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Illumina/Grail Prohibition: The End of the Beginning for EU Review of "Killer Acquisitions"?

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On September 6, 2022, the European Commission (Commission) announced that it had prohibited the acquisition by Illumina Inc., a U.S company supplying sequencing- and array-based solutions for genetic and genomic analysis, of Grail LLC, another U.S. company that develops blood tests for the early detection of cancers, under the EU Merger Regulation (EUMR). Grail has no revenues in the EU and the transaction did not meet the thresholds for mandatory notification under the EUMR or any Member State merger review law. The Commission's prohibition is unprecedented in several ways.

Illumina/Grail was the first case the Commission accepted for review (and the only one prohibited) under a policy **announced** on March 26, 2021 to allow the Commission to review competitively significant transactions that don't meet the EUMR's turnover-based thresholds. Under this policy, the Commission can review sub-threshold transactions at the request of one or more Member State competition authorities (NCAs) under Article 22 EUMR. This article, known as the "Dutch clause," was originally intended to allow Member States without merger review laws to request the Commission to review (presumably local) transactions. The Commission's exercise of jurisdiction over a foreign-to-foreign transaction with no nexus to any particular Member State was controversial; only four EU NCAs participated in the *Illumina/Grail* referral request, while at least seven reportedly expressed concerns and declined to join.

Illumina has already brought and lost several legal challenges, but it has vowed to keep fighting and to appeal the Commission's prohibition decision. Legal finality may thus be years away, but the Commission's prohibition decision, following a court victory in July, may energize the Commission and set the stage for it to take jurisdiction over other so-called "killer acquisitions."

Background: Article 22 EUMR and "Killer Acquisitions"

In September 2020, Executive Vice-President Margrethe Vestager gave a **speech** outlining the Commission's plan to publish a "full report" in early 2021 on the results of the Commission's 2016 **consultation** on procedural and jurisdictional aspects of EU merger control. In the 2016 consultation, the Commission proposed revising the EUMR by adding a transaction value-based threshold to capture high-value acquisitions of start-ups and small targets below the EUMR's turnover thresholds. This proposal followed another, informal consultation on the possible

extension of the EUMR to capture non-controlling investments. Both proposals were widely criticized, and the Commission did not pursue them.

Instead, in her September 2020 speech, Vestager announced that the Commission would adopt a new approach to encouraging Member State authorities to refer transactions below the EUMR thresholds for Commission review. Delivering on this promise in March 2021, the Commission published a **communication** on the application of the referral mechanism set out in Article 22 (the Article 22 Guidance)and an **evaluation** of the results of the 2016 consultation (the Staff Working Paper).

Article 22 EUMR allows Member States to request the Commission to examine mergers that do not meet the EUMR's turnover-based thresholds but affect trade between the Member States and threaten significantly to affect competition within the territory of the Member State or States making the request. Article 22 EUMR was drafted at a time when a number of Member States lacked their own merger review regimes and wanted to be able to call on the Commission for assistance to review (presumably local) transactions.

With the implementation of merger control regimes in almost all Member States, the Commission developed a practice of discouraging referral requests from Member States that did not have jurisdiction over the transaction in question, on the basis that such transactions were unlikely to have a significant impact on the EU internal market. According to the Commission, however, market developments have resulted in more transactions involving companies with a significant actual or potential competitive role even though they generate little or no turnover. The Commission noted particularly transactions in the digital economy; transactions in sectors, such as pharmaceuticals, where innovation is an important parameter of competition; and transactions involving companies with access to or impact on competitively valuable assets, such as raw materials, intellectual property rights, data or infrastructure.

The Staff Working Paper considered whether the EUMR's purely turnover-based jurisdictional thresholds for EU merger control exclude potentially problematic mergers, in particular, high-price transactions for targets having low turnover in the digital, pharma and other sectors. The paper concluded that the EUMR thresholds, complemented with the EUMR's referral mechanisms, have generally proved effective, and introducing a transaction-value-based threshold would not be appropriate since such values may not correlate with potential competitive significance. On the other hand, some transactions that could impact competition are not caught by the EUMR. The Commission concluded that its previous approach of discouraging referrals under Article 22 EUMR where the concentration falls outside the national merger control thresholds limited the effectiveness of referrals as a corrective mechanism.

