

# Schering-Plough at the Supreme Court: Justices Decline to Resolve the FTC-DOJ Dispute Regarding “Reverse” Payments

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After years of intense litigation in multiple forums, the debate regarding antitrust treatment of “reverse” payments in settlements of patent litigation between manufacturers of branded and generic pharmaceuticals at last reached the Supreme Court . . . almost. In spite of the opportunity to resolve an unusually public disagreement between the nation’s two principal antitrust enforcement agencies—the Federal Trade Commission and the Antitrust Division of the Department of Justice—the Court declined to take the case.

After a setback before the Eleventh Circuit in *Schering-Plough*, the FTC filed a petition for certiorari, asking the Court to review and overturn the decision of the court of appeals. Although the FTC and the DOJ generally proceed in tandem before the high court, in *Schering* the Commission took the rare step of proceeding alone. The disagreement between the two agencies then became even more public when the Court specifically requested the views of the Solicitor General. In response, the Solicitor General—as a representative of the DOJ, and in collaboration with officials from the Antitrust Division—requested that the Court deny the FTC’s petition. The Court’s subsequent decision to deny cert has interesting implications, but almost certainly will not be the last word on the issue.

The disagreement between the FTC and the DOJ reflects widespread uncertainty regarding the competitive impact of brand/generic settlements containing reverse payments (i.e., a payment from the patent holder to the alleged infringer). Both sides agree that the effect of such payments is sufficiently ambiguous that their presence alone should not trigger per se treatment of a settlement agreement. Beyond that, however, positions diverge. The FTC has taken the position that reverse payments should trigger heightened antitrust scrutiny, as they are often made in return for an anticompetitive delay in generic entry. In the absence of such payments, the Commission argues, the parties to the settlement would negotiate the date of entry as a true reflection of the strength of their relative positions in the underlying patent litigation. Others—including both settling defendants and, now, the DOJ—have taken the position that the FTC’s view is unduly restrictive and contrary to the general policy in favor of litigation settlements. While the Supreme Court’s denial of cert in *Schering* is not likely to bring this debate to conclusion, it is likely to have an impact on the future course of the debate in a number of important ways.

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## Background—Brand/Generic Pharmaceutical Settlements and Reverse Payments

The regulatory backdrop for the *Schering* case is the complicated procedure for Food & Drug Administration approval of generic drug products. This procedure is largely governed by the Hatch-Waxman Act,<sup>1</sup> which was enacted to reduce impediments to the introduction of low-cost generic

<sup>1</sup> Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

drugs. Among other features, the Act created a variety of incentives to spur potential generic entrants to challenge questionable drug patents. These incentives were extremely effective, and led to a dramatic increase in patent litigation between branded and generic drug makers.

Not surprisingly, the increase in litigation was accompanied by an increase in litigation settlements. Given the economic incentives in play in the pharmaceutical marketplace, the FTC became concerned that at least some of these settlements were not in the best interest of consumers. The Commission observed that, in many instances, the difference in price between branded and generic drugs was so substantial, and the decline in price after generic entry so rapid, that it would be in the best interests of both the brand and the generic to collude to delay entry while sharing the resulting monopoly profits. The Commission subsequently identified certain categories of “red flag” settlements, where the likelihood of such a collusive arrangement was greatest. These included settlements involving reverse payments.

In March 2001, the FTC filed suit challenging two settlements involving branded drug manufacturer Schering-Plough—one with generic drug maker Upsher-Smith and a second with ESI Lederle. Both settlements involved Schering’s patented extended-release formulation of K-Dur 20, a potassium chloride product primarily used to treat potassium depletion in coronary artery disease patients. Although both agreements contemplated entry prior to the expiration of Schering’s patent, and called for Schering to license other, non-K-Dur 20 drug products from the generic competitor, the FTC was not convinced. According to the complaint, in both instances, the size of the reverse payment was disproportionate and unrelated to the value of the licenses. The quid pro quo for these payments therefore appeared to be the competitor’s delay in entry—an unlawful restraint of trade in violation of both Section 5 of the FTC Act<sup>2</sup> and Section 1 of the Sherman Act.<sup>3</sup>

### The Administrative Law Judge’s Opinion

FTC complaint counsel proceeded through the Part III litigation mechanism, the first step of which is a trial before an Administrative Law Judge—in this case, Judge D. Michael Chappell. The ALJ made extensive factual findings and concluded that there was nothing improper about the reverse payments, which appeared to reflect an arms-length assessment of the litigation settlement, as well as the value of the additional products that Schering had licensed from the alleged infringers.<sup>4</sup> The ALJ explained that, in order to assess the value and purpose of the settlement, it was first necessary to inquire into the strength of the underlying patent claims. Because the strength of those claims could not be reliably determined, complaint counsel simply had no grounds for its assertion that Schering’s payments did not represent fair value for settlement of the claims.<sup>5</sup> The ALJ consequently dismissed the complaint.

