

# Litigation Notes

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## FTC ANTITRUST COMPLAINT AGAINST CEPHALON

The FTC filed an antitrust case against **Cephalon** in the U.S. District Court in the District of Columbia charging monopolization of the market for Provigil, a narcolepsy drug, because of the reverse payment patent settlements it entered into with **Barr Labs**, **Teva**, **Mylan** and **Ranbaxy** in late 2005 and early 2006. Barr, Teva, Mylan and Ranbaxy all share first-to-file status on Provigil and would have entered the market on an at-risk basis in 2006 if the reverse payment settlements had not been reached. The FDA is effectively precluded from approving any other ANDA for generic Provigil until 180 days after one of the first filers has entered the market, and since all of them have agreed to stay off of the market until 2012, then unless a court intervenes, Cephalon will have four more years of market exclusivity.

**In our analysis, although the reverse payment agreements in this case really are illegal under the antitrust laws, and although the FTC commissioners and staff are genuinely persuaded that reverse payment agreements, including the Cephalon agreements, are illegal and would like to stop them, the fact is that the “deck is stacked” against the FTC on this issue and it cannot win the war against reverse payment settlements by itself. Accordingly, we think the way to bet is that the FTC will eventually fall on its face, the courts will continue their confusion about reverse payment patent settlements and Cephalon will enjoy the entire four years of patent protection provided by the settlement agreements. We think that Democrats in the White House could get U.S. Supreme Court review of reverse payment settlements, but we think the current Court would wiggle out somehow so as to avoid a definitive ruling that the settlements are illegal.**

The facts of the Cephalon settlements, as alleged in the FTC complaint, are that Cephalon entered into four separate agreements with the generic manufacturers, each of which provided for some cash to the generic manufacturer plus some non-cash consideration, in return for which each generic manufacturer agreed to stay out of the market for generic Provigil until 2012. The patent at issue had not already been held to be invalid, but the generic manufacturers had made good arguments in their pending cases that the patent was easily avoidable and in fact had been avoided by all of the generic manufacturers that had filed ANDAs on the drug.

On the merits, we think that these reverse payment settlement agreements are illegal under U.S. antitrust laws. We think that the sharing of “monopoly rents” between a patent holder and a potential infringer in order to forestall competition in the market covered by the patent is a per se violation of Section 1 of the Sherman Act regardless of whether the patent is valid or infringed. Additionally, we think that both the antitrust laws and the Hatch-Waxman Act strongly embrace the policy underlying this rule, and we think the public policy of favoring negotiated settlements of litigation has little or no countervailing weight against the policies underlying the Sherman Act, especially in the context of Hatch-Waxman Act

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litigation. We also think that the contrary views expressed in the Eleventh Circuit's Schering-Plough decision, the Second Circuit's Tamoxifen decision and the amicus briefs of the Solicitor General are simply mistaken.

Our view of the legality of reverse payment settlements, we think, is consistent with the FTC's view and is also consistent with the 2003 view of the Sixth Circuit Court of Appeals in the Cardizem CD case, but the pertinent question for Cephalon is whether this view will become established law within the next four years, destroying its ability to profit from Provigil sales. For reasons explained below, we don't think so.

To us, the FTC has made several smart moves in the Cephalon case so far. First, it invoked its power to seek injunctions in the district courts, which will permit a resolution of the case much more quickly than if it attempted to use its own cumbersome agency proceeding mechanism.

Second, it elected to proceed with a monopolization case against Cephalon alone rather than to sue all of the parties to the settlement agreements on a restraint of trade theory. Commissioner Jon Leibowitz filed a separate statement explaining that he would have preferred to include the generic manufacturers as codefendants, since it is the agreement of these companies to refrain from marketing that, under the Hatch-Waxman Act, precludes all other potential competitors as well. However, it will be easier for the FTC to proceed against Cephalon alone, and if it can win, then the settlements will be held illegal and we think the result will be the same.

Third, it filed the case in the U.S. District Court in D.C., appeals from which are in the D.C. Circuit Court of Appeals, which has not yet ruled on reverse payment settlements in Hatch-Waxman cases. Also, a few days before filing the Cephalon case it submitted an amicus brief in the Federal Circuit Court of Appeals, also in D.C., in the Ciprofloxacin case. The Ciprofloxacin case, on appeal from the U.S. District Court in Brooklyn, is yet another reverse payment case, but in this case the private purchaser plaintiffs persuaded the Second Circuit Court of Appeals (which decided the Tamoxifen case) to allow the appeal to go to the Federal Circuit because patent issues were involved.

Despite these initial smart moves, however, it appears to us that the Cephalon case is likely to progress slowly in the court system. The FTC said in its complaint that it is seeking a permanent injunction against Cephalon, but it did not say that it was seeking a preliminary injunction. It could move for a preliminary injunction at any time, but the most it could get from such a motion would be a statement from the court that it had a "substantial probability of success," not an official declaration that the settlement agreements are illegal. Accordingly, the preliminary injunction route would not accomplish anything. To get a permanent injunction, on the other hand, the FTC will have to go through the entire pretrial phase, including expert reports, followed by the trial, then followed by waiting for the decision, then the petition for reconsideration, then the appeal to the D.C. Circuit and waiting for that decision, and then, finally, the appeal to the U.S. Supreme Court. This entire process will take years.

