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Pharmaceutical Antitrust Litigation in 2015—Settlements, Product Hopping, and REMS

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I. INTRODUCTION

As 2015 comes to a close, pharmaceutical competition issues continue to dominate headlines as they remain an area of significant focus for federal and state antitrust enforcers and in the courts. Discussion about what constitutes “competitive” levels of pharmaceutical prices can be heard everywhere from campaign debates to Wall Street. Meanwhile, government officials, individual consumers, intermediate distributors and retailers, and, in some cases, generic pharmaceutical companies continue to turn to antitrust law as an enforcement tool. This article reflects on 2015 activity in three important areas—“pay-for-delay” patent settlements, “product hopping,” and abuse of Risk Evaluation and Mitigation Strategies (“REMS”) systems.

Since the late ‘90s, there has been intense scrutiny of “reverse payment” or “pay-for-delay” patents settlements, leading up to the Supreme Court’s seminal *Actavis* decision in 2013. Since that decision, both the Federal Trade Commission (“FTC”) and private plaintiffs have continued to bring cases in this area, often testing the boundaries of *Actavis* and compelling district courts and courts of appeals to wrangle over how to apply *Actavis*.

At present, more than a dozen cases—some of them brought in the pre-*Actavis* period—are at various stages in the federal and state courts. During 2015, a number of decisions in these cases have provided clarity, while others have perplexed antitrust practitioners and the clients they counsel. This article reviews these key decisions, which set the stage for several potentially important appeals decisions in 2016.

While most of the pharmaceutical competition cases brought over the last decade and a half have involved patent settlements, 2015 likewise has witnessed several important decisions regarding conduct alleged to have been undertaken by brand firms to delay generic competition. Product hopping and REMS have garnered the attention of antitrust enforcers at both state and federal levels, the continued attention of Congress, and suits filed by generic competitors and class plaintiffs. Decisions issued regarding such conduct over the last year have shed light on

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whether the antitrust laws are a viable tool against such conduct; but, at the same time, have raised questions by some parties that using the antitrust laws to combat branded conduct in this manner will harm innovation and patient safety.

Following the numerous court decisions in the last year in all of these areas and the continued focus on such conduct by government entities and private litigants, it is clear that pharmaceutical antitrust litigation will persist and likely expand in the coming years. This article examines the recent case law developments and sheds light on major upcoming decisions and trends.

II. PAY-FOR-DELAY PATENT SETTLEMENT UPDATE

In 2015, U.S. district courts and appellate courts continued to examine application of the Supreme Court decision in *FTC v. Actavis*,² to Hatch-Waxman patent litigation settlement agreements. While *Actavis* focused on the potential anticompetitive effects of purely monetary pay-for-delay settlements (in which a “large and unexplained” payment is alleged to have been made by the brand pharmaceutical manufacturer to the alleged patent infringer to delay generic entry), subsequent district and appellate court rulings have grappled with issues such as non-monetary payment allegations, the sufficiency of allegations about the value of payments, and the application of traditional antitrust concepts like causation to these cases.

A. Pay-For-Delay Analysis in the District Courts:

Over a dozen cases are currently being litigated in the district courts. The year 2015 saw several substantive decisions on motions to dismiss and summary judgment, and one jury trial verdict.

At the dismissal phase, three district courts considered whether certain licenses constituted anticompetitive payments under *Actavis*:

1. In *In re AndroGel*,³ the Eastern District of Pennsylvania dismissed the FTC’s pay-for-delay claims based on an authorized generic license granted by the brand, AbbVie, to the generic, Teva, for an unrelated cholesterol product (Tricor) that, according to the FTC, “was highly profitable for Teva, but made no independent business sense for AbbVie.”⁴
2. In *In re Aggrenox*, the District of Connecticut dismissed certain state law claims, but allowed federal pay-for-delay claims based on allegations of a cash payment, and a license and co-promotion agreement for Aggrenox.⁵
3. In *In re Solodyn*, the District of Massachusetts dismissed sham litigation claims and state-law claims, but allowed federal pay-for-delay claims based on joint-development agreements and promises of future negotiations for unrelated drugs.

² *FTC v. Actavis*, 133 S. Ct. 2223 (2013).

