decisions in cases M.10188 – Illumina / GRAIL (Article 6(1)(c) decision and prohibition decision under Article 8(3)); M.10483 – Illumina / GRAIL (Article 14 procedure); M. 10493 – Illumina / GRAIL (interim measures under Article 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))

(Only the English text is authentic)

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Withdrawal decision Regulation (EC) 139/2004
Date: 6/9/2024

EUROPEAN
COMMISSION

Brussels, 6.9.2024
C(2024) 6433 final

COMMISSION DECISION

of 6.9.2024

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(Text with EEA relevance)

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(Text with EEA relevance)

(Only the English text is authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union[1],

Having regard to the Agreement on the European Economic Area, and in particular Article 57 thereof,

Having regard to Council Regulation (EC) No 139/2004 of 20.1.2004 on the control of concentrations between undertakings[2]

Having regard to the judgment of the Court of Justice of the European Union in Joined Cases C-611/22 P and C-625/22 P, delivered on 3 September 2024,

Whereas:

1. INTRODUCTION – PROCEEDINGS BEFORE THE EUROPEAN COMMISSION

1.1. The main merger control proceedings[3]

(1) On 19 April 2021, the Commission 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 (the "Referral Decisions").[4] 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

[1] OJ C 115, 9.8.2008, p.47.

[2] OJ L 24, 29.1.2004, p. 1 ('the Merger Regulation'). With effect from 1 December 2009, the Treaty on the Functioning of the European Union ('TFEU') has introduced certain changes, such as the replacement of 'Community' by 'Union' and 'common market' by 'internal market'. The terminology of the TFEU will be used throughout this decision.

[3] Case M.10188 – *Illumina / GRAIL.*

[4] Case M.10188 – *Illumina / GRAIL*, Commission decisions of 19.4.2021 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 20.4.2021, C(2021) 2894 final, addressed to Iceland.

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.

(2) On 16 June 2021, following the Referral Decisions, the Commission received notification of the Transaction from Illumina pursuant to Article 4 of the Merger Regulation.

(3) On 22 July 2021, the Commission adopted a decision under Article 6(1)(c) of the Merger Regulation (the "Article 6(1)(c) Decision")[5] 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 NGS systems (upstream) and the development and supply of NGS-based cancer detection tests (downstream), and therefore decided to initiate proceedings under Article 6(1)(c) of the Merger Regulation.

(4) On 18 August 2021, while the Commission's review was still ongoing, Illumina publicly announced that it had completed its acquisition of GRAIL.

(5) On 6 September 2022, the Commission adopted a decision under Article 8(3) of the Merger Regulation (the "Article 8(3) Decision"),[6] declaring the Transaction incompatible with the internal market and the functioning of the EEA Agreement. In that decision, the Commission concluded that, post-Transaction, the combined entity would have the ability and the incentive to engage in input foreclosure strategies (the "Input Foreclosure Strategies") against GRAIL's rivals in the market for (i) NGS-based cancer detection tests at the development stage worldwide, which would have adverse effects in the EEA, and thereby in the Referring Countries, and (ii) NGS-based early cancer detection tests (in particular multi-cancer early detection ("MCED") tests) at the commercialisation stage, which would have adverse effects in the EEA and at national level in the Referring Countries. The Commission also concluded that the commitments submitted by Illumina did not eliminate the significant impediment to effective competition arising from the Transaction.

1.2. The Article 8(5)(a)[7] and Article 8(5)(c)[8] proceedings

(6) On 29 October 2021, in response to Illumina's closing of the Transaction while the Commission's in-depth investigation was still ongoing, the Commission adopted a decision pursuant to Article 8(5)(a) of the Merger Regulation (the "Article 8(5)(a) Decision"),[9] in which the Commission concluded that the Transaction had been implemented in contravention of the standstill obligation in Article 7 of the Merger

[5] Case M.10188 – *Illumina / GRAIL*, Commission decision of 22.7.2021 pursuant to Article 6(1)(c) of Council Regulation No 139/2004 and Article 57 of the Agreement on the European Economic Area, C(2021) 5624 final.

[6] Case M.10188 – *Illumina / GRAIL*, Commission decision of 6.9.2022 pursuant to Article 8(3) of Council Regulation No 139/2004 and Article 57 of the Agreement on the European Economic Area, C(2022) 6454 final.

[7] Case M.10493 – *Illumina / GRAIL (Interim measures under Article 8(5)(a)).*

[8] Case M.10938 – *Illumina / GRAIL (Interim measures under Article 8(5)(c)).*

[9] Case M.10493 – *Illumina / GRAIL (Interim measures under Article 8(5)(a))*, Commission decision of 29.10.2021 pursuant to Article 8(5)(a) of Council Regulation No 139/2004 and Article 57 of the Agreement on the European Economic Area, C(2021) 7675 final.

Regulation while a decision as to the compatibility of the Transaction with the internal market had not yet been taken at the time, and imposed interim measures on the Parties (the "Article 8(5)(a) Interim Measures").