### The Commission Opinion

As expected, complaint counsel appealed the ALJ’s decision to the full five-member Commission, sitting as an appellate panel. The Commission saw the case quite differently, and accorded little deference to the ALJ’s extensive findings of fact. In its opinion reversing the ALJ, the Commission interpreted essentially the same evidence as supporting the opposite conclusion, explaining that

<sup>2</sup> 15 U.S.C. § 45.

<sup>3</sup> 15 U.S.C. § 1.

<sup>4</sup> Schering-Plough Corp., 2002 FTC LEXIS 40, 244–60 (June 27, 2002) (Initial Decision).

<sup>5</sup> *Id.* at 240.

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“many specific findings and the ultimate factual conclusions in the Initial Decision are flawed.”<sup>6</sup> The Commission held, for example, that the size of the settlement payments reflected neither the value of the licenses granted to Schering nor the value of the settled claims.<sup>7</sup> Relying heavily on an analysis of the parties’ respective economic incentives, the Commission concluded that, in the absence of an alternative explanation, the payments must have been made in return for a delay in generic entry.<sup>8</sup> The Commission also rejected the ALJ’s holding that the strength of the underlying patent was the linchpin of any competitive analysis, noting that such an inquiry “would not be necessary, practical, or particularly useful.”<sup>9</sup> Based on this reasoning, the Commission held the defendants liable, reversed and vacated the ALJ’s opinion, and replaced it with a remedial order.

### The Eleventh Circuit Opinion

Schering subsequently appealed to the Eleventh Circuit which, in turn, reversed the Commission.<sup>10</sup> The Eleventh Circuit cited its own prior decision in *Valley Drug*<sup>11</sup> for the proposition that neither per se nor rule of reason analysis governs in antitrust cases involving patents. Rather, a unique third mode of analysis applies, which 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.<sup>12</sup> Applying this test, the court concluded that Schering was entitled to the full exclusionary force of its patent until the Commission demonstrated that the patent was either invalid or not infringed. Absent such a showing, the court reasoned that the Commission could not prove that either of the settlements had an anticompetitive effect, as both contemplated generic entry before expiration of the patent and were therefore within the patent’s “exclusionary potential.” The court also called into question many of the Commission’s findings of fact. Although the court acknowledged its obligation to defer to the agency on issues of fact, in many instances it appeared to substitute the findings of the ALJ for those of the Commission. The court took particular exception to the Commission’s finding that the size of Schering’s payments to Upsher-Smith significantly exceeded the value of the licensed drug products, remarking that “[t]o borrow from the Commission’s own words, we think its conclusion . . . is ‘not supported by law or logic.’”<sup>13</sup> Indeed, the court seemed to question the very integrity of the FTC’s procedure for review, stating that “[i]t would seem as though the Commission clearly made its decision before it considered any contrary conclusion.”<sup>14</sup>

### The Petition for Certiorari

Taking a final bite at the apple, the Commission petitioned the Supreme Court. The Commission’s petition for cert presented two questions for review: (1) whether a settlement payment from a pharmaceutical patent holder to a would-be generic competitor, in return for the generic’s agreement

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<sup>6</sup> Schering-Plough Corp., 2003 FTC LEXIS 187, 189 (Dec. 8, 2003) (Opinion of the Commission).

<sup>7</sup> *Id.* at 169, 173–74.

<sup>8</sup> *Id.* at 60–67.

<sup>9</sup> *Id.* at 79.

<sup>10</sup> Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005).

<sup>11</sup> Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294 (11th Cir. 2003).

<sup>12</sup> *Schering*, 402 F.3d at 1066.

<sup>13</sup> *Id.* at 1070.

