Pharma, Medical Device, and Biotech Antitrust Update: New Developments and What They Mean

Rich Parker, Adam Di Vincenzo, Deirdre Taylor, Eric Stock, and Kaitlin Zumwalt

May 6, 2020

FTC Merger Enforcement

- FTC oversees all pharmaceutical, medical device, and biologics transactions
- Substantive Standards:
  - Section 7 of the Clayton Act: Prohibits transactions where the effect "**may be substantially to lessen competition, or to tend to create a monopoly**"
  - Section 5 of the FTC Act: Prohibits "**unfair methods of competition**"

FTC Merger Enforcement





- Five Commissioners, three Republicans and two Democrats
- Each has expressed views (some divergent) regarding industry mergers:
  - Chair Simons: "[V]ery concerned . . . with drug pricing" and that the FTC "is committed to maintaining competition in the pharmaceutical industry"
  - Commissioner Chopra: "Status quo" antitrust analysis fails to "unearth the full set of harms to patients and innovation, based on the history of anticompetitive conduct of the firms seeking to merge and the characteristics of today's pharmaceutical industry when it comes to innovation."
  - Commissioner Slaughter: FTC's "analytical approach is too narrow" and "should more broadly consider whether any pharmaceutical merger is likely to exacerbate anticompetitive conduct."
  - Commissioner Wilson: While concerned about high prices, some enforcement proposals "fall outside the [FTC's] jurisdiction and legal authority."

FTC Merger Enforcement: COVID-19

- Overall, the FTC's merger review (HSR) process is operational, and is slowly returning back to "normal" with WFH protocols in place
  - Early terminations were suspended in March, but resumed by April
  - FTC requesting extensions for Second Request decisions (Timing Agreement modifications)
- Merging parties should factor new procedures and risks into antitrust "efforts" provisions and termination dates in M&A agreements
- Phillips: "[T]he burden has been lessened because there is less M&A going on"
  - While M&A volumes have dropped, FTC will continue to apply the same enforcement standards. Effects of crisis on competition and competitors may still be a factor.
- Calls for a "merger freeze" and other legislation under consideration, but face resistance in Congress

Key Issue: Are the Merging Parties' Products Complements or Substitutes?

- Threshold question: Do the merging parties compete or potential compete?
  - Many conditions require tailored treatment that is specific to the patient.
  - Physicians prescribe treatments based on patient condition and many other factors

- FTC will examine treatment options for patients, which may vary from patient to patient
  - For some patients, the merging parties' products are substitutes
  - Other patients may use the products as complements (e.g., combination therapy)
  - Still others will see them as neither complements nor substitutes

- Physician and KOL views are vitally important, but there may be differences in opinion
  - Understanding of how physicians treat patients with this condition
    - *FTC v. Lundbeck, Inc.* (2010): FTC loses merger challenge based on physician testimony that merging parties' PDA treatments were not substitutes
  - Physicians generally have little or no experience with pipeline drugs
    - Prior to FDA approval, FTC and merging parties must account for speculative efficacy claims and potential safety issues or side effects

Key Issue: Potential and "Nascent" Competition

- FTC will probe potential future competition from an innovative but nascent "pipeline" product that, if successful, might threaten other party's on-market product

- There is often uncertainty regarding FDA approval and future impact on competition
  - Section 7 of the Clayton Act is concerned with "probabilities" not "ephemeral possibilities." *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962).

- For this reason, where a divestiture is required, the FTC policy is to seek divestiture of the on-market, FDA approved product; FTC generally will not accept "pipeline divestitures"

Key Issue: How Will Merger Affect Innovation?

In addition to future competition, FTC will examine any effect on *existing* efforts to innovate.

1. Incentives to Innovate
   - Will merged firm invest in innovation as parties would without the merger?
   - Will the prospect of lower profits from incumbent product sales reduce investments?

2. Speed to market
   - Will the merged firm delay launch or clinical trials to preserve sales of the incumbent product?

3. Resources
   - Does a buyer have needed expertise and resources a smaller target lacks?
   - Do greater resources counter theoretical concerns about innovation?

Key Issue: Patents

- Does merger remove potential patent barrier, or create one?

- By merging patent portfolios, does the merged firm gain the ability to delay new entry?
  - Do acquired patents, in combination with existing patents, make it more difficult for competitors to "innovate around" patents?

