



Mergers: Commission adopts interim measures to prevent harm to competition following Illumina's early acquisition of GRAIL

Brussels, 29 October 2021

The European Commission has adopted interim measures to restore and maintain the conditions of effective competition following Illumina's early acquisition of GRAIL, which is in breach of the standstill obligation under the [EU Merger Regulation](#).

Executive Vice-President Margrethe **Vestager**, in charge of competition policy, said: *"By implementing their merger while the Commission's in-depth investigation into this transaction is still ongoing, Illumina and GRAIL have put at risk the effectiveness of our ex-ante merger control enforcement. This is why we are adopting today measures aiming to prevent harm to competition in the interim period until our final decision on the substance of the case is taken. In designing the interim measures, we made sure GRAIL and other companies can continue developing their innovative cancer detection technology so that it can reach patients as quickly as possible, thus saving many lives."*

On 22 July 2021 the Commission had [opened an in-depth investigation](#) into the effects of the proposed combination of Illumina and GRAIL. Shortly thereafter, on 18 August 2021, while the Commission's review was ongoing Illumina publicly announced that it had completed its acquisition of GRAIL. On [20 September 2021](#), the Commission sent a Statement of Objections to the two companies informing them of the interim measures it intended to adopt in response to their alleged breach of the standstill obligation under the EU [Merger Regulation](#).

After having heard the parties, with today's decision, the Commission adopts binding interim measures.

This is the first time the Commission adopts interim measures following an unprecedented early implementation of a concentration. The interim measures aim to prevent the potentially irreparable detrimental impact of the transaction on competition as well as possible irreversible integration of the merging parties, pending the outcome of the Commission's merger investigation.

In particular, the interim measures adopted today provide that:

- GRAIL shall be kept separate from Illumina and be run by (an) independent Hold Separate Manager(s), exclusively in the interest of GRAIL (and not of Illumina).
- Illumina and GRAIL are prohibited from sharing confidential business information, except where the disclosure is required to comply with the law or in line with the ordinary course of their supplier-customer relationship.
- Illumina has the obligation to finance additional funds necessary for the operation and development of GRAIL.
- The business interactions between the parties shall be undertaken at arm's length, in line with industry practice, hence without unduly favouring GRAIL to the detriment of its competitors.
- GRAIL shall actively work on alternative options to the transaction to prepare for the possible scenario in which the deal would have to be undone in case the Commission were to declare the transaction incompatible with the internal market.

The measures are legally binding on both Illumina and GRAIL. The measures will be applicable during an interim period, pending the final outcome of the Commission's in-depth merger investigation. Their compliance will be closely monitored by a Monitoring Trustee to be approved by the Commission. Should the parties fail to comply with any of the measures, they would face the risk of penalty payments of up to 5% of their average daily turnover and/or fines of up to 10% of their annual worldwide turnover under Articles 15 and 14 of the EU Merger Regulation respectively.

In parallel, and as communicated on [20 August 2021](#), the Commission will continue to investigate whether Illumina's and GRAIL's decision to implement their transaction pending the Commission's in-depth investigation constitutes an infringement of the EU Merger rules that may trigger the

imposition of fines under Article 14 of the EU Merger Regulation. If the Commission were to conclude that Illumina and GRAIL are liable, it could impose a fine of up to 10% of the companies' annual worldwide turnover.

The Commission is also continuing its in-depth investigation into the transaction and has until 4 February 2022 take a decision.

Companies and products

Illumina, headquartered in the US, is a global genomics company, which develops, manufactures and commercialises NGS systems, including sequencing instruments, consumables and related services. Illumina's NGS systems are medical devices used in a variety of applications, including by customers in the oncology space that develop and run blood-based tests that can detect cancer or select appropriate therapies for cancer patients. Illumina's global turnover in 2020 was USD 3 billion. In Europe, Illumina commercialises its products both directly and via distributors.

GRAIL, also headquartered in the US, is a healthcare company developing blood-based cancer tests based on genomic sequencing and data science tools. GRAIL's flagship product is "Galleri", an early multi-cancer detection test, whose purpose is to detect around 50 cancers in asymptomatic patients from a blood sample. In April 2021, GRAIL initiated a limited commercialisation of Galleri in the US. GRAIL has two additional pipeline products: (i) a diagnostic aid for cancer testing used to confirm a diagnosis of cancer in symptomatic patients, and (ii) a minimal residual disease test, to detect potential relapse in patients after cancer treatments. GRAIL was founded by Illumina in 2016, and was spun off later in the same year.

Background

The obligation not to implement a notifiable transaction either before its notification or before it has been declared compatible with the common market is laid down in Article 7(1) of the EU Merger Regulation. This standstill obligation prevents potentially irreparable negative impact of transactions on the market, as well as possible irreversible integration of merging parties, pending the outcome of the Commission's merger investigations.

Compliance with the standstill obligation is essential for legal certainty, enables the Commission to conduct a correct analysis of the impact of mergers in the market and prevents the potentially detrimental impact of transactions on the competitive structure of the market.

Article 8(5)(a) of the EU Merger Regulation authorises the Commission to take appropriate interim measures to restore or maintain the conditions of effective competition when parties breach the standstill obligation while the Commission's review of a merger is pending.

The ability of the Commission to impose fines in the event of a breach of Article 7(1), or Article 8(5) (a) is laid out in Article 14(2) (b) and (c) of the EU Merger Regulation.

More information will be available on the Commission's [competition website](#), in the Commission's [public register](#) under case numbers [M.10493](#) (for the interim measures), [M.10188](#) (for the merger review investigation), and [M.10483](#) (for the Article 14 procedure).

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Press contacts:

[Arianna PODESTA](#) (+32 2 298 70 24)

[Maria TSONI](#) (+32 2 299 05 26)

General public inquiries: [Europe Direct](#) by phone [00 800 67 89 10 11](#) or by [email](#)