<sup>14</sup> *Id.* at 1065.

to delay entry, constitutes an unlawful restraint of trade; and (2) whether the Eleventh Circuit erred in holding that the Commission's decision was not supported by "substantial evidence."<sup>15</sup> With respect to the first question, the Commission argued that Supreme Court review was warranted due to a circuit split between the Sixth and Eleventh Circuits on the reverse payment issue, as well as the compelling public interest in the substantial consumer savings that could potentially result from earlier generic drug entry.<sup>16</sup> As to the second question, the Commission argued that, while the Eleventh Circuit had stated the correct rule on administrative deference, it had failed to follow it, leaving the Supreme Court as the only authority with the power to correct the error.<sup>17</sup>

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In a case characterized by many odd twists and turns, what happened next was perhaps the most surprising development of all. Although the views of the federal government were seemingly already represented by the Federal Trade Commission, the Court expressly requested the views of the United States, as represented by the Solicitor General's Office and the Antitrust Division of the Department of Justice. Even more surprisingly, the FTC's sibling agency then proceeded to argue that the Commission's petition should be denied.

On the reverse payment issue, the DOJ argued that there was no circuit split justifying the Court's review. As the Department pointed out, the Sixth Circuit opinion identified by the FTC was qualitatively different—in that the settlement at issue there encompassed additional, non-patented drugs that were not the subject of the infringement suit—and therefore did not create a circuit split with the *Schering* opinion.<sup>18</sup> As a brief opposing cert, rather than a brief on the merits, one might have expected the DOJ filing to stop there. However, it went on to discuss the reverse payment issue at length, largely adopting the Eleventh Circuit position that reverse payments are a logical response by a pharmaceutical patent holder to the settlement pressures created by the Hatch-Waxman regulatory structure. The DOJ also argued that, although the Eleventh Circuit's review of the Commission's opinion did not comport with the "substantial evidence" test, "plenary review of the court of appeals' application of the substantial-evidence standard in this case would not be an appropriate exercise of this Court's certiorari jurisdiction."<sup>19</sup>

As if the preceding developments had not created sufficient drama, Supreme Court rules provided that the FTC was entitled to file a response to the brief of the United States. The Commission used its supplemental brief to emphasize two principal arguments. First, with respect to the issue of administrative deference, the Commission argued that "[t]he court of appeals' rote utterance of correct legal standards should not insulate its errors from review."<sup>20</sup> The Commission observed that, as recently as the current term, the Court had reversed a court of appeals decision on precisely this basis.<sup>21</sup> In response to the DOJ's arguments that the controversy was not sufficiently ripe, and that the current case was not an appropriate vehicle for addressing the important legal issues raised therein, the Commission pointed to the potentially "staggering" impact of the

<sup>15</sup> FTC Petition for a Writ of Certiorari 1 (Aug. 29, 2005), available at <http://www.ftc.gov/os/2005/08/050829scheringploughpet.pdf>.

<sup>16</sup> *Id.* at 23–25.

<sup>17</sup> *Id.* at 26.

<sup>18</sup> Brief for the United States as Amicus Curiae 17 (May 17, 2006), available at <http://www.usdoj.gov/atr/cases/f216300/216358.pdf>.

<sup>19</sup> *Id.* at 13.

<sup>20</sup> Supplemental Brief for the Petitioner 7 (June 12, 2006), available at <http://www.ftc.gov/os/adjpro/d9297/060612certiorarisupplementalbrief.pdf>.

<sup>21</sup> *Id.* at 8 (citing *Rice v. Collins*, 126 S. Ct. 969, 971 (2006)).

Eleventh Circuit's decision on consumers of prescription drugs. Given that "billions of dollars in added prescription drug costs *annually* are at stake," it would not be appropriate to simply allow additional reverse payment cases to percolate through the federal court system.<sup>22</sup> Instead, the Commission argued, immediate Supreme Court review was needed.

The dispute ended, anticlimactically, with the Court's denial of cert just two weeks later.<sup>23</sup>

### Impact of These Developments

While the showdown between the FTC and the DOJ has certainly been dramatic, it is not clear that this will be the turning point in the reverse payment debate. Although the manner in which the agencies expressed their contrasting views was unexpected—indeed, surprising—the substance of the views expressed in the cert petition exchange is, by now, familiar to many. Nevertheless, the recent developments in the *Schering* case, including the Court's denial of cert, raise a number of interesting questions:

***Is the litigation component of the reverse payment debate coming to a conclusion?*** Probably not. Mere denial of the FTC's petition, while undeniably a victory for proponents of reverse payment settlements, is unlikely to constitute the final word on the reverse payment issue. As the DOJ observed in its brief, private parties (many of them espousing antitrust theories almost identical to the FTC's), have already filed challenges to a number of brand/generic settlements. It is reasonable to assume that these plaintiffs will avoid the Eleventh Circuit with as much determination as pharmaceutical defendants will seek its embrace. Indeed, the DOJ specifically noted that one group of private plaintiffs, along with the State of Pennsylvania, has filed suit in a district court within the Third Circuit to challenge the settlement agreements at issue in *Schering*.<sup>24</sup>

***What are the prospects for a non-litigation solution?*** While it would be a stretch to say that the prospects are good, the possibility of a legislative solution has been raised. Almost immediately following the Court's denial of cert, four U.S. Senators—Charles Grassley (R-Iowa), Herb Kohl (D-Wis.), Patrick Leahy (D-Vt.), and Charles Schumer (D-N.Y.)—vowed to reverse the Eleventh Circuit's *Schering* decision. Specifically, the Senators proposed to amend the Federal Trade Commission Act to define the use of reverse payments as an act of unfair competition. With midterm elections looming, however, any such legislative solution is certainly a long way off.

***Will the FTC continue to play a role in the reverse payment debate?*** Probably, although the Commission's role may be more limited. The Court's denial of the FTC's cert petition is clearly a blow to the agency's enforcement efforts in the reverse payment area. Because the Commission's administrative decisions are reviewable in any circuit in which the defendant resides or does business, the Eleventh Circuit would presumably become the forum of choice for defendants in reverse payment cases, with predictable results for the FTC's success rate. Although this development would not eliminate the antitrust litigation risk associated with reverse payments, the mere possibility of such a result appears to have bolstered the confidence of many potential defendants. The FTC reports that, of brand/generic settlements filed with the agency, zero contained reverse payments in 2004, three contained such payments in 2005 (the year of the Eleventh

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<sup>22</sup> *Id.* at 2.

<sup>23</sup> *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006).

<sup>24</sup> *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517 (D.N.J. 2004).

Circuit's *Schering* decision), and six more containing such payments have already been filed in 2006.<sup>25</sup>

**Is the FTC's role likely to change in some significant way?** At least one FTC Commissioner has indicated that the agency is considering filing future reverse payments cases in federal district court, rather than proceeding through the Part III administrative litigation process, to avoid the otherwise inevitable appeal to the Eleventh Circuit.<sup>26</sup> While it remains to be seen whether the Commission will actually employ this procedural stratagem, recent developments suggest that the agency's commitment to challenging reverse payments remains strong. Just weeks after the denial of cert in *Schering*, the Commission exercised its authority under a pre-existing consent order with Bristol-Myers to deny approval of a brand/generic settlement relating to the blood thinner Plavix, largely on the grounds that the settlement contained a reverse payment.<sup>27</sup> Although the Plavix situation is unique, and is unlikely to be repeated, it nevertheless seems to suggest a continuing willingness on the part of the agency to advance the legal theory rejected by the Eleventh Circuit.

**Can litigants expect less administrative deference to the FTC in future cases?** Probably not. The Eleventh Circuit's *Schering* decision could very well become the *Bush v. Gore* of administrative deference cases—a closely watched and much discussed opinion that is never subsequently cited. Regardless of whether the FTC is legally empowered to do so,<sup>28</sup> it is unlikely that, barring exceptional circumstances, it would reject the findings of its own ALJ so completely in future cases. Likewise, it is unlikely that any court of appeals, including the Eleventh Circuit, would apply the “substantial evidence” test in a manner that gave so little deference to the Commission. Doubtless, at least some of the Eleventh Circuit's frustration with the Commission resulted from the Commission's refusal to adhere more closely to the court's *Valley Drug* decision, and it was certainly a diplomatic, if not a legal, error for the Commission to characterize certain aspects of that decision as “not supported by law or by logic.” Nevertheless, while the *Schering* case is unlikely to have a lasting impact on the “substantial evidence” test, it could spur a reexamination of the FTC's Part III process—pursuant to which the same Commission that votes to approve the filing of a complaint before an ALJ subsequently hears any appeal of the ALJ's decision—which some litigants have criticized as biased against defendants.

