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**“Good Luck” Post-Actavis:
Current State of Play on “Pay-
for-Delay” Settlements**

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I. INTRODUCTION

Chief Justice Roberts’ statement “good luck to the district courts” in his dissent in *FTC v. Actavis* was certainly prophetic.² Since the Court’s issuance of that decision in June 2013, the district courts have been dragged into numerous additional cases—more than a dozen cases are currently pending—and more than a half dozen decisions have come down with rulings providing a broad spectrum of interpretations as to what the Court meant by a “large and unexplained” payment.

The U.S. Federal Trade Commission (“FTC”), which brought the *Actavis* case, has added further layers of complexity to pharmaceutical companies trying to understand the post-*Actavis* landscape. On September 8, 2014, the FTC brought its first “pay-for-delay” case since it filed the *Actavis* case back in January 2009—a case against AbbVie that also includes sham litigation claims—and has launched at least three significant investigations during 2014. The FTC also, changing tack after more than a decade, is now pursuing disgorgement in “pay-for-delay” cases, although the dissenting votes of the two Republican Commissioners in the *AbbVie* case may indicate a lack of uniformity on this issue, and perhaps indicate some break in the lock-step bipartisan support “pay-for-delay” cases have enjoyed at the FTC since the late 1990’s.

This article examines the current quagmire in the courts, the FTC’s recent activities, and finally explores growing interest outside the United States in getting into the “pay-for-delay” fray.

II. WHAT IS A “LARGE” AND “UNEXPLAINED” PAYMENT AND HOW DOES ONE PLEAD IT?

This fall, Judge Peter Sheridan in the District of New Jersey issued two significant opinions in the “pay-for-delay” arena.³ Up until this point, district courts had split on whether *Actavis* applies only to reverse payments of cash.⁴ Judge Sheridan offered a third approach to the

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² *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, at 2245 (U.S. 2013) (Roberts, J., Dissenting).

³ *In re Lipitor Antitrust Litig.*, 2014 U.S. Dist. LEXIS 127877 (D.N.J. 2014); *In re Effexor XR Antitrust Litig.*, 2014 U.S. Dist. LEXIS 142206 (D.N.J. 2014).

⁴ *Compare In re Nexium Esomeprazole Antitrust Litig.*, 2014 U.S. Dist. LEXIS 126954, at *75 (D. Mass. Sept. 4, 2014) (“unlawful reverse payments are not limited to monetary payments”) with *In re Lamictal Direct Purchaser Antitrust Litig.*, 2014 U.S. Dist. LEXIS 9257, at *22 (D.N.J. Jan. 24, 2014) (“the Supreme Court considered a reverse payment to involve an exchange of money”).

binary framework set forth in previous decisions. Specifically, he concluded that while non-monetary payments could constitute reverse payments under *Actavis*, a complaint must demonstrate a “reliable cash value of the non-monetary payment”⁵ and dismissed the *Lipitor* and *Effexor* complaints for failing to do so. These decisions and their implications are discussed in more detail below.

A. *Lipitor*

In *Lipitor*, direct purchaser plaintiffs filed suit against Pfizer and Ranbaxy for allegedly entering into a “pay-for-delay” settlement with respect to Pfizer’s blockbuster cholesterol drug, Lipitor (atorvastatin).⁶ According to plaintiffs, Ranbaxy agreed to take a later entry date under the settlement in exchange for the following payments from Pfizer to Ranbaxy: (1) a “sweetheart” agreement to dismiss Pfizer’s damages claims against Ranbaxy (likely worth hundreds of millions of dollars) in unrelated patent litigation (the Accupril II litigation) for a token payment of \$1 million; and (2) foreign patent litigation settlements permitting Ranbaxy to launch generic Lipitor in at least 11 non-U.S. markets prior to patent expiration.