³ *In re AndroGel*, No. 14-5151 (E.D. Pa. May 6, 2015) (Order).

⁴ Press Release, Federal Trade Commission, FTC Sues Pharmaceutical Companies for Illegally Blocking Consumer Access to Lower-Cost Versions of the Blockbuster Drug Androgel (Sept. 8, 2014) available at <https://www.ftc.gov/news-events/press-releases/2014/09/ftc-sues-pharmaceutical-companies-illegally-blocking-consumer>.

⁵ *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224 (D. Conn. 2015) *motion to certify appeal granted*, No. 3:14-MD-2516 SRU, 2015 WL 4459607 (D. Conn. July 21, 2015).

Counsel may have difficulty reconciling these decisions in providing advice to clients.

District courts have also considered motions to dismiss complaints challenging terms relating to the marketing of authorized generic products and early entry provisions. In *In re Lidoderm*, the Northern District of California dismissed certain state law claims, but allowed federal pay-for-delay claims to proceed based on a promise by the brand firm to delay introduction of an authorized generic version of Lidoderm for seven and half months (also known as a “no-AG” provision), and supplying without charge \$96 million worth of branded Lidoderm patches.⁶ In *In re Actos*, the Southern District of New York dismissed in its entirety the indirect purchaser complaint, which brought state and federal antitrust claims based on alleged pay-for-delay in the form of early-entry licenses, acceleration clauses, and a non-exclusive authorized generic license.⁷

Two substantive post-dismissal decisions also were issued this year, each of which considered anticompetitive harm and causation issues:

In *In re Wellbutrin XL*, the Eastern District of Pennsylvania granted GlaxoSmithKline’s motion for summary judgment, finding the settlement agreements not actionable under *Actavis* despite the presence of a “no-AG” provision, a sublicense for an unrelated drug, an early-entry license for generic Wellbutrin XL, and the promise of a guaranteed supply of Wellbutrin XL. The Court found that the plaintiffs failed to establish either anticompetitive harm or causation in part because the settlements permitted the underlying patent litigation to continue (although, the Court emphasized, it was not creating a bright-line test that could “easily [be] exploited” as a “loophole”).⁸

Additionally, the Court believed it significant that that the generic manufacturer Teva would not have agreed to settlement at all without securing the “no-AG” provision, which Teva erroneously believed at the time of negotiation was necessary to retain its rights as first-filer under the Hatch Waxman Act. Further, the Court found that the settlements were on the whole procompetitive, because they provided competition-enhancing benefits to the generics such as broader patent rights and product supply. Finally, the Court considered it significant that the FTC had an opportunity to object to the settlement, but did not.

In re Nexium is the only pay-for-delay case to reach a jury verdict. Plaintiffs challenged settlement agreements that contained: (1) a no-AG provision, (2) acceleration clauses, (3) licenses for unrelated drugs, and (4) forgiveness for liabilities resulting from at-risk launches of other products. The claims that went to trial were the Section 1 claims and their state equivalents against all defendants except Dr. Reddy’s Laboratories, which had settled with the plaintiffs on the eve of trial.

Teva subsequently settled with the plaintiffs after five weeks of trial, and the jury reached its verdict one week later. The jury found that although AstraZeneca exercised market power in a

⁶ *In re Lidoderm Antitrust Litig.*, No. 14-md-02521-WHO, 2015 WL 2089223, at *3 (N.D. Cal. May 5, 2015); *In re Lidoderm Antitrust Litig.*, No. 3:14-md-02521 (N.D. Cal. Nov. 11, 2014) (Order Granting in Part and Denying in Part Motion to Dismiss).

⁷ *In re Actos End Payor Antitrust Litig.*, No. 13-cv-9244 RA, 2015 WL 5610752 (S.D.N.Y. Sept. 22, 2015).

⁸ *In re Wellbutrin XL Antitrust Litig.*, No. 08-2431, 2015 U.S. Dist. LEXIS 127373 at 8 (E.D. Pa. Sept. 23, 2015).

relevant market and made a “large and unjustified” payment to Ranbaxy that was unreasonably anticompetitive, plaintiffs failed to prove causation. In particular, the plaintiffs failed to show that, but for the payment, earlier generic entry would have occurred.⁹ Following entry of judgment, the Court denied the plaintiffs’ motion for a new trial.

