



## ***FTC v. Actavis: Supreme Court to Address Reverse-Payment Settlement Agreements***

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On March 25, 2013, the U.S. Supreme Court will hear oral argument in *Federal Trade Commission v. Actavis, Inc., et al.*<sup>2</sup> and for the first time will address the antitrust implications of reverse-payment agreements.<sup>3</sup>

The FTC has expressed concerns with reverse-payment agreements for over a decade, challenging them in a number of enforcement actions over the years with varying degrees of success.<sup>4</sup> Private litigants have attacked them as

well. The result has been a split among the circuit courts, most recently with the Eleventh Circuit upholding the agreements in *Actavis* and the Third Circuit disapproving of them in *In re K-Dur Antitrust Litigation*.<sup>5</sup>

*Actavis* began with a dispute over AndroGel®, the topical gel used to treat low testosterone levels in men. The respondents – patent holder Solvay Pharmaceuticals, Inc.<sup>6</sup> and generic manufacturers Watson Pharmaceuticals, Inc., Paddock Laboratories, Inc., and Par Pharmaceuticals, Inc. – ended their patent litigation in 2006 with settlements alleged to contain reverse-payment provisions. The FTC filed suit in 2009, alleging that the agreements violated Section 5 of the FTC Act. Over four years after that initial challenge – a case that Commissioner Leibowitz at the time billed as “yet another example of pharmaceutical

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<sup>2</sup> *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298 (11th Cir. 2012), *cert. granted*, 133 S. Ct. 787 (U.S. 2012) (No. 12-416), *sub nom.* *FTC v. Actavis*. For the petition for certiorari and other materials related to this case, *see* *FTC v. Actavis*, SCOTUSblog (last visited Mar. 18, 2013), <http://www.scotusblog.com/case-files/cases/federal-trade-commission-v-watson-pharmaceuticals-inc/>. *FTC v. Actavis* was formerly named *FTC v. Watson*, before Watson took the name of an acquisition target in January 2013.

<sup>3</sup> In a reverse-payment agreement, pharmaceutical companies agree to settle patent litigation in which a brand-name drug manufacturer (or patent holder) has challenged a generic drug manufacturer’s attempt to enter the market. The settlements usually involve the branded company compensating the generic manufacturer in exchange for the generic manufacturer’s agreement not to challenge the branded company’s patent and to delay entry for a period of time.

<sup>4</sup> *See, e.g.*, *In re Abbott Labs.*, No. C-3945 (F.T.C. May 22, 2000) (FTC entered consent order with defendant companies); *In re Hoechst Marion Roussel, Inc.*, No. 9293

(F.T.C. Apr. 2, 2001) (same); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (reversing FTC ruling that reverse-payment agreements violated the antitrust laws).

<sup>5</sup> *See* *Watson*, 677 F.3d 1298; *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012). The Second and Federal Circuits have followed the test laid out by the Eleventh Circuit. *See, e.g.*, *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008).

<sup>6</sup> Solvay is now known as AbbVie Products LLC.



companies turning competition on its head”<sup>7</sup> – the Supreme Court will take up the issue.

## Summary of the Issues Before the Supreme Court

At a broad level, the *Actavis* case involves the overlap of antitrust and patent law, as well as the Hatch-Waxman framework that regulates the market entry of generic pharmaceuticals. When a brand-name manufacturer and its would-be generic competitors settle patent claims with reverse-payment settlement agreements, do they unlawfully restrain competition?

