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ABA Section of Antitrust Law

Healthcare & Pharmaceuticals Committee

Recent Developments, Q2 2023

July 19, 2023

Today's Speakers

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Agenda

1. **European Updates**
   - New EU rules and guidelines on competitor collaborations
   - Disparagement of a rival as an antitrust offense
   - A record $ 510 million EU gun-jumping fine
2. **Updates from the FTC**
   - Commissioners Nominated / New Competition Bureau Director
   - FTC Walks Away from Health Care Guidelines
   - PBM Investigation
3. **U.S. Merger Enforcement**
   - Significant Proposed Changes to HSR Notification and Report Form
   - TODAY – Proposed Merger Guidelines Released
   - Pharmaceutical Merger Analysis Workshop readout
   - FTC Pursuing “Cross Market Bundling” Theory in Amgen / Horizon
   - FTC Sues to Block IQVIA’s acquisition of Propel Media
4. **U.S. Non-Merger Case Developments**
   - FTC Weighs in with Amicus Briefs on exclusive dealing, exclusion and reverse payment burdens of proof
   - Gilead, Teva Defeat $3.6 Billion Reverse Payment HIV Drug Antitrust Case at Trial

European Updates

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New EU ”Horizontals” Package

Update of 2010 package

In force: July 1, 2023 – June 30, 2035

Revised Horizontal Block Exemption Regulations (HBERs)

- R&D Agreements (Reg. 2023/1066)
- Specialization Agreements (Reg. 2023/1067)
- Safe harbours, hard-core restraints, withdrawal of exemptions

Revised Horizontal Guidelines

- Application of the HBERs
- Analysis of R&D and Specialization arrangements beyond the HBERs
- Analysis of other forms of competitor collaboration
  - Purchasing
  - Commercialization
  - Information exchange
  - Standard terms for purchase or sale
  - Sustainability

Framework of Assessment

Prohibited?

- Restrictive as per Article 101(1) TFEU ?

Block exempted?

- Satisfies specific criteria in
  - R&D BER?
  - Specialization BER?
  - Other BER?

If not, individually exempted?

- Permitted as per Article 101(3) TFEU
  - Efficiency gains?
  - Restrictions indispensable?
  - Fair share to consumers?
  - Not eliminate substantially competition

Assessment of R&D Agreements (Art 101(1))

Restrictive by ”object”

- Main purpose is not R&D, but an instrument of cartelisation
- Use R&D cooperation to
  - Prevent or delay entry
  - Coordinate outside R&D agreement
  - Limit potential of joint development when commercialized individually

Normally not restrictive

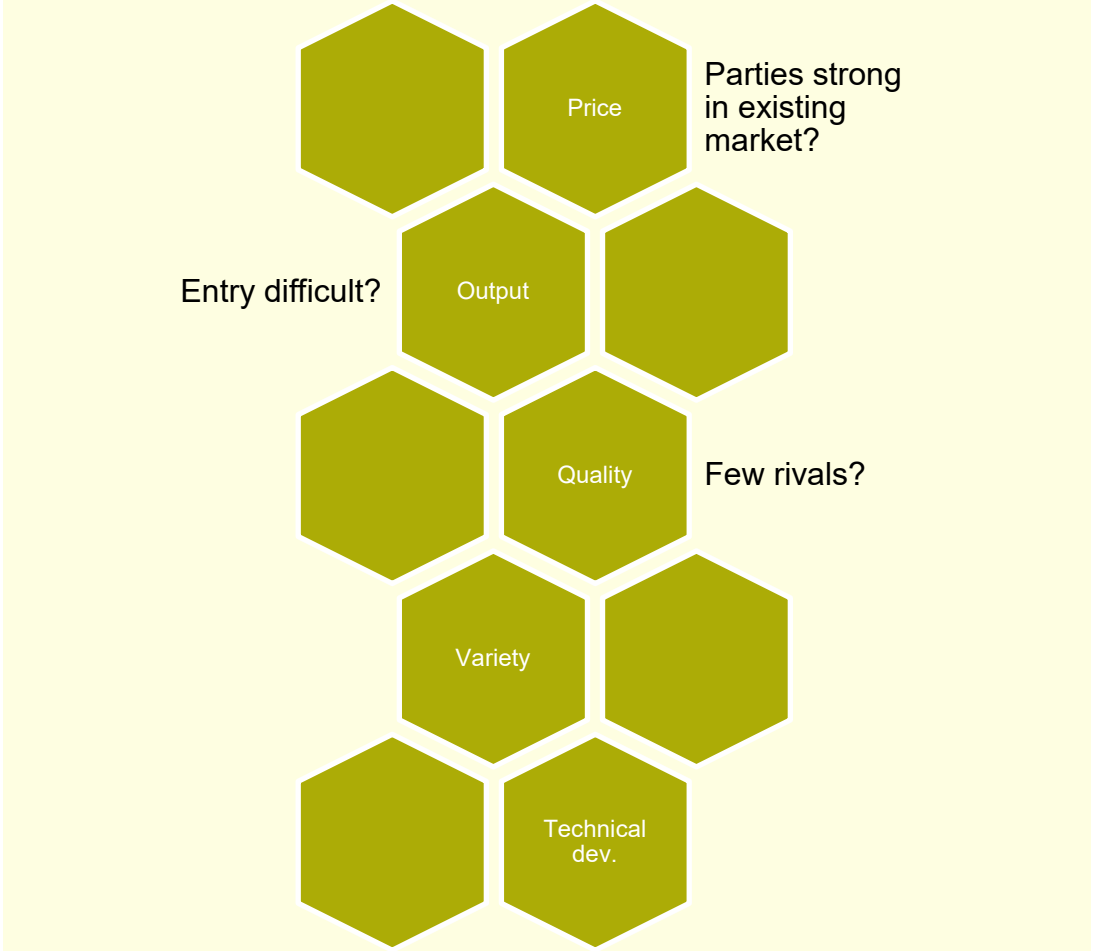
- Analyse affected existing markets and innovation
- Parties with complementary skills
- Not-competitors
- Outsourcing of captive R&D to e.g. CROs
- R&D absent joint exploitation rarely a concern, but can be if innovation is reduced

Restrictive effects?

