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Litigation Notes

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CEPHALON'S REVERSE PAYMENT SETTLEMENT LITIGATION

Quite a bit has happened since our last report on reverse payment settlements in the pharmaceutical industry, and therefore we decided to update our thinking on what is likely to happen to these settlements in the future. In particular, a new judge was assigned to the Cephalon case pending in the U.S. District Court in Philadelphia, since the case made no progress in over a year in front of the prior judge. Also, the U.S. Supreme Court is considering a petition for review of the Federal Circuit's ciprofloxacin decision issued last year, and it may decide before the end of June whether to hear the appeal.

In our thinking, the FTC's current view on the illegality of reverse payment settlements is correct on the merits, and we think that it will eventually be vindicated. However, the courts are confused by the fact that both branded and generic drug companies, seemingly adversarial, are so strongly unanimous in defending reverse payment settlement agreements, and their arguments, advanced by pillars of the legal community, have been effective in postponing an ultimate resolution of the issue. The recent trend at the U.S. Supreme Court is that it rescues the Federal Circuit from its excesses, and we think that the trend will apply to this case as well. However, we think that a U.S. Supreme Court decision on this issue is probably a year away, and when it comes, we think it is more likely to create additional confusion rather than to provide a black letter line establishing that reverse payment settlement agreements are illegal.

On the merits, we regard these settlements as nothing more than an agreement between two (or more) competitors to divide monopoly profits and to prevent the forces of competition from driving down prices to a competitive level. A reverse payment is, in effect, a payment by the branded company of the generic company's agreed-upon share of the monopoly profits. If patents were not involved, there would be no question that such an agreement is per se illegal under Section 1 of the Sherman Act.

Accordingly, the only relevant question is whether the fact that the branded company has a patent changes the legal calculus, and to us, on the merits, the answer is no. Although a patent is often described in shorthand as a "right to exclude," in truth it is a right to exclude only by means of legal process resulting in an injunction so long as the requirements for an injunction are met. Settlement agreements that incorporate illegal provisions cannot satisfy the public interest requirement for an injunction. As for the often-cited public policy favoring settlements of litigation, parties to a patent case can always negotiate a settlement by agreeing to a conventional patent license, and therefore it is not true that a case cannot be settled at all unless an illegal provision is allowed.

The fact that a patent is nothing more than a right to invoke legal process so as to obtain damages and, in a proper case, an injunction, is clear from the jurisprudence concerning covenants not to sue. The law is

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well-established that if a patentee provides a covenant not to sue, then the recipient of the covenant has no claim against the patentee that the patent in question is invalid or not infringed. Indeed, it is well established that in such a case the courts lack jurisdiction because there is no case or controversy. If the patentee's "right to exclude" was a more general right to exclude by any means available, then perhaps a case could be made that the patent grant creates an implied exception to other prohibitions in the law.

We read an amicus brief filed by 54 patent law professors urging the U.S. Supreme Court to review the ciprofloxacin case. Ironically, the brief conceded that there was no unanimity even among the professors as to how the issues presented by reverse payment settlements should be resolved. Instead, they said simply that the U.S. Supreme Court should resolve the already substantial conflict between the circuits regarding the legality of these agreements in the pharmaceutical context. The Sixth Circuit, they said, concluded that the agreements were *per se* illegal, whereas the Second Circuit and the Federal Circuit have now both ruled that the agreements are *per se legal*, unless the underlying litigation is a sham or if the patent was obtained by fraud. The Eleventh Circuit, they said, staked out a middle ground, holding that the agreements are legal unless they are unreasonable, which in turn requires an inquiry into whether the underlying patents at issue are strong or weak.

The FTC view, which to us is the legally correct view, is that a reverse payment settlement agreement is illegal whenever two conditions are both satisfied: (1) a net payment, in cash or in kind, from the patentee to the generic manufacturer, and (2) a commitment by the generic manufacturer to refrain from entering the market for a period of time. Under the FTC view, a payment from the branded company to the generic is okay provided there is no concomitant agreement by the generic to refrain from entering the market, and an agreement by the generic to refrain from entering the market is okay as long as it is not paid by the branded company for doing so. Accordingly, a settlement in which a generic receives no money but nevertheless agrees to stay out of the market until, say, two years prior to a patent's expiration would be permissible under the FTC approach.

The pharmaceutical industry's lawyers have become adept at postponing the ultimate resolution of whether and when these agreements are illegal, and we think that these talents will continue to be used to perpetuate confusion in the courts. The AndroGel case earlier this year is a good example of how these talents have been used. In that case, **Solvay Pharmaceuticals** and several generics persuaded Judge Mariana Pfaelzer to transfer an FTC challenge in a reverse payment case from a federal court in California to the judge in Georgia before whom the patent case was pending before the settlement. Georgia is in the Eleventh Circuit, which has already spoken on the issue, and therefore a transfer to a district court in the Eleventh Circuit effectively ends the FTC's challenge.

