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Are 'Reverse Payments' Becoming More Reasonable?

Law360, New York (April 02, 2009) -- Over the last several years, competition between branded and generic drugs have become an increasingly important focus for U.S. antitrust authorities and private antitrust plaintiffs.

One hot button issue in this area has been patent settlements between branded and generic competitors in which the branded company pays the generic substantial sums and the generic agrees to delay market entry.

The new administration and Congress have expressed concern that reverse payments have caused generic equivalents of branded drugs to stay off the market, thereby delaying the entry of lower-priced generic alternatives which would otherwise save consumers millions of dollars.

Congress (both the House and Senate) has once again introduced legislation to ban the practice of reverse payments between branded and generic drug manufacturers altogether.

These concerns have been echoed by the Federal Trade Commission and U.S. Department of Justice. In fact, FTC inquiries into reverse payment cases will likely be one of the top enforcement priorities of the new FTC Chairman, Jon Leibowitz.

In his Feb. 2, 2009, concurring statement in *FTC v. Watson Pharmaceuticals*, Chairman Leibowitz stated that "[e]liminating these pay-for-delay settlements is one of the most important objectives for antitrust enforcement in America today."

Similarly, antitrust AAG nominee Christine Varney has stated to Congress that she will "work with the Department of Justice to align the Federal Trade Commission and the DOJ on the reverse-payment issue. And if the courts continue to not reach the result that you and your committee thinks is appropriate, then legislation may be necessary."

Previously, although the DOJ held the view that reverse payments “may result in less competition than would likely have prevailed in the absence of the payment,” it advocated in 2006 against the Supreme Court accepting certiorari in the Schering-Plough case (certiorari which the FTC sought), regarding a perceived circuit-split as to the federal courts’ treatment of reverse payments under the antitrust laws.

Though the FTC has mounted several recent challenges to reverse payments, the courts have used diverse reasoning to reach different conclusions about the legality of these payments.

Lately, the legal trend has been to find reverse-payment arrangements reasonable so long as they do not exceed the scope of the patent(s) at issue, thereby foregoing condemnation of the arrangement under the per-se rule.

Although some hope that the Supreme Court will weigh in this year with the recently filed petition for certiorari in Ciprofloxacin, it has twice refused to review this issue.

Unless Congress or the Supreme Court weigh in soon, enforcers and private litigants will have to choose their battle grounds wisely, so as not to be barred by some courts’ stance that these arrangements are reasonable.

The Regulatory Framework

A competitor seeking to market a generic version of the branded drug must, as part of its abbreviated new drug application (ANDA), make one of several certifications about the branded company’s patent rights, if the relevant patent(s) are listed in the FDA’s patent registry, known as the Orange Book. The certification explains why the generic should be able to market its product notwithstanding the branded company’s patent rights.

One of the most common certifications in this situation is a Paragraph IV certification, in which the generic company certifies that the branded company’s patent is either invalid or not infringed by the generic product. The branded company then has 45 days to initiate a patent infringement lawsuit.

If the branded company files suit, the FDA cannot approve the generic’s ANDA until 30 months after the filing of the patent suit, the patent expires, or a court issues a final determination that either the generic drug does not infringe or the patent is invalid, whichever occurs first.

As an incentive to bring generic drugs to market, the first generic applicant to file an ANDA with a paragraph IV certification is eligible to receive market exclusivity for a period of 180 days from the date the generic enters the market.

As of 1993, the first applicant's exclusivity rights can be terminated if it fails to market the drug in order to avoid a bottleneck delaying other generic entry (under certain conditions).

The stakes are high in these Orange Book cases. A branded company often stands to lose millions of dollars a day once generic competitors enter the market and, therefore, has a tremendous incentive to bring an infringement lawsuit, which automatically delays generic entry.

The first generic entrant similarly stands to reap a huge financial windfall during the period of market exclusivity. But compromising on the timing of the first generic's entry as part of a patent settlement could serve both sides well, if both sides benefit more financially than if the generic would have entered the market.

Such settlements, however, raise thorny issues such as whether the branded company's patent rights justify this type of agreement and the extent to which the antitrust restrictions against market allocation can be used to prevent these agreements.

A key question in these suits revolves around the issue of how much deference courts should afford the branded company's patent rights.

For instance, do courts need to conduct a rigorous analysis of patent validity and infringement before deciding whether a settlement requiring a reverse payment can be deemed anticompetitive and therefore illegal?

Even if a patent is valid and infringed, meaning the patent holder can exclude the generic from the market for the duration of the patent, can a court still find a reverse payment unlawful?

The Courts' Differing Analytical Approaches

Courts have reached different, some might say conflicting, conclusions about the legality of these settlements. Some courts have found "reverse payments" to be illegal per se.

In other cases, the courts suggested that the branded company's patent rights gave it carte blanche to exclude the generic from the market, thereby negating any alleged causal

connection between the reverse payment and marketplace injury.

At least one other court and the FTC have taken the position that a valid and infringed patent would not necessarily foreclose an antitrust challenge if, in the absence of the reverse payment, the parties would have reached a more favorable settlement allowing the generic to enter the market earlier than the challenged settlement.

Although perhaps reconcilable at some level, these cases represent drastically different approaches to balancing the tensions between and among the antitrust, FDA, and patent considerations in this area.

The Per Se Approach

In the Cardizem case, the Sixth Circuit Court of Appeals found the reverse payment at issue to be per se unlawful. There, a branded pharmaceutical manufacturer agreed to pay a generic competitor \$10 million per quarter to stay off the market during the pendency of the patent case.

Not only did the agreement keep the first ANDA filer off the market, it prevented all other generics from coming to market because the first generic had agreed not to relinquish its 180-day exclusivity period, which created a bottleneck for subsequent generics.