- Concentration at innovation, technology, and product levels are considered
- Safe harbours
  - <25% on product- or technology market
  - 1+3(+) competing R&D efforts
- Additional factors next slide …

Potential Effects for R&D (Art 101(1))

Improvement of existing products/ technologies



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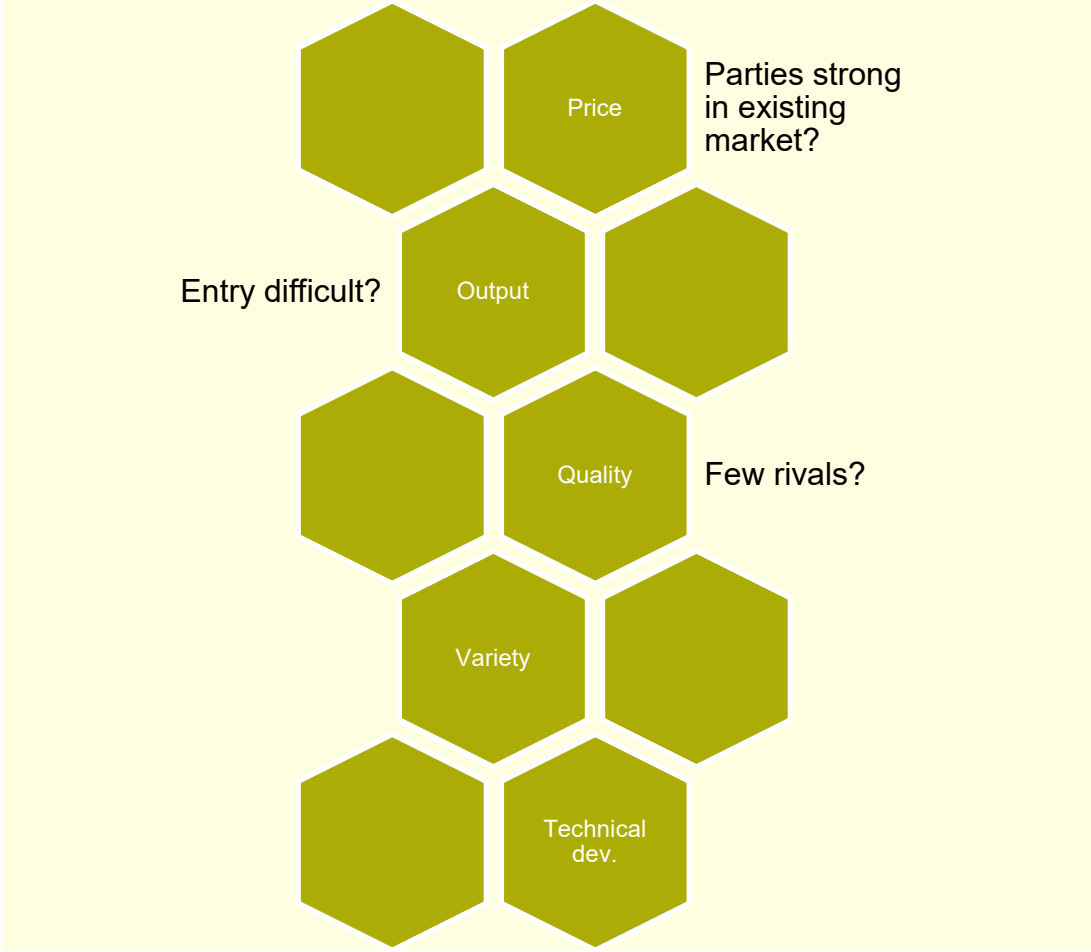
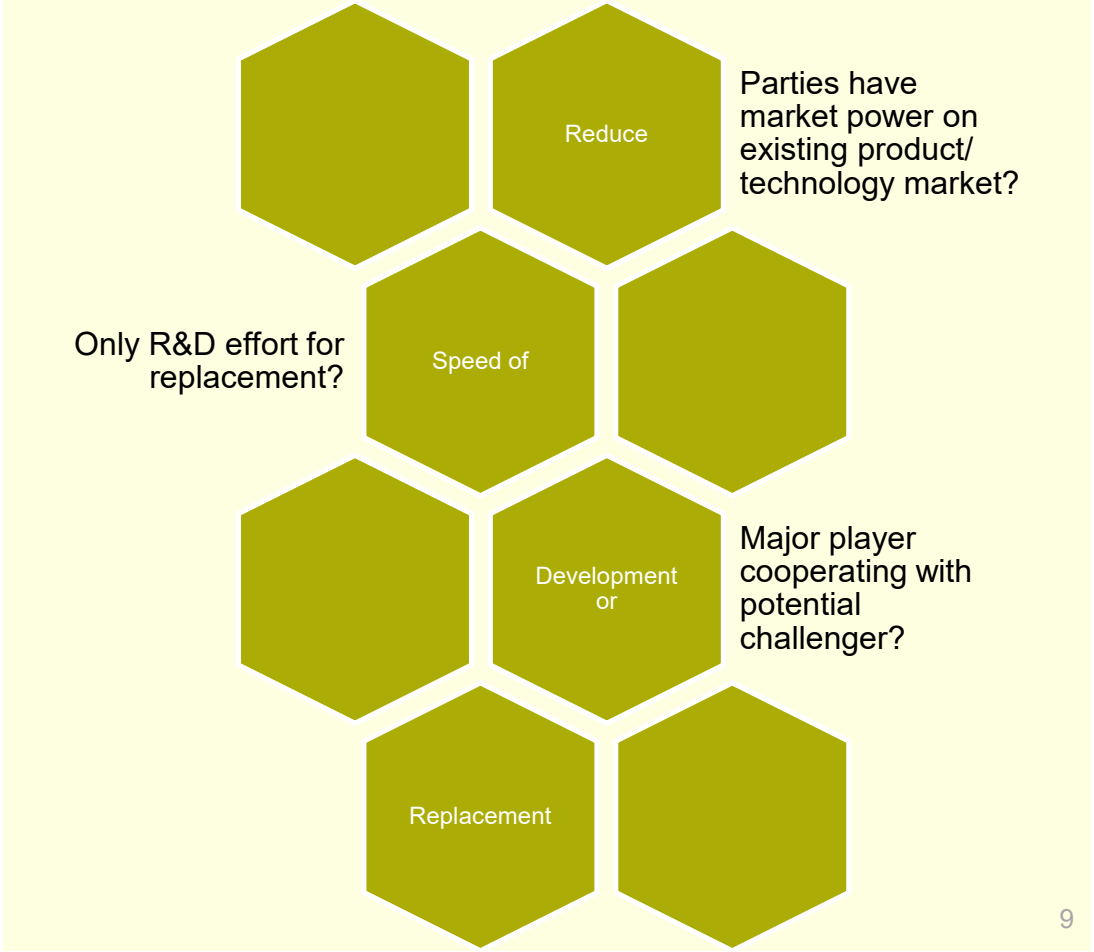


