

Illustrina/GRAIL: EC Blocks Transaction Below EU and Referring Member State Merger Control Thresholds for the First Time

September 15, 2022

In a landmark decision announced on September 6, 2022 (“**Decision**”), the European Commission (“**EC**”) prohibited the acquisition by Illustrina, a U.S. company specialising in genomic sequencing, of GRAIL, a U.S.-based start-up developing early cancer-detection tests (“**Transaction**”).¹

The EC blocked the Transaction even though it did not meet notification thresholds under the EU Merger Regulation (“**EUMR**”) or in any Member State: at the time of prohibition, GRAIL had not launched a product on the market and had no sales in the EEA. This is the first time the EC has reviewed – and blocked – a transaction falling below the EUMR and referring Member State notification thresholds.²

If you have any questions concerning this memorandum, please reach out to your regular firm contact or the following authors

BRUSSELS

Francisco Enrique González-Díaz
+32 2 287 2117
fgonzalez-diaz@cgsh.com

Lydia Bitsakou
+32 2 287 2242
lbitsakou@cgsh.com

Brian Cullen
+32 2 287 2148
bcullen@cgsh.com

LONDON

Nicholas Levy
+44 20 7614 2243
nlevy@cgsh.com

¹ EC Press Release IP/22/5364, [Mergers: Commission prohibits acquisition of GRAIL by Illustrina](#), September 6, 2022 (“**EC Press Release**”).

² The EC has previously blocked transactions referred to it by Member States before the adoption of their respective merger control regimes: *RTL/Veronica/Endemol*, Case IV/M.553, Commission decision of September 20, 1995; *Kesko/Tuko*, Case IV/M.784, Commission decision of November 20, 1996; and *Blokker/Toys “R” Us (II)*, Case IV/M.890, Commission decision of June 26, 1997.



Factual Background

Illumina's principal business is next-generation sequencing ("NGS") instruments and consumables. GRAIL is a start-up developing blood tests for the early detection of cancer – a nascent field.³ The Transaction is purely vertical in nature with Illumina operating upstream of GRAIL.

In September 2020, Illumina acquired GRAIL for \$8 billion.⁴ At the time of announcement – which still holds true at the time of the Decision – GRAIL had not launched a product on the market and had no sales in the EEA. The Transaction was not reportable at EU or Member State level.

But in February 2021, following a complaint, the EC invited a referral by national competition authorities ("NCAs") under Article 22 EUMR to enable the EC to investigate the Transaction in parallel to the U.S. Federal Trade Commission ("FTC") and the UK Competition & Markets Authority. The French NCA referred the Transaction in March 2021, and was then joined by the NCAs of Belgium, Greece, Iceland, the Netherlands, and Norway. The EC accepted the referral request in April 2021, and requested the merging parties to notify the Transaction to the EC.

Following unsuccessful preliminary challenges of the French and Dutch referral decisions in national courts, Illumina appealed the EC's decision to accept jurisdiction, arguing, in particular, that the EUMR was not intended to allow for the referral of transactions that do not meet national merger control thresholds and that, in any event, any change in Article 22 EUMR policy should not have been applied to Illumina's

acquisition of GRAIL. In a significant judgment rendered on July 13, 2022, the EU's General Court validated the EC's position set out in a March 2021 Guidance Paper⁵ encouraging NCAs to use Article 22 EUMR to refer transactions to the EC that do not meet national merger control thresholds, but which may threaten to significantly affect competition within the EU.⁶

Illumina notified the Transaction to the EC in June 2021 and closed the Transaction in August 2021 before the EC had completed its investigation. Illumina announced that it would hold GRAIL as a separate company during the EC's ongoing regulatory review. In October 2021, the EC adopted hold-separate and interim measures.⁷ Illumina's⁸ and GRAIL's⁹ appeals against the EC's interim measures are pending before the General Court.

The EC's Decision

On September 6, 2022, almost two years after its announcement, the EC prohibited the Transaction. The EC based its Decision on input foreclosure: that the Transaction would have enabled and incentivised Illumina to foreclose GRAIL's putative rivals that depend on Illumina's NGS technology from accessing an essential input they would need to develop and market blood-based early cancer detection tests. As a result, so the EC found, GRAIL's putative rivals would be disadvantaged compared to GRAIL in an emerging early cancer-detection testing market. Although Illumina offered remedies, the EC deemed that proposal insufficient to address its competition concerns.