The court found it significant that the agreement did not resolve the underlying patent litigation. Some have tried to reconcile this case with other cases eschewing the per se approach by noting that the payment at issue in Cardizem effectively excluded drugs falling outside the scope of the branded company's patent.

Cases Rejecting the Per Se Approach

Other courts have rejected the per se approach, the most recent of which was the Federal Circuit in *In Ciprofloxacin Hydrochloride Antitrust Litigation*.

In *Cipro*, Bayer, the holder of the '444 patent and Barr, the first would-be generic entrant, settled a patent infringement case as to the validity and enforceability of Bayer's '444 patent covering the drug.

In the settlement agreement, Barr agreed to not manufacture the generic version of the drug, in exchange \$398.1 million in exclusion payments. Later, other would-be generic entrants challenged the '444 patent, but it was upheld.

The Federal Circuit affirmed the district court's ruling that the settlement agreement at issue could not be challenged under the per se rule, and that the rule of reason applied.

According to the district court, "any adverse anti-competitive effects within the scope of the '444 patent could not be redressed by antitrust law," given that a patent by its nature was anticompetitive.

The Federal Circuit concluded that "the essence of the inquiry is whether the agreements restrict competition beyond the exclusionary scope of the patent," and further, unless there is evidence of fraud before the PTO or sham litigation, "the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment."

On March 23, 2009, plaintiffs filed a petition for certiorari with the Supreme Court, seeking reversal of the Federal Circuit's ruling.

The Eleventh Circuit in the Valley Drug and Schering-Plough cases refused to apply a per se analysis.

The settlement in Valley Drug contained a "reverse payment" and prohibited the generic from entering the market until the earlier of a final and unappealable determination of invalidity, a second generic drug's entry into the market, or the expiration of the patent.

In Schering-Plough, the FTC alleged that Schering had reached unlawful, anticompetitive settlements with not one, but two generic competitors.

After initiating patent suits against the generics, Schering agreed to settle the patent cases in exchange for the generics' agreements to refrain from entering the market for some period of time, but a lesser period of time than that remaining in Schering's patent term.

The generics, as part of the settlement, also agreed to license various products and technologies to Schering and Schering agreed to pay each generic a substantial sum of money — one received approximately \$60 million and the other received somewhere between \$15 to \$30 million.

The Eleventh Circuit held that the antitrust analysis must take into account (1) the exclusionary power of the patent, not in a post hoc manner, but based on the status of the patent at the time of settlement, i.e., before the patent had been found invalid; (2) the

extent to which the patent settlement agreement exceeds the patent's scope; and (3) the resulting anti-competitive effects.

Applying this framework, the court ruled that the patents at issue gave the defendants the lawful rights to exclude the generics from the market until the generics proved that the patent was invalid or not infringed.

The court voiced some concern that an unduly strict legal standard would discourage patent settlements, but drew a distinction between a situation in which uncertainty exists about validity and infringement from that in which the branded drug maker knows that its patent is invalid.

In Tamoxifen, the Second Circuit ruled that a reverse payment did not violate the antitrust laws. The plaintiffs argued that the reverse payment was per se unlawful because it was substantially more than the generic would have made by entering the market with its own generic drug.

But the appellate court concluded that the fact that a patent holder pays to protect its "patent monopoly," without more, does not establish an antitrust violation.

The correct inquiry, according to the Second Circuit requires a two-prong analysis: (1) whether the patent infringement claim amounts to a "sham" or fraud; and (2) whether the settlement agreement is limited to the scope of the patent.

According to the court, "so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product."

The Shopping Game

Given the courts' differing analyses, private plaintiffs and the FTC have been hard pressed to file actions in jurisdictions that would lend sympathetic ears (or at least create a further circuit split) as to reverse-payment cases. Indeed, defendants have challenged the FTC's choice of venue in two recent cases.

In Cephalon, the FTC filed an antitrust action in the U.S. District Court for the District of Columbia, challenging a reverse payment relating to the prescription wakefulness drug,

Provigil.

Cephalon had instituted a patent infringement action against four pharmaceutical companies that wished to sell generic modafinil products to compete with Cephalon's Provigil, and after two years of patent litigation, entered into settlement agreements whereby each would-be generic entrant agreed to forego entry until 2012 in exchange for payments from Cephalon.

In its decision to transfer venue, the U.S. District Court for the District of Columbia agreed with Cephalon that although a plaintiff's choice of forum is entitled to great deference, venue must be transferred to Pennsylvania where private actions were pending against Cephalon involving the same issues of law and fact.

Interestingly, the court agreed with Cephalon that FTC was clearly forum shopping:

"The commission is rather only shopping for a circuit split on the issue of reverse payment Hatch-Waxman settlements, and all the better if the FTC could potentially arrange for two courts of appeals — the Third and D.C. Circuits — to decide the question in the context of what is essentially the same case. ... [I]t strikes this court as both odd and unreasonable to do so at the expense of exposing a single defendant (engaged in a single course of conduct) to conflicting judgments in order to advance the agency's enforcement goals."

Defendants have also recently filed another motion to transfer venue in the FTC's reverse-payment case against Watson Pharmaceuticals, requesting a transfer from the Central District of California to the Northern District of Georgia, on the ground that the latter was more convenient to the parties, and that the FTC was clearly forum shopping.

Conclusion

We have not heard the last word on the antitrust implications of reverse payments in pharmaceutical settlements.

The antitrust enforcement agencies and private plaintiffs will continue to challenge these practices in jurisdictions that may be more sympathetic to their plight, while defendants will reassert the holdings of those cases finding reverse payments reasonable.

Perhaps the Supreme Court will weigh in this year with a definitive answer, unless Congress acts first to ban the practice altogether. There is more to come in this area, and companies and practitioners alike should stay keenly tuned.

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