- Orphan drug status (market exclusivity)
  - If one party with orphan drug status merges with competitor, merged firm may have ability to bring both to market
  - Thus, merger may *remove* obstacle and result in more treatments on the market

- Infringement lawsuits
  - Merger may resolve Hatch Waxman Act-based infringement litigation
  - In doing so, merger may remove uncertainty and delay that pipeline product may face absent the merger

Case Study – Roche/Spark

- Nascent competition theory
  - Spark was developing a gene therapy for Hemophilia A
  - Roche had existing treatment on market for Hemophilia A - Hemlibra
  - Multiple companies are developing gene therapies that may compete with Spark's

- Gene therapies are difficult to develop, and getting to market is highly uncertain
  - Predicting which treatment will achieve a breakthrough is a challenge
  - Merger would help Spark overcome challenges

- FTC found competing pipeline products would adequately incentivize Roche to invest in Spark's gene therapy

- Unanimous (5-0) Commission vote clearing the deal highlights that the facts of each case matter, in the end

Case Study – Bristol-Myers/Celgene

- As a condition of approving BMS' $74 billion acquisition of Celgene, the FTC required the divestiture of Celgene's Otezla to Amgen
  - Despite large divestiture, Commission vote was split 3-2
- Valued at $13.4 billion, it was the largest divestiture remedy ever obtained by the FTC or DOJ
- FTC alleged a relevant market for "oral treatments for moderate-to-severe psoriasis"
  - BMS was developing what the FTC viewed as the most advanced oral treatment for these patients
  - The FTC alleged that patients preferred convenience of oral treatment to injectables and efficacy of more advanced treatments to older generics
- FTC required the divestiture of the on-market product, pursuant to its policy

Case Study – Covidien/Newport Medical Instruments

- In 2012, FTC granted early termination of Covidien's $108 million acquisition of Newport Medical Instruments

- Newport Medical Instruments was allegedly a small developer of lower-cost, portable ventilators; Covidien allegedly made more expensive ventilators
  - FTC reported to be investigating whether merger contributed to today's shortage of ventilators

- Analysis of consummated mergers considers post-closing effects
  - FTC investigation is often triggered by a post-merger price increase
  - Here, the onset of a health crisis (COVID-19) 8 years after the merger caused a spike in demand for ventilators
  - "But-for" causation may be challenging to prove

- Demonstrates FTC's embrace of nascent competition theories

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Europe –Merger Control and Antitrust Developments

Merger control developments – UK jurisdictional reach

On 16 December 2019, the CMA cleared the acquisition by Roche Pharmaceuticals of Spark Therapeutics, in a decision that pushes the boundaries of the CMA's jurisdictional reach.

- CMA found that it has jurisdiction to intervene in transactions on the basis of a company's R&D efforts alone, i.e. in the absence of a commercialised product.
- Basis for establishing jurisdiction was the 'UK share of supply test':
  - Spark found to be 'active in the supply of haemophilia A treatments in the UK' based on expansive interpretation of the competitive process - supply of a product in the pharmaceuticals sector encompasses several stages; R&D stage is an integral part of the process.
  - Very limited UK nexus - Spark held certain UK/EU patents, had some employees undertaking activities in the UK and intended to include UK sites in clinical trials.
  - 25% share of supply test limited to "novel" therapies. Metrics relatively vague: (a) the number of full-time equivalent UK-based employees engaged in such activities; and (b) the 'procurement' of UK patents.

Merger control developments – pipeline competition/innovation

Review of pharmaceutical/bio-tech mergers continues to focus on pipeline competition and innovation

- AbbVie/Allergan – Commission approval dependent on divestment of upcoming IBD treatment, in decision focusing on class of biologics currently in development.

- GSK/Pfizer CH – Commission approval dependent on divestment of topical pain management product portfolio, including products under development.

- Johnson & Johnson/Tachosil – Commission opened in-depth investigation because of concerns that the merger may reduce potential competition and innovation for the supply of dual haemostatic patches. The transaction was subsequently abandoned.

- Illumina/PacBio – UK CMA provisionally found competition concerns from merger in Phase II, in-depth investigation because of concerns regarding loss of innovative constraint from PacBio. The transaction was subsequently abandoned.

Reverse settlements – ECJ judgement in *Paroxetine*

On 30 January 2020, the ECJ delivered a ruling on the assessment of settlement agreements between originator and generic pharmaceutical suppliers.

