# Federal Trade Commission

**Pharmaceutical Patent Settlements and the Supreme Court**

**Remarks of J. Thomas Rosch**
**Commissioner, Federal Trade Commission**

**at**

**CBI's 2nd Annual Life Sciences Compliance, Legal, and Regulatory Congress**
**Washington, DC**

**September 21, 2012**

The legal standard by which to evaluate pharmaceutical infringement settlements has been one of the most hotly litigated and debated antitrust questions over the last decade. Dozens of private actions and several FTC complaints have challenged these settlements as violations of the Sherman Act. Six circuit court of appeals have addressed the issue, resulting in a variety of holdings. The FTC, Congressional Budget Office, and industry associations have issued numerous reports studying pay-for-delay agreements, and hundreds of law reviews and economic journal articles have added a range of perspectives on this issue. In the last several sessions of Congress, legislation has been introduced to restrict these settlement agreements. The Supreme

---

The views stated here are my own and do not necessarily reflect the views of the Commission or other Commissioners. I am grateful to my attorney advisor, Darren Tucker, for his invaluable assistance in preparing this speech.

Court stands almost alone as the only relevant body not to have offered a view on the issue, having denied petitions for certiorari in several pay-for-delay cases.

With my comments today, I do not intend to reargue the FTC's position with respect to pay-for-delay pharmaceutical settlements. I'm guessing you've heard that enough times already – if not from the FTC, then from your antitrust counsel. Instead, I will share with you why I believe the Supreme Court will grant certiorari in either or both of the *K-Dur* and *Androgel* pay-for-delay cases and, as between these two cases, why the *Androgel* case is in a better posture for Supreme Court review. I will also provide updates on pay-for-delay legislation and other FTC advocacy efforts in this area.

## Background

Before getting to the crux of my argument, let me start by summarizing the federal court of appeals decisions that have considered the propriety of pay-for-delay pharmaceutical agreements under the antitrust laws.

The first Court of Appeals to address this issue was the DC Circuit in its 2001 *Andrx v. Biovail* decision.[1] In that case, the brand manufacturer agreed to compensate the first ANDA filer to delay marketing a generic product during the pendency of their infringement litigation. This had the effect of delaying the triggering of the first-filer's 180-day exclusivity period, thereby preventing entry from any other ANDA filer. Although the court of appeals affirmed the dismissal of the case on the pleadings, it suggested that similar restraints "could reasonably be viewed as an attempt to allocate market share and preserve monopolistic conditions"—language consistent with per se condemnation.[2]

[1] *Andrx Pharms, Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Circ. 2001).

[2] *Id*. at 811.

Two years later, the Sixth Circuit addressed the same interim agreement in the *Cardizem CD* case and concluded that it was "a classic example of a per se illegal restraint of trade."[3] However, the precise holding of *Cardizem CD* is unclear because the settlement agreement may have applied to products beyond the scope of the patent that was at issue.

In contrast, the Eleventh Circuit, in a series of cases, interpreted its jurisprudence to hold that pay-for-delay agreements are permissible as long as they do not exceed the scope of exclusionary potential of the patent at the time of the settlement. This has come to be known as the "scope of the patent" test. In its *Valley Drug*, *Schering-Plough*, and *Andrx v. Elan* decisions,[4] the Eleventh Circuit held that neither the rule of reason nor the per se test is appropriate for evaluating pay-for-delay agreements because the patent holder has a lawful right to exclude others from the market. According to the court, antitrust scrutiny of pay-for-delay agreements was contrary to the "general policy of the law . . . to favor the settlement of litigation,"[5] which was particularly relevant here, given the complexity and cost of patent litigation.[6] The *Valley Drug* decision, however, suggested that there could be antitrust liability where the "the patent was procured by fraud" or was known to be invalid.[7]

In the *Tamoxifen* case,[8] the Second Circuit adopted the scope of the patent test to evaluate pay-for-delay agreements. As that court explained, pharmaceutical infringement settlements do

---

[3] *In re Cardizem CD Antitrust Litig*., 332 F.3d 896, 908 (6th Cir. 2003).

