



Mergers: The Commission adopts a Statement of Objections in view of adopting interim measures following Illumina's early acquisition of GRAIL

Brussels, 20 September 2021

The European Commission has sent a Statement of Objections to Illumina and GRAIL informing them of the interim measures it intends to adopt following the companies' alleged breach of the standstill obligation under the [EU Merger Regulation](#). These measures aim to restore and maintain effective competition while the Commission's review of the acquisition of GRAIL by Illumina is pending.

Executive Vice-President Margrethe **Vestager**, in charge of competition policy, said: *"Illumina and GRAIL completed their merger, while our investigation is still ongoing. Under our rules, companies have to wait for the Commission's clearance before implementing deals that are subject to our review. The standstill obligation is a cornerstone of our ex-ante merger control regime which aims at preventing harmful effects to competition while our review is ongoing. This is the first time companies openly implement their deal while we are carrying out an in-depth investigation. Today, we send our objections to the companies informing them of the measures we intend to take to prevent the potentially detrimental impact of the transaction on the competitive structure of the market."*

On 22 July 2021, the Commission [opened an in-depth investigation](#) to assess the proposed acquisition of GRAIL by Illumina under the EU Merger Regulation. However, on 18 August 2021, Illumina publicly announced that it had completed its acquisition of GRAIL, while the Commission's review of the proposed transaction is still pending.

Under the EU [Merger Regulation](#), companies should not implement concentrations that are subject to the Commission's review unless and until they have been notified and cleared by the Commission (the "standstill obligation").

In today's Statement of Objections, the Commission takes the preliminary view that, by closing their deal, Illumina and GRAIL breached the *standstill* obligation and that interim measures to restore or maintain effective competition are appropriate in this case.

This is the first time the Commission intends to adopt interim measures following an unprecedented early implementation of a concentration it is investigating. 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.

The envisaged interim measures take note of Illumina's own unilateral proposal to hold GRAIL separate, but go beyond Illumina's proposal in addressing a number of serious shortcomings identified in that proposal.

GRAIL and Illumina now have the opportunity to respond to the Commission's Statement of Objections in writing and orally. After hearing the parties, the Commission may make the interim measures binding and Illumina and GRAIL would be legally obliged to comply with them. The Commission is empowered to impose periodic penalty payments in case of non-compliance. Moreover, companies failing to comply with interim measures can be fined up to 10% of their annual worldwide turnover under Article 14 of the Merger Regulation.

In parallel, and as communicated on [20 August 2021](#), the Commission will continue to investigate whether Illumina 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. 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.

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

A Statement of Objections is a formal step in an investigation, where the Commission informs the companies concerned in writing of the objections raised against them. The companies can then access the Commission's file, reply in writing and request an oral hearing to present their comments on the case to representatives of the Commission.

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. In this way, market forces work for the benefit of consumers.

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 the case number [M.10493](#) (for the interim measures) and under the case number [M.10188](#) (for the merger review investigation).

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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](#)