Substitution or replacement of existing products/ technologies



Abuse of Dominance (Art 102): Disparagement

Belgium's Competition Authority fined Novartis €2.8m (ABC-2023-P/K-02)

- Novartis markets Lucentis (*ranibizumab*), a Genentec-developed wet age-related macular degeneration (wet AMD) treatment
- Roche markets Avastin (*bevacizumab*), a Genentec-developed cancer block buster, used off label in wet AMD
- Novartis and Roche were found to hold a "collective" dominant position
- Novartis found to have abused that position since

> It established that Novartis, producer of Lucentis, continued to warn ophthalmologists, hospitals and regulator about the risks of an off label use of Avastin even after the publication of studies that no longer allowed to do so without qualification or reference to the scientific uncertainty created by these studies. It therefor considered these communications to be misleading the light of the case law of the Court of Justice of the European Union.

Explicit or Tacit Collusion?

Cartel agreement (2014)
Fines: Roche €90m, Novartis €92m
Upheld on appeal

"dissemination, in a context of scientific uncertainty, to
the EMA, healthcare professionals and the general public of
misleading [safety] information [concerning off-label use],
with a view to reducing the competitive pressure resulting from [off-label use],
constitutes a restriction of competition 'by object' for the purposes of [Article 101 TFEU]"
F. Hoffmann-La Roche Ltd v AGCM (Case C-179/16) ECLI:EU:C:2018:25, para. 95

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Cartel agreement (2022)
Fines: Roche €12.5m; Novartis €18.5m
Dismissed on appeal (2022)
- No evidence of collusion

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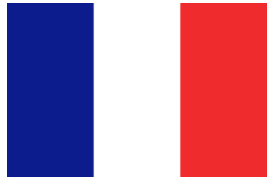


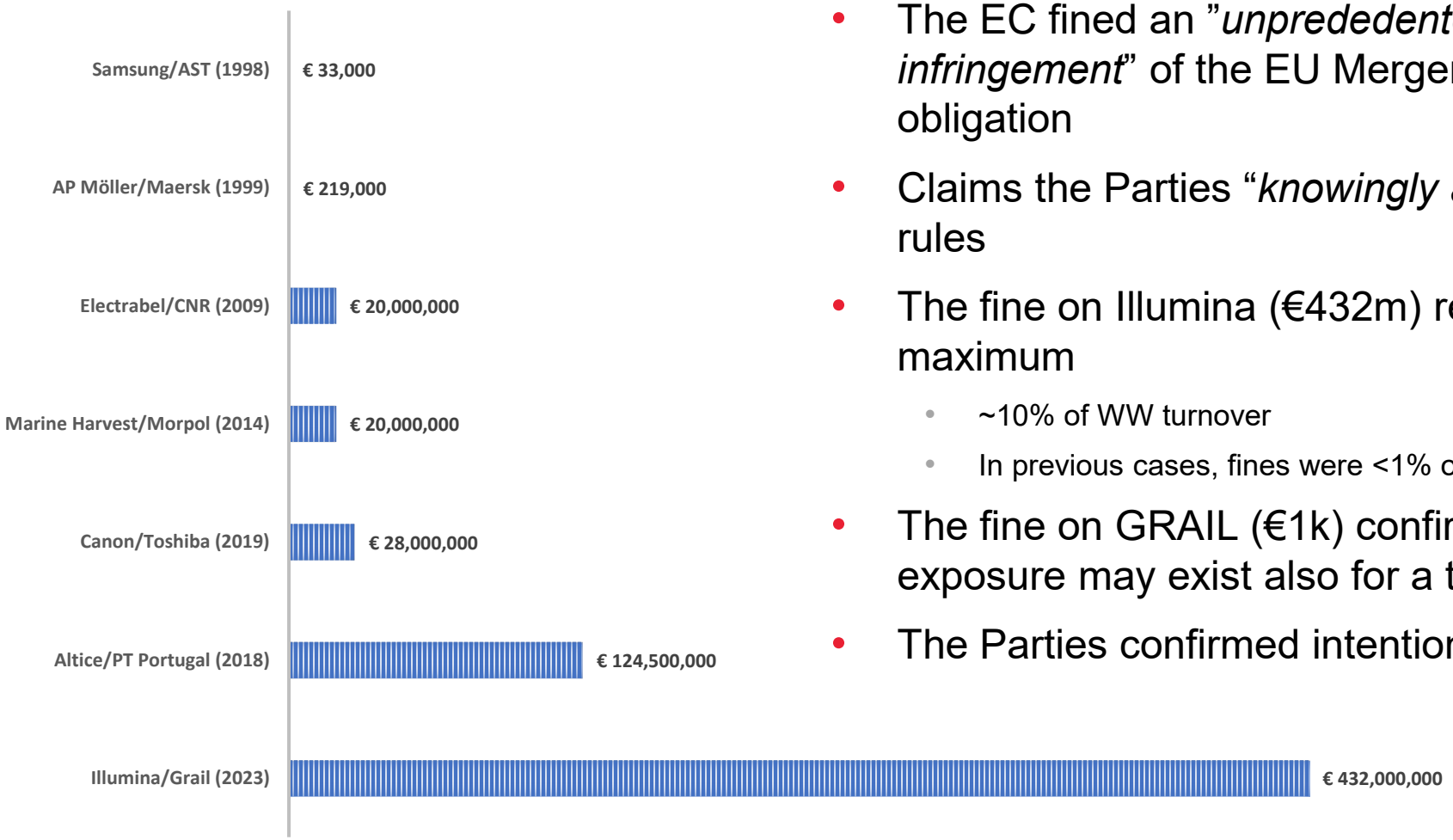
Abuse of collective dominance (2022)
Fines: Roche/Genentech €59.7m, Novartis €385.1m
Dismissed on appeal (2023)
- Dominant firms have freedom of speech, fully entitled to defend interests, but must compete on the merits
- Statements reflected accurate knowledge at the time