At the present time, Supreme Court review of this issue is being blocked by the Solicitor General's office, to which the Supreme Court looks for guidance in deciding which cases to accept for review. The Solicitor General advised against the Schering-Plough case two years ago for reasons that seemed logical at the time, i.e., the fact that the Commission had reversed its own administrative law judge, thus creating uncertainties about the factual record. However, when the Tamoxifen case came along and the Solicitor General again advised against review, we began to think that an executive decision had been made to safeguard reverse payment settlements and consequent high drug prices for the benefit of the branded and generic pharmaceutical industries.

Specifically, the Solicitor General advised the Supreme Court to deny review of the Second Circuit's

Tamoxifen decision for several reasons, none of which are persuasive. First, it argued that the case was moot since the patent had expired in 2002, but it was moot only for injunction purposes, and a damages remedy would still have been available.

Second, it also argued that since state law violations had also been alleged, the case presented a question not considered in the lower courts regarding preemption by the federal patent laws of state antitrust laws. Inadequate consideration in the lower courts of a fundamentally irrelevant question does not normally deter the U.S. Supreme Court from accepting a case for review, and we think it is a pretty weak excuse.

Third, the Solicitor General argued that certain facts of this case, i.e., that the settlement was entered after a district court ruling invalidating the patent, were unlikely to recur, since vacatur of invalidation rulings are no longer permissible while a patent case is on appeal. We agree with the FTC that the validity of the patent is irrelevant to the legality of a reverse payment settlement, but if it *is* relevant, then the Tamoxifen case is actually *ideal* for articulating the principle at issue because of the factual record in the lower court.

Fourth, the Solicitor General argued that the forfeiture provisions of the 2003 Hatch-Waxman Act amendments made it impossible for a first filer to use its 180-day exclusivity to block other entrants. Perhaps, but there are still plenty of Hatch-Waxman cases governed by the prior law, and in any event the so-called manipulation of the 180-day exclusivity period is not the only antitrust issue presented by reverse payment settlements.

The Solicitor General's reliance on bogus arguments to keep reverse payment cases out of the Supreme Court indicates to us that the current Administration is seeking to insulate the profits of the branded and generic drug industries. If so, then that bodes well for the \$4 billion that Cephalon "saved" as a result of the settlements. If Democrats win control of the White House in November, they will probably have a different attitude toward reverse payment cases, but first, a proper case would have to be presented on which a new Solicitor General appointed by Democrats could opine, and second, the Democrats would need to have organized their thoughts well enough to present a cogent argument. Even then, it is quite possible that the same arguments influencing the current Solicitor General against the appeal would also influence the current Supreme Court itself if it were to accept a case for review.

Whether a Solicitor General appointed by Democrats can get a case into the Supreme Court quickly is another question. We are aware of two possible reverse payment cases that could get to the Supreme Court more quickly, including the Ciprofloxacin case recently appealed to the Federal Circuit and the private purchaser class actions against Cephalon and the generic manufacturers currently pending in the U.S. District Court in Philadelphia.

It seems unlikely that the Philadelphia class actions will ever get anywhere, since they have been pending for two years already and have not yet gotten past the initial motions to dismiss. The failure of the judge to move this case forward more quickly was probably a factor motivating the FTC to challenge Cephalon's reverse payment settlements, and it may also have motivated the FTC to style the case as a monopolization case against Cephalon alone rather than as a restraint of trade case against all of the parties to the settlement agreements.

The Ciprofloxacin case, however, could conceivably move quickly enough so that a new Solicitor General appointed next year could advocate Supreme Court review before the end of 2009, meaning that the case would be heard and decided sometime in 2010. If the ruling happened to invalidate reverse payment settlements, it would still take time to apply it to Cephalon, perhaps cutting off the monopoly as early as 2011.

It is more likely, we think, that the majority of the Supreme Court will continue the confusion of the

Solicitor General and the lower courts and will release a decision that requires even more lower court litigation in order to determine what it means. So far, the Solicitor General believes that a “rule of reason” approach is appropriate for evaluating reverse payment cases and that it is necessary to determine whether the patent holder has a “strong case” or a “weak case.” The Second Circuit thinks that the only issue is whether the patent holder’s infringement claim is a “sham” or is “otherwise baseless.” The dissenting judge in the Second Circuit, Judge Pooler, thinks that the important issue is the amount that the patent holder paid to the interloper to protect the market, compared to the amount that the interloper could have made during the period in question. To the Eleventh Circuit, the strength or weakness of the patent is irrelevant, since the only proper issue is the exclusionary scope of the patent on its face and whether the settlement extends the monopoly beyond *that* scope.

To us, every one of these positions is nonsense, but if the lower courts can be that wrong on these issues, then it is likely that the Supreme Court will also be confused by them and will make a further mess of things.

That said, we also have to admit that the Supreme Court’s recent decisions in the patent context have impressed us as mostly well-reasoned and appropriate, and therefore we do not rule out the possibility that it will do a good job on this issue as well. We think that if it starts with the eBay decision, under which patent injunctions are appropriate only when all of the normal prerequisites for an injunction are satisfied, and if it perceives that the public policy favoring settlements is not affected by a proscription against illegal settlements, then we doubt it will be fooled by lower court mistakes on reverse payments.