Under Article 22 EUMR, Member States making a referral request must do so within 15 working days of the date on which the transaction is notified or otherwise "made known" to the Member State concerned. The Article 22 Guidance says that the "notion of 'made known' should be interpreted as implying sufficient information to make a preliminary assessment as to the existence of the criteria relevant for the assessment of the referral." Since what information will be sufficient may not be knowable in advance, the triggering event for an Article 22 EUMR referral timeline will often be unclear.

Once a referral request has been made, the Commission will inform Member State authorities and the parties without delay. Other Member States may join the initial request within 15 working

days. The Commission will have an additional 10 working days to decide whether to accept the referral, for a total of 40 working days (plus potentially several more days between the date the Commission receives the first referral request and the date on which it notifies other Member States). If the Commission does not take a decision within this period, it is deemed to have accepted the referral request.

Once the Commission informs the parties that a referral request has been made, the EUMR obligation to suspend implementation kicks in (unless and until the Commission decides not to accept the request). As a result, under Article 22 EUMR, the EUMR's suspensory obligation can arise long after the parties have determined where filings will be required, and there is no way for them to know whether or when the EUMR suspension requirement will arise.

The Article 22 Guidance noted that the Commission can examine a transaction under Article 22 EUMR even if it has already been closed, although the Commission will generally not do so more than six months after closing (or when "material facts" about the concentration have been made public in the EU, if later). The Commission said it would cooperate closely with NCAs to identify concentrations that may constitute potential candidates for referral and consider complaints from third parties.

The Illumina/Grail Case (So Far)

The referral. On September 20, 2020, Illumina entered into an agreement and plan of merger to acquire sole control of Grail. On December 7, 2020, the Commission received a complaint, which led to a number of exchanges between the Commission and the complainant, and reached a preliminary conclusion that the transaction could be the subject of a referral under Article 22 EUMR.

On February 19, 2021, the Commission informed the Member States of the transaction and explained why it considered that the concentration appeared to satisfy the conditions for referral. The Commission invited the Member States to submit a referral request, and the French NCA (the ACF) did so on March 9, 2020, thereby triggering the EUMR's standstill provision. The Belgian, Dutch and Greek NCAs (as well as Iceland and Norway) joined the French referral request later that month, and the Commission accepted the referral on April 19. The Commission considered the Article 22 EUMR deadlines to have been observed on the ground that the transaction had been "made known" to the ACF on February 19, 2021 by the Commission's letter, which contained the information needed for the ACF to carry out a preliminary assessment of the grounds for referral. Similarly, the other NCAs' requests to join the ACF's request met the EUMR deadlines because they were within 15 working days of the date (March 10) on which the Commission informed them of the request.

Illumina appealed on April 28, 2020, losing in the first instance in July 2022. Illumina argued, among other things, that the Commission could not accept a referral request from an NCA in jurisdictions where a merger review law exists but the referred transaction does not meet the thresholds for notification, since the Commission's interpretation was contrary to the EUMR"s "one-stop shop" principle and the principles of legal certainty, subsidiarity and proportionality. The General Court rejected these arguments based on its analysis of the literal, contextual, historical and teleological interpretations of Article 22 EUMR.

Illumina also argued that the ACF's referral request was made out of time and in any case infringed the principles of legal certainty and "good administration". Illumina argued that the Commission's view of when the Article 22 EUMR timelines begins to run would imply that a concentration should be notified de facto in all Member States, regardless of whether local law requires notification. Illumina noted that the transaction was the subject of a press release on September 21, 2020, a preliminary examination by the CMA in November and December 2020 and a "second request" by the U.S. Federal Trade Commission (the FTC) on November 9, 2020.