(7) The purpose of the Article 8(5)(a) Interim Measures was to restore and maintain conditions of effective competition following Illumina's acquisition of GRAIL in breach of the standstill obligation.[10] In particular, the Article 8(5)(a) Interim Measures provided that GRAIL was to be kept separate from Illumina, the Parties were prohibited from sharing confidential business information with only minor exceptions, Illumina had the obligation to maintain GRAIL's viability without favouring GRAIL to the detriment of its competitors and GRAIL was required to prepare for a possible divestment.

(8) The Article 8(5)(a) Decision provided that the Article 8(5)(a) Interim Measures were applicable until either (i) a final decision was adopted under Article 8(1), (2) or (4) of the Merger Regulation or (ii) merger proceedings regarding the Transaction were terminated before the Commission had adopted a final decision under Article 8(1), (2) or (3) of the Merger Regulation. The Article 8(5)(a) Decision further provided that, in any event, the Article 8(5)(a) Interim Measures were to expire twelve months after the notification of the Article 8(5)(a) Decision (this notification took place on 3 November 2021).

(9) As the expiration date for the validity of the Article 8(5)(a) Interim Measures was approaching and the conditions (i) and (ii) as set out in paragraph (8) above had not materialised, the Commission initiated the procedure to impose new interim measures to ensure that Illumina and GRAIL remain separate and the conditions of effective competition are maintained. Following the adoption of the Article 8(3) Decision, the legal basis for the interim measures was Article 8(5)(c) of the Merger Regulation.

(10) 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 (the "Article 8(5)(c) Decision").[11] The Article 8(5)(c) Interim Measures are largely similar to the Article 8(5)(a) Interim Measures, except for some minor adjustments.

1.3. Article 14 proceedings[12]

(11) On 12 July 2023, the Commission adopted a decision pursuant to Article 14(2) of the Merger Regulation (the "Article 14 Decision"),[13] finding that both Illumina and GRAIL breached Article 7(1) of the Merger Regulation by implementing the

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[10] As stated in recital (100) of the Article 8(5)(a) Decision, the Article 8(5)(a) Interim Measures aim at maintaining what remains of the effective conditions of competition and at restoring them to the extent possible, by (i) avoiding that any significant impediment to effective competition to which the Transaction may give rise would already be unleashed on the market, and (ii) safeguarding the *effet utile* of measures on the basis of Article 8(4) of the Merger Regulation in the event that the Transaction were to be declared incompatible with the internal market.

[11] Case M.10938 – *Illumina / GRAIL (Interim measures under Article 8(5)(c))*, Commission decision of 28.10.2022 pursuant to Article 8(5)(c) of Council Regulation No 139/2004 and Article 57 of the Agreement on the European Economic Area, C(2022) 7889 final.

[12] Case M.10483 – *Illumina / GRAIL (Article 14 procedure).*

[13] Case M.10483 – *Illumina / GRAIL (Art. 14 procedure)*, Commission decision of 12.7.2023 pursuant to Article 14(2) of Council Regulation No 139/2004 and Article 57 of the Agreement on the European Economic Area, C(2023) 4623 final, and corrigendum of 14.7.2023, C(2023) 5500 final.

Transaction prior to the completion of the Commission's in-depth investigation of the Transaction. The Commission imposed a fine of approximately EUR 432 million on Illumina and EUR 1 000 on GRAIL.

1.4. Article 8(4) Decision

(12) 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 (the "Article 8(4) Decision").[14] The Article 8(4) Decision included Disposal Measures, which required Illumina to restore the situation prevailing prior to the implementation of the Transaction. Illumina was ordered to dispose of GRAIL as a going concern on terms of disposal approved by the Commission in accordance with the procedure described in the decision. Subject to the Commission's prior approval and in accordance with the terms of the Disposal Measures, Illumina was allowed to choose in principle any method of disposal and execute the disposal within the Divestiture Period (which may be extended). The Article 8(4) Decision also included Transitional Measures, consisting of (i) Hold Separate Measures; (ii) Measures regarding the independence, autonomy and funding of GRAIL; (iii) Measures regarding arm's length interactions and "no fait accompli" obligations; (iv) Ring-fencing measures; (v) Reporting obligations; (vi) Monitoring Trustee provisions; and (vii) Preparatory Divestment Steps.

1.5. Approval of Divestment Plan

(13) 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. The Commission found that the divestment plan submitted by Illumina met all the conditions set out in its decision imposing restorative measures on Illumina and GRAIL.

(14) On 21 June 2024, as part of the preparations for the spin-off, GRAIL LLC was converted from a Delaware limited liability company into a Delaware corporation and renamed GRAIL, Inc.

(15) On 24 June 2024, Illumina completed the spin-off of GRAIL. GRAIL, Inc. is now an independent company listed on the stock exchange, whose shares began to be traded on the Nasdaq stock exchange on 25 June 2024. At the date of the spin-off of GRAIL, Illumina maintained its minority share of 14.5% in GRAIL, Inc.