- Low threshold for what constitutes potential competition. Test is whether generics supplier "*has in fact a firm intention and an inherent ability to enter the market*" and "*market entry does not meet barriers to entry that are insurmountable*". Patent is part of legal and economic context but not an insurmountable barrier; and may be an indicator of competition in itself.
- Clarification of when settlements will be "object" infringement. Transfer of value is not sufficient to make agreement a restriction "by object" (essentially equivalent to US *per se* standard). However, uncertainty as to litigation outcome cannot justify the transfer of value. Question is whether the transfer of value "*can have no other explanation that the commercial interest of the parties to the agreement not to engage in competition on the merits*".
- Low threshold for "effect" infringement. No need to establish probability of generic winning the patent case, or that a less restrictive form of a settlement could have been found.
- Confirms reach of "abuse" doctrine. ECJ found that series of settlement agreements could be part of a "*contract-oriented strategy*" with a foreclosure effect on the market.

Implications of the ECJ judgement in *Paroxetine*

- High risk that patent settlements involving a value transfer between an originator and a generic supplier that has demonstrated a clear intention to compete could attract antitrust scrutiny – low threshold set by ECJ was not expressly limited to situations involving process patents.

- Reverse settlements require careful evaluation of whether factors justifying the value transfer exist and of effect on generic incentives to enter.

- ECJ likely to adopt similar approach in pending appeals against EC infringement decisions in *Lundbeck (citalopram)* and *Servier (perindopril)*. Further guidance on approach when these judgements are delivered

High drug prices – UK Court of Appeal judgement in *Phenytoin*

On 10 March 2020, the UK Court of Appeal upheld the CAT's judgement quashing the CMA decision that Pfizer and Flynn Pharma (Flynn) had abused their dominant positions in the market by pricing their epilepsy drug (Phenytoin) unfairly.

The judgement provides important clarification of how the *United Brands* test for excessive pricing should be applied.

- **Not a mutually exclusive test.** The test in United Brands ("whether a price has been imposed which is either unfair in itself or when compared to competing products") does not allow the authority to focus on one limb to the exclusion of evidence relating to the other.

- **No need for hypothetical benchmark in all cases.** To assess economic value, an authority can select from variety of possible benchmarks, including costs of the undertaking.

The CMA has signalled that it will continue with its enforcement activities against what it sees as unfairly high prices.

Covid-19 impact on antitrust enforcement

- **Impact on existing investigations.** Resource constraints in light of Covid-19 are having an impact on the ability of authorities to carry on work as normal.
  - The CMA has announced that two investigations into market sharing have been paused while it focuses on Covid workstreams.

- **Commission comfort for pharma cooperation.** Publication by the Commission of a "temporary framework" guidance on cooperation, particularly in relation to the supply of medicines and medical equipment. "Comfort letter" issued to Medicines For Europe.

- **Strong signal of ongoing enforcement against high prices.** Ongoing vigilance against abusive conduct or excessively high prices:
  - European Commission is reported to be "actively looking at" exclusionary conduct and price increases, whether those are collusive prices or excessive pricing.
  - CMA letter to pharmaceutical companies warning against "profiteering"; launch of taskforce to monitor market developments and take enforcement action.

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Pharmaceutical Antitrust: Non-Merger Enforcement and Litigation

Efforts to Address Drug Prices: *FTC v. Vyera Pharmaceuticals*

Earlier this year, the FTC , New York AG, and other state AG offices filed a complaint against Vyera Pharmaceuticals, LLC and its leadership—including "Pharma Bro" Martin Shkreli.

- Allege anticompetitive plan to exclude generic competition for the drug Daraprim in addition to instituting a 4000% price increase.
- Theories in complaint:
  1. Limiting generics' access to Daraprim for testing by entering into agreements with distributors.
  2. "Data-blocking" agreements preventing those distributors from selling sales data and masking size of the Daraprim business to potential generic entrants; and
  3. Restrictions to potential competitors' access to the active ingredient in Daraprim.
- Complaint seeks monetary and injunctive relief, including a lifetime ban for Shkreli from the pharmaceutical industry.

Product-Hopping: *FTC v. Reckitt Benckiser*

In July 2019, Reckitt Benckiser (RB) entered into a $1.4 billion settlement to resolve potential criminal and civil liability arising from an alleged effort to increase sales of its opioid addiction treatment, Suboxone.

- Monopolization claim was part of the resolution
- FTC alleged monopoly maintanence by:
  - Discontinuing production of Suboxone Tablets, thus requiring market to convert to Suboxone Film based on, *inter alia*, alleged false claims related to safety; and
  - Submitting an allegedly meritless citizen petition to the FDA.

