February 2024

OCTOBER – DECEMBER 2023: KEY THEMES AND TAKEAWAYS

UNITED STATES

- **New Merger Guidelines Released**

  The US Federal Trade Commission (FTC) and US Department of Justice Antitrust Division (DOJ) issued their updated Merger Guidelines on December 18, 2023. The new guidelines include several potential enforcement theories from the prior guidelines but also introduce new concepts not addressed in prior versions. A theme of the new guidelines is increased scrutiny on a variety of different transaction types, including (1) mergers between close competitors, even if the parties compete in a broad market, (2) mergers involving a potential entrant, (3) transactions in industries that have experienced or are experiencing significant consolidation, and (4) vertical transactions. The Merger Guidelines are not the law, but they do signal a focus on an enforcement-oriented approach consistent with trends seen lately. A more detailed assessment is available here.

- **FTC Focused on Pharmaceutical Companies**

  The FTC continues to closely scrutinize pharmaceutical transactions, including exclusive licenses. For example, on December 11, 2023, the FTC issued an administrative complaint and sought a preliminary injunction to block Sanofi's proposed exclusive licensing

agreement involving Maze Therapeutics' pipeline Pompe disease treatment. Sanofi currently offers the only first line therapy for Pompe disease. Maze's Phase 2-ready developmental drug would introduce a new method of treatment, as it can be distributed orally instead of through biweekly infusions. Maze and Sanofi entered into an agreement whereby Sanofi would obtain an exclusive license to Maze's drug and Sanofi would help fund the costs of development and use its resources and expertise to advance the treatment. The FTC alleged that the deal would eliminate Maze as a nascent competitor and allow Sanofi to maintain its monopoly, preventing consumers from reaping the benefits of innovation and price cuts.

Pfizer, in contrast, secured FTC clearance to purchase cancer drugmaker Seagen for $43 billion, but only after a second request and agreeing to donate all US royalties for Bavencio, a bladder-cancer treatment, to the American Association for Cancer Research. The FTC did not require a consent decree, but Pfizer publicly stated it would donate Bavencio royalties to address FTC concerns.

In addition to the continued skepticism of pharmaceutical deals, the FTC also issued a policy statement warning that the improper listing of patents of branded drugs in the FDA's catalog of "Approved Drug Products with Therapeutic Equivalence Evaluations," more commonly known as the "Orange Book," could trigger legal action under Section 5 of the FTC Act for unfair methods of competition. Manufacturers seeking approval for a generic drug must certify that the generic does not violate an Orange Book patent or that the listed Orange Book patent is invalid or will not be infringed by the generic drug. Drugs listed in the Orange Book can be entitled to an automatic 30-month stay on approval while companies litigate a generic drug's potential patent infringement. The FTC policy statement suggests this can be exploited to deter or delay generic products from entering the market and inflate drug prices for consumers. Since the policy statement was published, the FTC has issued challenges to more than 100 patents in the Orange Book, notifying pharmaceutical companies via letter that they have 30 days to withdraw, amend, or certify under penalty of perjury that the identified patents are proper.

- **FTC Targets "Moat-Building" Mergers**

  Several recent FTC merger challenges have focused on Guideline 5 of the new Merger Guidelines, stating "mergers can violate the law when they create a firm that may limit access to products or services that its rivals use to compete." Complaints in several recent cases have alleged the combined firm would have the "ability and incentive" to control inputs, products or services used by competitors, creating barriers to entry or competition. The FTC recently challenged Intercontinental Exchange Inc's acquisition of Black Knight Inc., raising concerns about the "ability and incentive" of the combined firm to impede third-party loan service providers' access to its loan-origination systems. Similar allegations were brought in seeking to block IQVIA Holding Inc.'s acquisition of Propel Media Inc. There,

the complaint alleged that the combined firm would have the "ability and incentive" to disadvantage current and/or emerging rivals through IQVIA's control of leading data inputs such as healthcare professionals' identities and prescribing data. Likewise, in challenging Amgen Inc.'s acquisition of Horizon Therapeutics plc., the FTC cited concerns that Amgen would have the "ability and incentive" to condition rebates for its broad product portfolio on its customers refusing to include competing products on their formularies. Finally, the FTC's ongoing challenge to Microsoft's acquisition of Activision Blizzard Inc., on appeal and before an administrative law judge, also focuses on Microsoft's "ability and increased incentive" to control Activision's video game titles in a way that could disadvantage competitors to Microsoft's Xbox gaming console. While the FTC has not relied solely on Guideline 5 in forming the allegations in these complaints, there is a clear focus on these foreclosure theories.