The General Court rejected this argument, concluding that "the concept of 'made known to the Member State concerned', as set out in the second subparagraph of Article 22(1) of that regulation, must be interpreted as meaning that it requires the relevant information to be actively transmitted to that Member State, enabling it to assess, in a preliminary manner, whether the conditions for a referral request under that article have been satisfied" (para. 211). By contrast, the General Court agreed with Illumina that the Commission's invitation letter was sent within an unreasonable period of time, considering that the complaint was received on December 7, 2020. Since the court concluded that the Commission's delay had not impaired Illumina's rights of defense, however, it declined to annul the Commission's decision accepting the referral requests on this basis.

Illumina plans to appeal the General Court's judgment, but the outcome of that appeal may not be known for years. For a more detailed discussion of the General Court's judgment, see here and here.

Gun-jumping and interim measures. While Illumina's challenge to the Commission's jurisdiction was pending, Illumina closed its acquisition of Grail on August 18, 2021. If the transaction had not closed before the "Outside Date" of September 20, 2021 (subject to extension until December 20, 2021 to obtain specified antitrust approvals (apparently not including EUMR approval), Illumina could have been required to pay a significant "Regulatory Termination Fee" (Sections 9.01 and 9.03 of the agreement and plan of merger).

The Commission announced on August 20, 2021 that it was opening a gun-jumping investigation and imposed interim measures in October 2021. However, the Commission held off pursuing its gun-jumping investigation pending the outcome of Illumina's jurisdictional challenge, sending a statement of objections (SO) only in July 2022. The Commission can be expected to adopt a decision imposing a significant fine for gun-jumping in the coming months – Illumina has set aside $453 million for such a fine. Such a large gun-jumping fine would be unprecedented; the current global record is the Commission's 2018 fine on Altice of EUR 124.5 million (reduced on appeal to EUR 118.2 million).

The Commission's interim measures required that Grail be kept separate from Illumina and run by an independent Hold Separate Manager; confidential business information not be shared except as required by law or in line with their supplier-customer relationship; Illumina finance additional funds necessary for Grail's operation and development; business interactions between the parties be undertaken at arm's length, in line with industry practice, without unduly favoring Grail to the detriment of its competitors; and Grail actively work on alternative options to the transaction. These measures seem to be inspired by conditions applicable to businesses that an acquirer is required to divest after closing under a conditional EUMR approval decision, but imposing these requirements as interim measures was unprecedented.

Prohibition decision. As mentioned, on September 6, 2022, the Commission adopted a decision prohibiting Illumina's acquisition of Grail. Assuming that Illumina does not voluntarily sell Grail, the Commission may commence proceedings under Article 8(4) EUMR to order it to divest Grail. Such a procedure would be highly unusual and likely trigger another round of court challenges.

Although the full public version has not been published, the Commission's press release describes it in considerable detail. The Commission found that the transaction would give Illumina the ability and incentive to foreclose competition by Grail's rivals, for instance by refusing to supply its next-gen sequencing (NGS) systems to rivals (and/or increasing prices, degrading quality or delaying supplies).

The Commission found that Grail and its rivals are engaged in an innovation race to develop and commercialize early cancer detection tests. Illumina could foreclose this innovation competition because Grail's rivals rely on Illumina's NGS systems to develop and run their tests. There are no credible alternatives in the short to medium term, and the barriers to entry are significant. Moreover, switching NGS provider would be a long and costly process. According to the Commission, Illumina would have clear incentives to foreclose Grail's rivals even though Illumina's sales of NGS technology to those rivals represents a small proportion of Illumina's sales and profits, NGS-based early cancer detection testing is expected to expand rapidly and to become highly lucrative (reaching more than EUR 40 billion per annum by 2035). Given the market potential and close innovation competition, the Commission considered that Illumina would have an immediate incentive to foreclose GRAIL's rivals, even if it would only realize benefits at a later stage.