Product Hopping Issues

- Hard switch vs. soft switch
- Product improvement
- Limited government action

FTC Enforcement Against Reverse Payments: *Impax v. FTC*

- Settlement between Endo and Impax relating to Opana ER
  - Impax agreed to compromise entry date in future.
  - Endo allegedly agreed to a no AG provision; a cash guarantee to Impax in the event the market for Opana ER declined before Impax could enter the market (which resulted in a $102 million payment); and a payment in connection with independent development and co-promotion deal.
- ALJ Decision
  - Considered all procompetitive benefits of the Impax-Endo settlement as a whole.
  - Dismissed the complaint because the consumer benefits of consumer access to Opana ER prior to patent expiration outweighed the theoretical anticompetitive harm.
- Commission Overrules ALJ
  - Commissioners found there was evidence of a possibility that Impax could have launched generic product earlier than compromise entry date; determined there was a large, unjustified payment.
  - Did not consider procompetitive benefits; found not adequately linked to reverse payment.

Appellate Issues: *Impax v. FTC*

1. *What showing of anticompetitive harm is required?*
   - FTC alleged, absent settlement, Impax might have entered prior to agreed entry date.
   - Impax argues FTC erred in not first "defining the baseline level of competition absent" challenged settlement, and comparing to level of competition that occurred after settlement.
2. *How close must the "link" be between a restraint and an alleged procompetitive benefit?*
   - Impax argues that the FTC incorrectly considered the reverse payment itself as the "restraint," and thus failed to analyze the procompetitive of other aspects of the settlement agreement.
3. *Must the FTC prove the existence of a less restrictive settlement agreement was possible, to overcome procompetitive benefits?*
   - Impax argues that the FTC failed to do so. Impax also argues that the FTC improperly imposed a presumption that ANDA litigation can be settled without reverse payments.

California Legislation on Reverse Payments

On October 27, 2019, California enacted Assembly Bill 824 in an effort to increase antitrust scrutiny of reverse payment patent settlement agreements.

- Under *FTC v. Actavis*, a plaintiff bears the burden of showing a "large and unjustified" reverse payment and an overall "anticompetitive effect."
- Under AB 824, anticompetitive effects are **presumed** once an antitrust plaintiff or enforcement body shows that the generic manufacturer agrees to limit or delay its market entry and receives **"anything of value"** in the patent settlement.
- AB 824 further requires the factfinder to presume that the relevant product market comprises only the branded drug, the non-reference drug accused of infringement, and any other biosimilar or AB-rated generics to the reference product.
- Risk that individuals could be exposed to liability under statute

California Legislation: "Anything of Value"

- AB 824 contains detailed definition of "anything of value"

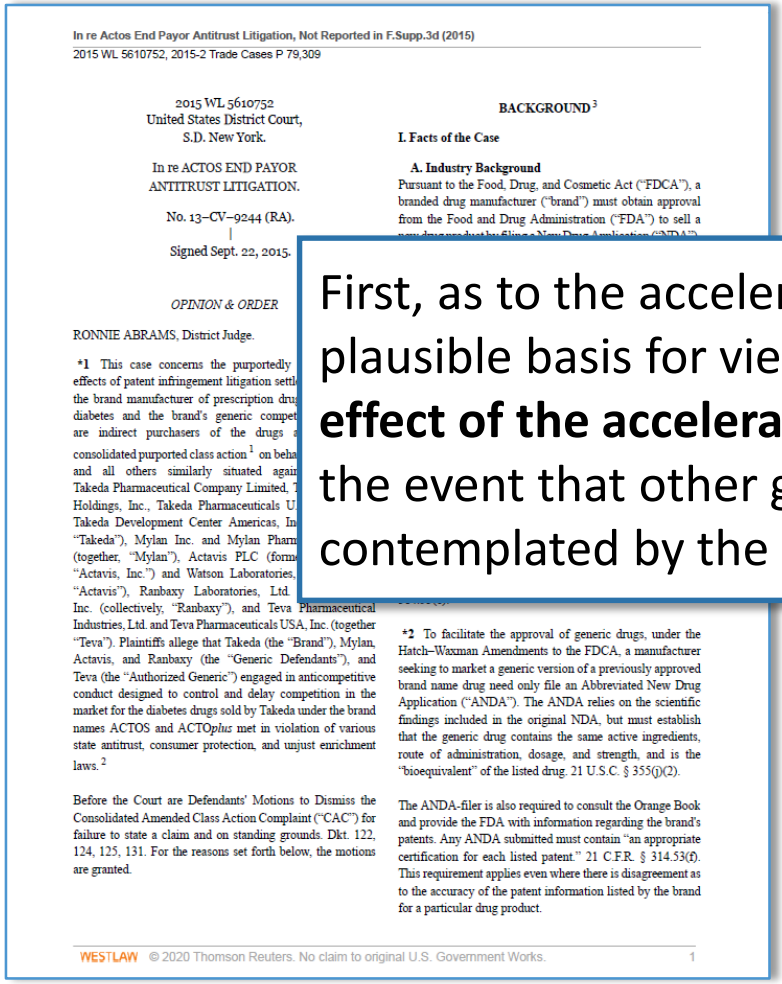
- Definition includes, among other things:
  - "No-AG" provisions
  - Exclusive licenses