Further appeal pending

Two Active EC Investigations (Art 102)

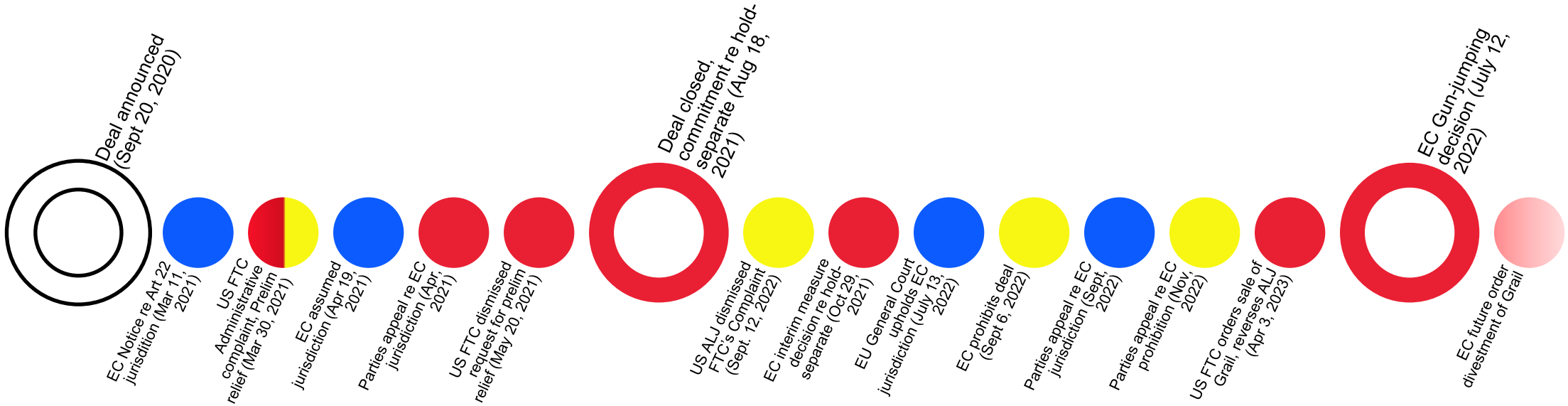
- **TEVA**: Copaxone (*glatiramer acetate*), used in the treatment of relapsing forms of multiple sclerosis
  - Investigated conduct: an alleged (unilateral) disparagement campaign targeted at healthcare professionals to cast doubts about the safety and efficacy of rival *glatiramer acetate* medicines and their therapeutic equivalence with Copaxone
- **Vifor**: Ferinject (*ferric carboxymaltose*), used the treatment of iron deficiency and iron deficiency anaemia
  - Investigated conduct: an alleged (unilateral) misleading communication campaign, primarily targeting healthcare professionals, which may have unduly hindered a rival's uptake in the European Economic Area

EUMR: Record-Breaking Gun-Jumping Fines



- The EC fined an "*unprededented and very serious infringement*" of the EU Merger Regulation's 'standstill' obligation
- Claims the Parties "*knowingly and intentionally*" broke the rules
- The fine on Illumina (€432m) reached the statutory maximum
  - ~10% of WW turnover
  - In previous cases, fines were <1% of WW turnover
- The fine on GRAIL (€1k) confirms, for the first time, that exposure may exist also for a target
- The Parties confirmed intentions to appeal

Summary of *Illumina/Grail* Stages



- Vigorous contest and controversy on jurisdiction, substance, and closing modalities

Updates from the FTC

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FTC Personnel Updates

- On July 3, 2023, President Biden announced his intent to nominate two Republicans to fill the FTC Commissioner seats that have been vacant since Noah Phillips resigned in October 2022 and Christine Wilson resigned in March 2023

- **Melissa Holyoak**: Solicitor General of Utah
  - Former President and General Counsel of Hamilton Lincoln Law Institute, a Washington, D.C.-based public interest firm representing consumers challenging unfair class actions and regulatory overreach, and previously in private practice