B. Appellate Court Activity

In 2015, appellate courts began to weigh in on the contours of the *Actavis* decision, with the activity focused in the Third Circuit so far.

In *In re Lamictal*, the Third Circuit reversed Judge Walls of the District of New Jersey and ruled that a no-AG provision could constitute a “reverse payment” under *Actavis*, because it may be “an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of competition.”¹⁰ The Third Circuit rejected the defendants’ contention that by the brand agreeing not to introduce its own authorized generic, it was merely exercising its rights to grant an exclusive license. Instead, the Court concluded that the defendants were “us[ing] valuable licensing in such a way as to induce a patent challenger’s delay.”¹¹

The *Lamictal* opinion appears to apply to other non-monetary provisions besides no-AG provisions, indicating that other types of payments could also constitute payments under *Actavis*. Noting that *Actavis* is primarily concerned with payments that “negatively impact consumer welfare by preventing the risk of competition,” the Court explained that it does “not believe *Actavis*’s holding can be limited to reverse payments of cash.”¹² The defendants filed a petition for rehearing *en banc*, which was denied, and have since indicated their intention to file a *writ for certiorari* to the U.S. Supreme Court.

The Third Circuit will have a second opportunity to address *Actavis* in *In re Effexor* and *In re Lipitor*, two pay-for-delay cases that will be heard concurrently because of “the similarity of the reverse payment claims raised” in each litigation.¹³ The *Lipitor* plaintiffs had pleaded that the alleged payments—a generic *Lipitor* license and a promise to dismiss certain damages claims—were “worth hundreds of millions of dollars[.]”¹⁴ Meanwhile, the *Effexor* plaintiffs alleged an anticompetitive payment in the form of a no-AG provision, but did not plead a detailed estimate of its value.

Judge Peter G. Sheridan, who presided over both cases, dismissed each complaint, finding that a “nonmonetary payment must be converted to a reliable estimate of its monetary value so that it may be analyzed against the *Actavis* factors.”¹⁵ On appeal, the Third Circuit will first assess

⁹ *In re Nexium (Esomeprazole) Antitrust Litig.*, 309 F.R.D. 107 (D. Mass. 2015), as amended (Aug. 7, 2015).

¹⁰ *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 394 (3d. Cir. 2015).

¹¹ *Id.* at 406–07.

¹² *Id.* at 403–04.

¹³ *In re Lipitor Antitrust Litig.*, No. 14-4202, at 2 (3d. Cir. July 8, 2015).

¹⁴ *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523, 541 (D.N.J. 2014).

¹⁵ *In re Effexor XR Antitrust Litig.*, No. 3:11-cv-05479, 2014 U.S. Dist. LEXIS 142206 at *62 (D.N.J. Oct. 6, 2014); *In re Lipitor Antitrust Litig.*, No. 3:12-cv-02389 (D.N.J. Nov. 5, 2014) (Order Granting Motion to Dismiss) (dismissing the case because the plaintiffs “did not calculate the reasonable valuation of the Pfizer/Ranbaxy alleged reverse payment.”).

the application of *Actavis* to these three distinct forms of alleged payments, and (assuming *Actavis* applies) provide guidance as to what plaintiffs must allege to satisfy pleading requirements.

III. PRODUCT HOPPING

There was significant litigation activity in the product-hopping arena this year with important decisions at the district court level and the first appellate ruling to address the issue. Most significantly, the courts that have substantively examined product-hopping cases this year came to some divergent conclusions. The Second Circuit took up this issue—one of first impression in the circuit courts—and held that forcing or coercing consumers to switch to a different product iteration in order to thwart generic competition and maintain a monopoly constituted illegal product hopping in violation of the Sherman Act.

The Third Circuit is now set to review this issue on the appeal of a district court ruling much to the contrary, in which the Eastern District of Pennsylvania held, in part, that similar product-hopping conduct did not constitute an antitrust violation.