[4] *Andrx Pharms., Inc. v. Elan Corp., PLC*, 421 F.3d 1227 (11th Cir. 2005); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

[5] *Schering*, 402 F.3d at 1072.

[6] *See id*. at 1073-74.

[7] *Valley Drug*, 344 F.3d at 1307 n.19.

[8] *Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litig*.), 466 F.3d 187 (2d Cir. 2006).

agreement, standing alone, was anticompetitive. Instead, the FTC sought to fit its case within the scope of the patent test by alleging that Solvay was "not likely to prevail" in its infringement litigation against the generic firms.[14] In other words, the FTC alleged that Solvay's patent was weak. The FTC urged the court to adopt a rule that an exclusion payment is unlawful if, based on an objective assessment at the time of the settlement, the patent would not have blocked entry.[15]

The Eleventh Circuit began by restating its prior holding that the proper analysis of a reverse payment settlement of patent litigation "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."[16] Under this test, "[a]bsent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent."[17]

a patent holder was to succeed in a settled lawsuit if it had not been settled."[18] Doing these types of retrospective assessments, in the court's view, would also undo the benefits of settlement and discourage future settlements.

The FTC sought en banc review of the Eleventh Circuit's decision, which was denied. The FTC has not yet made a decision whether to file a petition for certiorari with the Supreme Court. That petition would be due by October 16. More on that later.

Finally, in July of this year, the Third Circuit handed down its decision in the *K-Dur*

The court was also concerned that the scope of the patent test would immunize from antitrust scrutiny settlement agreements involving weak or narro

Despite the stark differences between the *K-Dur* test and the scope of the patent test, they are similar in one respect: they both avoid consideration of the merits of the underlying infringement litigation. In *K-Dur*, the Third Circuit stated that "there is no need to consider the merits of the underlying patent suit" and did not identify the strength of the patent as a potential defense.[26] And as I previously noted, the *Androgel* opinion rejected the FTC's attempt to evaluate the strength of Solvay's infringement claims.

Not long after the *K-Dur* decision, Merck and Upsher-Smith filed a motion to stay the Third Circuit's mandate pending the filing of a petition for writ of certiorari in the Supreme Court. That motion was denied. Merck and Upsher-Smith then filed separate petitions for a writ of certiorari with the Supreme Court.[27] The plaintiffs have not yet filed their responses to those petitions.

Certiorari is Likely

With that background in mind, I'd now like to offer six reasons why, despite declining several prior requests to hear a pay-for-delay case, the Supreme Court is likely to grant certiorari in either or both of the *Androgel* and *K-Dur* cases.

First and most important, as a result of the *K-Dur* decision, there is now a clear circuit split.[28]

circuits, most pharmaceutical settlement agreements involving delayed entry have *no* risk of antitrust liability, while in the Third Circuit *all* of these agreements are presumed to violate the antitrust laws.

There can be no credible argument that some factual distinction justifies the divergence in legal standards because the Third Circuit's *K-Dur* decision and the Eleventh Circuit's *Schering* decision involved the same settlement agreement. As Upsher-Smith stated in its cert petition, "It cannot be that a single settlement agreement may vi

Court suspended proceedings in the *Cipro* state-court litigation pending action by the U.S. Supreme Court on Merck and Upsher-Smith's cert petitions in the *K-Dur* case.[31]

The second reason the Supreme Court is likely to grant certiorari is because it will have the benefit of two recent well-written appellate decisions. Notwithstanding my long-standing concerns regarding pay-for-delay agreements, I have to acknowledge the analytical strength of the Eleventh Circuit's *Androgel* decision. It is by far the best written of the decisions applying the scope of the patent test. As a trial lawyer for over forty years, the court's discussion of the unpredictability of litigation and companies' risk aversion to high-stakes, all-or-nothing litigation resonated with me. In particular, the court's point that settlements are *most* likely to occur when liability is *least* clear is a powerful argument against trying to evaluate the strength of a patent claim with hindsight.