- **Andrew Ferguson**: Solicitor General of the Commonwealth of Virginia
  - Former Chief Counsel to Senate Republican Minority Leader Mitch McConnell (R-KY) and Chief Counsel for Nominations and the Constitution to then Judiciary Committee Chair Lindsey Graham (R-SC)
  - Previously, Ferguson was in private practice, representing clients in antitrust litigation and before the FTC and DOJ

Henry Liu, a partner with Covington & Burling, is expected to replace Holly Vedova as director of the FTC Bureau of Competition

Liu has spent the last 14 years representing companies in antitrust and consumer class actions

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FTC Withdraws Health Care Enforcement Policy Statements

- On July 14, the Commission announced the withdrawal of policy statements related to enforcement in health care markets:
  - Statements of Antitrust Enforcement Policy in Health Care (1996)
  - Statement of Antitrust Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (2011)
- Statements established a "safety zone" for hospital mergers to allow small, rural hospitals to merge and expand services without fear of antitrust scrutiny
- Also provided guidance and safety zones on matters such as information sharing, joint purchasing arrangements, joint ventures to purchase and operate costly healthcare equipment, and collaboration by Medicare providers through accountable care organizations
- Initially issued to forestall legislation that would have exempted hospitals and physicians from antitrust law

Federal Trade Commission Withdraws Health Care Enforcement Policy Statements

Outdated statements no longer serve as useful guidance or reflect market realities

July 14, 2023

Tags: Competition | Office of Policy Planning | Bureau of Competition | Nonmerger | Health Care

The Federal Trade Commission announced today the withdrawal of two antitrust policy statements related to enforcement in health care markets: *Statements of Antitrust Enforcement Policy in Health Care*, published in August 1996, and *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* from October 2011.

"Given the profound changes in these markets over the last 30 years, the statements no longer serve their intended purpose of providing accurate guidance to market participants. Rather, the Commission's extensive record of enforcement actions, policy statements, and competition advocacy in health care provide more up-to-date guidance to the public. The Commission will continue its enforcement by evaluating on a case-by-case basis mergers and conduct in health care markets that affect consumers."
– FTC Withdrawal Press Release

Updates on Commission's PBM Investigation

- In June 2022, the Commission launched an investigation into the six largest PBMs, requiring them to turn over extensive information and records regarding their business practices for the last five years
- Inquiry is examining PBMs' role in the pharmaceutical system and their practices, including:
  - charging fees and clawbacks to unaffiliated pharmacies
  - steering patients towards PBM-owned pharmacies
  - potentially unfair auditing of unaffiliated pharmacies
  - the use of complicated and opaque pharmacy reimbursement methods;
  - negotiating rebates and fees with drug manufacturers that may skew the formulary incentives and impact the costs of prescription drugs to payers and patients.
- On May 17, 2023, the Commission expanded its inquiry, issuing additional compulsory orders to two group purchasing organizations ("GPOs"), also called rebate aggregators, which negotiate rebates with drug manufacturers on behalf of the PBMs and hold the contracts that govern those rebates
- On June 8, the Commission further expanded its inquiry, issuing an additional compulsory order to a GPO

On July 20, the Commission "will vote to issue a statement cautioning against reliance on prior advocacy statements and studies related to pharmacy benefit managers (PBMs) that no longer reflect current market realities"

U.S. Merger Enforcement

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FTC Proposes Sweeping Changes to HSR Rules That Could Substantially Increase Burden, Time to Prepare Filings

- On June 27, 2023, the FTC announced a proposal for a radical overhaul to the HSR premerger notification program that, if adopted, would dramatically increase costs, burden and the time required to prepare filings for transactions that must be notified

Key Changes:

- Narrative descriptions of the horizontal overlaps and supply relationships between the filing persons.
- A more extensive production of transaction-related documents (including drafts) and ordinary course business documents (e.g., describing market conditions) collected from a broad range of individuals at each notifying party.
- Details about investment vehicles, corporate relationships and the structure of entities involved (such as private equity investments).
- Details regarding previous acquisitions (including transactions that were not required to be notified to the agencies under the HSR Act).
- Identification of pipeline or pre-revenue products and overlaps for such products anticipated to have annual revenue totaling more than $1 million within two years.
- Information to assess the potential impact of the transaction on labor markets, including questions about the merging parties' employees and the services employees perform.

- Next steps: proposed rules remain subject to a 60-day public comment period, after which the Agencies will consider whether to adopt, amend or reject the proposed rules or to extend the comment period

TODAY – Proposed Merger Guidelines Released

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For Release

FTC and DOJ Seek Comment on Draft Merger Guidelines

Proposed guidelines would address the many ways mergers can weaken competition, harming consumers, workers, and businesses

July 19, 2023

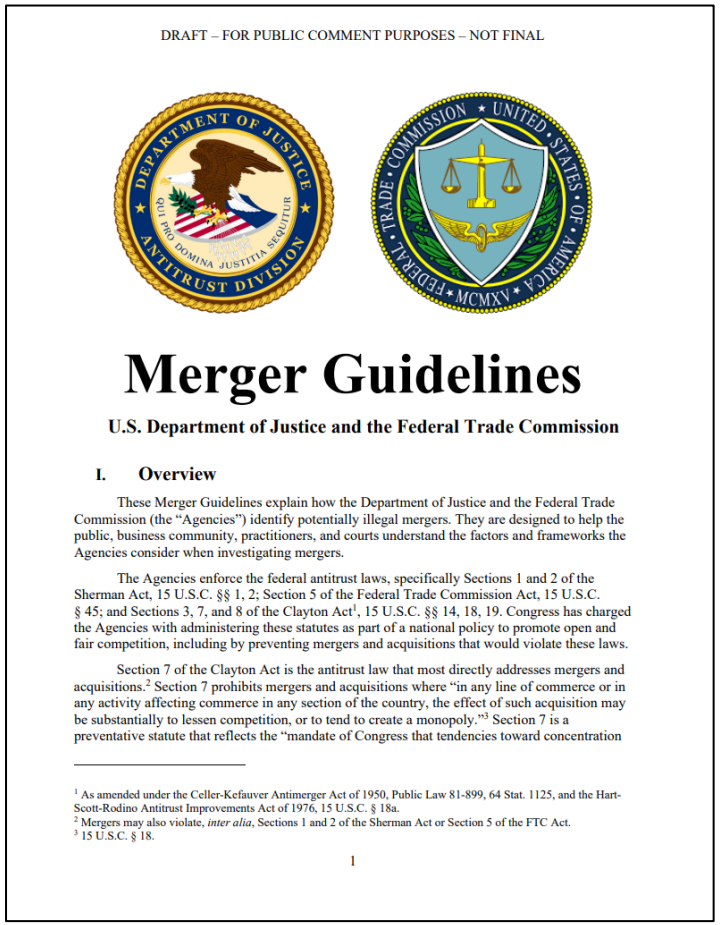
Tags: Competition | Bureau of Competition | Merger | Horizontal | Vertical | attempted monopolization | dual enforcement/DOJ | efficiencies | Herfindahl-Hirschman Index (HHI) | market power | monopolization | vertical restraint

