European Commission - Press release

Mergers: Commission prohibits acquisition of GRAIL by Illumina

Brussels, 6 September 2022

The European Commission has prohibited, under the EU Merger Regulation, the implemented acquisition of GRAIL by Illumina. The merger would have stifled innovation, and reduced choice in the emerging market for blood-based early cancer detection tests. Illumina did not offer remedies sufficient to address these concerns.

Executive Vice-President Margrethe **Vestager**, in charge of competition policy, said: "*Today we prohibited Illumina's implemented acquisition of GRAIL. In a race with other companies, GRAIL is developing a blood-based early cancer detection test. If successful, these tests will revolutionise our fight against cancer and help to save millions of lives. Illumina is currently the only credible supplier of a technology allowing to develop and process these tests. With this transaction, Illumina would have an incentive to cut off GRAIL's rivals from accessing its technology, or otherwise disadvantage them. It is vital to preserve competition between early cancer detection test developers at this critical stage of development. As Illumina did not put forward remedies that would have solved our concerns, we prohibited the merger.*"

The Commission's investigation

Today's decision follows an in-depth investigation by the Commission of the merger, which leads to the vertical integration of Illumina, the unrivalled supplier of NGS systems for genetic and genomic analysis, with GRAIL, a customer of Illumina using NGS systems to develop cancer detection tests. These tests use a simple blood sample to detect different cancers in asymptomatic patients at an early stage and have the potential to be a game changer in the fight against cancer. The acquisition would have enabled and incentivised Illumina to foreclose GRAIL's rivals, who are dependent on Illumina's technology, from access to an essential input they need to develop and market their own tests. As a result, GRAIL's competitors would be put in a disadvantaged position compared to GRAIL.

During the investigation, the Commission received feedback from a large number of customers and competitors, as well as from experts in the field of NGS-based cancer detection tests and from national authorities. Market players were concerned that, following the transaction, Illumina would cut access to its NGS technology to GRAIL's rivals, or otherwise disadvantage them, to gain control over the promising early cancer-detection testing market.

The Commission's Decision

The Commission found that Illumina would have had the ability and the incentive to engage in foreclosure strategies against GRAIL's rivals. It could for instance refuse to supply its NGS systems to GRAIL's rivals, increase the prices, or degrade quality and delay supplies. The Commission considered that those strategies would have resulted in a significant detrimental effect on competition in developing and marketing NGS-based cancer detection tests in the European Economic Area (EEA).

The Commission found that GRAIL and its rivals are currently engaged in an innovation race to develop and commercialise early cancer detection tests. While there is still uncertainty about the exact results of this innovation race and the future shape of the market for early cancer detection tests, protecting the current innovation competition is crucial to ensure that early cancer detection tests with different features and price points will come to the market. More specifically:

- Illumina would have **the ability to foreclose GRAIL's rivals**. GRAIL and its rivals rely on Illumina's NGS systems to develop and run their tests. Early cancer detection test developers need high-throughput NGS systems, with a reliable support network and a solid track record. Today, only Illumina's equipment meets these requirements and the investigation showed that there are no credible alternatives to Illumina in the short to medium term. In addition, barriers to entry are significant. This is in particular due to the risk of intellectual property litigation, the need for GRAIL's rivals to rely on an NGS player that has an installed base of instruments in third party laboratories, can compete with Illumina's ongoing innovation, has a developed and stable technology, and proven reliability of support services over time. Moreover, switching

NGS provider would be a long and costly process for GRAIL's rivals, without a guarantee of success.

- Illumina would have clear **incentives to foreclose GRAIL's rivals**. While Illumina's sales of NGS technology to GRAIL's rivals represent a small proportion of its sales and profits, NGS-based early cancer detection testing is expected to expand rapidly and to become highly lucrative. Based on predictions, by 2035 this market would reach more than EUR 40 billion per annum, on a global basis. Given this enormous market potential and the ongoing close innovation competition in the development of early cancer detection test, the Commission considered that Illumina would have an incentive to foreclose GRAIL's rivals already today, despite benefitting from this action only at a later stage. In fact, the investigation showed that GRAIL's flagship test "Galleri", while enjoying a first mover advantage, is not unique, and several players are currently developing cancer detection tests that would closely compete with Galleri in the near future absent the transaction.