- **Fifth Circuit Fuels FTC's Vertical Mergers Agenda**

  On December 15, 2023, the US Court of Appeals for the Fifth Circuit issued its decision in the *Illumina/GRAIL* case. The court sided with the FTC that it had reason to find anticompetitive harm from the proposed deal, but also noted the FTC had committed "legal error" in treating Illumina's proposed fix – an "open offer" made available to everyone in the industry – as a remedy. The Fifth Circuit directed the lower court to evaluate whether the "open offer" would address the FTC's foreclosure concerns. Due primarily to a European Commission ruling, Illumina has announced it will divest GRAIL. The decision will no doubt embolden the agency's efforts to combat vertical mergers. Indeed, the FTC's final Merger Guidelines were published shortly after this decision and reflect a heightened focus on vertical mergers, even quoting from the *Illumina/Grail* decision. Still, the agencies are finding resistance in the courts, particularly for the idea that a vertical remedy to address anticompetitive harms of a merger must maintain the same level of competition as pre-merger. Federal judges have reiterated that the Clayton Act only blocks mergers that "substantially" threaten competition.

- **FTC Losing Streak Reverses During the Fourth Quarter**

  The FTC won two major merger challenges in court, *Illumina/GRAIL* and *IQVIA/Propel*, and in a third transaction, *Sanofi/Maze*, the parties abandoned the transaction shortly after the FTC filed a complaint. (The DOJ also prevailed in its challenge in *JetBlue/Spirit*, but the actual decision was published in January 2024, which we will address in more detail in the next quarterly snapshot). At a high level, all three challenges involved very strong facts for the FTC. *IQVIA/Propel* involved a three-to-two merger, and *Sanofi/Maze* involved a monopolist purchasing essentially the only competitor developing a drug that would compete against the monopolist's own product. Although the *Illumina/GRAIL* Fifth Circuit decision was the first vertical merger challenge that the FTC or DOJ has won in decades, it

involved a monopolist purchasing the only test kit on the market today. Therefore, the FTC had strong arguments that competitors developing competing test kits may be foreclosed from access/interoperability with Illumina's equipment.

EUROPEAN UNION

- ***Ex post* Review in the Merger Control Sphere Occurring More and More Frequently**

  Although traditionally the EU merger control system is an *ex ante* system, 2023 marked a notable increase in *ex post* investigations by competition authorities, meaning that regulators can investigate and challenge consummated transactions. In practice, this will result in businesses having to face increased scrutiny of their transactions where these could previously fly under the radar or even where such transactions were not notifiable. Enforcers – the European Commission (Commission) as well as national competition authorities – are taking more interest in transactions that are below filing thresholds but are of competitive significance (including so-called "killer acquisitions"). Two important contributors to this trend in 2023, with likely profound effects in 2024, are the *Towercast* and *Illumina/GRAIL* cases.

  Towercast involved a transaction that escaped review under the European Merger Regulation (EUMR) or French merger-control rules, as it did not meet the *ex ante* EU/national merger control thresholds and was not referred to the Commission under Article 22 EUMR. The European Court of Justice (ECJ) ruled that non-notifiable concentrations can be reviewed by EU member states' competition authorities and their courts as a possible abuse under Article 102 Treaty for the Functioning of the European Union (TFEU). The assessment involves determining whether a dominant undertaking substantially impedes competition in the market in which it is (or has become) dominant as a result of acquiring another undertaking. Almost immediately following this judgment, the Belgian competition authority became the first national competition authority to open an *ex officio ex post* investigation of the incumbent Belgian telecom operator Proximus's takeover of the assets of fixed-internet provider EDPnet. The investigation was abandoned following Proximus's divestiture of EDPnet to another telecom operator.