The parties have argued for two very different approaches to the judicial treatment of reverse payments. On the one hand, the pharmaceutical companies have asserted that the court should adopt the **scope-of-the-patent test**. Under this deferential standard – adopted by the Eleventh Circuit as described below – a court must determine whether a reverse-payment agreement’s anticompetitive effects “fall within the scope of the exclusionary potential of the patent.” That is, the court asks whether the agreement prevents generic entry beyond the patent’s expiration date. If not, absent sham litigation or fraud in obtaining the patent, the agreement raises no competitive concerns.<sup>8</sup> The FTC, on the other hand, has advocated for a **quick-look rule of reason test**, the standard adopted by the Third Circuit in *K-Dur* that treats

reverse payments as presumptively unlawful.<sup>9</sup> Whether the court adopts one of these tests – or another approach<sup>10</sup> – will likely depend on its position on the following overlapping issues:

**1. What deference should be given to the fact that the brand-name manufacturer owns a patent?** The FTC has argued that accused infringers have prevailed in a substantial percentage of lawsuits. As such, the FTC asserts that simply holding a patent does not give a company the right to use reverse payments to exclude rivals who have challenged that patent’s validity. The companies, on the other hand, argue that almost all judicial precedent in this area *presumes validity* – and rightly so, according to them. They contend that reverse-payment settlements are a necessary tool for patent holders to protect and maintain the lawful exclusionary rights granted them by the patent.<sup>11</sup>

**2. What are the real-life effects of reverse-payment agreements – either on generic**

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<sup>9</sup> See Brief for the Petitioner at 33, 37-38, *Actavis*, 133 S. Ct. 787 (U.S. 2012) (No. 12-416) (“FTC Brief”); *In re K-Dur*, 686 F.3d at 218. Under this test, the court does give the defendants an opportunity to demonstrate that the payments have a lawful purpose; for example, the defendants can show the agreements were consideration for unrelated property or services, were commensurate with litigation costs, or were for “certain unusual business or litigation justifications.” The Third Circuit, however, has indicated that successful rebuttals would be “probably rare.” *In re K-Dur*, 686 F.3d at 218.

<sup>10</sup> For example, in *Tamoxifen*, Judge Pooler wrote a dissent in support of an analysis focusing on “the strength of the patent as it appeared at the time at which the parties settled.” *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 228 (2d Cir. 2006) (Pooler, J., dissenting). This standard, previously supported by the FTC but jettisoned on petition to the Supreme Court, was rejected by the Eleventh Circuit in *Watson*. See discussion *infra*.

<sup>11</sup> See, e.g., FTC Brief, *supra* note 9, at 25, 43-45; Brief for Respondent Solvay at 10-11, *Watson*, 133 S. Ct. 787 (U.S. 2012) (No. 12-416) (“Solvay Brief”).

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<sup>7</sup> Press Release, Fed. Trade Comm’n, FTC Sues Drug Companies for Unlawfully Conspiring to Delay the Sale of Generic AndroGel Until 2015 (Feb. 2, 2009), <http://www.ftc.gov/opa/2009/02/androgel.shtm>.

<sup>8</sup> *Watson*, 677 F.3d at 1310-12. The court also asks whether the agreement excludes drugs from the market in addition to those addressed in the patent litigation, and whether the agreement applies to other companies not involved in the litigation.



**entry dates, or otherwise?** This issue, of course, has permeated the case and is disputed. The FTC contends that reverse-payment agreements delay generic entry and cost consumers substantial sums annually. The companies challenge this contention and point out that the settlements often result in entry earlier than the patent's expiration date. Moreover, they argue that the FTC's position ignores that any short-term benefits to consumers would be cancelled out by a decrease in long-term consumer welfare from a weakening of the incentives of pharmaceutical innovation under the patent system. They also say that the FTC's rule would discourage settlement and raise litigation costs for everyone involved. Both sides have pointed to empirical data to support their arguments.<sup>12</sup>

**3. To what extent are reverse-payment settlement agreements similar to other horizontal agreements between competitors that have been deemed *per se* unlawful under federal law?** From the FTC's perspective, the use of reverse payments closely resembles the quintessential anticompetitive practice where an incumbent firm pays a potential competitor to stay out of the market. The manufacturers argue that this is a faulty analogy, since a settlement within the scope of a valid and infringed patent has *no* anticompetitive effect, according to them. The FTC's proposed "quick-look" rule of reason test, they say, is rarely used and should be reserved for agreements that unquestionably harm competition.<sup>13</sup>

**4. Would the FTC's proposed test be appropriate or workable in practice?** The

<sup>12</sup> See, e.g., FTC Brief, *supra* note 9, at 7-8, 23-34; Brief for Respondent Actavis, Inc. (f/k/a Watson Pharmaceuticals, Inc.) at 15, 39-41, Watson, 133 S. Ct. 787 (U.S. 2012) (No. 12-416) ("Actavis Brief").