A. Product Hopping in the Second Circuit

The Second Circuit examined product hopping in *New York v. Actavis*, affirming a preliminary injunction requiring Actavis (now known as Allergan) to continue selling an older version of its branded Alzheimer's drug, Namenda, until a generic version could enter the market.¹⁶ New York Attorney General Eric Schneiderman originally brought the suit in September 2014 alleging that Actavis would violate antitrust laws through plans to switch the market from their original immediate release Namenda ("IR") to an extended release version ("XR") before a generic version of Namenda IR could launch—effectively forcing consumers to use the XR version and continue to pay monopoly prices. It was alleged that Actavis intended to use the switch to foreclose or delay generic competition for its Alzheimer's drug franchise.

Last December, U.S. District Judge Robert Sweet granted a preliminary injunction requiring Actavis to continue to manufacture and distribute Namenda IR and offer the product on similar terms and conditions that were available when Namenda XR entered the market "until thirty days after July 11, 2015 (the date when generic memantine will first be available)."¹⁷

In May, the Second Circuit affirmed the District Court's injunction, with U.S. Circuit Judge John Walker writing on behalf of the 3-0 panel. The Court explained that "[b]y effectively withdrawing Namenda IR prior to generic entry, defendants forced patients to switch from Namenda IR to XR—the only other memantine drug on the market. . ." and that this "hard switch crosses the line from persuasion to coercion and is anti-competitive."¹⁸ Had Actavis not discontinued Namenda IR, the Court noted that "patients and doctors [could have] evaluate[d] the products and their generics on the merits in furtherance of competitive objectives."¹⁹

¹⁶ *New York v. Actavis*, 787 F.3d 638, 643 (2d Cir. 2015).

¹⁷ *New York v. Actavis*, No. 14 Civ. 7473 (S.D.N.Y. Dec. 15, 2014) (Order Granting Preliminary Injunction).

¹⁸ *Id.*

¹⁹ *New York v. Actavis*, 787 F.3d at 654.

Defendants had also argued that there was no antitrust injury or harm because a generic company could effectively launch a generic version of Namenda IR (even after the brand product had been pulled from the market) and market it without relying on state substitution laws as generics typically do. The Court rejected this argument and agreed with the District Court's finding that "competition through state drug substitution laws is the only cost-efficient means of competing available to generic manufacturers," and reasoned that an antitrust violation does not require that a generic be barred "from all means of distribution" if they are "bar[red] . . . from the cost-efficient ones."²⁰

On November 4, 2015, defendants filed a petition for a *writ of certiorari*, urging the Supreme Court to determine (1) whether electing to not sell a patented product and selling a different patented product can violate the Sherman Act, and (2) whether drug manufacturers have a duty to facilitate the operation of state "substitution laws to maximize competitors' sales."²¹ On November 25, 2015, the parties to the litigation announced a settlement under which defendants paid New York for its litigation costs and defendants agreed to withdraw their petition for a *writ of certiorari*.²²

B. Product Hopping in the Third Circuit

The Third Circuit has been the venue for two recent district court cases regarding product-hopping allegations, including the appeal of a summary judgment order dismissing the claims in *Mylan Pharmaceuticals Inc. v. Warner Chilcott PLC* ("Doryx"). In April, Judge Diamond of the Eastern District of Pennsylvania granted summary judgment on behalf of Warner Chilcott (now part of Allergan), holding that the defendants did not have market power and that, even if they did, the alleged product hopping of the anti-acne drug Doryx did not constitute an antitrust violation.²³ Mylan's allegations in the suit focused on multiple alleged product hops by Warner Chilcott including (i) a switch from a capsule to a tablet, (ii) numerous changes in the dosage strength, (iii) labeling additions and subtractions, and (iv) the addition of single and dual scoring to the tablets.

In contrast to the Second Circuit's analysis that issued the following month in *Namenda*, Judge Diamond held that there was "no evidence of anticompetitive conduct" and that "Defendants did not exclude competition when they reformulated Doryx, introduced new versions of Doryx into the marketplace, marketed the new versions of Doryx, and withdrew old versions."²⁴ Despite the court's factual findings that the defendants withdrew old versions of the product from the market, deemed "hard switch" conduct by other courts, and made the various

²⁰ *Id.* at 655–66 (internal citations omitted).

²¹ *New York v. Actavis*, 787 F.3d 638 (2d Cir. 2015), *petition for cert. filed*, No. 15-587 at ii (U.S. Nov. 4, 2015).