  Illumina/GRAIL entails an unprecedented restorative request from the Commission for Illumina to unwind its already completed transaction with GRAIL. It involved a below-threshold transaction that was referred to the Commission by several EU member states due to its competitive significance (evidenced by its deal value of USD 7.1 billion). Illumina unlawfully closed the transaction while the Commission was reviewing and the Commission subsequently blocked the transaction for vertical concerns. In the summer of 2023, the Commission imposed the largest-ever gun-jumping fine as well as the first-ever fine on a target company.

Both cases illustrate significant risks and ambiguities for companies wishing to engage in M&A transactions that may not be reportable in a particular jurisdiction. It also provides competitors opportunities to challenge non-reportable transactions in light of the increasing use of the referral mechanism for non-notifiable concentrations. Parties to transactions that are not notifiable on the EU or national level can no longer be certain that such transactions will not be reviewed.

It is clear that this trend will affect the technology and artificial intelligence (AI) industries, in particular. In this context, the German competition authority (*Bundeskartellamt*) recently examined whether Microsoft's investment in OpenAI required a notification under the merger-control regime in Germany, but ultimately decided it was not reportable. At the time of Microsoft's initial investment in 2019, the regulator determined that Microsoft had indeed gained a material competitive influence. However, at that time OpenAI did not have any substantial operations in Germany as to trigger a notification. The *Bundeskartellamt* also clarified that any increased influence over OpenAI on Microsoft's part would trigger a re-examination of such notification obligation, and that these findings were no guarantee that the cooperation is compliant with horizontal competition rules. Both the Commission and the UK Competition and Markets Authority (CMA) have announced that they are also reviewing whether this investment was reportable under, respectively, the EUMR and UK merger control. The Commission launched a call for contributions on January 9, 2024, regarding competition in virtual worlds and generative AI, while the CMA has just closed its invitation to comment on January 3, 2024, in advance of its formal investigation starting.

ENFORCEMENT IN KEY INDUSTRIES[1]

Healthcare, Pharmaceuticals & Biotechnology

Technology, Media & Communications

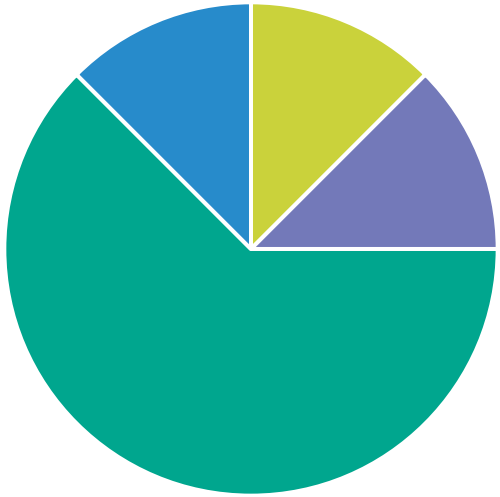
Retail & Consumer Productions

Chemicals & Industrial Prods. or Services

Transportation & Energy

Other

United States



Europe & the UK

[1] For the United States, the graphs include cases we are aware of in which an antitrust enforcement agency issued a second request at some point and the investigation remained ongoing during the quarter, the agencies accepted a consent order or issued a complaint initiating litigation against the transaction, or the transaction was abandoned after an antitrust investigation. For Europe and the United Kingdom, the graphs include cases where an antitrust enforcement agency issued a Phase II process or a clearance decision, or challenged the transactions, or the transaction was abandoned after an antitrust investigation.