2. PROCEEDINGS BEFORE THE UNION COURTS

2.1. Illumina's action for annulment of the Referral Decisions

(16) On 28 April 2021, Illumina sought the annulment of the Referral Decisions before the General Court of the European Union (Case T-227/21).

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[14] Case M.10939 – *Illumina / GRAIL (Restorative Measures under Article 8(4)(a))*, Commission decision of 12.10.2023 pursuant to Article 8(4)(a) of Council Regulation No 139/2004 and Article 57 of the Agreement on the European Economic Area, C(2023) 6737 final.

(17) On 13 July 2022, the General Court upheld the Referral Decisions, confirming the Commission's jurisdiction to examine the Transaction.[15]

(18) 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).

(19) On 3 September 2024, the Court of Justice of the European Union upheld the appeals, concluding that Article 22 of the Merger Regulation does not authorise the Commission to accept referrals of concentrations from Member States that have established a national regime of control of concentrations and are not competent to examine those concentrations under their own national law. Accordingly, 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.

2.2. Other proceedings before the Union Courts

(20) Illumina sought the annulment of the Article 8(5)(a) Decision on 1 December 2021 before the General Court (Case T-755/21). GRAIL also challenged the Article 8(5)(a) Decision on 11 January 2022 (Case T-23/22). The judicial proceedings were stayed in both cases until the decision that closes proceedings in Case T-227/21. On 29 August 2022, following the judgment of 13 July 2022 in Case T-227/21, the General Court decided to stay the proceedings in Cases T-755/21 and T-23/22 again, until the judgment of 13 July 2022 in Case T-227/21 becomes final.

(21) On 10 January 2023, Illumina sought the annulment of the Article 8(5)(c) Decision before the General Court (Case T-5/23). On 21 February 2023, the General Court stayed the proceedings in Case T-5/23, until Illumina's appeal in Case C-611/22 P is finally determined.

(22) On 17 November 2022, Illumina lodged an action for annulment against the Article 8(3) Decision. The proceedings before the General Court are currently pending (Case T-709/22).

(23) On 26 September 2023, Illumina lodged an action for annulment of the Article 14 Decision (Case T-591/23). On 9 July 2024, the General Court stayed the proceedings in Case T-591/23 until the decision of the Court of Justice ruling on the appeal brought against the decision of the General Court in Joined Cases C-611/22 P and C-625/22 P.

(24) On 22 December 2023, Illumina lodged an action for annulment against the Article 8(4) Decision. The proceedings before the General Court are currently pending (Case T-1190/23).

3. CONCLUSION

(25) In light of the judgment of the Court of Justice of the European Union in Joined Cases C-611/22 P and C-625/22 P that sets aside the judgment of the General Court in Case T-227/21 and annuls the Referral Decisions, the Commission had no jurisdiction to investigate the Transaction under the Merger Regulation.

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15 Case T-227/21 – *Illumina v Commission*, judgment of the General Court of 13 July 2022 *(EU:T:2022:447).*

(26) 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) 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.

HAS ADOPTED THIS DECISION:

Article 1

The following decisions are withdrawn in their entirety:

Case M.10188 – *Illumina / GRAIL*, Commission decision of 22.7.2021 pursuant to Article 6(1)(c) of Council Regulation No 139/2004 and Article 57 of the Agreement on the European Economic Area, C(2021) 5624 final.

Case M.10188 – *Illumina / GRAIL*, Commission decision of 6.9.2022 pursuant to Article 8(3) of Council Regulation No 139/2004 and Article 57 of the Agreement on the European Economic Area, C(2022) 6454 final.

Case M.10493 – *Illumina / GRAIL (Interim measures under Article 8(5)(a))*, Commission decision of 29.10.2021 pursuant to Article 8(5)(a) of Council Regulation No 139/2004 and Article 57 of the Agreement on the European Economic Area, C(2021) 7675 final.

Case M.10938 – *Illumina / GRAIL (Interim measures under Article 8(5)(c))*, Commission decision of 28.10.2022 pursuant to Article 8(5)(c) of Council Regulation No 139/2004 and Article 57 of the Agreement on the European Economic Area, C(2022) 7889 final.

Case M.10483 – *Illumina / GRAIL (Art. 14 procedure)*, Commission decision of 12.7.2023 pursuant to Article 14(2) of Council Regulation No 139/2004 and Article 57 of the Agreement on the European Economic Area, C(2023) 4623 final, and corrigendum of 14.7.2023, C(2023) 5500 final.

Case M.10939 – *Illumina / GRAIL (Restorative Measures under Article 8(4)(a))*, Commission decision of 12.10.2023 pursuant to Article 8(4)(a) of Council Regulation No 139/2004 and Article 57 of the Agreement on the European Economic Area, C(2023) 6737 final.

Article 2

This Decision is addressed to:

Illumina, Inc.

5200 Illumina Way

San Diego, California 92122

United States of America

GRAIL, Inc.
1525 O'Brien Drive
Menlo Park, California 94025
United States of America

Done at Brussels, 6.9.2024

For the Commission

(Signed)
Margrethe VESTAGER
Executive Vice-President