- Definition excludes, among other things:
  1. Acceleration clauses based on the NDA holder's marketing a different dosage strength or form;
  2. Waiver of damages accrued from an at-risk launch of the generic drug; and
  3. "Reasonable future litigation expenses" that have been previously documented.

Acceleration Clauses – Effects on Competition

- Ordinary acceleration clauses not expressly exempted in California legislation.
- Type of "MFN" agreement that accelerates generic entry date
  - Common triggers include a final court judgement of patent invalidity, licensed entry by another generic, or a successful at-risk launch by another generic.
- Competitive effects of acceleration clauses:
  - Procompetitive: Acceleration clauses facilitate settlement and often allow settling generics to enter the market earlier than otherwise.
  - Plaintiffs' argument: Some plaintiffs have alleged that acceleration clauses may reduce the incentives of later generics to challenge the patent, especially where the earlier settling generic retains a 180-day exclusivity period.

Acceleration Clauses – *In re Actos* (S.D.N.Y.)



In re Actos End Payor Antitrust Litigation, Not Reported in F.Supp.3d (2015)
2015 WL 5610752, 2015-2 Trade Cases P 79,309

2015 WL 5610752
United States District Court,
S.D. New York.

In re ACTOS END PAYOR ANTITRUST LITIGATION.

No. 13–CV–9244 (RA).

Signed Sept. 22, 2015.

OPINION & ORDER

RONNIE ABRAMS, District Judge.

*1 This case concerns the purportedly effects of patent infringement litigation settl the brand manufacturer of prescription dru diabetes and the brand's generic compet are indirect purchasers of the drugs consolidated purported class action [1] on beha and all others similarly situated agai Takeda Pharmaceutical Company Limited, Holdings, Inc., Takeda Pharmaceuticals U Takeda Development Center Americas, In "Takeda"), Mylan Inc. and Mylan Pharm (together, "Mylan"), Actavis PLC (form "Actavis, Inc.") and Watson Laboratories, "Actavis"), Ranbaxy Laboratories, Ltd. Inc. (collectively, "Ranbaxy"), and Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (together "Teva"). Plaintiffs allege that Takeda (the "Brand"), Mylan, Actavis, and Ranbaxy (the "Generic Defendants"), and Teva (the "Authorized Generic") engaged in anticompetitive conduct designed to control and delay competition in the market for the diabetes drugs sold by Takeda under the brand names ACTOS and ACTO*plus* met in violation of various state antitrust, consumer protection, and unjust enrichment laws. [2]

Before the Court are Defendants' Motions to Dismiss the Consolidated Amended Class Action Complaint ("CAC") for failure to state a claim and on standing grounds. Dkt. 122, 124, 125, 131. For the reasons set forth below, the motions are granted.

BACKGROUND [3]

I. Facts of the Case

A. Industry Background

Pursuant to the Food, Drug, and Cosmetic Act ("FDCA"), a branded drug manufacturer ("brand") must obtain approval from the Food and Drug Administration ("FDA") to sell a

*2 To facilitate the approval of generic drugs, under the Hatch–Waxman Amendments to the FDCA, a manufacturer seeking to market a generic version of a previously approved brand name drug need only file an Abbreviated New Drug Application ("ANDA"). The ANDA relies on the scientific findings included in the original NDA, but must establish that the generic drug contains the same active ingredients, route of administration, dosage, and strength, and is the "bioequivalent" of the listed drug. 21 U.S.C. § 355(j)(2).

The ANDA-filer is also required to consult the Orange Book and provide the FDA with information regarding the brand's patents. Any ANDA submitted must contain "an appropriate certification for each listed patent." 21 C.F.R. § 314.53(f). This requirement applies even where there is disagreement as to the accuracy of the patent information listed by the brand for a particular drug product.