**Do these developments reflect a growing divergence between the FTC and the DOJ?** It is notable that the DOJ did not weigh in on its own initiative, but only after the Supreme Court expressly requested the views of the Solicitor General. That being said, when considered together with the DOJ's refusal to sign on to the FTC's Second Request reform proposal in February, the *Schering* brief marks the second public disagreement between the two agencies in just a few

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<sup>25</sup> Jon Leibowitz, Commissioner, FTC, Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-a-ck!, Address Before the Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust 4–5 (Apr. 24, 2006), available at <http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf>.

<sup>26</sup> *Id.* at 8.

<sup>27</sup> John Carreyrou, *States Reject Deal on Plavix in Blow to Bristol-Myers*, WALL ST. J., July 29, 2006, at A2.

<sup>28</sup> It is worth noting that, on this point, the FTC gets the better of the argument. The Commission is authorized to review de novo both the factual findings and legal conclusions of an Administrative Law Judge. 16 C.F.R. § 3.54(a). In contrast, an appellate court is obligated to defer to the findings of the Commission when those findings are supported by “substantial evidence,” meaning that those findings are supported by “such relevant evidence as a reasonable mind might accept as adequate,” not that the reviewing court “mak[ing] its own appraisal of the testimony, picking and choosing for itself among uncertain and conflicting inferences” would reach the same conclusion. *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 454 (1986).

months. Furthermore, the DOJ's decision not to simply defer on the issue of an appropriate standard for antitrust analysis of reverse payments is somewhat surprising in light of the longstanding division of responsibilities between the two agencies. Restraints of trade in the pharmaceutical industry are clearly within the purview of the Health Care Products and Services Division of the FTC's Bureau of Competition. The FTC has also done a substantial amount of "competition R&D" in this area.<sup>29</sup>

**Do these developments have implications beyond the pharmaceutical context?** Had the Court taken the case, the implications could have potentially been more sweeping. One significant issue that has attracted less attention than others is the fundamental disagreement among the three decision makers regarding the core legal rules through which the principles underlying the antitrust laws should be implemented. The ALJ adopted what would certainly be regarded as the most well-established, if not the most desirable, approach by dividing the universe of potential restraints into those subject to per se and those subject to rule of reason analysis. The FTC, in contrast, rejected this formalistic approach, and—relying on both the Supreme Court's *California Dental*<sup>30</sup> opinion and its own *PolyGram*<sup>31</sup> opinion—asserted that antitrust analysis should extend over a continuum responsive to the facts of individual cases. Per se and rule of reason analysis (meaning a fact intensive definition of markets, calculation of shares, etc.) are two points on that continuum, but a full rule of reason analysis is not required where more direct evidence of competitive effects is available. The Eleventh Circuit, in contrast, insisted that neither per se nor rule of reason analysis was appropriate, but rather a third approach, unique to antitrust cases involving patents, should be applied. Had the Court taken the admittedly ambitious step of using the *Schering* case as the vehicle to address this big picture issue, its guidance would have been most welcome. Due to the denial of cert, this fundamental issue will likely continue to be analyzed differently in different forums.

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## Conclusion

Although the *Schering* case ultimately did not answer the fundamental question at issue—whether or not the antitrust laws should condemn reverse payments in the pharmaceutical context—it did provide an interesting and revealing glimpse into the imperfect process by which such questions are resolved. Indeed, the case constituted a kind of worst case scenario, highlighting not only the potential flaws of the FTC's Part III process, but of the entire dual agency structure for federal antitrust enforcement. While these flaws are well known, rarely have they been exposed so dramatically, and in a single case. It is perhaps this fact, more than any other, that makes the anticlimactic finale of the case so surprising, as it seems to suggest that reverse payments present legal issues of such uncommon difficulty that even the nation's antitrust enforcers could not agree on a common approach. Such an intractable controversy, one would think, is ripe for resolution by the Supreme Court. ●

<sup>29</sup> See, e.g., Bureau of Competition, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in Fiscal Year 2005* (Apr. 2006), available at <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf>; Press Release, Federal Trade Commission, FTC Proposes Study of Competitive Impacts of Authorized Generic Drugs (Mar. 29, 2006), available at <http://www.ftc.gov/opa/2006/03/authgenerics.htm>; Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration* (July 2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

<sup>30</sup> *California Dental Ass'n v. FTC*, 526 U.S. 756 (1999).

<sup>31</sup> *PolyGram Holding, Inc.*, 5 Trade Reg. Rep. (CCH) ¶ 15,453 at 22,453–58 (FTC 2003).