Federal Circuit Joins Other Circuits: Reverse Payments in ANDA Settlements Are Not Per Se Violations of the Antitrust Laws

On October 15, the United States Court of Appeals for the Federal Circuit issued an opinion in *In re Ciprofloxacin Hydrochloride Antitrust Litigation,* holding that a settlement involving "reverse payments" from a patentee to a party seeking to market a generic copy of the patented drug is not per se illegal under the antitrust laws. The Federal Circuit affirmed the grant of summary judgment against an antitrust claim brought by indirect purchasers of the drug Ciprofloxacin (Cipro) and several advocacy groups against Bayer, the holder of the patent on the drug.

The Court stated that a finding of a per se violation of the antitrust laws is only appropriate where the Court could "predict with confidence" that the settlement agreement would be found to violate the antitrust laws under a "rule of reason" analysis. Here, the Court found that the settlement agreements satisfied the rule of reason test, because they did not extend beyond the scope of the patent ("the exclusionary zone"). Further, the Court relied on the fact that the agreements did not prevent challenges to the patent in suit by others. In fact, during the pendency of this litigation, the patent owner had prevailed in four other patent infringement suits.

The Federal Circuit affirmed that "any adverse anti-competitive effects within the scope of the [patent in suit] could not be redressed by antitrust law. This is because a patent by its very nature is anti-competitive," granting the inventor the statutory right to exclude others from making, using, offering for sale or selling the patented invention in the U.S. during the term of the patent. "Thus, 'a patent is an exception to the general rule against monopolies and to the right of access to a free and open market.'"

The Federal Circuit's decision is consistent with decisions in the Second and Eleventh Circuits rejecting challenges to settlements including reverse payments from a branded drug company to a would-be generic in exchange for a delay in the release of the generic product arguably covered by an unexpired U.S. patent.

The settlement agreements in *In re Ciprofloxacin* were entered into before 2003 amendments to the Hatch-Waxman Act requiring a patent holder and a first ANDA filer to submit settlement agreements for review by the U.S. Federal Trade Commission and the U.S. Department of Justice. The FTC, although not a party to this case, filed an amicus brief in support of the appellants. The filing is consistent with the FTC's longstanding position that settlements of patent infringement actions in the pharmaceutical area that involve reverse payments will be subject to strict scrutiny. Absent a definitive ruling from the U.S. Supreme Court or legislation clarifying the status of such settlements, FTC review and court challenges to them remain a possibility.