<sup>13</sup> See, e.g. FTC Brief, *supra* note 9, at 20-21; Solvay Brief, *supra* note 11, at 10.

FTC, of course, argues that it is. If reverse payments are discouraged, the FTC says, the manufacturers could use alternative methods of settling patent litigation that do not undermine their competitive relationship – for example, through compromise on an entry date. The FTC argues that settlements involving early entry but not payment are very common in this type of patent litigation. In any event, the FTC says, this method is superior to the scope-of-the-patent test, which it believes gives *no* meaningful antitrust scrutiny to reverse-payment agreements. The companies assert that the FTC's rule is not administrable and would radically expand antitrust liability. Even the FTC's definition of a "payment" is hopelessly ambiguous, they say.<sup>14</sup>

There are other issues at play as well. In the lower courts, the parties also argued over Congressional motivation behind the Hatch-Waxman Amendments, sound policy in this arena in general, and how often generic manufacturers succeed in the underlying litigations. As discussed below, the Eleventh and Third Circuits emerged on opposite sides of this debate.

### **The AndroGel® Litigation (Eleventh Circuit): Factual Background and the FTC's Challenge**

The *Actavis* litigation began when the FTC challenged two reverse-payment agreements concerning AndroGel®. The FDA approved the drug in 2000 and Solvay Pharmaceuticals, Inc. began marketing and selling it. The drug was successful, with revenues in the U.S. totaling more than \$1.8 billion between 2000 and 2007.<sup>15</sup>

<sup>14</sup> See, e.g. FTC Brief, *supra* note 9, at 39-46; Actavis Brief, *supra* note 12, at 3.

<sup>15</sup> Watson, 677 F.3d at 1304.



In 2003, a few months after the Patent and Trademark Office issued Solvay a patent, two potential generic drug competitors – Watson Pharmaceuticals and Paddock Laboratories – filed Abbreviated New Drug Applications (ANDAs) with the FDA, and made “paragraph IV” certifications alleging that Solvay’s patent was either invalid or would not be infringed by the manufacture, use, or sale of their generic drugs. Solvay filed patent infringement suits against Watson and Paddock in the U.S. District Court for the Northern District of Georgia. In doing so, Solvay’s action triggered the statutory 30-month stay on the FDA’s approval of the generic drugs. The generic manufacturers counterclaimed that Solvay’s patent was invalid.<sup>16</sup>

After several years of litigation, the 30-month stay ended in January 2006, and the FDA approved Watson’s generic drug. Both Watson and Par Pharmaceuticals – a company that Paddock teamed with to share litigation costs – predicted they would soon begin selling a generic version of AndroGel®. Then, on September 13, 2006, after summary judgment motions were fully briefed, Solvay settled both actions.<sup>17</sup>

In the settlements, Solvay agreed to share profits of AndroGel® with the generic manufacturers. It estimated annual payments of approximately \$15 - \$30 million for Watson, \$2 million for Paddock, and \$6 million for Par. The generic companies, in turn, agreed not to market their versions for about nine years – but five years earlier than the patent’s expiration date. The parties also entered business promotion agreements, in which Watson agreed to promote AndroGel® to urologists, Paddock agreed to

serve as a backup supplier of AndroGel®, and Par agreed to promote the drug to primary care physicians.<sup>18</sup>