Today, the Federal Trade Commission and the Department of Justice are releasing a draft update of the Merger Guidelines, which describe and guide the agencies' review of mergers and acquisitions to determine compliance with federal antitrust laws. The goal of this update is to better reflect how the agencies determine a merger's effect on competition in the modern economy and evaluate proposed mergers under the law. Both agencies encourage the public to review the draft and provide feedback through a public comment period that will last 60 days.

Related actions

Statement of Commissioner Alvaro M. Bedoya Joined by Chair Lina M. Khan and Commissioner Rebecca Kelly Slaughter Regarding the Proposed Merger Guidelines Issued by the Federal Trade Commission & U.S. Department of Justice

FTC-DOJ Merger Guidelines (Draft for Public Comment)



DRAFT – FOR PUBLIC COMMENT PURPOSES – NOT FINAL

Merger Guidelines

U.S. Department of Justice and the Federal Trade Commission

I. Overview

These Merger Guidelines explain how the Department of Justice and the Federal Trade Commission (the "Agencies") identify potentially illegal mergers. They are designed to help the public, business community, practitioners, and courts understand the factors and frameworks the Agencies consider when investigating mergers.

The Agencies enforce the federal antitrust laws, specifically Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2; Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45; and Sections 3, 7, and 8 of the Clayton Act[1], 15 U.S.C. §§ 14, 18, 19. Congress has charged the Agencies with administering these statutes as part of a national policy to promote open and fair competition, including by preventing mergers and acquisitions that would violate these laws.

Section 7 of the Clayton Act is the antitrust law that most directly addresses mergers and acquisitions.[2] Section 7 prohibits mergers and acquisitions where "in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly."[3] Section 7 is a preventative statute that reflects the "mandate of Congress that tendencies toward concentration

[1] As amended under the Celler-Kefauver Antimerger Act of 1950, Public Law 81-899, 64 Stat. 1125, and the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. § 18a.
[2] Mergers may also violate, *inter alia*, Sections 1 and 2 of the Sherman Act or Section 5 of the FTC Act.
[3] 15 U.S.C. § 18.

1

“The Future of Pharmaceuticals: Examining the Analysis of Pharmaceutical Mergers” Workshop Key Findings

Concentration levels

Merger review examining whether a merger increases dominance in individual product markets, with divestiture of overlapping products as the remedy, “ignores complex customers in pharmaceutical markets, and cross-market effects due to firm size”

M&A activity, not r&d excellence, is why same companies remain at top; very small firms originate 70% of new active substances; no evidence that firm size increases r&d

Divestiture remedies

Examination of seventeen FTC pharmaceutical merger enforcement cases between 2008–18 involving fifty-six pipeline product divestitures preliminarily found that only 36 percent of those products have an active marketing license today

Innovation

Empirical evidence indicates that M&A in the pharmaceutical industry reduces the research efforts of merging companies and their competitors; increased risk that overlapping projects between acquirers and targets will be delayed or terminated

Prior bad acts

Past anticompetitive conduct, including pay-for-delay, price fixing and territorial allocation, patent thicket strategies, and fraud on the patent office, are attempts to corner the market on particular drugs and should be taken into account in merger analysis

FTC Pursuing "Cross Market Bundling" Theory in Amgen / Horizon

- On December 12, 2022, Amgen announced an agreement to acquire Horizon Therapeutics, for approximately $27.8 billion
- On May 16, 2023, the FTC sued in federal court to block the proposed transaction
- Complaint alleges that Amgen will have the ability and incentive to bundle Horizon's products with Amgen's portfolio to foreclose future competition
  - FTC alleges that Horizon has two orphan drugs that do not face competition today, but may in the future
  - Post-transaction, the FTC alleges that Amgen's "most likely strategy through which Amgen could [suppress that emerging competition] is by leveraging [Amgen's] existing portfolio of blockbuster drugs in multi-product contracts with PBMs and payers"
  - Complaint asserts: "Amgen's history suggests this would likely include conditioning rebates to PBMs or payers on one or more of its must carry blockbuster drugs in exchange for the PBMs or payers denying coverage to, or otherwise disfavoring, actual or potential rivals" to Horizon's drugs
- On June 22, FTC also filed an administrative complaint

"FTC has delayed the Transaction for months … based on a novel and highly speculative 'cross-benefit' and 'cross-market' bundling theory that has no legal or factual support. And it does so despite Amgen committing to the FTC, before the agency filed its Complaint, that it would not engage in the very conduct about which the FTC alleges concern. Putting to one side that Amgen would have neither motive nor ability to engage in that conduct, Amgen also made clear that it would be willing to formalize that commitment in a binding consent order" – Answer and Affirmative Defenses of Amgen and Horizon to Plaintiff's Complaint