Notable US Cases

PARTIES	AGENCY	CASE TYPE (CLEARED; CONSENT; CHALLENGED; ABANDONED)	MARKETS / STRUCTURE (AS AGENCY ALLEGED)	SUMMARY & OBSERVATIONS
IQVIA Holdings Inc. (IQVIA) / Propel Media Inc. (PMI)	FTC	Challenged and abandoned following court injunction	Programmatic advertising for healthcare products, namely prescription drugs, to doctors and other healthcare professionals. FTC alleges the merging parties are two of the top three providers.	On July 17, 2023, the FTC filed a complaint and sought a temporary restraining order and preliminary injunction in federal court seeking to block IQVIA Holdings Inc.'s (IQVIA) acquisition of Propel Media Inc (PMI). The complaint alleged that IQVIA's Lasso Marketing and PMI's DeepIntent make up two of the three largest providers of programmatic advertising, known as demand-side platforms (DSPs), that specifically targets healthcare professionals with advertising for healthcare products, namely pharmaceutical drugs. The FTC alleged that healthcare DSPs operate in a distinct market from other DSPs because they exclusively serve the healthcare industry and possess unique characteristics and capabilities to serve healthcare advertising clients. The FTC alleged that the acquisition would eliminate head-to-head competition between Lasso and DeepIntent, leading to increased prices, reduced quality and diminished innovation. The FTC also alleged that the combined firm would have the "ability and incentive" to disadvantage current and/or emerging rivals by leveraging its data post transaction. The complaint notes that IQVIA controls online information for healthcare professionals' "identity data" and prescription and claims data "prescribing data" that make up key inputs for healthcare programmatic advertising relied on by competing healthcare DSPs. An evidentiary hearing took place in the US District Court for the Southern District of New York from late November through December 2023. On December 29, 2023, Judge Edgardo Ramos granted a preliminary injunction pending the FTC's administrative proceeding to block the transaction related to the horizontal issues. Judge Ramos did not rule on the vertical issues. The parties subsequently abandoned the transaction.

PARTIES	AGENCY	CASE TYPE (CLEARED; CONSENT; CHALLENGED; ABANDONED)	MARKETS / STRUCTURE (AS AGENCY ALLEGED)	SUMMARY & OBSERVATIONS
JetBlue Airways / Spirit Airlines	DOJ	Challenged and enjoined	Two of the largest "ultra-low cost" scheduled air passenger service providers	The trial to determine the fate of the JetBlue Airways and Spirit Airlines merger, which began on October 31, 2023, had its closing arguments on December 5, 2023. In March 2023, the DOJ initially filed suit to block the acquisition, alleging that Sprit Airlines is a maverick in the industry that forces other airlines to reduce prices. According to the DOJ, JetBlue's acquisition would remove Sprit Airlines as a threat and lead to higher consumer prices, particularly in areas where its routes compete head-to-head with JetBlue. DOJ also expressed concerns with the potential post-merger service offerings because Spirit Airline's current business model gives customers the option to pick unbundled fares and pay for add-ons (such as a carry-on bag). JetBlue contends that in the post-COVID environment its acquisition of Spirit Airlines would allow it to better compete with the four major airlines in the United States that together control 80% of the market. JetBlue also emphasized that it has already offered to divest gates at Fort Lauderdale, Boston, Newark and New York to address antitrust concerns. Thus, this represents another example of litigating the fix. In January 2024, the judge presiding over the case granted the DOJ's injunction, and JetBlue is now appealing that decision.

PARTIES	AGENCY	CASE TYPE (CLEARED; CONSENT; CHALLENGED; ABANDONED)	MARKETS / STRUCTURE (AS AGENCY ALLEGED)	SUMMARY & OBSERVATIONS
Sanofi / Maze Therapeutics Inc.	FTC	Challenged and abandoned	Pompe disease pharmaceutical treatments	On December 11, 2023, the FTC filed an administrative complaint to block Sanofi's proposed licensing agreement with Maze Therapeutics relating to Pompe disease, a rare genetic disorder. The FTC alleged that the only viable treatment for the disease is enzyme replacement therapy (ERT), which consists of biweekly infusions of enzymes. The FTC alleged that Sanofi currently holds a monopoly in the treatment of Pompe disease through ERT. Maze Therapeutics is developing an alternative treatment to Pompe disease. If approved, Maze's drug would be less burdensome for patients as it can be administered orally rather than through infusions. Sanofi entered into an agreement with Maze whereby it would acquire an exclusive global license to Maze's technology, including its developing treatment for Pompe disease. In return, Sanofi would pay $130 million in cash, $20 million in equity investments once Maze completed its initial public offering, up to $605 million in contingent development and commercialization payments, and royalties on future sales of licensed products. The FTC alleged that this licensing agreement would eliminate Maze as a nascent competitor, reducing innovation and keeping costs high. Sanofi abandoned the agreement the same day the complaint was filed.