Likewise, the Third Circuit's *K-Dur* opinion contains, in my judgment, the most concise, persuasive argument against the scope of the patent test. The court focuses on the key defect of that test, namely that it condones pay-for-delay deals where the patent is weak, i.e., where the patent would have been declared invalid or not infringed if the litigation had continued. I also think the court's structured rule-of-reason approach was excellent: it provides guidance to lower courts on how to evaluate pay-for-delay deals, puts the burden on settling parties to justify these

---

Circuit's scope of the patent test to Apotex's claims and the Third Circuit's test for the other claims. (Apotex brought both antitrust and patent claims.)

[31] Order, In re Cipro Cases I & II, Case No. S198616 (Cal. Sept. 12, 2012) ("On its own motion, the court stays further briefing in this matter pending action by the United States Supreme Court in Merck & Co. v. Louisiana Wholesale Drug Co., No. 12-245, and Upsher-Smith Laboratories, Inc. v. Louisiana Wholesale Drug Co., No. 12-265, and further order of this court."). This proceeding consists of nine coordinated cases brought by indirect Cipro purchasers under California's Cartwright Act. Briefing before the California Supreme Court was nearly complete when the court entered its stay order.

On September 10, Wyeth filed a motion to stay in the Effexor XR litigation pending the Supreme Court's decision in *K-Dur*. The court has not ruled on that motion.

agreements, and is consistent with several Supreme Court decisions encouraging the lower courts to develop structured rule of reason approaches.

The third reason the Supreme Court is likely to grant certiorari is that additional "percolation" of the pay-for-delay issue in the lower courts and in the scholarly literature is unlikely to be fruitful. The FTC has not filed any recent pay-for-delay cases, and its only two existing cases are in the Third and Eleventh Circuits, both of which have already addressed the issue. As I previously mentioned, the FTC's Cephalon case has been suspended pending a decision by the Court on certiorari. The only case that might have resulted in an appellate decision in the near future that I am aware of is the *Cipro* litigation in California.[32] But as I mentioned, the California Supreme Court has suspended those proceedings pending action by the U.S. Supreme Court. Also, given the hundreds of law review articles, briefs, and studies addressing pay-for-delay issues, it is hard to imagine that additional time will give the Supreme Court the benefit of any novel evidence or arguments that may be developed.

The fourth reason the Supreme Court is likely to grant certiorari in a pay-for-delay case is that the Court has shown a recent interest in both patent and antitrust cases. The Court has handed down six antitrust decisions in the last five years,[33] which is a high rate by historical standards. Likewise, the Court has handed down a number of significant patent decisions over the same period, including:

> *eBay*, which held that an injunction should not automatically issue based on a finding of patent infringement;[34]

[32] *In re Cipro Cases I & II*, Case No. S198616 (Cal.)

[33] *Weyerhaeuser v. Ross-Simmons Hardwood Lumber*, 549 U.S. 312 (2007); *Bell Atlantic v. Twombly*, 550 U.S. 544 (2007); *Leegin Creative Leather Products v. PSKS, Inc.*, 551 U.S. 877 (2007); *Credit Suisse First Boston Ltd. v. Billing*, 551 U.S. 264 (2007); *Pacific Bell Telephone v. LinkLine Communications*, 555 U.S. 438 (2009); *American Needle v. NFL*, 130 S. Ct. 2201 (2010).

[34] *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

*KSR*, which made it easier to challenge patents on the basis of obviousness;[35]

*Bilski*, which revised the standard for determining the patentability of a process and held that abstract ideas were not patentable; and[36]

*Microsoft v. i4i*, which affirmed that invalidity must be shown by clear and convincing evidence.[37]

What's interesting is that the Court has not shown a lot of sympathy for either antitrust plaintiffs or patent holders. Five of the six antitrust decisions during this time narrowed the scope of liability under the antitrust laws or heightened pleading standards for plaintiffs. Likewise, three of the four patent decisions narrowed the ability of inventors to patent their ideas or to obtain certain forms of judicial relief.