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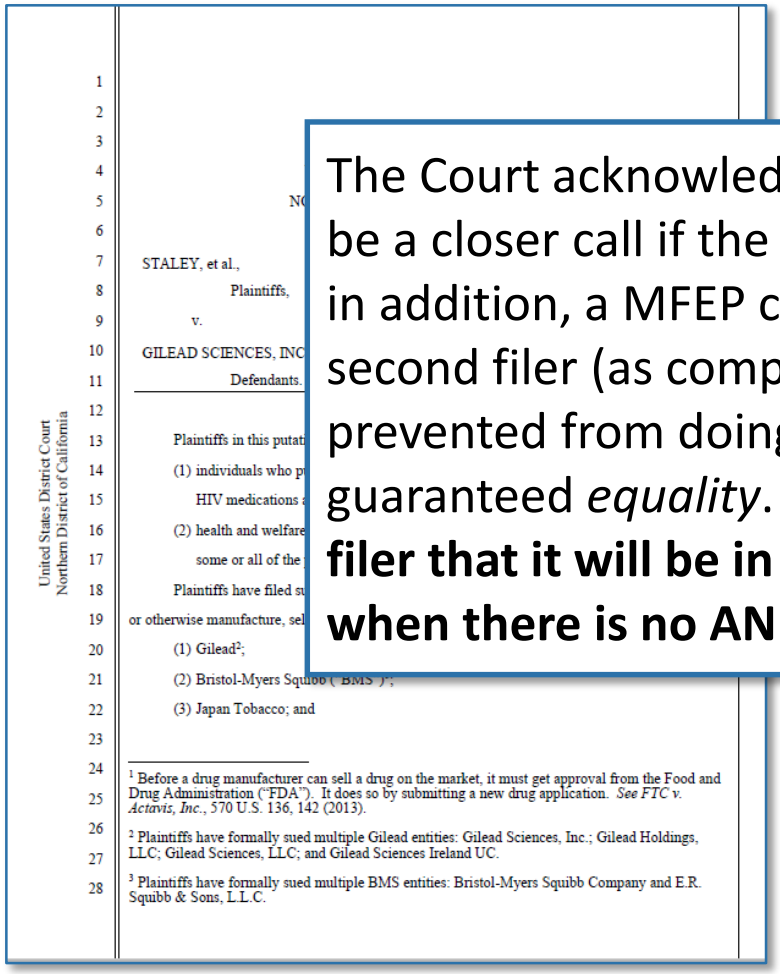
First, as to the acceleration clauses, Plaintiffs have failed to set forth any plausible basis for viewing them as anticompetitive. . . . The **practical effect of the acceleration clauses** was thus to **increase competition** in the event that other generics entered the market earlier than contemplated by the agreement.

In re Actos End Payor Antitrust Litig., 2015 WL 5610752, at *15 (S.D.N.Y. Sept. 22, 2015) (dismissing antitrust claim premised on acceleration clauses), *aff'd in part, vacated in part on other grounds*, 848 F.3d 89 (2d Cir. 2017).

Acceleration Clauses – *Staley v. Gilead Sciences* (N.D. Cal.)



United States District Court
Northern District of California

STALEY, et al.,
Plaintiffs,
v.
GILEAD SCIENCES, INC
Defendants.

Plaintiffs in this putati
(1) individuals who p
HIV medications
(2) health and welfare
some or all of the
Plaintiffs have filed su
or otherwise manufacture, sel
(1) Gilead[2];
(2) Bristol-Myers Squibb ("BMS")[3];
(3) Japan Tobacco; and

[1] Before a drug manufacturer can sell a drug on the market, it must get approval from the Food and Drug Administration ("FDA"). It does so by submitting a new drug application. *See FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013).