²² Press Release, New York Attorney General, A.G. Schneiderman Announces Resolution of Lawsuit That Protected Alzheimer's Patients From Anticompetitive Tactic Aimed At Maintaining Higher Drug Prices (Nov. 25, 2015) *available at* <http://www.ag.ny.gov/press-release/ag-schneiderman-announces-resolution-lawsuit-protected-alzheimer%E2%80%99s-patients>.

²³ *Mylan Pharma., Inc. v. Warner Chilcott*, No. 12-3824, slip op. at 20–21 (E.D. Pa. Apr. 16, 2015).

²⁴ *Id.* at 21.

product switches “primarily to defeat generic competition,” Judge Diamond concluded that the plaintiff “failed to produce initial evidence of anticompetitive conduct.”²⁵

Judge Diamond appeared to reject the entire legal theory of product hopping, noting that “any firm, even a monopolist, may . . . bring its products to market whenever and however it chooses.”²⁶ Finding that product-hopping conduct is *per se* lawful contradicts both the Second Circuit’s *Namenda* holding, as well as numerous other cases finding antitrust liability for certain product changes.²⁷

Judge Diamond’s opinion also appears to be at odds with another product-hopping opinion issued a few months earlier in his own district, *In re Suboxone*.²⁸ In that case, Judge Goldberg denied defendant Reckitt’s motion to dismiss, finding that a “hard switch” could constitute anticompetitive conduct because the “threatened removal of the tablets from the market in conjunction with . . . alleged fabricated safety concerns could plausibly coerce patients and doctors to switch” to the new product.²⁹

One of the key differences between *Namenda* and *Suboxone* on one hand and *Doryx* on the other is the courts’ consideration of how the pharmaceutical market functions and the role of generic substitution laws. Like in the *Namenda* district court and circuit court opinions, Judge Goldberg in *Suboxone* found that “various market forces unique to the pharmaceutical industry make generic substitution the cost-efficient means of competing for companies selling generic pharmaceuticals,” pointing to the “disconnect between the person paying for the prescription and the person selecting the appropriate treatment.” As a result, he explained that “the ordinary market forces that would allow consumers to consider price when selecting a product are derailed.”³⁰

In contrast, Judge Diamond in *Doryx* rejected this notion, finding that “[e]ven if Defendants’ product changes prevented Mylan from taking advantage of more profitable means of distributing its generic Doryx, the changes did not ‘bar’ Mylan from the market or ‘severely restrict the market’s ambit.’”³¹

In September, Mylan appealed Judge Diamond’s ruling to the Third Circuit, which should be fully briefed and argued in 2016. The FTC, the American Antitrust Institute, a group of prominent law professors, and a number of consumer organizations all filed *amici* briefs in support of Mylan’s appeal.

²⁵ *Id.*

²⁶ *Id.* (internal citations omitted).

²⁷ See e.g. *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001); *C.R. Bard, Inc. v. M3 Sys.*, 157 F.3d 1340, at 1382 (Fed. Cir. 1998).

²⁸ *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665 (E.D. Pa. 2014).

²⁹ *Id.* at 682.

³⁰ *Id.* at 683–84.

³¹ *Mylan Pharma., Inc. v. Warner Chilcott*, No. 12-3824, slip op. at 24 (E.D. Pa. Apr. 16, 2015) (internal citations omitted).

C. Other Product-Hopping Developments

In the wake of the Second Circuit's decision in the *Namenda* case, union health groups filed a suit against Warner Chilcott alleging that the brand company violated antitrust laws by implementing a "hard switch" to remove the ulcerative colitis drug Asacol from the market before patents were set to expire in order to prevent generic competition and maintain their monopoly.³² In line with the Second Circuit's *Namenda* decision, plaintiffs allege that Warner Chilcott executed a "hard switch" to force or coerce consumers to switch to the new products—products that are not facing imminent generic competition—by removing the older version from the market.³³ In October, the plaintiffs filed a motion to consolidate all end-payor class actions, which is currently pending before the court.

Given the result of New York's litigation in *Namenda*, it seems likely that product-hopping conduct will continue to be scrutinized by government enforcers and private litigants. Developments in the pending cases—the forthcoming Third Circuit analysis in *Doryx* in particular—may provide some clarity on how this conduct will be evaluated under the antitrust laws, and determine whether this conduct remains a focus of antitrust litigation in the coming years.