On September 12, 2014, Judge Sheridan dismissed direct purchasers’ complaint with prejudice. The court found that *Actavis* was not restricted to cash payments, but that any non-monetary payment alleged “must be converted to a reliable estimate of its monetary value so that it may be analyzed against the *Actavis* factors such as whether it is ‘large’ once the subtraction of legal fees and other services provided by generics occurs.”⁷

For the payment alleged through Pfizer’s agreement to dismiss damages in the *Accupril II* litigation, plaintiffs generally argued that the non-monetary payment could be the same amount as the bond posted in the patent litigation (\$200 million) or it could be the difference in the brand’s gross sales (\$525 million to \$70 million) with and without a generic competitor. However, the court found that these estimates were insufficient, as plaintiffs never attempted to value this non-monetary payment to a reliable measure of damages through a risk-adjusted lost profits analysis. Similarly, for foreign market licenses, the court determined that the complaint “lack[ed] any foundation to estimate the cash value of the alleged licenses granted in other countries.”⁸ Because the complaint failed to provide a reliable foundation showing a cash value of the non-monetary payment, its reverse payment allegations were implausible.

The court also noted that plaintiffs failed to consider, or even address, the fact that the payments (even if clearly pled) could have constituted “saved litigation costs.” According to the court, the agreement settled three U.S. patent infringement litigations and 23 foreign legal actions, so the saved litigation costs could have been in the hundreds of millions of dollars. Plaintiffs’ failure to attempt to properly value the alleged reverse payments, including the subtraction of any saved litigation costs, made any analysis of whether such payments were “large” impossible.

⁵ *In re Lipitor Antitrust Litig.*, 2014 U.S. Dist. LEXIS 127877, at *65.

⁶ Indirect purchaser plaintiffs also filed suit and, in a separate, later-issued opinion, Judge Sheridan dispatched their claims for similar reasons.

⁷ *Id.* at 64.

⁸ *Id.* at 72.

In response to Judge Sheridan's decision, direct purchaser plaintiffs filed a motion to amend the judgment to permit them leave to file an amended complaint.⁹

B. Effexor

In *Effexor*, direct purchaser plaintiffs filed suit against Wyeth and Teva for allegedly entering into a "pay-for-delay" settlement with respect to Effexor XR (venlafaxine hydrochloride), an anti-depressant drug. According to plaintiffs, Teva agreed to accept a later generic entry date under the settlement in exchange for Wyeth's promise to refrain from marketing an authorized generic product during Teva's first 180-days on the market (a "no-AG agreement").

On October 7, 2014, similar to his *Lipitor* decision, Judge Sheridan dismissed plaintiffs' "pay-for-delay" allegations with prejudice.¹⁰ While Judge Sheridan found that the no-AG agreement alleged in *Effexor* did have value, plaintiffs did not convert it to a specific value using a reliable method. Specifically, plaintiffs asserted that the no-AG payment was worth over \$500 million by: (1) claiming that "Teva would realize about double the volume of generic sales at significantly higher, supra-competitive prices,"¹¹ and (2) that, for Paxil (a similarly sized drug), another generic firm told the FDA that the presence of an authorized generic cost the company approximately \$400 million during its 180-day exclusivity period. The court, however, found that plaintiffs' \$500 million calculation based on these facts to be "vague and amorphous."¹²

In addition, the court noted that the question of whether there is a "reverse payment" involved more than just an analysis of the no-AG agreement. To analyze a payment, one must: (1) value any consideration flowing from the patentee to the claimed infringer, which may take forms other than cash; (2) deduct from that payment the patent holder's avoided litigation costs; and (3) deduct from that payment the value of goods, services, or other consideration provided by the claimed infringer to the patent holder as part of the same transaction (or linked transactions). The resulting net payment is "otherwise unexplained" and hence an unlawful reverse payment.

Here, in addition to failing to reliably calculate the value of the no-AG promise, plaintiffs failed to set forth a reliable foundation for valuing Wyeth's saved litigation costs or the royalty payments paid by Teva to Wyeth. Because plaintiffs did not reliably value the "payment" under the court's three-step analysis, the court could not determine whether it was reverse (i.e., whether the resulting net payment flowed from alleged infringer to patent holder), whether it was "large," or whether it was "unexplained."

On October 21, 2014, direct purchasers filed a motion asking Judge Sheridan to reconsider his decision to dismiss plaintiffs' complaint in *Effexor*, and allow them to re-plead.¹³ The crux of plaintiffs' motion for reconsideration is that it was a clear error of law for Judge Sheridan to dismiss plaintiffs' complaint—under a "novel" pleading standard that the judge

⁹ Motion to Amend Judgment, *In re Lipitor Antitrust Litig.*, 2014 U.S. Dist. LEXIS 127877 (D.N.J. 2014).