Illumina's proposed remedies

The remedies offered by Illumina did not adequately address the Commission's competition concerns so that it could be concluded that competition would be preserved on a lasting basis. They did not fully remove Illumina's ability or incentives to foreclose GRAIL's rivals and would thus not have prevented the transaction's detrimental effect on competition. In particular Illumina submitted:

- **A licence open to NGS suppliers to some of Illumina's NGS patents, and a commitment to stop patent lawsuits** in the US and Europe against the NGS supplier BGI Genomics (China) for three years. This commitment aimed at reducing IP related barriers to entry and thereby making it easier for NGS suppliers, in particular BGI, to bring their products to the market. But based on the Commission's analysis and extensive market testing, these commitments would not have ensured the emergence of a credible alternative to Illumina for GRAIL's rivals in the short to medium term. The patent licence would have only had a limited impact because the covered patents were due to expire in the short term, and because Illumina has many other patents that competitors would need to develop an alternative NGS system. In addition, other significant barriers hinder the emergence of a credible alternative to Illumina for GRAIL's rivals. Moreover, the commitments did not address the concern that even if alternative NGS systems emerged, switching provider would be a long and costly process for GRAIL's rivals, without a guarantee of success.
- **A commitment to conclude agreements with GRAIL's rivals under the conditions set out in a standard contract.** The provisions contained in these contracts would be applicable until 2033. This commitment aimed at ensuring that GRAIL's rivals enjoy continued access to Illumina's NGS systems. But based on extensive testing and our findings, these commitments were unlikely to be effective in practice as they did not effectively address all the possible foreclosure strategies that Illumina could engage in. For example, this commitment did not effectively address the risk that Illumina would foreclose GRAIL's rivals by degrading the technical support for its NGS systems. Moreover, the investigation showed that it would have been easy for Illumina to circumvent its obligations under the commitments and grant preferential treatment to GRAIL, thereby making it harder for GRAIL's rivals to successfully compete. In addition, these commitments would have been difficult to monitor due to their complexity and the fact that GRAIL's rivals would hardly have been able to detect breaches.

The Commission conducted an extensive analysis of the proposed commitments, including testing their efficacy with the relevant market participants.

Based on this, the Commission found that the remedies offered by Illumina were not sufficient to address the competition concerns whereby emergent competition in blood based early cancer detection tests would be hindered or even eliminated. As a result, the remedies were not sufficient to prevent the harm to innovation in the area of NGS-based cancer detection tests resulting from the Transaction.

Therefore, the Commission has **prohibited the transaction**.

Where a concentration that has been declared incompatible with the internal market has been already implemented, the Commission may under Article 8(4) or the EU Merger Regulation, dissolve the concentration or take other appropriate measures. The Commission will assess in due course whether and which additional steps will be required.

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 2021 was USD 4.5 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", a multi-cancer early 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.

Referral to the Commission

On 19 April 2021, the Commission accepted a referral 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 would affect trade within the single market and threatened 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.

By judgment of 13 July 2022, the General Court of the EU upheld the Commission's referral decisions of 19 April 2021, thereby confirming the Commission's jurisdiction to examine the impact of the transaction in the territories of Belgium, France, Greece, Iceland, the Netherlands, and Norway.

Interim measures, gun jumping proceedings and unbundling

On 18 August 2021, while the Commission's review was still ongoing, Illumina publicly announced that it had completed its acquisition of GRAIL. As a result, the Commission adopted interim measures on 29 October 2021 to restore and maintain the conditions of effective competition, under Article 8(5)(a) of the EU Merger Regulation, which are applicable for twelve months as of their notification to Illumina and GRAIL.

In parallel, the Commission opened an investigation on 20 August 2021 to assess whether Illumina breached the 'standstill obligation'. In this context, the Commission adopted a Statement of Objections on 19 July 2022, alleging that Illumina and GRAIL had breached the EU Merger Regulation by implementing the acquisition prior to obtaining the Commission's merger control approval. If the Commission were to conclude that Illumina and GRAIL did implement the transaction in breach of the EU Merger Regulation, it could impose a fine of up to 10% of each companies' annual worldwide turnover.

Where a concentration that is declared incompatible with the internal market has been already implemented, the Commission may order to dissolve the concentration or other appropriate measures, under Article 8(4) of the EU Merger Regulation. The Commission may also take interim measures appropriate to restore or maintain conditions of effective competition, under Article 8(5)(c) of the EU Merger Regulation. The Commission will assess in due course whether any such additional steps will be required.

Merger control rules and procedure

The transaction was notified to the Commission on 16 June 2021, and the Commission opened an in-depth investigation on 22 July 2021. Since then, the deadline of the procedure was suspended two times due to the failure of Illumina to provide the Commission with information requested in a timely manner.

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) or for which it acquired jurisdiction by virtue of referral from Member States (see Articles 4(5) and 22 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 the past ten years, the Commission has approved over 3 000 mergers. Today's prohibition is only the tenth merger that the Commission has blocked over the same period.

There are currently three ongoing Phase II merger investigations: the proposed acquisition of OMV Slovenija by MOL, the proposed acquisition of Pfleiderer Polska by Kronospan, and the proposed acquisition of VOO and Brutélé by Orange.

For more information

More information will be available on the Commission's competition website, in the Commission's public register under case number M.10188. Information on the interim measures is available under case number M.10493, and on the gun jumping proceedings under case number M.10483 .

IP/22/5364

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