As required under the Medicare Modernization Act, the parties reported their settlements to the FTC.<sup>19</sup> The FTC investigated the agreement and, in 2009, filed suit in federal court in the Ninth Circuit against the four companies, alleging violations of Section 5 of the FTC Act. The case was later transferred to and consolidated with a number of private antitrust actions in the Northern District of Georgia, which is where the patent claims had been litigated.<sup>20</sup>

In its complaint, the FTC alleged that Solvay was not likely to prevail in the underlying patent litigation. Since Solvay’s patent was unlikely to prevent generic entry, the FTC contended, the reverse payments extended a monopoly that the patent laws did not authorize and thereby restrained competition. The district court disagreed. It granted the defendants’ motion to dismiss, reasoning the FTC’s argument about the likely outcome of the patent litigation did not constitute an allegation that the settlements “exceed[ed] the scope” of the patent – that is, the settlements excluded only AndroGel® from the market, did not prevent generic entry beyond the patent’s expiration, and applied only to the companies involved in the litigation.<sup>21</sup>

<sup>18</sup> In re Androgel, 687 F. Supp. 2d at 1375-76.

<sup>19</sup> See Watson, 677 F.3d at 1305 (citing 21 U.S.C. § 355 note).

<sup>20</sup> *Id.* at 1305; Press Release, Fed. Trade Comm’n, FTC Sues Drug Companies for Unlawfully Conspiring to Delay the Sale of Generic AndroGel Until 2015 (Feb. 2, 2009), <http://www.ftc.gov/opa/2009/02/androgel.shtm>.

<sup>21</sup> Watson, 677 F.3d at 1305-06; In re Androgel, 687 F. Supp. 2d at 1376-79. The district court also rejected the plaintiffs’ argument that it should be presumptively unlawful for companies to settle a dispute with reverse payments.

<sup>16</sup> *Id.*

<sup>17</sup> *Id.* at 1304-05; In re Androgel Antitrust Litig. (No. II), 687 F. Supp. 2d. 1371, 1374-75 (N.D. Ga. 2010).



## Appeal to the Eleventh Circuit: The Arguments

On appeal, the FTC asked the Eleventh Circuit to reverse the lower court on one of two grounds. First, the FTC argued that the district court had misconstrued its precedents by finding the evidence regarding the strength of a challenged patent and the likelihood of non-infringement to be irrelevant. To the contrary, the FTC said, the court's precedents permitted a rule that "an exclusion payment is unlawful if, viewing the situation objectively as of the time of the settlement, it is more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date."<sup>22</sup> A plaintiff could show that a patent settlement effectively exceeds the scope of its patent by demonstrating the weakness of the branded company's claims of patent protection.

Alternatively, the FTC argued, if the district court had correctly construed its precedents, then those precedents should be overruled and a rule that reverse-payment agreements are presumptively unlawful should be adopted in their place. The burden would then shift to the defendants to justify their agreement, by showing that the payment was not for delayed entry or that the settlement otherwise served beneficial goals cognizable under the rule of reason.<sup>23</sup>

The patent holder countered that the settlements had enabled it to protect and maintain the lawful exclusionary rights of its patent. The companies further argued that reverse-payment agreements are neither surprising nor suspicious, given the Hatch-Waxman litigation framework, and to

<sup>22</sup> Brief of Plaintiff-Appellant Federal Trade Commission at 15, *Watson*, 677 F.3d 1298 (11th Cir. 2012) (No. 10-12729-DD), 2010 WL 5064779.