IV. REMS

In recent years, there has been an increasing focus on REMS, which impose distribution restrictions to manage a known or potential serious safety risk associated with certain drugs, as a potential mechanism to block or stall generic entry. In these situations, generic companies—unable to obtain samples of brand drugs in order to conduct bioequivalence testing necessary to get FDA approval due to the distribution restrictions—have not been able to purchase samples from the brand company directly. A number of generic firms and private plaintiffs have filed suits against branded manufacturers alleging that a brand's refusal to provide drug samples necessary for potential generic entrants to conduct bioequivalence testing, under the guise of patient safety, is anticompetitive.

A. *Thalomid and Revlimid (D.N.J.)*

Two recent REMS-based antitrust claims relate to the *Thalomid* and *Revlimid* REMS programs operated by brand firm Celgene. One was filed by a generic company that alleged it was denied samples by Celgene, and the other was filed by a class of indirect purchasers. Both cases survived motions to dismiss based on similar allegations that Celgene refused to provide

³² *Teamsters Union 25 Health Services & Insurance Plan v. Allergan*, No. 1:15-cv-12730 (D. Mass. June 22, 2015); *United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund v. Allergan plc*, No. 1:15-cv-12731 (D. Mass. June 22, 2015); *Wisconsin Masons' Health Care Fund v. Allergan*, No. 15-cv-13208-DJC (D. Mass. Sept. 21, 2015); *Minnesota Laborers Health and Welfare Fund v. Allergan*, No. 15-cv-13405 (D. Mass. Sept. 21, 2015); *Pennsylvania Employees Benefit Trust Fund v. Allergan*, No. 15-cv-13407 (D. Mass. Sept. 21, 2015); *AFSCME Health and Welfare Fund v. Allergan*, No. 15-cv-13408 (D. Mass. Sept. 21, 2015).

³³ See, e.g., *Teamsters Union 25 Health Services & Insurance Plan v. Allergan*, No. 1:15-cv-12730 at 9 (D. Mass. June 22, 2015) (Complaint) ("To further this scheme, the name-brand manufacturer often removes the original drug from the market entirely—known as a 'hard switch'—right before patent expiration.").

samples to generic companies even after those companies had obtained FDA approval to receive the samples.³⁴

More specifically, in *Mylan v. Celgene* Mylan alleged that Celgene “used REMS as a pretext to prevent [plaintiff] from acquiring the necessary samples to conduct bioequivalence studies, even after the FDA determined that [plaintiff’s] safety protocols were acceptable to conduct those studies.”³⁵ The complaint further alleged that instead of providing samples after the FDA determined Mylan’s bioequivalence protocols were acceptable, Celgene made “arbitrary and onerous information requests” designed solely to protect its market power.³⁶

In December 2014, District Court Judge Salas denied the defendant’s motion to dismiss, rejecting Celgene’s argument that a firm has no duty to deal with its competitors absent “both prior dealings and irrational profit sacrifice.”³⁷ The Court found this argument unpersuasive because “there remains valid Supreme Court law imposing an affirmative duty to deal when no prior course of dealing was alleged.”³⁸

Additionally, the Court found sufficient that the plaintiff “pled that there is no legitimate business reason for [defendant’s] actions, which it argues are solely motivated by its goal to obtain long-term anticompetitive gain.”³⁹ Likewise, the indirect purchasers’ case in *In re Thalomid and Revlimid Antitrust Litigation* survived the defendant’s motion to dismiss in October of this year.⁴⁰ Both cases are currently in discovery.

B. Letairis (S.D. Minn.; D. N.J.)

Two cases involving the drug Letairis, one in the Southern District of Minnesota⁴¹ and the other in the District of New Jersey,⁴² appear to suggest that firms face greater difficulties in pursuing an antitrust suit to secure REMS-protected samples without first attempting to secure samples through non-futile, available regulatory processes. The plaintiffs in both cases filed antitrust suits against brand firm Gilead after it denied plaintiffs’ multiple requests for samples of branded Letairis.