³ Illumina formed GRAIL but spun it off in 2016 and retained a 14.5% shareholding. See Illumina Press Release, [Illumina to Acquire GRAIL to Launch New Era of Cancer Detection](#), September 21, 2020.

⁴ Illumina Press Release, [Illumina to Acquire GRAIL to Launch New Era of Cancer Detection](#), September 21, 2020.

⁵ [Commission Guidance on the application of the referral mechanism set out in Article 22 of the Merger Regulation to certain categories of cases](#), March 26, 2021.

⁶ See Cleary Gottlieb Alert Memo, [Illumina/Grail: General Court Upholds EC's Merger Referral Policy, Expanding EC Jurisdiction Over Non-reportable Transactions](#), July 18, 2022.

⁷ EC Press Release IP/21/5661, [Mergers: Commission adopts interim measures to prevent harm to competition following Illumina's early acquisition of GRAIL](#), October 29, 2021.

⁸ Case T-755/21 – *Illumina v. Commission* ([pending](#)).

⁹ Case T-23/22 – *GRAIL v. Commission* ([pending](#)).

The EC identified input foreclosure concerns. The EC explored competition concerns on putative markets for innovation and commercialization, where GRAIL and its putative rivals would be “*currently engaged in an innovation race to develop and commercialise early cancer detection tests.*”¹⁰ Against this background, the EC found that Illumina would have had the ability and incentive to foreclose GRAIL’s putative cancer detection test rivals. Foreclosure strategies could include delaying, degrading, or refusing to supply NGS systems to GRAIL’s putative rivals, or increasing the price of their NGS systems.

- First, the EC concluded that Illumina would have the ability to foreclose those of GRAIL’s putative downstream rivals that rely on Illumina’s NGS systems to develop early cancer detection tests. The EC considered that GRAIL’s rivals, which require high-throughput NGS systems with a reliable support network and a solid track record, could only source NGS systems from Illumina in the short- to medium-term in a market that would be characterized by high barriers to entry and long and costly switching.
- Second, the EC found that Illumina would have an incentive to foreclose GRAIL’s putative rivals in light of the lucrative and expanding early cancer detection market, expected to be worth €40 billion per annum globally by 2035. This, the EC reasoned, would give Illumina sufficient incentive to engage in input foreclosure by diverting profits from GRAIL’s putative rivals to the merged entity (even though GRAIL’s flagship Galleri test has not yet entered the EEA market).

The EC dismissed Illumina’s proposed remedies. Having made a binding offer to all of GRAIL’s rivals, Illumina submitted an extensive remedy package to

alleviate the EC’s concerns. Having conducted a market investigation, the EC found the remedies insufficient to prevent harm to innovation in NGS-based cancer detection tests.

- Upstream, Illumina committed to license NGS patents to NGS suppliers, and to stop patent litigation in the US and Europe against its competitor BGI for three years. The EC concluded that the upstream commitments “*would not have ensured the emergence of a credible alternative to Illumina for GRAIL’s rivals in the short to medium term,*”¹¹ because NGS rivals would require access to other Illumina patents and due to the putatively onerous and uncertain switching process for GRAIL’s rivals.
- Downstream, Illumina offered a comprehensive remedy package including a commitment to supply GRAIL’s rivals under standard conditions until 2033. The Commission had accepted similar downstream access remedies in previous cases.¹² But the EC considered that Illumina’s commitments did not remove the risk of Illumina degrading technical support for its NGS systems, and would be complex to monitor.

Legal And Practical Implications Of The EC’s Decision

Illumina has already announced that it will appeal the Decision to the General Court, following its appeal to the Court of Justice of the General Court’s July 2022 judgment finding the EC had jurisdiction under Article 22 EUMR.¹³ Two important implications may be noted:

- **FTC investigation.** The Decision – the EC’s second prohibition decision in 2022¹⁴ – diverges

¹⁰ EC Press Release.

¹¹ EC Press Release.

¹² See, e.g., Case COMP/M.8665 – *Discovery/Scripps*, Commission decision of February 6, 2018; Case COMP/M.7822 – *Dentsply/Sirona*, Commission decision of February 25, 2016.

¹³ Illumina Press Release, [Illumina Intends to Appeal European Commission’s Decision in GRAIL Deal](#), September 6, 2022.