¹⁰ Judge Sheridan, however, allowed plaintiffs' *Walker-Process* claim to proceed.

¹¹ *In re Effexor XR Antitrust Litig.*, 2014 U.S. Dist. LEXIS 142206, at *67.

¹² *Id.* at *69.

¹³ Motion to Reconsider, *In re Effexor XR Antitrust Litig.*, 2014 U.S. Dist. LEXIS 142206 (D.N.J. 2014).

announced after the complaint was filed—with prejudice. Plaintiffs asserted that they could set forth specific allegations valuing the no-AG agreement even under the court’s heightened pleading standard, and claimed to do so in their proposed amended complaint, which was attached to their motion for reconsideration.

C. Implications

As a result of Judge Sheridan’s decisions in *Lipitor* and *Effexor*, we expect that plaintiffs, in the future, will include significant detail in their complaints regarding the method by which they are calculating the cash value of any non-monetary payment. For example, in their motion for reconsideration in *Effexor*, plaintiffs spent over 20 paragraphs in their proposed amended complaint on valuing the alleged non-monetary reverse payment—the no-AG clause—in an attempt to calculate the cash value of the non-monetary payment using an industry-reliable method.¹⁴ In particular, if other district courts adopt Judge Sheridan’s pleading standard, plaintiffs may even be inclined to engage economists or other experts in preparing their complaints to help bolster key valuation allegations on alleged payments through non-monetary settlement provisions.

Moreover, given that on November 19, 2014 the Third Circuit heard the oral argument on the *Lamictal* appeal—concerning whether a no-AG agreement can be a reverse payment under *Actavis*—it will also be interesting to see whether the panel will rule on Judge Sheridan’s proposed pleading standard in its forthcoming opinion. While the issue is not directly before the Third Circuit, it could opine more broadly on what is required to properly allege a payment under *Actavis*, as it will be the first Circuit court to issue a decision on this issue. Clients and practitioners alike should stay apprised on continued developments in the direct purchaser plaintiffs’ motions for leave to re-plead in *Lipitor* and *Effexor* as well as the Third Circuit’s forthcoming decision in *Lamictal*.

III. FTC HAS BEEN INVIGORATED POST-ACTAVIS

After years of waiting for the Supreme Court to weigh in on the “pay-for-delay” debate, the Court’s decision in *FTC v. Actavis* has invigorated the FTC’s enforcement efforts. The *Actavis* ruling certainly did not give the FTC everything it wanted, as the Court rejected the FTC’s preferred “presumption of illegality” standard that had been set forth by the Third Circuit in *K-Dur*.¹⁵ However, the Court’s rejection of the “scope of the patent” test favored by several circuits, and expression of concern about patent settlements that contained “large and unexplained” payments, certainly left the FTC feeling emboldened post-*Actavis* to investigate and challenge settlements.

The FTC’s foray back into the federal courts in the *AbbVie* suit reflects the FTC’s continued skepticism regarding “side-deal” arrangements. The FTC filed its September 8, 2014 complaint against *AbbVie*, *Abbott*, *Unimed*, *Besins*, and *Teva* in the Eastern District of

¹⁴ *Id.* at ¶ 284-305.

¹⁵ *In re K-Dur Antitrust Litig.*, 686 F.3d 197, at 218 (3d Cir. 2012) (“the finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade”).

Pennsylvania. The decision to file the complaint was a 3-2 decision, with Commissioners Wright and Ohlhausen dissenting. The case involves the same drug (Androgel) as in the *Actavis* case.

The complaint alleges that, as trial approached in the AbbVie/Teva Androgel patent litigation, AbbVie entered into a “pay-for-delay” settlement with Teva to prevent Teva from winning the patent litigation and opening up the generic market. While the complaint’s “pay-for-delay” allegations are heavily redacted, it appears that the compensation was in the form of a side deal—namely a “product supply” agreement for Teva to serve as the authorized generic for AbbVie’s TriCor product.¹⁶ The complaint alleges that the authorized generic agreement enabled Teva to compete “before independent generic entry is expected,”¹⁷ and suggests that Teva got a far higher split of profits than is typical in these sorts of deals.