The Southern District of Minnesota was the first court to rule on the substantive issues in the case and granted the defendants’ motion to dismiss on the following grounds:

First, [plaintiff] is able to obtain samples by engaging a REMS-certified physician to write a prescription. Thus, Letairis is not completely unavailable. Second, complying with FDA requirements requiring a valid prescription before dispensing Letairis constitutes a valid business reason to refuse to dispense

³⁴ *Mylan Pharma., Inc. v. Celgene Corp.*, No. 2:13-cv-02094-ES (D.N.J. Dec. 22, 2014) (Oral Opinion); *In re Thalomid and Revlimid Antitrust Litig.*, No. 14-6997 (D.N.J. Oct. 29, 2015).

³⁵ *Mylan Pharma., Inc. v. Celgene Corp.*, No. 2:13-cv-02094-ES at ¶7 (D.N.J. April 3, 2014) (Complaint).

³⁶ *Id.* at ¶92.

³⁷ *Mylan Pharma., Inc. v. Celgene Corp.*, No. 2:13-cv-02094-ES at 14 (Defendant’s Motion to Dismiss).

³⁸ *Mylan Pharma., Inc. v. Celgene Corp.*, No. 2:13-cv-02094-ES at 16–17 (Oral Opinion).

³⁹ *Id.* at 17.

⁴⁰ *In re Thalomid and Revlimid Antitrust Litig.*, No. 14-6997 (D.N.J. Oct. 29, 2015) (Order).

⁴¹ *Natco Pharma Ltd. v. Gilead Sciences, Inc.*, No. 0:14-cv-03247 (D. Minn. Sept. 29, 2015) (Opinion and Order).

⁴² *Zydus Pharma., Inc. v. Gilead Sciences, Inc.*, No. 3:14-cv-07080 (D.N.J. Nov. 17, 2015).

Letairis outside of the REMS requirements. Thus, [plaintiff] fails to state an actionable claim under Section 2.⁴³

However, the Court did note that “should [plaintiff] pursue all appropriate avenues to obtain samples of Letairis and still maintain that Defendants are liable for antitrust violations, [plaintiff] can again file an action.”

Following the Southern District of Minnesota opinion, Gilead filed a letter with the District of New Jersey in a separate suit brought against Gilead by generic firm Zydus stating its view of the difference between the Letairis conduct and the conduct at issues in the above mentioned *Thalomid/Revlimid* cases. The letter stated that the plaintiffs in the latter pled that they attempted to acquire samples through normal regulatory channels prior to filing suit, while the plaintiffs in the Letairis cases failed to exhaust their regulatory options.⁴⁴ Specifically, the letter states that the *Thalomid/Revlimid* plaintiffs successfully pled that the drugs at issue “could only be obtained from the manufacturer.”⁴⁵ Zydus subsequently voluntarily dismissed its suit.⁴⁶

C. Suboxone (E.D. Pa.)

The plaintiffs in *In re Suboxone*, in addition to the product-hopping allegations discussed above, also brought a claim premised on REMS-related conduct.⁴⁷ Unlike the traditional REMS fact pattern discussed above, in which a brand allegedly blocked a generic firm from obtaining necessary samples, the plaintiffs’ REMS allegations regarding Suboxone concern defendant’s use of “baseless delay tactics” to stall the development of an FDA-mandated single shared REMS program.⁴⁸ In that case, generic firms were able to obtain samples, but the defendants stalled efforts by the generic to join the brand firm’s REMS program, which is required by FDA for marketing of the approved generic products.

The District Court ultimately dismissed the REMS portion of the plaintiffs’ case, finding that “there [was] no long-standing, preexisting course of dealing between [defendant] and the Generics” and that “the antitrust laws do not impose a duty on [defendant] to aid the Generics in obtaining expeditious approval of an ANDA.”⁴⁹ Nevertheless, the Court declined to dismiss the product hopping and additional claims regarding “sham citizen petitions,” and the case is now in discovery.

D. Additional Focus on REMS and Restricted Distribution

Potential antitrust concerns regarding pharmaceutical conduct rose to national prominence recently following Turing Pharmaceuticals’ decision to increase the price of their off-patent toxoplasmosis drug Daraprim from U.S. \$13.50 to \$750 per pill. While Daraprim is

⁴³ *Natco Pharma Ltd. v. Gilead Sciences, Inc.*, No. 0:14-cv-03247 at 19–20 (Opinion and Order).