¹⁴ In January 2022, the EC prohibited Hyundai Heavy Industries’ acquisition of Daewoo. EC Press Release IP/22/343, [Mergers: Commission prohibits proposed acquisition of Daewoo Shipbuilding & Marine](#)

from the opinion of the FTC’s Chief Administrative Law Judge who, on September 1, 2022, dismissed the FTC’s claims that Illumina would have an incentive to foreclose GRAIL’s putative rivals from accessing its NGS technology, or provide more costly or degraded access post-Transaction.¹⁵

The FTC Judge and the EC diverge, at least, on two questions. First, whether GRAIL faces potential competition in a market for innovation to commercialize a competing product to Galleri. If not – as the FTC Judge found – Illumina could not have an incentive to foreclose GRAIL’s putative rivals, as there are none. Second, whether Illumina’s remedies are sufficient to address any putative foreclosure concerns. The FTC Judge found that they are, whereas the EC found the proposed remedies insufficient. The ultimate outcome is uncertain as the FTC has announced that it will appeal the FTC Judge’s decision.¹⁶

- **Interim measures.** In October 2021, the EC adopted interim measures under Article 8(5)(a) EUMR requiring Illumina to hold GRAIL separate and to continue funding the development of its innovative cancer-screening detection test. Commissioner Vestager indicated that these interim measures “*will continue to apply.*”¹⁷
- **Restorative measures.** When announcing the Decision, Commissioner Vestager indicated that “*I intend to suggest in due course a separate decision ordering Illumina and GRAIL to dissolve the transaction and restore GRAIL’s independence.*”¹⁸
- **Gun-jumping investigation.** On July 19, 2022, the EC sent a Statement of Objections to Illumina alleging that the merging parties had breached Article 14 EUMR by implementing the

Transaction while the EC’s investigation was ongoing. The outcome of this investigation is likely to hinge, among other things, on whether Illumina’s appeal of the General Court’s Article 22 EUMR judgment will succeed: should Illumina prevail, the EC’s investigation would lack any legal basis.

Beyond the case at issue, the Decision has a number of broader implications for future transactions:

- First, the Decision confirms the uncertainty created by the EC’s March 2021 Guidance Paper in respect of transactions involving targets that have no activities or turnover in the EU. Companies and their advisors can no longer rely on EU and national brightline thresholds to assess whether the EC will review a given transaction. GRAIL’s absence of a launched product or sales in the EU show that the EC is ready to take an expansive approach in determining whether a transaction “*affects trade between Member States*” and “*threatens to significantly affect competition*” (for jurisdictional purposes) or is liable to “*significantly impede effective competition*” (for substantive purposes). To address this uncertainty, buyers may need to obtain EEA Member State and EC guidance as to whether a given transaction is a likely referral candidate or anticipate the possibility that such acquisitions may be subject to remedies or, in the worst case, may have to be unwound.

The notification obligation under Article 14 of the Digital Markets Act (“**DMA**”) will facilitate future use of Article 22 EUMR for referrals to the EC. Companies that are subject to the DMA will be required to inform the EC of intended transactions involving “*another provider of core platform*

[Engineering by Hyundai Heavy Industries Holdings](#), January 13, 2022.

¹⁵ Reuters, [U.S. judge backs Illumina deal for Grail in blow to FTC](#), September 2, 2022.

¹⁶ FTC, [Complaint Counsel’s Notice of Appeal](#), September 2, 2022.

¹⁷ EC SPEECH/22/5371, [Remarks by Executive Vice-President Vestager on the Commission decision to prohibit the acquisition of GRAIL by Illumina](#), September 6, 2022.

¹⁸ *Ibid.*

services or of any other services provided in the digital sector” regardless of whether they meet EU or Member States’ merger control thresholds.

- Second, the Decision confirms the EC’s increasing scrutiny of vertical mergers and its skepticism of non-divestiture-like remedies. This increased scrutiny includes placing greater emphasis on the impact of putative foreclosure on potential competition concerns. The EC’s reliance on this theory is noteworthy given its rejection by the FTC Judge.

Illumina’s appeals of the Decision and the General Court’s Article 22 judgment will be watched with considerable interest given the significant implications for the EC’s jurisdiction and substantive appraisal of concentrations under the EUMR.

...

CLEARY GOTTLIB