FTC Sues to Block IQVIA, World's Largest Health Care Data Provider, from Acquiring Propel Media

- FTC alleges IQVIA's Lasso Marketing and PMI's DeepIntent are two of the top three providers of programmatic advertising, known as demand-side platforms, that targets health care professionals with advertising for pharmaceutical drugs and other health care products
- FTC also alleges IQVIA controls leading provider identity and prescribing behavior data that is essential for health care demand-side platforms to compete
- July 17 administrative complaint alleges that proposed ~$800 million acquisition would:
  - (1) give IQVIA a market-leading position in programmatic advertising for health care products, namely prescription drugs, to doctors and other health care professionals; and
  - (2) increase IQVIA's ability and incentive to withhold key data to prevent rival companies and potential entrants from effectively competing by "raising prices for its data, reducing data quality, or restricting advertisers from using its data"

LASSO an IQVIA business

deepintent

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U.S. Non-Merger Case Developments

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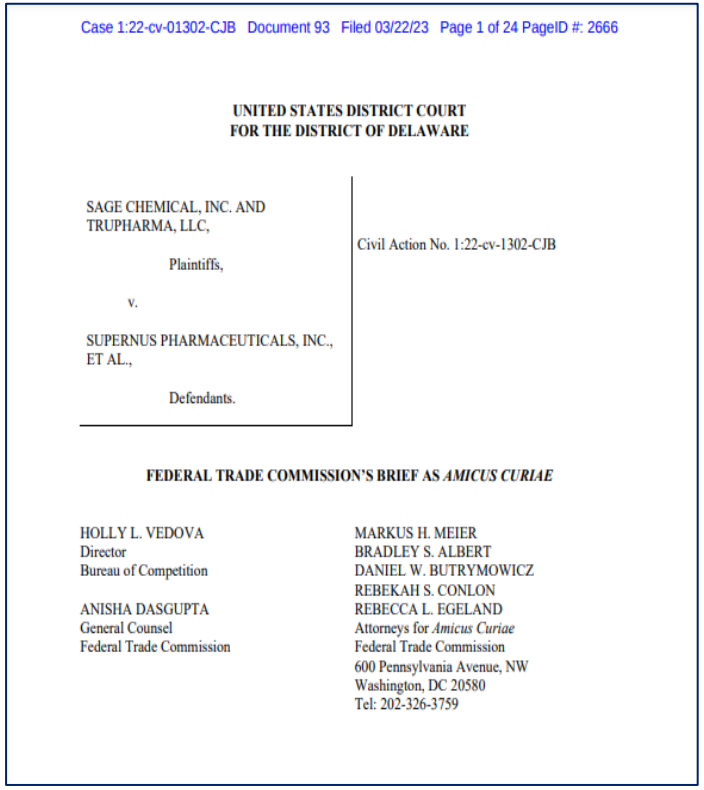
FTC Weighs in on *Sage Chemical v. Supernus Pharmaceuticals (Mar. 22, 2023, D. Del.)* – generic exclusion

- FTC brief urges the court to consider four points in determining whether the district court should grant defendant's motion to dismiss:
  - 1) Exclusion of a generic competitor not only harms that competitor, but also competition and consumers more generally;
  - 2) Sage and TruPharma's development of a generic apomorphine cartridge to substitute as a refill for branded cartridges is not improper "free riding" within the meaning of antitrust law;
  - 3) Exclusive agreements like the one between Supernus and the manufacturer of the injectable pen can be unlawful when they foreclose a competitor's access to a key input, even if the potential competitor could theoretically develop an alternative version; and
  - 4) Defining a relevant antitrust market requires assessing which products are available to consumers if prices are raised above a competitive level and single-brand or single-manufacturer markets may be appropriate when there are no adequate substitutes



Case 1:22-cv-01302-CJB Document 93 Filed 03/22/23 Page 1 of 24 PageID #: 2666

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SAGE CHEMICAL, INC. AND TRUPHARMA, LLC,

Plaintiffs,

v.

SUPERNUS PHARMACEUTICALS, INC., ET AL.,

Defendants.

Civil Action No. 1:22-cv-1302-CJB

FEDERAL TRADE COMMISSION'S BRIEF AS *AMICUS CURIAE*

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FTC Weighs in on *Applied Medical v. Medtronic* (July 3, 2023, C.D. Cal.) – exclusive dealing / bundling

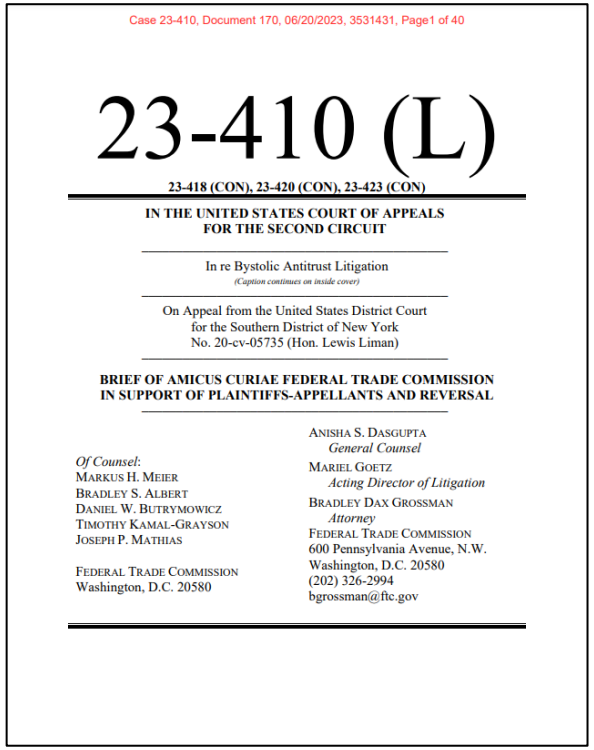
- FTC seeks to clarify the legal standards that apply to exclusive-dealing and bundling arrangements
- FTC argues that Medtronic's argument are flawed and apply the wrong legal standard