<sup>23</sup> *Id.* at 15-18, 43-44.

outlaw them would discourage settlement, increase litigation costs, and stifle innovation.<sup>24</sup>

## The Eleventh Circuit's Ruling: The Scope-of-the-Patent Test

The Eleventh Circuit acknowledged the difficulty at the heart of the case – and, indeed, reverse-payment cases in general. The task, the court said, was to "resolve the tension between the pro-exclusivity tenets of patent law and the pro-competition tenets of antitrust law."<sup>25</sup> In the end, the court agreed with the pharmaceutical companies, and adopted the rule that, absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.<sup>26</sup> The court's decision was grounded in three prior decisions in which it addressed reverse-payment agreements:

- In *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003), the court found the reverse-payment agreements to be lawful under a "scope of the patent" analysis, reasoning that what counted was the patent's *potential* exclusionary power as it appeared *at the time of settlement*. Because the agreements did not necessarily decrease the level of competition in the market, subjecting the agreements to *per se* condemnation was inappropriate.<sup>27</sup>

<sup>24</sup> *Watson*, 677 F.3d at 1301; Brief for Appellees Unimed Pharmaceuticals, LLC, Abbott Products, Inc., and Watson Pharmaceuticals, Inc. at 45-52, *Watson*, 677 F.3d 1298 (11th Cir. 2012) (No. 10-12729-DD), 2010 WL 5064781.

<sup>25</sup> *Watson*, 677 F.3d at 1306.

<sup>26</sup> *See id.* at 1312.

<sup>27</sup> *See id.* at 1307-08.



- In *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), the court reiterated what it said in *Valley Drug*. A proper analysis, the court said, requires an examination of (1) the scope of the exclusionary potential of the patent, (2) the extent to which the agreements exceed that scope, and (3) the resulting anticompetitive effects. Since the settlements at issue permitted the generic manufacturers to enter the market *prior* to the expiration of the patent, the court held that the settlements did not impermissibly extend the patent monopoly.<sup>28</sup>
- Finally, in *Andrx Pharmaceuticals, Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005), the Eleventh Circuit held the plaintiff had sufficiently pled an antitrust claim against a patent holder. The court found the reverse-payment agreement to be distinguishable from those in *Valley Drug* and *Schering-Plough* because the generic manufacturer had agreed to *never* market a generic version of the patented drug. Furthermore, the plaintiff had alleged the agreement permitted the generic manufacturer refrain from triggering its 180-day exclusivity period, blocking other generic competition from entering.<sup>29</sup>

In *Watson*, the Eleventh Circuit rejected the FTC's efforts to limit or distinguish these opinions. It reasoned that the FTC's position equated a likely result – failure of an

infringement claim – with an actual result. “[I]t is simply not true,” the court wrote, “that an infringement claim that is ‘likely’ to fail actually will fail.”<sup>30</sup> The court offered the example of a claim with a 49% chance of prevailing. More likely than not, the claim would fail. Yet 49 out of 100 times, it would succeed and keep the competitor out of the market. “[A] chance is only a chance, not a certainty,” the court continued, and “[a] party likely to win might not want to play the odds for the same reason that one likely to survive a game of Russian roulette might not want to take a turn...”<sup>31</sup> The Eleventh Circuit continued, “[W]hat the FTC proposes is that we attempt to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to judgment. If we did that we would be deciding a patent case within an antitrust case about the settlement of the patent case, a turducken task.”<sup>32</sup>

The court also took issue with the FTC's economic argument, reasoning that if the patent were vulnerable, as the FTC argued was the case in *Watson*, then presumably the monopoly profits would be eaten away as more and more generics filed their own paragraph IV certifications attacking the patent.<sup>33</sup>

On appeal to the Supreme Court, the FTC has conceded that a test that required the court to delve into the merits of the patent litigation would be “doctrinally anomalous and likely unworkable in practice.”<sup>34</sup> Instead, the FTC has emphasized its preference for a rule that treats

<sup>28</sup> See *id.* at 1309-10.

<sup>29</sup> See *id.* at 1311. The Hatch-Waxman Act grants a valuable exclusivity period to the first company to file an ANDA, which only begins running when that company enters the market (with some statutory exceptions that have changed over time).

<sup>30</sup> *Id.* at 1312.

<sup>31</sup> *Id.* at 1312-13.