The complaint is also novel in that it alleges that AbbVie pursued sham litigation against Teva and Perrigo, asserting infringement of its ‘894 patent even though Teva and Perrigo’s formulations were clearly outside of the literal scope of the ‘894 patent and did not infringe. Nearly 14 pages of the total 40 pages in the complaint focus on sham litigation—which indicates that the sham claims are of significant importance to the FTC. This case marks the first ever FTC challenge to Hatch-Waxman litigation on sham grounds, although this is an area that the FTC has previously probed.

Focusing back on the “pay-for-delay” allegations, the agreement at issue does not raise any particularly novel issues. The FTC—and private plaintiffs—have challenged numerous “side-deal” arrangements over the past decade and a half. What is of note in *AbbVie* is a new standard set forth by the FTC that is novel, and not reflected in the Court’s *Actavis* decision. The new standard is as follows: If the generic receives anything from the brand that it could not obtain as a result of winning the patent litigation, it is a reverse payment under *Actavis*.¹⁸ While this standard has appeared in other private suits and some academic works, the Court in *Actavis* certainly did not set forth a standard along these lines and no district court since then has endorsed or offered an opinion on whether this standard is consistent with *Actavis*.

It is also quite noteworthy that the Commission vote in the *AbbVie* suit was 3-2 with Republican Commissioners Ohlhausen and Wright voting against filing the complaint. All prior FTC “pay-for-delay” consents and suits since the late 1990s were brought on a bi-partisan basis, and Ohlhausen and Wright have supported various recent FTC amicus briefs stating that no-AG agreements constitute compensation. It is unclear why they dissented in this instance as they did not issue dissenting statements when the complaint issued. One potential area of divergence, which could be at least part of the rationale for the dissenting votes, is that the *AbbVie* complaint seeks disgorgement. Prior FTC “pay-for-delay” complaints did not seek disgorgement,¹⁹ and

¹⁶ Complaint at ¶120, *FTC v. AbbVie, Inc.*, 2:14-cv-05151, (E.D. Pa. 2014).

¹⁷ *Id.* at ¶126.

¹⁸ *See Id.* at ¶124 (“The TriCor authorized generic deal was something Teva could not have obtained had it won the AndroGel patent infringement litigation. Even if Teva had prevailed in the AndroGel litigation, it would not have secured a right to sell an authorized generic version of TriCor.”).

¹⁹ The FTC complaint in its Cephalon litigation did not seek disgorgement, although the FTC did later amend its position in that case. Complaint, *FTC v. Cephalon, Inc.*, 551 F. Supp. 2d 21 (D.D.C. 2008).

Commissioners Ohlhausen and Wright have expressed concern over the use of this tool except in a few narrow circumstances.²⁰

As far as the pipeline for new FTC challenges following the *AbbVie* suit, the Commission appears to be dedicating significant resources to investigating settlements. Following the *Actavis* decision, Chairwoman Ramirez testified before the Senate Judiciary Committee in July 2013 stating: “The Supreme Court’s decision in *Actavis* confirms that [reverse payment] settlements harm consumers and competition, and the Commission will continue to aggressively prosecute these anticompetitive settlements.”²¹ Additional statements from FTC officials at the time further indicated that the FTC would be reviewing prior patent settlement filings to find appropriate cases for challenge.

In the wake of these statements, there are a number of publicly disclosed FTC investigations that have emerged over the last year.²² As part of these investigations, the FTC has issued broad subpoenas, sought investigational hearings of numerous party witnesses, and taken an aggressive position on subpoena compliance in particular with regard to privilege claims.

It remains to be seen whether any of these investigations will ripen into litigation. The FTC is busy with three ongoing federal court litigations. In addition to the *AbbVie* case, the FTC is back in discovery in the *Actavis* case following remand to the district court in Georgia, and the ongoing *Cephalon* case in federal court in Philadelphia could end up in trial following the court’s oral argument on summary judgment that took place on November 6, 2014.

Thus, while the FTC waited for years for a Circuit split to emerge, which ultimately resulted in the *Actavis* decision, it now is proceeding post-*Actavis* with a significant number of litigations and investigations. Companies thus need to remain cognizant about whether their settlements could lead them into an investigation and the courts, while at the same time keeping their eye on private plaintiffs, as discussed above, who likewise remain very active in challenging patent settlements.