Commission's Arguments

- A plaintiff alleging unlawful exclusive dealing need not plead a numerical percentage of sales foreclosed
- Exclusive contracts are not conclusively legal just because they are "short term" – and even if that were true, exclusive contracts that last three years are not short term
- A contract can constitute exclusive dealing even if it is not formally binding. What matters is the contract's "practical effect"
- An exclusive-dealing plaintiff need not allege that there are no "alternative distribution channels"
- To plead unlawful bundling, an antitrust plaintiff need not specify the defendant's exact prices and costs
- When an antitrust plaintiff challenges a defendant's bundled "discounts," it is not complaining that the defendant's prices are too low. A defendant's "discount" may be a self-serving label for a pricing structure under which no consumer actually receives a lower price

FTC Weighs in on *Bystolic Antitrust Litigation* (June 20, 2023, 2d Cir.) – reverse payments

- FTC amicus brief seeks to establish the legal standard that applies in reverse-payment settlement cases, arguing that "plaintiffs challenging a reverse payment settlement only need to plead market power and facts from which a court can infer a large and unjustified reverse payment was tendered"
- Plaintiffs alleged that:
  - (1) Forest made large reverse payments to at least five separate generic companies as part of settlements keeping those companies from introducing rival products for at least eight years; and
  - (2) Forest made the payments via side deals that were unusual and lacked obvious procompetitive rationales
    - Side deals included payments to supply raw materials, acquire patents, supply other drugs, jointly develop other products and invest in drug development efforts
- District court dismissed amended complaint, finding that "[p]laintiffs' factual allegations regarding the side deals . . . do not show that they are large and unjustified," which is a key requirement to holding such patent deals to be anticompetitive reverse payments under the Supreme Court's 2013 *Actavis* ruling
- Commission argues in its brief that "[t]aken together, [plaintiffs'] allegations create a plausible inference that Forest unlawfully paid the generics not to compete"



Case 23-410, Document 170, 06/20/2023, 3531431, Page1 of 40

23-410 (L)

23-418 (CON), 23-420 (CON), 23-423 (CON)

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

In re Bystolic Antitrust Litigation

(Caption continues on inside cover)

On Appeal from the United States District Court
for the Southern District of New York
No. 20-cv-05735 (Hon. Lewis Liman)

BRIEF OF AMICUS CURIAE FEDERAL TRADE COMMISSION
IN SUPPORT OF PLAINTIFFS-APPELLANTS AND REVERSAL

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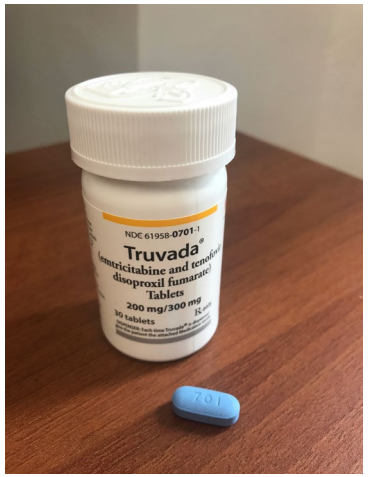
Gilead, Teva Defeat $3.6 Billion Reverse Payment HIV Drug Antitrust Case at Trial *Background*

- Case stems from a 2014 patent litigation settlement between Gilead and Teva resolving Teva's challenge to Gilead's patents for two blockbuster HIV drugs, Truvada and Atripla
- Plaintiffs alleged that Gilead "paid" Teva to agree to a later entry date by providing the company six months of contractual exclusivity as the only seller of Truvada and Atripla generics in exchange for allowing Gilead to maintain its monopoly until that date
- Teva had been the first to file an ANDA, entitled to 180 days of regulatory exclusivity, but forfeited its first-to-file status because it failed to obtain FDA approval of its ANDA
- The settlement agreement permitted Teva to enter with its generic alternatives to Gilead's HIV drugs in September 2020, or 180 days before Gilead licensed any other generic — essentially reinstating Teva's forfeited first-to-file status
- Court denied defendants' motion to dismiss in 2020, accepting plaintiffs' market definition that included Truvada, Atripla, and its generics, but said it was not clear what broader product market would include



Cooley

Gilead, Teva Defeat $3.6 Billion HIV Drug Antitrust Case at Trial: Key Arguments and Jury Findings

- **Market Power:** Plaintiffs failed to show that Gilead had market power within a market that included Truvada and/or Atripla
  - Plaintiffs defined the relevant market to encompass only the HIV drugs Atripla, Truvada, and their generic equivalents and pointed to the steep decline in prices for Truvada and Atripla once many generic equivalents launched
  - Defendants argued that the relevant market included Atripla, Truvada, their generic equivalents, and alternative HIV therapies and that within this broader market, defendants lacked market power
- **Reverse Payment**: Plaintiffs failed to show that Gilead made a reverse payment to Teva to delay entry of generic competition entry date earlier than Sept. 30, 2020
  - Plaintiffs alleged that Gilead's "payment" to Teva was in the form of six months of de facto generic exclusivity that delayed generic competition and prolonged Gilead's alleged monopoly prices for Atripla and Truvada, leading to a $3.6 billion overcharge.
  - Defendants countered that there was neither a payment between Gilead and Teva or delayed entry and that Teva knew Gilead's HIV patent was strong and that Teva was unlikely to prevail in the patent trial
    - Notably, Teva waived its attorney-client privilege, allowing defendants to rely heavily on privileged material, including Teva's chief IP counsel's belief that it had only a 17.5% chance of winning the patent litigation