<sup>32</sup> *Id.* at 1315.

<sup>33</sup> *Id.*

<sup>34</sup> FTC Brief, *supra* note 9, at 53.



reverse-payment settlement agreements as presumptively unlawful – a standard that the plaintiffs successfully advocated for in the Third Circuit.

### The Third Circuit: K-Dur Litigation

Whereas the Eleventh Circuit questioned whether a federal court’s analysis of a patent claim was at all desirable, or even remotely feasible, the Third Circuit reached a different conclusion just a few months later in *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012).

In that case, the Third Circuit analyzed the antitrust implications of two reverse-payment agreements entered into by Schering-Plough Corporation concerning K-Dur, a sustained-release potassium chloride supplement. In one agreement, Schering agreed to pay Upsher-Smith Laboratories, the first filer, at least \$60 million over three years, and Upsher agreed to refrain from marketing its generic potassium chloride supplement for about four years.<sup>35</sup> The parties came to agreement just hours before the U.S. District Court for the District of New Jersey was to rule on their cross motions for summary judgment and begin, if necessary, a patent trial.<sup>36</sup>

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<sup>35</sup> Schering also entered an agreement with ESI Lederle to settle a similar case in the Eastern District of Pennsylvania. In that case, however, the parties had agreed to court-supervised mediation before a magistrate judge. The parties agreed Schering would pay ESI at least \$5 million, and ESI would receive a royalty-free license to market K-Dur – but not for several years. Schering ended up paying ESI an additional \$10 million dollars. K-Dur, 686 F.3d at 205-06.

<sup>36</sup> *Id.* at 205-06. Upsher also granted Schering licenses to manufacture and sell several other pharmaceutical products it had developed. The companies claimed that the \$60 million was solely for the licenses – a claim the court found unconvincing.

The FTC had previously challenged the same settlement agreement and lost in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (discussed in the prior section). *In re K-Dur Antitrust Litigation*, however, involved a series of private litigations that were consolidated in the District of New Jersey. After the lower court found for the defendants, the Third Circuit reversed. The court held that a quick-look rule of reason analysis was appropriate, and courts should treat any payment from a patent holder to a generic manufacturer as *prima facie* evidence of an unreasonable restraint of trade. That evidence could only be rebutted by a showing that the payment (1) was for a purpose other than delayed entry, or (2) offered some pro-competitive benefit.<sup>37</sup>

In so holding, the Third Circuit criticized the district court’s application of the scope-of-the-patent test, taking issue with the test’s presumption of validity, which it called “almost un rebuttable.”<sup>38</sup> The Third Circuit asserted there was no significant support for this presumption, which “assume[d] away the question being litigated” in the patent suit.<sup>39</sup> Patent challengers were often successful. The presumption of validity in a case challenging the validity of a patent was intended “merely as a procedural device” and did not constitute a substantive right of the patent holder. Furthermore, in infringement cases, the burden is on the patent holder to demonstrate infringement.<sup>40</sup>

The court also pointed to Supreme Court precedent on the judicial testing of weak patents

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<sup>37</sup> *Id.* at 218.

<sup>38</sup> *Id.* at 214.

<sup>39</sup> *Id.*

<sup>40</sup> *Id.*



and Congressional motivation behind the Hatch-Waxman Amendments, even citing a case from 1892 for the proposition that “[i]t is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.”<sup>41</sup> The court also noted that the judicial preference for settlement of litigation should not displace Congress’s determination that, as the court described it, “litigated patent challenges are necessary to protect consumers from unjustified monopolies by brand name drug manufacturers.”<sup>42</sup> Courts should “be mindful of the fact that, ‘[a] patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office.’”<sup>43</sup>

Finally, the Third Circuit questioned whether challenges by other generic manufacturers would suffice to eliminate weak patents preserved through reverse payments.<sup>44</sup>

### The FTC’s Arguments for Certiorari

Although the FTC had suffered a loss in *Watson*, it saw opportunity with a petition for review by the U.S. Supreme Court. With the private purchasers’ *K-Dur* win, a circuit split had taken shape.