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Illumina Inc. / GRAIL Inc.	FTC	Challenged and divested	Research, development and commercialization of MCED tests	The FTC first issued a complaint to block Illumina's proposed acquisition of GRAIL in March 2021. GRAIL is a biotechnology company that produces multi-cancer early detection (MCED) tests. Illumina is a provider of DNA sequencing. MCED tests rely on next-generation sequencing (NGS) platforms to analyze blood samples drawn for MCED tests. Illumina is the dominant supplier of NGS platforms. The FTC alleged that the vertical deal would stifle competition for MCED tests and reduce innovation because Illumina would have the ability and incentive to foreclose competitors to GRAIL in the MCED market. To assuage antitrust concerns, Illumina announced it would make available a standardized supply contract (the open offer) to all US customers. The contract would provide its NGS platforms for the same price and with the same access as provided to GRAIL. In September 2022, an administrative law judge ruled that the FTC had failed to prove that the merger was likely to cause a substantial lessening of competition. In April 2023, the FTC voted 4-0 to reverse the ALJ's dismissal and ordered Illumina to divest. Illumina petitioned the Fifth Circuit to review the FTC's order. The Fifth Circuit heard arguments in September 2023. In December 2023, the Fifth Circuit ruled that there was substantial evidence to support the FTC's ruling that the deal would lessen competition. At the same time, the FTC improperly treated Illumina's proposed fix as a remedy, and thus the Fifth Circuit vacated and remanded the case for further proceedings where the open 0ffer would be considered in determining whether the transaction, in light of that offer, was likely to substantially lessen competition. Thereafter, Illumina announced it would divest GRAIL.

Notable European & UK Cases

PARTIES	AGENCY	CASE TYPE (CLEARED; CHALLENGED; ABANDONED)	MARKETS / STRUCTURE (AS AGENCY ALLEGED)	SUMMARY & OBSERVATIONS
Hitachi Rail / Thales GTS	EC / CMA	Conditional clearance	Providers of interlockings and automated train protection wayside systems (overlay and resignaling), Hitachi is also a manufacturer and provider of rolling stock for mainline and urban trains.	On, respectively, October 30, 2023, and December 7, 2023, the European Commission and the CMA cleared the acquisition of Thales by Hitachi Rail, subject to conditions. Hitachi Rail is a wholly owned subsidiary of Hitachi Ltd and a global provider of transport solutions, including rolling stock, signaling systems, turnkey solutions, maintenance services and components, in the European Economic Area and the UK. Thales GTS offers various solutions across four core business lines: (1) mainline signaling, (2) urban rail signaling, (3) integrated communication and supervision solutions, and (4) revenue-collection systems in the European Economic Area and the UK. Based on its separate investigations, the Commission and the CMA found that the transaction raised serious competition concerns, as it would have reduced competition and led to higher prices and less innovation in the markets for rail mainline signaling projects in, respectively, France and Germany, and in the UK. In these markets, the transaction would have combined two close competitors and the merged entity would have acquired very high market shares. As a result, Hitachi Rail committed to divest its mainline signaling platforms in France and Germany, and its interlockings, overlay and resignaling projects in the UK.
Siemens AG / Chargeco Topholding B.V. (Heliox)	CMA	Found not to qualify decision	Providers of chargers for electric passenger buses and electric heavy goods vehicles	On December 1, 2023, the CMA decided not to investigate the anticipated acquisition of Heliox by Siemens as the turnover test of the Enterprise Act 2002 was not met. The CMA considered various descriptions of the supply of goods in respect of which the parties overlap in the UK, as well as various measures of share of supply, and requested relevant information from customers and competitors of the parties. This analysis and testing found that the share of supply test was not met.

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