The Commission rejected the remedies Illumina offered to address the Commission's competition concerns. Illumina offered a licence to NGS suppliers to some of Illumina's NGS patents, and a commitment to stop patent lawsuits in the U.S. and Europe against the NGS supplier BGI Genomics (China) for three years to reduce IP-related barriers to entry. But the Commission received negative feedback from its market test and found that these commitments would not have ensured the emergence of a credible alternative to Illumina in the short to medium term. Among other things, the covered patents were due to expire in the short term, and Illumina has many other patents that competitors would need to develop an alternative NGS system. Even if alternative NGS systems emerged, switching provider would be a long and costly process without a guarantee of success.

Illumina also offered a commitment to conclude agreements with Grail's rivals based on a standard contract until 2033. But the Commission found that the commitment did not address all the possible foreclosure strategies, such as degrading the technical support to Grail rivals for Illumina's NGS systems. The Commission also found that the proposed commitments would be difficult to monitor and easy for Illumina to circumvent.

For the Commission to prohibit a vertical merger is highly unusual, especially based on a relatively untested "innovation competition" theory of harm. The most complete expositions of innovation competition theories come from Dow/DuPont and Bayer/Monsanto in 2017 and 2018, respectively, but those were horizontal transactions approved subject to conditions. The time period the Commission relies on to support its analysis of Illumina's incentive to discriminate against Grail's rivals – through 2035 – is also unusually long. On appeal, Illumina will likely argue (among other

things) that the Commission's findings are speculative and that it failed to meet its burden of proof.

The remedies the Commission rejected in this case are similar to remedies it has accepted in previous vertical mergers. In the U.S., a federal administrative judge recently ruled against the FTC's challenge to the transaction on the ground that the remedies Illumina offered addressed the antitrust concerns. Illumina will also likely argue that the Commission should have accepted its proposed remedies, though (assuming they agree that the Commission has satisfied its obligation to show that the transaction would lead to a significant impediment to effective competition) it is unclear whether the EU courts would override the Commission's assessment of those remedies' effectiveness.

Main Takeaways

Illumina/Grail has broken new ground in many ways: it is the first case accepted under the Commission's new approach to "killer acquisitions", the first EUMR case subjected to interim measures, the first vertical merger prohibited on an innovation competition theory of harm; and (potentially) a record gun-jumping fine. *Illumina/Grail* may soon generate more firsts, with Illumina appealing a potential divestiture order under Article 8(4) EUMR. With multiple appeals promised or under way, this transaction will likely create new law for years to come.

Meanwhile, however, some important implications from the transaction are already clear. First, the Commission's confidence in its approach to Article 22 EUMR referrals will be reinforced by the General Court's decision and its conclusion that both cases so-far reviewed (*Illumina/Grail* and *Facebook/Kustomer*) raised serious antitrust issues. Although Article 22 EUMR referrals will no doubt remain relatively rare, more such cases are likely, and formerly skeptical NCAs may become more favorable.

Second, the *Illumina/Grail* prohibition decision will further concentrate the minds of parties to sub-EUMR threshold transactions and their counsel. Since publication of the Article 22 Guidance, the documentation of transactions not triggering EUMR thresholds have had to address the possibility of an EU suspensory obligation arising due to an Article 22 EUMR referral request. But the *Illumina/Grail* prohibition raises the stakes, especially for transactions in sensitive sectors. Transaction parties will need to weigh the risk of a referral request and consider how best to avoid unpleasant surprises in light of the General Court's holding on when the Article 22 EUMR timeline starts to run. One possibility could be proactively briefing the Commission, although such a briefing could potentially trigger a referral request in a transaction that would otherwise have gone unchallenged.

Third, to judge by the amount Illumina has reserved in its financial statements, the Commission's expected gun-jumping fine may set a new global record. Given the exceptional circumstances of the case, however, it may remain an outlier.

Fourth, the prohibition underscores the importance the Commission attaches to innovation competition and perhaps growing skepticism over the effectiveness of behavioral remedies like non-discrimination commitments. On the other hand, the Commission's theory of harm in *Illumina/Grail* is relatively untested. Assuming the planned appeal goes ahead, guidance from future European court judgments will be very welcome.

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