In its petition for certiorari, the FTC emphasized the consequences of this split in authority. The conflict was particularly untenable, the FTC said, as the flexible venue provisions that apply to review of FTC enforcement decisions and private actions made forum shopping possible. Private plaintiffs could be expected to file suit in the Third Circuit, while drug manufacturers

seeking judicial review of an administrative order of the FTC could be expected to lay venue in the Eleventh Circuit. The FTC argued that it would be effectively disabled from proceeding administratively against any reverse-payment agreement because it would almost certainly face judicial review in a scope-of-the-patent district. The contradictory treatment of reverse-payment agreements had even resulted in contradictory outcomes in different districts over the same agreement.<sup>45</sup>

The FTC also highlighted how this question was of exceptional importance to one of the largest commercial markets in the United States. Reverse payment agreements were dictating the speed with which generic drugs reached the market – and costing consumers billions of dollars each year by slowing their entry. The FTC pointed to its studies showing that, as generic competition sets in, the price of a generic drug settles at approximately 15% of the original brand-name drug’s price.<sup>46</sup> Moreover, a substantial number of fully litigated patent cases resulted in invalidity. Yet if reverse-payment agreements were treated as *per se* lawful, they would be extremely attractive to both the brand-name and generic manufacturers.<sup>47</sup>

Finally, the FTC argued, this particular case was a superior vehicle for addressing the issue because it was brought by the FTC, an agency Congress had charged with challenging unfair methods of competition, and its posture was straightforward – final dismissal following a complaint for declaratory and injunctive relief.<sup>48</sup>

<sup>41</sup> *Id.* at 214, 216 (quoting *Pope Mfg. Co. v. Gormully*, 144 U.S. 224 (1892)).

<sup>42</sup> *Id.* at 217.

<sup>43</sup> *Id.* at 214-15 (citing *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969)).

<sup>44</sup> *Id.* at 214-15.

<sup>45</sup> Petition for Writ of Certiorari at 14-15, *Actavis*, No. 12-416, (U.S. Oct. 4, 2012), 2012 WL 4750283.

<sup>46</sup> *Id.* at 16 (citing FTC Staff, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, Jan. 2010, at 8).

<sup>47</sup> *Id.* at 16-17, 20.

<sup>48</sup> *Id.* at 12.





## Conclusion

On December 7, 2012, the Supreme Court granted the FTC's certiorari petition, and oral argument is scheduled for March 25, 2013.

The Supreme Court's ruling is eagerly anticipated by antitrust practitioners, government enforcement officials, and the pharmaceutical industry. Numerous amicus briefs have been filed, including briefs by the AARP and Representative Henry Waxman.<sup>49</sup> Notably, while the antitrust and business communities await a ruling from the Supreme Court, some members of Congress have recently re-started legislative efforts to halt the use of such agreements. In February 2013, several senators introduced a bill entitled the Preserve Access to Affordable Generics Act.<sup>50</sup> The bill, which mirrors past legislative attempts to curtail the use of reverse-payment agreements,<sup>51</sup> would establish a presumption of illegality for reverse-payment agreements and grant the FTC the authority to issue regulations implementing and interpreting the Act.

But whether or not the Supreme Court finds reverse-payment agreements presumptively unlawful or legislation seeking to ban such agreements will ever secure enough votes in Congress, after more than a decade of challenging the legality of reverse-payment agreements in courts around the country, the FTC finally gets its day before the Supreme Court.

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<sup>49</sup> For a list and copies of the various amicus briefs, see *FTC v. Actavis*, SCOTUSblog, *supra* note 2.

<sup>50</sup> See S. 214, 113th Cong. (2013).

<sup>51</sup> See S. 27, 112th Cong. (2011); S. 369, 111th Cong. (2009).