The FTC had argued in the AndroGel case that the strength of the patent was not relevant to the legality of the settlement and that therefore there was no need to transfer the case, but Judge Pfaelzer did not agree. Accordingly, the transfer order is a precedent of sorts that reverse payment settlements do not violate the antitrust laws if the patent in question is strong. We think that Judge Pfaelzer is wrong on this point, since if a patent is strong, then there is no need for the patent owner to pay out a small fortune to deflect the challenger. Moreover, the only way to determine whether a patent is truly strong is to expose it to the vigor of the adversarial process, which plainly does not exist once the plaintiff and the defendant have agreed on a division of the monopoly profits. In any event, the strength-of-the-patent argument has no application to a potential entrant whose product does not infringe, such as in the Cephalon case.

White & Case, the law firm that fought the AndroGel battle against the FTC, employed two novel tactics as insurance to strengthen the industry's position in the case. One tactic was to cause the first-filing generic, **Par Pharmaceuticals**, to waive its 180-day exclusivity. The argument, sure to confuse some judges, is that if the 180-day exclusivity is waived, then there can be no antitrust violation because

anyone else is free to enter the market. However, it also settled with **Watson Pharmaceuticals**, the only other filer, so that in the end, no generic manufacturer is on the launching pad ready to enter the market, thus buying valuable time in which the market is free of competition. The second tactic was to convert the negotiated settlement into a consent order signed by the judge in Georgia, thus giving it a possible argument that the agreement is immune from antitrust scrutiny because of the Noerr-Pennington doctrine. In the FTC case against Cephalon, the company's lawyers perceived that Judge Barclay Surrick, the federal judge in Philadelphia assigned to the purchaser class actions, was extremely slow, if not comatose, and they managed in early 2008 to persuade Judge John Bates of the U.S. District Court in D.C. to transfer the FTC case to Philadelphia for consolidation with these purchaser class actions. One year later, on May 6, 2009, Judge Surrick had still not ruled on a then-pending motion to dismiss, and the chief judge of the district suddenly reassigned the case to a different judge, Judge Mitchell Goldberg, for further proceedings.

Judge Goldberg is a relatively new judge in the district, having been appointed by President George W. Bush, and although his views regarding reverse payment settlements are not known, we think that a good working hypothesis is that his views are consistent with the views of the Solicitor General under President Bush. Those views, as we recall, were that U.S. Supreme Court review should be postponed until an ideal case came along, which could be never, and further, that the strength of the patent was a relevant consideration in evaluating the legality of reverse payment settlement agreements. As mentioned above, acceptance of the strength-of-the-patent argument is a backdoor way of permitting reverse payment settlements. There is no way that a judge can determine whether a patent is weak without exposing it to a meaningful adversarial process, and there is no indication how strong a patent would have to be in order to justify the desired antitrust immunity.

Additionally, it has become clear that political party affiliation is a good indicator of person's views regarding the legality of reverse payment settlements, which further supports our hypothesis on Judge Goldberg's likely views. We say this because last week in the House of Representatives, the House committee considering H.R. 1706 (to ban reverse payment settlements in the pharmaceutical industry) voted 16-10 to approve the bill. Not a single Republican voted for it, and not a single Democrat voted against it. In the Senate, however, there are two Republican senators who actually support the Senate bill, which mirrors the House bill closely.

The other major factor that could influence the Cephalon case is the currently pending petition for U.S. Supreme Court review of the Federal Circuit's ciprofloxacin case. It is possible that the Supreme Court will agree to hear, or not to hear, the case prior to the end of the current term, which concludes at the end of this month. However, in the past, the Supreme Court refused to hear appeals in two other reverse payment cases, having been advised both times by the Solicitor General that it should decline review.

In the present case, the Supreme Court has not requested advice from the Solicitor General, but as it happens, the Second Circuit *did* ask for the Solicitor General's opinion and was informed that an opinion would be forthcoming in the first week in July. The Second Circuit, coincidentally, has a case before it involving the same drug and the same reverse payment settlement.

Accordingly, we think that the Supreme Court is likely to wait for the Solicitor General's opinion in the Second Circuit case before making its own decision on whether to grant review. If so, then a decision on review will not be made until October, and if review is granted, a decision in the case would not be likely until 2010. The lawyer representing the pharmaceutical industry stated at the oral argument on April 28, 2009 in the Second Circuit that industry representatives have asked to "exercise our rights to meet with the appropriate people with the government to express our views before they write the letter."