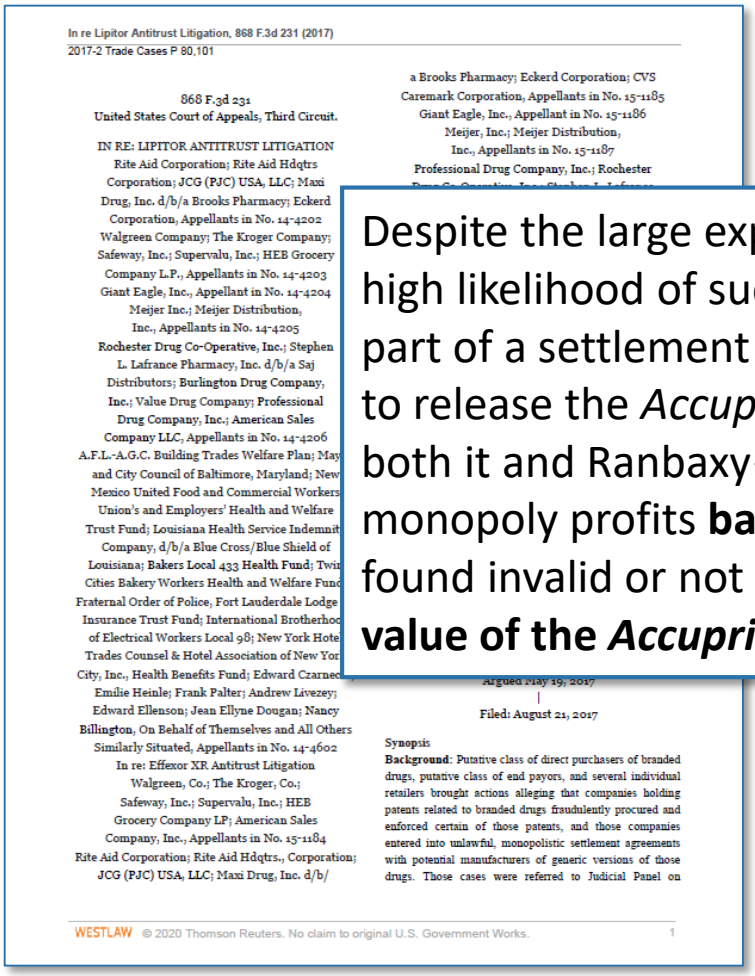
[2] Plaintiffs have formally sued multiple Gilead entities: Gilead Sciences, Inc.; Gilead Holdings, LLC; Gilead Sciences, LLC; and Gilead Sciences Ireland UC.

[3] Plaintiffs have formally sued multiple BMS entities: Bristol-Myers Squibb Company and E.R. Squibb & Sons, L.L.C.

The Court acknowledges that the antitrust claims here would arguably be a closer call if the Court was dealing with just a MFE clause and not, in addition, a MFEP clause. A MFE clause is not as clear a deterrent to a second filer (as compared to a first filer) because a second filer is simply prevented from doing better than the first filer but is nevertheless guaranteed *equality*. In contrast, **a MFEP clause guarantees a second filer that it will be in a *worse* position compared to the first filer even when there is no ANDA Exclusivity**.

Staley v. Gilead Sciences, Inc., C.A. No. 19-cv-02573-EMC (N.D. Cal. Mar. 30, 2020), D.I. 273 (denying motion to dismiss antitrust claim premised on acceleration clauses).

At-Risk Damages Settlements – *In re Lipitor* (3d Cir. 2017)



In re Lipitor Antitrust Litigation, 868 F.3d 231 (2017)
2017-2 Trade Cases P 80,101

868 F.3d 231
United States Court of Appeals, Third Circuit.

IN RE: LIPITOR ANTITRUST LITIGATION
Rite Aid Corporation; Rite Aid Hdqtrs Corporation; JCG (PJC) USA, LLC; Maxi Drug, Inc. d/b/a Brooks Pharmacy; Eckerd Corporation, Appellants in No. 14-4202
Walgreen Company; The Kroger Company; Safeway, Inc.; Supervalu, Inc.; HEB Grocery Company L.P., Appellants in No. 14-4203
Giant Eagle, Inc., Appellant in No. 14-4204
Meijer Inc.; Meijer Distribution, Inc., Appellants in No. 14-4205
Rochester Drug Co-Operative, Inc.; Stephen L. Lafrance Pharmacy, Inc. d/b/a Saj Distributors; Burlington Drug Company, Inc.; Value Drug Company; Professional Drug Company, Inc.; American Sales Company LLC, Appellants in No. 14-4206
A.F.L.-A.G.C. Building Trades Welfare Plan; May and City Council of Baltimore, Maryland; New Mexico United Food and Commercial Workers Union's and Employers' Health and Welfare Trust Fund; Louisiana Health Service Indemnit Company, d/b/a Blue Cross/Blue Shield of Louisiana; Bakers Local 433 Health Fund; Twin Cities Bakery Workers Health and Welfare Fund; Fraternal Order of Police, Fort Lauderdale Lodge Insurance Trust Fund; International Brotherhoo of Electrical Workers Local 98; New York Hote Trades Counsel & Hotel Association of New Yor City, Inc., Health Benefits Fund; Edward Czarnec Emilie Heinle; Frank Palter; Andrew Livezey; Edward Ellenson; Jean Ellyne Dougan; Nancy Billington, On Behalf of Themselves and All Others Similarly Situated, Appellants in No. 14-4602
In re: Effexor XR Antitrust Litigation
Walgreen, Co.; The Kroger, Co.; Safeway, Inc.; Supervalu, Inc.; HEB Grocery Company LP; American Sales Company, Inc., Appellants in No. 15-1184
Rite Aid Corporation; Rite Aid Hdqtrs., Corporation; JCG (PJC) USA, LLC; Maxi Drug, Inc. d/b/a Brooks Pharmacy; Eckerd Corporation; CVS Caremark Corporation, Appellants in No. 15-1185
Giant Eagle, Inc., Appellant in No. 15-1186
Meijer, Inc.; Meijer Distribution, Inc., Appellants in No. 15-1187
Professional Drug Company, Inc.; Rochester

