



Mergers: Commission opens in-depth investigation into proposed acquisition of GRAIL by Illumina

Brussels, 22 July 2021

The European Commission has opened an in-depth investigation to assess the proposed acquisition of GRAIL by Illumina, under the EU Merger Regulation. The Commission is concerned that the proposed acquisition may reduce competition and innovation in the emerging market for the development and commercialisation of cancer detection tests based on sequencing technologies.

Executive Vice-President Margrethe **Vestager**, responsible for competition policy, said: "*Cancer detection tests based on next generation sequencing technologies could revolutionise how cancer is detected and thus emerge as a game changer in the fight against the disease. It is very important to preserve market conditions allowing the best solutions to emerge for the tests to ultimately reach the market at affordable prices, for the benefit of patients. We have today opened an in-depth investigation precisely to assess whether the proposed transaction, which will combine the activities of Illumina and GRAIL, would threaten the ability of developers of cancer detection tests to effectively compete in this area and bring innovative products to the market.*"

Illumina is a global health technologies company, and leading supplier of next generation sequencing ("NGS") systems for genetic and genomic analysis, which include NGS instruments, consumables and ancillary services. **GRAIL** is a customer of Illumina, and develops cancer detection tests relying on NGS systems.

The Commission's preliminary concerns

Following its preliminary investigation, the Commission has concerns about the impact of the transaction on the development and supply of NGS-based cancer detection tests. The Commission is concerned that, as a result of its combination with GRAIL, Illumina could engage in vertical input foreclosure strategies given its leading position in the NGS systems that are crucial inputs for the development and commercialisation of NGS-based cancer detection tests. The preliminary investigation suggests that Illumina could have the ability to engage in these foreclosure strategies given its leading position in NGS systems and that Illumina could have an economic incentive to foreclose GRAIL's rivals.

Such foreclosure strategies could have an adverse impact on GRAIL's rivals and European patients, in particular by hampering innovation, reducing the choice, innovative features and performance of products available to patients, doctors and health systems, and increasing barriers to enter the NGS-based cancer detection tests space.

The Commission will now carry out an in-depth investigation into the effects of the transaction to determine whether its initial competition concerns are confirmed.

The proposed transaction was notified to the Commission on 16 June 2021. The Commission now has 90 working days, until 29 November 2021, to take a decision. The opening of an in-depth inquiry does not prejudice the outcome of the investigation.

Referral request

On 19 April 2021, the Commission accepted a request from France, joined by Belgium, Greece, Iceland, the Netherlands and Norway, to assess the proposed acquisition of GRAIL by Illumina under the EU Merger Regulation. The proposed transaction did not meet the turnover thresholds of the EU Merger Regulation, and was not notified in any Member State, but met the criteria for referral under Article 22 of the EU Merger Regulation. In particular, the Commission found that the proposed transaction affects trade within the single market and threatens to significantly affect competition within the territory of the Member States that made the referral request, and that a referral was appropriate because GRAIL's competitive significance is not reflected in its turnover.

The Commission's [Article 22 Guidance](#) describes the categories of cases that may constitute suitable candidates for a referral in situations where the transaction is not notifiable under the laws of the referring Member State(s), and the criteria that the Commission may take into account in exercising

its discretion to accept such referrals.

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. Today, Illumina remains GRAIL's largest (non-controlling) shareholder, with a 14.5% stake.

Merger control rules and procedures

The Commission has the duty to assess mergers and acquisitions involving companies with a turnover above certain thresholds (see Article 1 of the [Merger Regulation](#)) and to prevent concentrations that would significantly impede effective competition in the EEA or any substantial part of it.

The vast majority of notified mergers do not pose competition problems and are cleared after a routine review. From the moment a transaction is notified, the Commission generally has 25 working days to decide whether to grant approval (Phase I) or to start an in-depth investigation (Phase II).

In addition to the current transaction, there are four ongoing Phase II merger investigations: the [proposed merger between Cargotech and Konecranes](#), the [proposed acquisition of Air Europa by IAG](#), the [proposed acquisition of Trimo by Kingspan Group](#) and the [proposed acquisition of DSME by HHiH](#).

More information will be available on the Commission's [competition website](#), in the [public case register](#) under the case number [M.10188](#).

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