The fifth reason to expect Supreme Court review of a pay-for-delay case is that I expect there will be significant advocacy from the business and legal communities for the Court to grant certiorari. Already Merck and Upsher-Smith have filed separate cert petitions, and other pharmaceutical companies and trade associations are likely to submit supporting briefs. I am hopeful that the FTC will have an opportunity to add its voice to this chorus and urge the Court to grant certiorari in either or both of the *Androgel* or *K-Dur* cases. Our Chairman, Jon Leibowitz, has publicly described his desire to "encourage the Supreme Court to resolve this issue."[38]

The sixth and final reason the Court is likely to grant certiorari is that the issue is of great importance to the pharmaceutical industry and to consumers. Many pharmaceutical companies

---

[35] *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007).

[36] *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

[37] *Microsoft Corp. v. i4i L.P.*, 131 S. Ct. 2238 (2011).

[38] Oral Statement of Commissioner Jon Leibowitz, Hearing of the Senate Judiciary Committee (Jan. 17, 2007), *available at* http://www.ftc.gov/speeches/leibowitz/071701oralstatement.pdf.

are headquartered in the Third Circuit and are therefore subject to the *K-Dur* decision, which has the potential to affect the economics of the industry in a significant way. The same is true for consumers of pharmaceutical products. The FTC has estimated that pay-for-delay agreements cost consumers $3.5 billion a year.[39] While I am skeptical of this calculation, there's no question that a lot of money is involved.

I must say, however, that I listed this reason last for good reason. I don't think that the importance of the issue to the pharmaceutical industry or the volume of commerce involved is likely to be a significant factor in the Supreme Court's decision of whether to take a pay-for-delay case. The Court often declines to hear cases whose resolution will have a significant effect on a particular segment of the economy. For example, the Court declined to grant certiorari for the Third Circuit's 2003 *LePage*'s decision,[40] which arguably heightened the risk of antitrust liability for a far greater volume of commerce and broader range of industries than the *K-Dur* decision. Likewise, the Supreme Court has declined to grant cert in several prior pay-for-delay cases.

Assuming that the Supreme Court agrees to hear a pay-for-delay case and resolve the circuit split, how is it likely to rule? I am not going to venture a guess. The fact that the Court has been unfriendly to both antitrust plaintiffs *and* patent holders in recent years makes this a tough one to score.

One possibility I do want to mention, however, is that the Supreme Court will go its own way. Because of the rather stark circuit split that currently exists, many commentators assume

39

that the issue before the Court will be whether to adopt the scope of the patent test or to follow the Third Circuit's presumptive illegality standard. It's certainly possible that the Court will adopt one of these tests, but I think it's just as likely that it will adopt some intermediate test or a variant on one of these tests.

For example, the Court could try to fashion a test that deals with the Third Circuit's concerns about weak patents and with the Eleventh Circuit's concerns about the uncertainty of patent litigation. Here are a couple of suggestions for such a rule. First, a judgment could be made as of the time that the parties begin negotiating a deal. This would result in elimination of the war between experts that are typically hired after a deal is struck in order to justify the deal. I have suggested this before.[41] Second, in considering the legality of a pay-for-delay settlement, a court should apply Rule 56 rigorously. That is to say, whenever possible it should decide summarily whether liability for invalidity or non-infringement is either clear or remote.[42] This would result in the court being able to weed out claims that should not have been made while at the same time not reinventing the

extensive evidentiary record concerning the challenged settlement," on account of the nine-week administrative trial by an FTC administrative law judge in the *Schering*

to enforce Section 5 against pay-for-delay settlements, as well as to engage in related rulemaking.