Argued May 19, 2017

Filed: August 21, 2017

Synopsis
Background: Putative class of direct purchasers of branded drugs, putative class of end payors, and several individual retailers brought actions alleging that companies holding patents related to branded drugs fraudulently procured and enforced certain of those patents, and those companies entered into unlawful, monopolistic settlement agreements with potential manufacturers of generic versions of those drugs. Those cases were referred to Judicial Panel on

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Despite the large expected damages arising from the Accupril suit and the high likelihood of success, Pfizer subsequently released its *Accupril* claims as part of a settlement agreement with Ranbaxy. . . . Pfizer's alleged agreement to release the *Accupril* claims, therefore, was an inducement—valuable to both it and Ranbaxy—to ensure a longer period of supracompetitive monopoly profits **based on the Lipitor patent**, which was at risk of being found invalid or not infringed. **Those allegations sufficiently plead that the value of the *Accupril* claims was large and their release was unjustified.**

In re Lipitor Antitrust Litig., 868 F.3d 231, 253–54 (3d Cir. 2017)

Class Certification: Numerosity

There have been increased challenges to numerosity in direct purchaser actions.

- Challenging numerosity in direct purchaser class actions can be effective because:
  - There are a limited number of pharmaceutical wholesalers;
  - Manufacturers and direct purchasers may have arbitration agreements; and
  - Many wholesalers have the financial resources to bring suits individually.

- Examples of cases where numerosity was at issue:
  - In 2016, Third Circuit in *Modafinil* **denied** certification of class of 22 DPPs.
  - In 2018, court in N.D. Ga. in *Androgel* **denied** certification of class of 18 DPPs.
  - In 2019, court in the E.D. Pa. in *Niaspan* **granted** certification of class of 48 DPPs.

Class Certification: Predominance and Ascertainability:

Recent decisions show that courts are increasingly unwilling to certify classes containing uninjured class members because determining injury requires individualized inquiry.

- *In re Asacol Antirust Litigation*, 907 F.3d 42 (1st Cir. 2018)
  - At least 10% of the class would have been brand loyal and thus uninjured.
  - First Circuit denied certification because it contained this proportion of uninjured class members, and identifying uninjured class members would either
    - (1) require "a line of thousands of class members waiting their turn to offer testimony and evidence on individual issues," or
    - (2) would fail to protect a defendant's Seventh Amendment rights.
  - On remand, plaintiffs moved for a third-party payor only class, which the district court denied.

Use of averages: *In re Lamictal* (3d Cir. 2020)

In *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 19-1655, 2020 WL 1933260 (3d Cir. Apr. 22, 2020), the Third Circuit vacated and remanded class certification of a direct purchaser class.

- Direct purchasers alleged that GlaxoSmithKline made anticompetitive reverse payment to Teva to settle a patent lawsuit concerning the epilepsy drug, Lamictal.
- Appeal addressed claims by direct purchasers that they overpaid for the generic version of Lamictal.
- Third Circuit held that the district court abused its discretion when it assumed, absent a rigorous analysis, that the plaintiffs' expert's use of averages to show harm was acceptable.
  - Defendants' expert provided evidence of significant variation among class members.
  - District court was required to make factual findings, including resolving these expert disputes, in deciding whether to grant class certification.

- Case shows the increasing scrutiny given in pharmaceutical antitrust class actions.

Presenters

Adam Di Vincenzo
Partner
Washington D.C.
ADivincenzo@gibsondunn.com
+1 202.887.3704

Rich Parker
Partner
Washington D.C.
RParker@gibsondunn.com
+1 202.955.8503

Deirdre Taylor
Partner
London
DTaylor2@gibsondunn.com
+44 (0)20 7071 4274

Eric Stock
Partner
New York
EStock@gibsondunn.com
+1 212.351.2301

Kaitlin Zumwalt
Associate
Washington D.C.
KZumwalt@gibsondunn.com
+1 202.955.8583