⁴⁴ *Zydus Pharma., Inc. v. Gilead Sciences, Inc.*, No. 3:14-cv-07080 (Oct. 14, 2015) (Letter from Gavin Rooney, Counsel for Gilead Sciences, Inc. to Honorable Freda L. Wolfson, U.S.D.J.).

⁴⁵ *Id.*

⁴⁶ *Zydus Pharma., Inc. v. Gilead Sciences, Inc.*, No. 3:14-cv-07080 (D.N.J. Nov. 17, 2015) (Notice of Voluntary Dismissal).

⁴⁷ *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d at 687.

⁴⁸ *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13-md-2445 at ¶3B (E.D. Pa. Aug. 15, 2013) (Complaint).

⁴⁹ *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. at 687.

not subject to the FDA's formal REMS requirements, the drug is distributed in a restricted manner that could make it difficult for potential generic entrants to access the drug for bioequivalence studies. This issue has caught the attention of several key policy-makers who have suggested Turing's control over Daraprim's distribution may have contributed to Turing's ability to effectuate and maintain a 5,000 percent price increase on a sixty-year old drug.

In October, Senator Amy Klobuchar (D-MN)⁵⁰ and former Secretary of State Hillary Clinton⁵¹ both sent letters to the FTC urging the agency to investigate Daraprim and other instances of restricted distribution programs being used to maintain supracompetitive pricing. Senator Klobuchar's letter acknowledged that unilateral price increases "no matter how unfair" do not run afoul of the antitrust laws, but also stated that "[i]f a company were to employ [a restricted distribution system] to deny competitors supply for use in generic application, it would be doing more than simply raising prices."⁵²

Secretary Clinton's letter urged the FTC to study "what has become an increasing problem in the pharmaceutical industry—dramatic price increases that result in drugs remaining artificially high and causing a real barrier for consumers, while there is a very long lag in approval of potential competitors onto the market."⁵³ Additionally, she called on the agency to "investigate whether the restricted distribution of Daraprim amounts to anticompetitive behavior," and explained that abuse of a restricted distribution programs could force consumers to face "unconscionably high prescription drug prices with little or no means of relief."⁵⁴

The New York Attorney General's Office also has raised similar concerns regarding Turing's control over Daraprim distribution.⁵⁵ This shows further government interest regarding conduct that may impede a firm's ability to develop and distribute lower-priced generic products. The recent litigation where such claims have survived motions to dismiss further indicates that litigation and investigation of such issues is likely to continue in the coming years.

⁵⁰ Letter from Senator Amy Klobuchar to Chairwoman Edith Ramirez, Federal Trade Commission (Oct. 7, 2015) *available at* <http://www.klobuchar.senate.gov/public/2015/10/klobuchar-calls-for-ftc-investigation-of-pharmaceutical-companies-for-possible-antitrust-violations-in-light-of-recent-alarming-drug-price-increases>.

⁵¹ Letter from Hillary Clinton, Former Secretary of State to Chairwoman Edith Ramirez, Federal Trade Commission (Oct. 19, 2015) *available at* <https://www.hillaryclinton.com/p/briefing/statements/2015/10/15/clinton-urges-federal-actions-after-turing-price-hike/>.

⁵² Letter from Senator Amy Klobuchar to Chairwoman Edith Ramirez, Federal Trade Commission (Oct. 7, 2015) *available at* <http://www.klobuchar.senate.gov/public/2015/10/klobuchar-calls-for-ftc-investigation-of-pharmaceutical-companies-for-possible-antitrust-violations-in-light-of-recent-alarming-drug-price-increases>.

⁵³ Letter from Hillary Clinton, Former Secretary of State to Chairwoman Edith Ramirez, Federal Trade Commission (Oct. 19, 2015) *available at* <https://www.hillaryclinton.com/p/briefing/statements/2015/10/15/clinton-urges-federal-actions-after-turing-price-hike/>.

⁵⁴ *Id.*

⁵⁵ Andrew Pollack, *New York Attorney General Examining Whether Turing Restricted Drug Access*, N.Y. TIMES (Oct. 12, 2015) *available at* <http://www.nytimes.com/2015/10/13/business/new-york-attorney-general-examining-if-turing-restricted-drug-access.html>.