The Kohl–Grassley bill does not condemn such settlements outright. Instead, it creates a presumption that pay-for-delay settlements are anticompetitive, which the settlement parties may rebut with "clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement."[45] The Kohl–Grassley bill is thus similar to the Third Circuit's *K-Dur* standard, except that the standard of proof on the respondents is clear and convincing evidence, which I think is a mistake. As far as I know, there is no precedent for employing this heightened standard, which may chill settlements of litigation and stack the deck too much in the Commission's favor.

The other pending bill in the Senate is known as the Bingaman–Vitter "Fair and Immediate Release of Generic Drugs Act."[46] It was introduced and referred to committee on November 16, 2011. This bill approaches the pay-for-delay problem from a regulatory angle, as opposed to an enforcement angle. Specifically, the Bingaman–Vitter bill would neutralize the impact of pay-for-delay agreements on timely generic entry. The bill's basic approach is to grant "share[d] exclusivity" to "any generic filer who wins a patent challenge in the district court or is not sued for patent infringement by the brand company."[47]

---

[45] *Id.* § 3(a).

[46] Fair and Immediate Release of Generic Drugs Act, S. 1882, 112th Cong. (2011), *available at* http://www.gpo.gov/fdsys/pkg/BILLS-112s1882is/pdf/BILLS-112s1882is.pdf.

[47] Summary, Sen. Jeff Bingaman, Bingaman–Vitter–Brown–Merkley Fair and Immediate Release of Generic Drugs Act of 2011 (Nov. 16, 2011), *available at* http://bingaman.senate.gov/policy/FAIRGenerics.pdf.

The bill pending in the House is the Protecting Consumer Access to Generic Drugs Act of 2012,[48] which was introduced by Representative Bobby Rush and referred to committee in February. This bill is the reincarnation of a bill that died in the previous session of Congress.[49] The Rush bill would prohibit all pay-for-delay agreements without affording respondents any opportunity to show that the settlement agreements were pro-competitive or justified by the strength of the patent. However, the bill would give the FTC rulemaking authority to exempt certain pay-for-delay agreements from this prohibition "if the Commission finds such agreements to be in furtherance of market competition and for the benefit of consumers."[50] The bill also amends the Federal Food, Drug, and Cosmetic Act so that an applicant forfeits market exclusivity if it enters into a pay-for-delay agreement.

In addition to these three bills, there have been several attempts to add pay-for-delay provisions to emergency legislation. This has been an unfortunate development in my view. The proper standard by which to evaluate infringement settlement agreements in the pharmaceutical industry is too important an issue to be tacked on to any other legislation and should receive full debate by the relevant Congressional committees and subcommittees.

[48] Protecting Consumer Access to Generic Drugs Act of 2012, H.R. 3995, 112th Cong. (2012), *available at* http://www.govtrack.us/congress/bills/112/hr3995/text.

[49] Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009), *available at* http://www.govtrack.us/congress/bills/111/hr1706.

[50] H.R. 3995 § 3. The bill states that a violation "shall be treated as an unfair and deceptive act or practice and an unfair method of competition in or affecting interstate commerce prohibited under section 5 of the Federal Trade Commission Act," which means that the FTC is the only entity that can enforce the bill's prohibitions. *Id.* § 2(c).

Last year, I criticized proposals to restrict pay-for-delay settlements as part of the deficit reduction package that was considered by the so-called "super committee."[51] And in May of this year, I raised concerns about efforts to tack the Bingaman–Vitter bill onto "must have" legislation reauthorizing the FDA's ability to collect user fees.[52] Both times, I also criticized the savings claimed by those in favor of these restrictions as speculative. In each of these situations, the pay-for-delay restrictions were not added to the larger legislative package.

I expect that not much will happen on the legislative front for a while because of the potential for the Supreme Court to resolve the circuit split. However, if and when the Court rules on the issue, there is likely to be a strong push by the losing side for legislation to overturn the Court's decision. We saw that in the wake of the Supreme Court's recent *Leegin* decision, which gave greater flexibility to manufactur

whether a branded company's commitment not to launch an authorized generic ("AG") in competition with a generic company during the 1