IV. PATENT SETTLEMENT INVESTIGATIONS GO GLOBAL

While the focus on “pay-for-delay” settlements began in the United States, interest in such agreements has gone global in recent years as international antitrust enforcers have increasingly focused on pharmaceutical patent settlements—a trend that undoubtedly will

²⁰ See Statement of Commissioner Maureen K. Ohlhausen – Dissenting from the Commission’s Decision to Withdraw its Policy Statement on Monetary Equitable Relief in Competition Cases, FTC File No. P859910 (July 31, 2012) available at http://www.ftc.gov/sites/default/files/documents/public_statements/statement-commissioner-maureen-k.ohlhausen/120731ohlhausenstatement.pdf; Joshua D. Wright, “The Federal Trade Commission and Monetary Remedies,” Remarks at the 18th Annual Competition Law and Policy Workshop, (July 19, 2013) available at http://www.ftc.gov/sites/default/files/documents/public_statements/federal-trade-commission-monetary-remedies/130719monetaryremedies.pdf.

²¹ *Pay-for-Delay Deals: Limiting Competition and Costing Consumers Before the S. Judiciary Comm*, 113th Cong. 1 (July 23, 2013) (statement of Edith Ramirez) available at http://www.ftc.gov/sites/default/files/documents/public_statements/statement-chairwoman-edith-ramirez-pay-delay-settlements/130923pfdopeningstatement_0.pdf.

²² Press reports have noted certain of these investigations. See, e.g., David McLaughlin, *U.S. Steps Up Probes of Deals to Block Generic Drugs*, BLOOMBERG (June 23, 2014) available at <http://www.bloomberg.com/news/2014-06-23/u-s-steps-up-probes-of-deals-to-block-generic-drugs.html>.

continue. Global pharmaceutical companies need to be mindful of antitrust risk, both in and outside the United States, as they negotiate and enter into these agreements.

A. European Commission

Since 2009, the European Commission (“EC”) has closely monitored pharmaceutical patent settlements. In July 2014, the EC handed down its largest penalty related to a “pay-for-delay” settlement when it imposed a U.S. \$449 million fine on Servier for “abusing its dominance” by entering into settlements that the EC believed kept generic versions of Perindopril, a blood pressure medication, off the market.²³ The EC also imposed U.S. \$120.2 million worth of fines on the five generic firms involved in the agreements.

The *Servier* case is not the first time the EC has investigated patent settlements. In 2013 it fined Lundbeck and various generic firms \$195.5 million²⁴ and Johnson & Johnson and Novartis \$22.4 million²⁵ because of “pay-for-delay” agreements; however, the *Perindopril* case was the EC’s most aggressive case yet. Not only did the EC impose its largest “pay-for-delay” fine to date, *Servier* was also the first time the EC investigated a pharmaceutical patent settlement under a dominance standard. The *Johnson & Johnson* and *Lundbeck* cases, on the other hand, were brought under the EC’s authority to regulate restrictive agreements. By using both the restrictive agreement and dominance standards, which is akin to bringing a claim under both Sections 1 and 2 of the Sherman Act, the EC has signaled that it will continue to challenge pharmaceutical patent settlements.

B. Canada

Until recently, Canada was not viewed as a country that was playing a role in investigating or challenging pharmaceutical patent settlements. However, at a recent conference on global pharmaceutical antitrust issues, John Pecman, Canada’s Commissioner of Competition, indicated that Canada will pursue criminal cases predicated on “reverse-payment settlements” in certain circumstances.²⁶ No other country to date has indicated that they view such settlements as raising criminal antitrust implications.

Pecman explained that the Competition Bureau, Canada’s antitrust enforcers, “would be more inclined to commence an inquiry under [Canada’s] criminal provision” in three circumstances: (1) patent settlements that include “conduct with respect to markets or products that are not the focus of the patent litigation,” (2) patent settlements that include conduct “beyond the scope of the patent,” or (3) patent settlements where there is “direct or circumstantial evidence that indicates that the settlement is a vehicle for a ‘naked restraint’ on competition.”

²³ Melissa Lipman, *3 Key Facts from the EU’s Latest Pay-For-Delay Case*, LAW360, (July 15, 2014) available at <http://www.law360.com/articles/557308/3-key-facts-from-the-eu-s-latest-pay-for-delay-case>.

²⁴ Kathryn Brenzel, *EU Fines Lundbeck \$125.6M in Pay-For-Delay Probe*, LAW360, (June 19, 2013) available at <http://www.law360.com/articles/451345>.

²⁵ Stewart Bishop, *J&J, Novartis Fined \$22.4M over Pay-For-Delay Deal*, LAW360, (Dec. 10, 2013) available at <http://www.law360.com/articles/494572>.

²⁶ John Pecman, Canadian Commissioner of Competition, Remarks at the Global Antitrust Institute Conference: Global Antitrust Challenges for the Pharmaceutical Industry, (Sept. 23, 2104) available at <http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03817.html>.

He further explained that settlements where “a generic agreed to enter beyond the expected expiry date of the patent in exchange for a payment” or where “the evidence suggest[s] that [the] payment was strictly to delay or prevent entry” would likely lead to criminal investigations.

Pecman also indicated that the Bureau would encourage regulatory changes designed to make it easier to monitor, and ultimately challenge, pharmaceutical patent settlements. He stated that the Bureau would like Canada to adopt a settlement notification system similar to the one in the United States, saying that it would “would furnish the Bureau with substantive information about settlement agreements and enhance [its] ability to address potentially anti-competitive agreements.”

C. India

This summer India’s competition authority, the Competition Commission of India (“CCI”), began investigating two sets of patent settlements between brand and generic firms.²⁷ The CCI’s analysis of these and other pharmaceutical patent settlements will likely mirror that of the FTC.

In 2012, the CCI entered into a Memorandum of Understanding with the FTC and U.S. Department of Justice (“DOJ”) that promised to increase coordination and communication between the agencies; additionally, FTC staff has served as advisors to help the CCI develop its antitrust policy.²⁸ Considering the FTC’s experience with patent settlements, and their history of working closely with the CCI, it is likely that India will apply similar standards as the FTC when investigating patent settlement agreements.

D. Other Countries Likely to Follow Suit

As so-called “pay-for-delay” issues continue to attract more attention, additional countries will invariably begin opening their own investigations. In fact, several countries have already taken actions on agreements that, in antitrust enforcers’ minds, were designed to delay generic entry.

Both the Administrative Council for Economic Defense (“CADE”)—Brazil’s competition authority—and the French Competition Authority (“FCA”) have recently issued fines against pharmaceutical companies that offered pharmacies and distributors discounts that allegedly were designed to hinder generic adoption.²⁹ Additionally, in February 2014, the Australian Competition and Consumer Commission filed an antitrust suit against Pfizer for similar

²⁷ *India Enters “Pay-for-Delay” Fray: CCI Investigating Pharmaceutical Patent Settlements*, WSGR, (Aug. 12, 2014) available at <http://www.wsgr.com/WSGR/Display.aspx?SectionName=publications/PDFSearch/wsgralert-CCI.htm>; *CCI to Scan Drug Patent Settlements*, LiveMint, (Aug. 3, 2014) available at <http://www.livemint.com/Companies/RVVDhRh7oTfpqIphkb6jM/CCI-to-scan-drug-patent-settlements.html>.

²⁸ *FTC and DOJ Sign Memorandum of Understanding With Indian Competition Authorities*, Federal Trade Commission (September 27, 2012) available at <http://www.ftc.gov/news-events/press-releases/2012/09/ftc-doj-sign-memorandum-understanding-indian-competition>.

²⁹ *Global Convergence on ‘Pay-for-Delay’ settlements*, BRISTOWS, (Oct. 16, 2014) available at <http://www.bristows.com/articles/global-convergence-on-pay-for-delay-settlements>.

conduct.³⁰ While the facts of these cases are not analogous to a traditional “pay-for-delay” case, the alleged anticompetitive effect, delayed generic entry, is identical. Companies should expect that France, Brazil, Australia, and many other countries may soon open their own pharmaceutical patent settlement investigations.

³⁰ Dan Prochilo, *Australia Hits Pfizer with Antitrust Suit Over Lipitor*, LAW360, (Feb. 13, 2014) available at <http://www.law360.com/articles/509768/australia-hits-pfizer-with-antitrust-suit-over-lipitor>.